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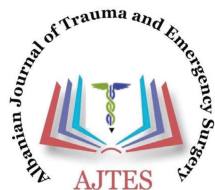


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The ATLS® Course: Empowering Healthcare Professionals for Excellence in Trauma Care

Agron Dogjani ^{1,3*}, Kastriot Haxhirexha ², Arben Gjata ¹, Kastriot Subashi ³

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Abstract

The Advanced Trauma Life Support (ATLS) course has become an indispensable tool in preparing health care professionals to provide optimal trauma care.

This article highlights the impact of the ATLS course on empowering healthcare professionals for excellence in trauma care.

By providing a standardized framework, enhancing critical decision-making skills, and promoting interdisciplinary collaboration, the ATLS course equips practitioners with the knowledge and skills necessary to effectively respond to trauma emergencies. Additionally, the course prepares healthcare professionals for the unpredictable nature of trauma care through simulation-based training and fosters a culture of continuous professional growth.

Through its emphasis on standardization, critical thinking, and continuing education, the ATLS course plays a vital role in improving patient outcomes and establishing a foundation for excellence in trauma care.

Conclusion: The ATLS course stands as a testament to the commitment of healthcare professionals to provide excellent trauma care. It empowers practitioners with the necessary knowledge, skills, and standardized approach to save lives in the critical moments following traumatic events.

Keywords: ATLS (Advanced trauma life support); medical education, trauma.

Introduction

Trauma remains the leading cause of death and posttraumatic temporary and permanent disability and posttraumatic mortality reaches 9% worldwide [1].

Because of this data, extensive efforts have been made to manage traumatic injuries at all levels.

Initially, efforts to improve trauma management focused on training prehospital staff, training hospital teams in the emergency department, and creating specialized trauma management teams within the hospital [2].

These improvements in trauma services subsequently contributed to the creation of trauma systems beginning in the 1970s [3], which provide care from prehospital care to rehabilitation, aligning with trauma prevention measures, education, scientific research, and quality management programs [4].

In recent decades, there has been a decrease in trauma mortality as a result of improved road safety legislation and media campaigns for trauma prevention[5].

Functionalization and advancement of trauma systems has resulted in improved trauma care, which has decreased M&M [6].

Trauma systems reflect collaboration among all health care providers to reduce preventable deaths and decrease morbidity and complications of injuries, which include

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trauma prevention programs, coordination of prehospital and hospital medical services management, rehabilitation care and care after discharge from the hospital for trauma victims, until their final integration into society [7].

A trauma center is a multispecialty hospital that provides multiple levels of care for patients with traumatic injuries. and are often the first step in implementing a trauma management system.

There is still no definitive definition of a trauma system, it is widely accepted that it takes years for a system to mature and become an integral part of the health system once implemented [8].

There are three steps to describe the stages of developing a trauma system: establishing a trauma center, establishing a trauma system, and maturing the trauma system.

The various characteristics of trauma systems have been highlighted in previous reviews [9].

Clinical outcomes of trauma management, such as mortality in trauma patients at different levels of the trauma system, have not been previously examined.

The objective of this article is to highlight the effectiveness of the ATLS course in reducing the mortality of victims at all levels of trauma management.

In the fast-paced world of healthcare, effective management of traumatic emergencies can mean the difference between life and death. [10]

As a call comes in from the field, the hospital team should begin to triage the patient based on their age, mechanism of injury, coagulation status, and other factors that can impact the management of the case[11, 12]

The principles of trauma management describe the basic concepts that providers need to know when treating various trauma injuries in a trauma setting.

The principles of ATLS focus on the management of traumatic injuries, using a team approach, which will highlight the value and basic roles of an interprofessional team, from assessment of the patient in the prehospital setting to their assessment and management after they have arrived at the emergency department. [10]

The Advanced Trauma Life Support (ATLS) course has emerged as a beacon of excellence, equipping healthcare professionals with the skills and knowledge needed to provide optimal trauma care. [13]

In this opinion article, we will delve into the value and significance of the ATLS course in empowering healthcare professionals for excellence in trauma care.

The implementation of modern trauma management requires a number of supporting pillars, where the ATLS philosophy is the key to the solution as follows,

Building a strong foundation in trauma education is very important, with the ATLS Course serving as a training foundation for healthcare professionals entering the field of trauma care.

Building a strong foundation in education is very important, with the ATLS Course serving as a training foundation for healthcare professionals entering the field of trauma care.[14]

It provides a structured framework and comprehensive education on the initial assessment, resuscitation and stabilization of trauma patients.

By instilling this solid foundation, the ATLS course ensures that healthcare professionals possess the essential skills necessary to respond effectively to traumatic emergencies.[15]

Promoting Standardization: One of the greatest strengths of the ATLS course lies in its promotion of standardization. By adhering to a common language and systematic approach, healthcare professionals trained in ATLS can seamlessly collaborate, regardless of their geographical location or medical background. This uniformity leads to enhanced communication, improved teamwork, and ultimately, better patient outcomes. [16]

Enhancing Critical Decision-Making: Trauma care often demands quick and accurate decision-making in high-pressure situations. The ATLS course hones the ability of healthcare professionals to think critically and make sound judgments when faced with time-sensitive and life-threatening scenarios. By training practitioners to rapidly assess, prioritize, and initiate appropriate interventions, the course empowers healthcare professionals to make informed decisions that can significantly impact patient survival.[17, 18]

Preparing for the Unexpected: Trauma care can present complex and unpredictable challenges. The ATLS course prepares healthcare professionals for these unexpected hurdles by incorporating simulation-based training. This practical experience allows practitioners to familiarize themselves with real-life trauma scenarios, enabling them to remain calm, adapt quickly, and make crucial decisions when faced with unforeseen circumstances. By honing their skills through simulation, healthcare professionals are better equipped to handle the dynamic and unpredictable nature of traumatic emergencies.[19]

Continual Professional Growth: The ATLS course is not a destination but rather a starting point for continuous professional growth in trauma care. It lays the groundwork for ongoing learning, encouraging healthcare professionals to stay updated with the latest advancements, research, and best practices in trauma management. By engaging in further education, attending conferences, and participating in advanced trauma courses, practitioners can expand their knowledge and expertise, ensuring the provision of high-quality, evidence-based care to their patients.[19, 20]

Conclusion:

The ATLS course stands as a testament to the commitment of healthcare professionals to provide excellent trauma care. It empowers practitioners with the necessary knowledge, skills, and standardized approach to save lives in the critical moments following traumatic events.

By fostering standardization, promoting critical decision-making, preparing for the unexpected, and facilitating ongoing professional growth, the ATLS course

plays an indispensable role in enhancing the quality and outcomes of trauma care worldwide.

It is through this investment in education and continuous improvement that we pave the way for a future where every trauma patient receives the best possible care, regardless of the circumstances.

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Emergency Access and Impact of Injuries Caused by Electrocutation and Lightning

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Abstract

Electrical injury is a physiological reaction caused by electric current passing through the body. Electric injuries can be caused by the impact and exposure to electric current or lightning either at home or at work.

The injury depends on the density of the current, tissue resistance, and duration of contact. Very small currents may be imperceptible or produce a light tingling sensation. Injuries can range from minor, moderate, to severe, and fatal injuries are just as likely to occur at home as in the workplace, with around 20 Australians dying each year from electric shock.

The purpose of this paper is to study how well-trained healthcare professionals in both pre-hospital and hospital settings are in treating patients in the case of electric shock and injuries caused by lightning, including the triage, assessment, monitoring, treatment, and transport with medical care in pre-hospital settings

The research was conducted based on data obtained from assessments of health care professionals based on anamnestic data, the status of vital parameters, monitoring, medical procedures, system-level injuries, type of health care delivery, and location.

Conclusions: Given the discrepancies found in reporting pathological conditions and injuries pertaining to electrical burn wounds, a standardized system for classifying these pathological conditions is suggested. Although electric shock-related mortality is not the leading cause of death in high-prevalence areas, awareness needs to be raised.

Keywords: Electrical injury, triage, assessment, monitoring, treatment, medical care

Introduction

Electrical injury is a physiological reaction caused by electric current passing through the body.[1, 2] The injury depends on the density of the current, tissue resistance and duration of contact.[3]

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Very small currents may be imperceptible or produce only a light tingling sensation. [4]

A shock caused by a low and otherwise harmless current can startle an individual and cause injury due to pulling or falling. Stronger currents can cause discomfort or pain, while more intense currents can cause involuntary muscle contractions, preventing the person from freeing themselves from the source of electricity. [5]

Even larger currents result in tissue damage and can cause ventricular fibrillation or cardiac arrest. Consequences of electric shock can include amputations, bone fractures, and orthopaedic and musculoskeletal injuries [5]

If death results from an electric shock, the cause of death is generally called electrocution. [2].

Epidemiology. Electrical injuries affect more than 30,000 people a year in the United States and result in about 1,000 deaths. In 1993, 550 electrocutions were

reported in the US, 2.1 deaths per million population. At that time, cases of electrocution were on the decline. [1]

Electrocutions in the hard injuries in the workplace fell 23% between 2015 and 2019 from 2,480 to 1,900. In 2019, the top 5 states with the most electrical workplace fatalities were: (1) Texas (608); (2) California (451); (3) Florida account for the majority of these deaths. From 1980-1992, an average of 411 workers were electrocuted each year. [1]

Causes. Electric shock occurs when a person comes into direct contact with a high-voltage current, which then passes through the body. Several things can cause electric shock, including: Being struck by lightning, coming into contact with downed power lines, putting fingers or objects into an electrical outlet, touching damaged or broken cables or electrical equipment, and touching plugs. overloaded electrical. Electric shocks can cause ventricular arrhythmias, asystole, or death. In addition, respiratory muscle tetany as a result of contact with electricity can cause hypoxic cardiac arrest and death. Much of the morbidity which results from electrical injury is associated with burns and neurological dysfunction.[6]

Pathophysiology The minimum current that a human can feel depends on the type of current (AC or DC) as well as the frequency for AC. A person can feel electric current up to 1 mA for 60 Hz AC and up to 5 mA for DC. At about 10 mA, DC current passing through the arm of a 68-kilogram (150 lb) man can cause powerful muscle contraction; the victim is unable to voluntarily control muscles and cannot release an electrified object. This is known as the “release threshold” and is a criterion for shock hazard in electrical regulations. [1]

The extent of damage of tissues depends on the intensity and the continuance of the heating. Electricity generates more heat in less conductive tissues.[7]

The current, if high enough and delivered with sufficient voltage, can cause tissue damage, fibrillation, or cardiac arrest; more than 30 mA [7] AC (rms, 60 Hz) or 300 – 500 mA DC at high voltage can cause fibrillation. A sustained AC electric shock at 120 V, 60 Hz is a particularly dangerous source of ventricular fibrillation because it usually exceeds the release threshold while not delivering enough initial energy to move the person away from the source. However, the potential seriousness of the shock depends on the paths through the body that the currents take.[8] If the voltage is less than 200 V, then the human skin, more precisely the stratum corneum, is the main contributor to the impedance of the body in the case of a macro shock - the passage of current between two contact points on the skin. However, skin characteristics are non-linear.

If the voltage is above 450–600 V, then dielectric breakdown of the skin occurs. The protection provided by the skin is reduced by sweat, and this is accelerated if the electricity causes the muscles to contract above

the release threshold for a sustained period of time. If an electrical circuit is created by electrodes inserted into the body, bypassing the skin, then the potential for death is much higher than if a circuit is placed through the heart. This is known as a micro shock. Currents of only 10 μ A may be sufficient to cause fibrillation in this case with a probability of 0.2%. [1]

Macroshock entry point: Current across intact skin or touching the body, from arm to arm, or between an arm and a leg, can attack the heart, so it is much more dangerous than current between the leg and the ground. This type of shock by definition must pass into the body through the skin.

Microshock: Very small current source with a path connected directly to heart tissue. This is a mostly theoretical risk since modern equipment used in these situations includes protection against such currents. [10] [11].

Signs and symptoms.

Signs and symptoms of electric shock can vary depending on the type and amount of electrical voltage such as:

- Numbness and tingling
- Burns
- Convulsions
- Irregular heartbeat
- Irregular or difficult breathing
- Vision or hearing problems
- Muscle spasms
- Headache
- Loss of consciousness
- Cardiac arrest

Symptoms caused by touching a broken kitchen appliance cord are usually much less severe than those caused by higher voltage shocks from sources such as power lines or lightning.

Clinical evaluation. Cardiac dysrhythmias. TV, VF, AC are malignant dysrhythmias of the cardiac rhythm, and many other dysrhythmias can appear, such as; atrial fibrillation, atrial tachycardia, lead rhythms, with TSV, 1st and 2nd degree heart blocks and ventricular premature beats. ST segment abnormalities may be evident and usually resolve spontaneously. Coronary artery spasm and thrombosis can cause ischemia and myocardial infarction. Post-mortem studies demonstrate a variety of cardiac anatomical changes after electrical shock including widespread focal necrosis of the myocardium and specialized tissues such as the atrio-ventricular and sinoatrial nodes [1].

Respiratory system. Electric current can cause apnoea through tetany of the respiratory muscles or through interruption of the normal cyclic output of the respiratory center in the brainstem.

Skin burns. Skin burns are often full-thickness involving the typical entry and exit sites of the topical route, such as the hands and feet. Skin burns may

have a relatively small surface area and may lead to underestimation of internal burns produced by the current pathway.

Peripheral neurological features. Electrical exposure can result in high current densities within nerve tissue, causing significant damage. Effects can be immediate or delayed with paraesthesia and weakness. The ulnar and median nerves are commonly involved with injuries to the hand.

Characteristics of the Central Nervous System.

The application of electric current to the brain can cause loss of consciousness, confusion and amnesia, and/or convulsive attacks. A wide variety of neurological findings may be present such as hemiparesis, speech and visual disturbances. Involvement of the spinal cord may result in tetraplegia and paraplegia which may be transient or permanent. The incidence of spinal cord injury after high voltage electrical accidents varies between 2 and 27% [2].

Musculoskeletal characteristics. Deep muscle burns can cause contractures and deformities. Marked skeletal muscle necrosis can cause electrolyte abnormalities, myoglobinuria, and kidney damage. Oedema of the muscles within the myofascial sheaths can cause compartment syndrome. The gradation of tissues from most conductive to least conductive is as follows: neural tissue, blood vessels, muscles, skin, adipose tissue, bones[12].

Muscle tetany typically occurs in response to electrical stimulation at a frequency of 40 Hz to 110 Hz, a range in which most household currents exist. If this muscle contraction occurs in the hand, contraction of flexors will cause the affected individual to grasp the source and prolong contact with the electrical source.[1]

The legs. A photo showing a classic burn injury. There are two types of incoming burns on the palms from the electrical source and an exiting burn on the feet.

Secondary trauma can result from being thrown from the electrical source. Violent muscle contraction can cause fractures and dislocations especially around the shoulder girdle (e.g., characteristic posterior dislocation of the shoulder). Opisthotonos can produce vertebral fractures with secondary cord injury or cauda equina.

Features in the eye. Passage of current through or adjacent to the eye can cause burns to the cornea, sclera or deeper structures. Cataract formation is a delayed consequence of lens involvement.

Vascular injuries. Involvement of blood vessels in the current pathway can cause vascular spasm and thrombosis with possible distal ischemia. Delayed aneurysm formation can result in damage to the vessel wall. Intramural burns. Intraoral burns are more common in young children, particularly with toddlers exploring electrical household appliances or cables by placing them in mouth. Conduction of current may be aided by electrolyte-rich saliva. Delayed haemorrhage is a well-

known feature of intra-oral electrical burns. Haemostasis may initially appear satisfactory, but as the temporary current-induced vasospasm resolves, severe haemorrhage may result. Shrinkage of scar tissue has the potential to make intraoral burns particularly disfiguring. Effects on the foetus Amniotic fluid easily conducts electricity. If the gravid uterus is involved in the electrical pathway, the effects on the foetus can be devastating. Maternal cardiac arrest and dysrhythmias also compromise uteroplacental blood flow.

Emergency medical care. When electrocution occurs outdoors, treatment may also include steps to ensure the area is safe beforehand and how to help the victim. Visually examine the victim but do not touch them, otherwise you may endanger yourself by electrocuting yourself if they are still connected to the power source. Call EMS or have someone else call EMS 112. Check for a source of electricity and turn it off if possible. If this is not possible, use an object made of non-conductive material, such as wood or plastic. When you are sure that you are safe from electric shock, check the victim's breathing and pulse.

Begin cardiopulmonary resuscitation (CPR) immediately if cardiac arrest occurs. If the victim is breathing but appears to have fainted or has other signs of shock, place the victim in a prone position on the ground and elevate the legs in the Trendelenburg position.

Do not treat any burns or remove clothing and wait until EMS 112 arrives.

If a person or child experiences an electric shock at home, contact your health care provider, paediatrician or call EMS 112.

In some cases, the shock can cause internal damage that cannot be detected visually. A health care provider can evaluate for superficial burns, mouth burns, or other internal organ injuries. If the person has severe burns, they may need to be hospitalized for treatment and observation. [13]

Medical care for electric shock will depend on the amount of voltage involved. A minor incidence of electric shock may not require medical attention. Treatment for less severe incidents of electric shock may include pain medications, antibiotic ointments, and cleaning bandages for minor burns. Higher tension injuries will require a higher level of medical care and often have poorer survival outcomes.

Emergency medical care may require: Cardiopulmonary resuscitation, MIQ care, IV fluids, surgical monitoring and continuous observation. If you or a friend experiences an electric shock, it is important to be examined by a health care provider. Injuries from an electric shock depend on the voltage level, the source, the way it passed through the body, the person's age and general health. When to call EMS 112 if a person has been electrocuted when the patient has: Irregular heartbeat, muscle pain or muscle contractions, confusion,

breathing problems, cardiac arrest, convulsions, and/ or loss of consciousness.[14, 15]

Preventing. Best practices to prevent electric shock at home include: Cover all outlets, make sure the wires are properly insulated and covered. Keep cords out of reach of children; supervise children in areas with potential electrical hazards, such as electrical equipment near a bathtub or pool. Turn off the breaker when working with electricity in the house. Do not use electrical appliances in the bathroom or shower. In addition, there are several ways to prevent electrocution outside the home, including: Report any downed or broken power lines to your power company immediately; do not touch them under any circumstances. Do not drive or walk-through water if power lines may have fallen into the water. If you are in contact with an electrical source while in a car, stay in your car and get away if possible. If you are unable to leave, stay in your vehicle and call EMS 112. Wait for emergency services to arrive and do not let anyone near your vehicle. Call an electrician to fix electrical circuits that are wet or near water. If possible, turn off the power at the main breaker, but never step into standing water to access it.

Never work on or near an electrical source while standing in water, especially if using a power tool. Make sure electrical equipment is completely dry before restoring power. Have a certified electrician confirm that it is safe to turn the power back on. Turn off your main breaker if there is a burning smell but no obvious source, or if you can see sparks and broken wires when you turn the power back on. When installing or using a generator, talk to your utility company about usage. Do not use generators without approved automatic shut-off devices. Generators can be a fire hazard if they remain plugged in once power is restored.

Purpose of the work

The purpose of this paper is how well health care professionals are prepared in prehospital hospital environments in case of electric shock and lightning as in rapid triage, assessment, monitoring, treatment, care and transport with medical care in prehospital environments. Our research also evaluates the medical care professionals in non-hospital education and their training, quality of care, and skills in the implementation of CPR methods as well as general medical care. Also, did they know and professional skills with the basic courses of Basic Life Support® (BLS®), Advanced Cardiac Life Support and Basic Trauma Life Support® (BTLS®) [16, 17]

Objectives

Demonstrate ability to assess and manage emergency airway, breathing and circulation, in burns patients. Use a defibrillator if it's necessary, and administer appropriate therapy.

Formulate a list of possible diagnoses and prioritize the assessment elements, in this situations.

Build a disposition plan after stabilization in the emergency department, until will transfer to the definitive treatment.

Material and Methods

The research material was taken from the archive of the Emergency Clinic, UCKK for the period January-December 2022. The research is retrospective, descriptive, qualitative. In the research, patients of all age groups exposed to electric current and lightning as well as health care professionals were taken in relation to basic and advanced health care courses.

Specialty	Local Trauma centre	Regional Trauma centre	University Clinical Centre ED - Trauma centre
Emergency doctor	X	X	X
Trauma surgery/orthopaedics + special trauma surgery	X	X	X
Anaesthesiology	X	X	X
Vascular surgery			
General surgery	X	X	X
Radiology	X	X	X
Neurosurgery		X	X
Vascular surgery		X	X
Thoracic surgery			X
Otorhinolaryngology			X
Ophthalmology			X
Oral and maxillofacial surgery			X
Urology			X
Cardiac surgery			X
Paediatrics/paediatric surgery			optional
Gynaecology			optional
Burn centres			X

Table 1. Distribution of specialist doctors according to the level of emergency hospital service

a. Data collection methods and techniques

The research material was taken from the archive of the Emergency Clinic, UCCK for the period January - December 2022. The research is retrospective, descriptive, qualitative. All age groups exposed to electric current and lightning as well as health care professionals were taken in the research. The research was conducted on the basis of data obtained from the evaluations of health care professionals based on anamnestic data, the status of vital parameters, monitoring, medical procedures, injuries at the level of systems, type of health care provision and location.(tab. 1)

Protocols, updated interdisciplinary strategies and data analysis can provide knowledge of organizational structures and sufficient levels of effective medical staff for the management of multiple incidents in order to minimize the loss of life.

Access of multiple views in EMS 112, it is those in pre-hospital and emergency hospital environments that provide the layers of response which require a professionalized medical approach, treatment procedures and actions that help the process at all stages of the topic with an organized health system in terms of comprehensive plan by optimizing the process from the first phase. (NHTS, 2019). [16]

Description of the sample. In the sample, 52 cases were investigated who had contact or injuries from electric current and lightning strikes, investigating all age groups. The research was conducted on the basis of data obtained from the evaluations of health care professionals based on anamnestic data, the status of vital parameters, monitoring, medical procedures, injuries at the level of systems, type of health care provision and location.

Description of data processing. The description of data processing is realized through statistical parameters,

(worked Excel Word) structure index, arithmetic mean and standard deviation. Statistical tests: X2-test and T- test. The verification of the tests was done for the confidence level of 95% and 99%, respectively for $p < 0.01$ and $p < 0.05$.

Results

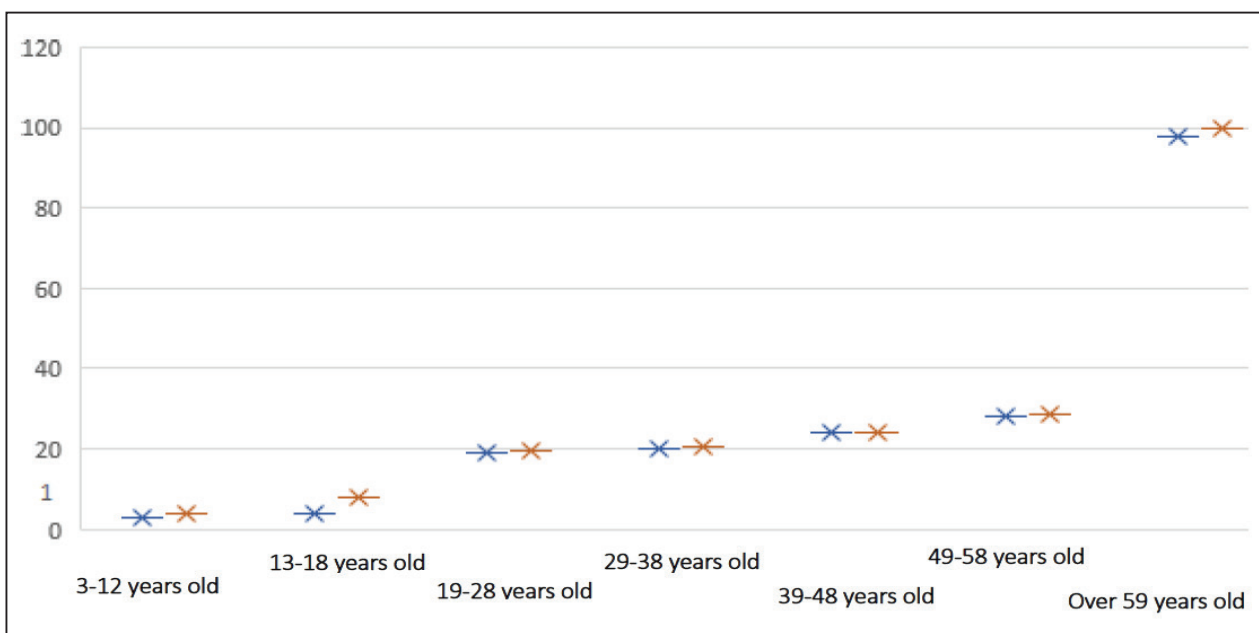
The research material was taken from the archive of the Emergency clinic, UCCK for the period January - December 2022. The research is retrospective, descriptive, and qualitative. All age groups exposed to electric current and lightning, as well as health care professionals, were taken in the research. The research was conducted on the basis of data obtained from the evaluations of health care professionals based on anamnestic data, the status of vital parameters, monitoring, medical procedures, injuries at the level of systems, type of health care provision and location.

In the research, 98 cases caused by electric shock and lightning were treated at the Emergency Clinic, UCCK for the period January-December 2022. The total number of patients seen in UCCK during this time was 78,200 and cases of electrical injuries were 98 cases or 0.12%.

In our study we have these epidemiological data, from the total number according to gender, there were 70 cases or 71.42% of men and 28 cases or 28.58% of women.

The average age of the patients included in the research was 1-10 years, the youngest patient was over 3 years and the oldest was over 59 years. (Graph 1).

According the distribution of cases by diseases and injuries, we had 22 cases or 42.3% of burns without supplementary injury, and burns with accompanying



Graphic 1. Number of cases by age group.

injury two or more had 30 cases or 51.7%, in this group we have this distribution as follow 20 cases of upper extremity fractures, 7 cases of lower extremity fractures; 9 cases of head injuries; 6 cases of chest injuries; abdominal injuries were 4 cases; spinal cord injuries were 2 cases; ventricular tachycardia was 8 cases; ventricular fibrillation was 2 cases; and me was 3 cases. (Tab. 2)

Illness / Injuries	No.of cases	%
Burns without supplementary injury	22	42.3
Burns with accompanying injury two or more	30	51.7
Total	52	100
Burns with accompanying injury two or more		
Fractures of the upper extremities	20	66.6
Fractures of the lower extremities	7	23.33
Head injuries	9	30.00
Chest injuries	6	20.00
Abdominal injuries	4	13.33
Spinal cord injuries	2	6.66
Pelvic injuries	2	6.66
Ventricular tachycardia	8	26.66
Ventricular fibrillation	2	6.66
Cardiac arrest	3	10.04
Total	30	

Table 2. The distribution of cases by diseases and injuries.

The article also includes an assessment of the percentage of the body affected by the burn and its depth, where we use this burn classification as follows [18]:

- **Minor:** First- and second-degree burns that cover less than 10% of the body are considered minor and rarely require hospitalization.
- **Moderate:** Second-degree burns that cover about 10% of the body are classified as moderate. Burns on the hands, feet, face or genitals can range from moderate to severe.
- **Severe:** Third-degree burns that cover more than 1% of the body are considered severe.

The number of cases according to the severity of diseases/injuries, with minor injuries were 13 cases or 25 %, moderate were 28 cases or 53.8 %, with serious injuries were 11 cases or 21.2%. (Tab. 3)

Severity of injuries	No.ofcases	%
Minor	13	25
Moderate	28	53.8
Serious	11	21.2
Total	52	100

Table 3. Number of cases according to severity of diseases/injuries.

The distribution of cases according to the assessment of vital signs (Hemodynamic Status), stable were 69 cases or 70.40% and unstable were 12 cases or 29.59%. (Tab. 4).

Hemodynamic Status	No.of cases	%
Stable	69	70.40
Nostable	29	29.59
Total	98	100

Table 4. Number of cases according to Hemodynamic Status

Out of the total number of 98 cases of electrocution. Numbness and tingling were 14 cases or 14.28%; Burns were 10 cases or 10.20%; Convulsions were 2 cases or 2.04%; Irregular heart beat was 24 cases or 24.48%; Vision or hearing problems were 7 cases or 7.14 %; Muscle spasms were 5 cases or 5.10 %; headache 21 cases or 21.42 %; and with fatigue paleness were 15 cases 15.30 %. (Tab.5).

According to signs and symptoms	No. ofcases	%
Numbness and tingling	14	14.28
Burns	10	10.20
Convulsions	2	2.04
Irregular heartbeats	24	24.48
Vision or hearing problems	7	7.14
Muscle spasms	5	5.10
Headache	21	21.42
fatigue paleness	15	15.30
Total	98	100.0

Table 5. Number of cases according to signs and symptoms.

From the total number of 98 cases that requested emergency medical help and care; BLS were 54 cases or 55.10 %, ACLS were 15 cases or 15.30 %, BTLS were 15 cases or 15.30 and ATLS 14 cases or 14.28 %, (Tab. 6).

Type of medicalcare	No. of cases	%
BLS	54	55.10
ACLS	15	15.30
BTLS	15	15.30
ATLS	14	14.28
Total	98	100

BLS® - Basic Life Support; ACLS® - Advanced Cardiac Life Support; BTLS® - Basic Trauma Life Support; ATLS® - Advanced Trauma Life Support;

Table 6. Type of medical care.

The total number of 98 cases with problems of conscience; with conscience there were 88 cases or 89.79% and without consciousness there were 10 cases or 10.21%. The number of cases with complications;

Complications 28 cases or 28.57% and No complications 70 cases or 71.43%. The distribution according the mode of treatment were the number of cases sent to the hospital or discharged home; 33 cases or 33.67 % and 65 cases or 66.33 % (Tab. 7).

	No.of cases	%
With disorders of conscience		
o Consciously	88	89.79
o Without conscience	10	10.21
Complications		
o Yes	28	28.57
o No	70	71.43
Mode of treatment		
o Hospitalized	33	33.67
o House.	65	66.33
Total	98	100

Table 7. Distribution of data according the conscience, Complications, and mode of treatments

Discussion

The discussion surrounding emergency access and the impact of injuries caused by electrocution and lightning is an important topic in the field of emergency medicine and public safety.

Electrocution and lightning-related injuries can have severe consequences, including organ damage, burns, neurological impairments, and even death.

In this discussion, we can explore various aspects related to emergency access and the impact of such injuries.[19]

Prehospital care is an essential part of the emergency health care continuum that is often initiated by a 122 call to a dispatch center.

Routinely, the need for emergency care is determined by trained personnel who receive such a call and dispatch the appropriate air and ground ambulances and other EMS responders to triage, treat, and transport the patient(s) to the appropriate care facility. healthcare, where final care is provided at the end.

This continuum of conventional care is provided through a coordinated and integrated emergency health care system with well-trained and well-equipped personnel in dispatch centers, ambulance agencies, hospitals and specialized care centers (trauma, burn, pediatric) using standardized protocols and guidelines. approved by medical directors [20]

This emergency healthcare system will be stressed to its limits during a mass casualty incident. Dispatch and regional call centers, local EMS agencies, and hospitals will take emergency measures utilizing their emergency operations plans and approved medical protocols to implement enhanced medical capabilities [21]

These measures may include

- Public safety answering points (PSAPs) and call centers that change their dispatch protocols dispatch fewer resources and allow EMS providers to respond to fewer calls for assistance [21]; transport destinations are being adjusted to allow transport to clinics or other alternative care sites other than hospitals [22]
- EMS personnel using disaster triage systems (sort, assess, life-saving interventions, treatment/transport; simple triage and rapid treatment [START]; and JumpSTART triage methods) so they can assess patients within 60 seconds and categorize them for immediate or delayed care [23, 24]
- EMS personnel using the National Incident Management System (NIMS) incident command system (ICS), which provides a consistent model for all organizations involved in disaster response.

In the event of a mass casualty incident in which emergency health care personnel, medical equipment and transportation, and hospital beds are in short supply, local EMS personnel will be forced to modify their care from conventional to crisis care.

This means moving from usual standards of care, in which the goal is to save everyone, to CSC, in which as many lives as possible are saved with the resources available.

Emergency access and response time: Prompt access to emergency medical services is crucial in cases of electrocution and lightning injuries. The ability to quickly reach the site of the incident, assess the situation, and provide appropriate medical care can significantly impact patient outcomes. Factors such as geographic location, infrastructure, transportation availability, and communication systems can influence response times and access to medical assistance.[25]

Training and preparedness: Healthcare providers, emergency responders, and community members should receive appropriate training to recognize and respond effectively to electrocution and lightning-related injuries. This includes knowledge about cardiopulmonary resuscitation (CPR), basic life support (BLS), and advanced cardiac life support (ACLS), as well as understanding the unique aspects of managing electrical and lightning injuries.[26, 27]

Medical management: Treating electrocution and lightning injuries requires a multidisciplinary approach. Medical interventions may include resuscitation, wound care, pain management, cardiac monitoring, neurological assessment, and treatment of associated injuries. In severe cases, specialized burn centers or trauma centers may be required for optimal care.

Prevention strategies: While emergency access and timely intervention are crucial, efforts should also focus on preventive measures. Public awareness campaigns, safety guidelines, and regulations regarding electrical

safety and lightning protection can help minimize the occurrence of such injuries. These initiatives should target both the general public and specific high-risk groups, such as outdoor workers, athletes, and individuals working with electrical equipment. [28]

Robust data collection and analysis can help identify trends, develop evidence-based guidelines, and improve prevention strategies. Collaborative efforts between emergency medicine, public health, and engineering disciplines can contribute to a comprehensive understanding of these injuries. [29]

Conclusion:

The discussion on emergency access and the impact of injuries caused by electrocution and lightning is essential for improving patient outcomes and developing effective prevention strategies. By addressing factors such as response time, training, medical management, prevention efforts, and research collaboration, we can work towards reducing the burden of these injuries and improving emergency care for affected individuals.

Recommendations

To institutionally support the advancement and strengthening of the health system at the primary, secondary and tertiary level, triage as an important component in the management of accidental situations

To design clinical guidelines, algorithms and triage protocols at the three levels of health care.

All health care professionals should be educated, trained with continuing courses in triage, communication, Basic Life Support -AED, ACLS, PHTLS. BTLs. ATLS.

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Characterization and Prevalence of Pediatric Ramp Lesions Associated with Anterior Cruciate Ligament Tears.

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Abstract

Background: Ramp lesions correspond to posterior meniscocapsular tears of the medial meniscus and are common with anterior cruciate ligament (ACL) tears. They cannot be recognized easily on preoperative magnetic resonance imaging (MRI) scans and are difficult to visualize even using standard arthroscopic approaches. We aim to (1) characterize and evaluate the prevalence of ramp lesions in pediatric patients at a major tertiary children's hospital, providing important insights into demographics, diagnosis, treatment, and functional disability and (2) evaluate the efficacy of MRI in its diagnosis.

Materials and Methods: We retrospectively reviewed patients under 21 years old undergoing posterior medial meniscal injuries and anterior cruciate ligament ruptures with arthroscopic examination and positive ramp lesions from 2018 to 2021. Patient demographics (including gender and age), initial presentation, physical examination findings, mechanism of injury, pre-operative radiologic findings, and treatment were collected and reviewed via electronic medical record. Exclusion criteria included patients over 18 years old, patients that did not have an MRI, and patients that were not treated surgically.

Results: There were 117 patients that met the inclusion criteria out of 690 patients. The mean age at diagnosis was 15.6±1.6 years and the mean BMI was 26.7±6.4. 83% of injuries occurred secondary to sporting activities. Ramp lesions were only detected on preoperative MRI in 63% of cases, suspected in 3%, and not detected in 33%. The sensitivity of the MRI was 63%.

Conclusions: Ramp lesions were found in 117/690 (16.9%) of patients undergoing ACL reconstruction. MRI had a low sensitivity rate of 63%. During ACL reconstruction, a careful review of the posteromedial compartment is important to recognize less obvious trauma. Lack of treatment may lead to continued instability and risk of complications in these patients.

Keywords: ACL, MRI, meniscus, reconstruction

Introduction:

The "Ramp" lesion is a particular injury subtype defined by a longitudinal vertical and/or oblique peripheral tear affecting the posterior horn of the medial meniscus (PHMM) that

may lead to meniscocapsular or meniscotibial disruption, often associated with ACL ruptures.[1]

A meniscocapsular separation at the PHMM is of special interest because of its potential hidden location within the posterior septum, especially when the knee is near full extension.

As such it is sometimes called a "hidden lesion" because this meniscocapsular tear is, topographically, located in the blind spot of the knee, being difficult to visualize by standard arthroscopic approaches [2] (Figure 1).

The medial meniscus has more peripheral attachments to the capsule and is significantly less mobile in the normal knee than the lateral meniscus. In biomechanical and anatomic studies, the PHMM serves as an important secondary restraint to anterior tibial translation [3], but ramp

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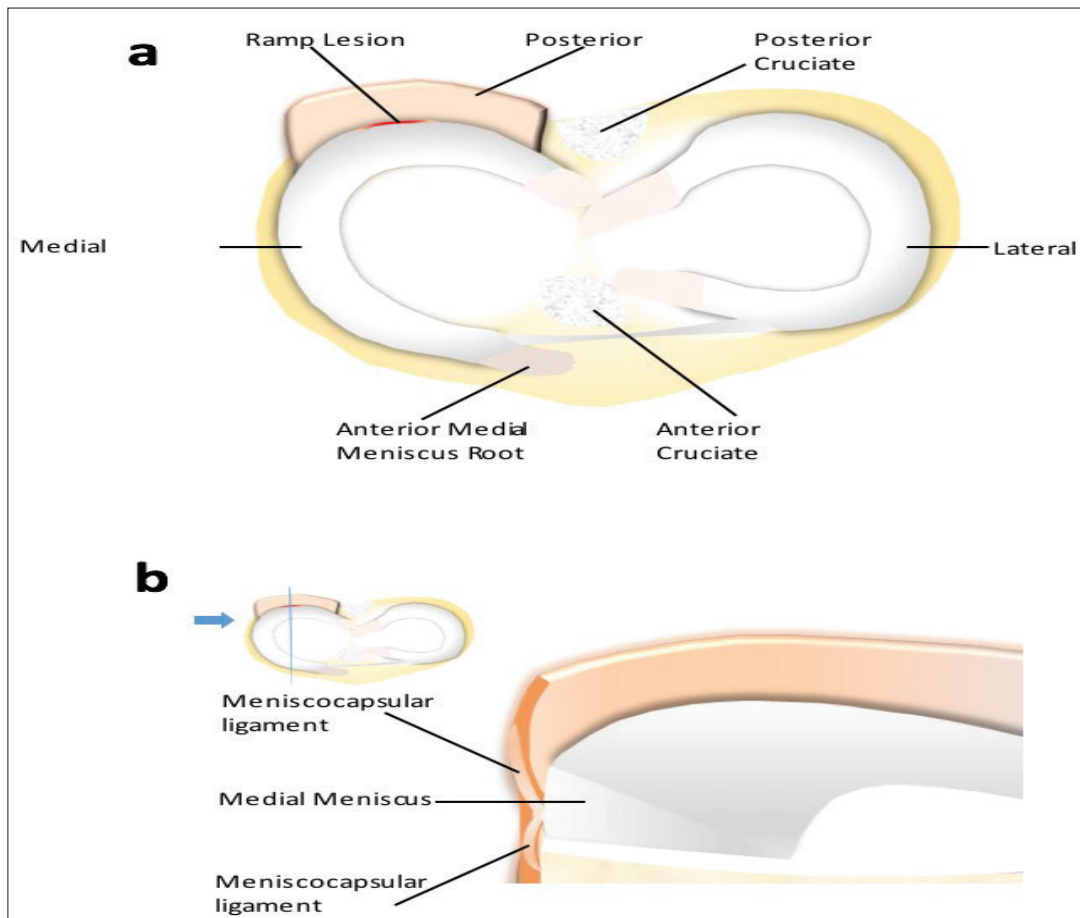


Figure 1. (a) Axial view of the middle level of the medial compartment, (b) Coronal view of the left knee showing posterior location of a Ramp.

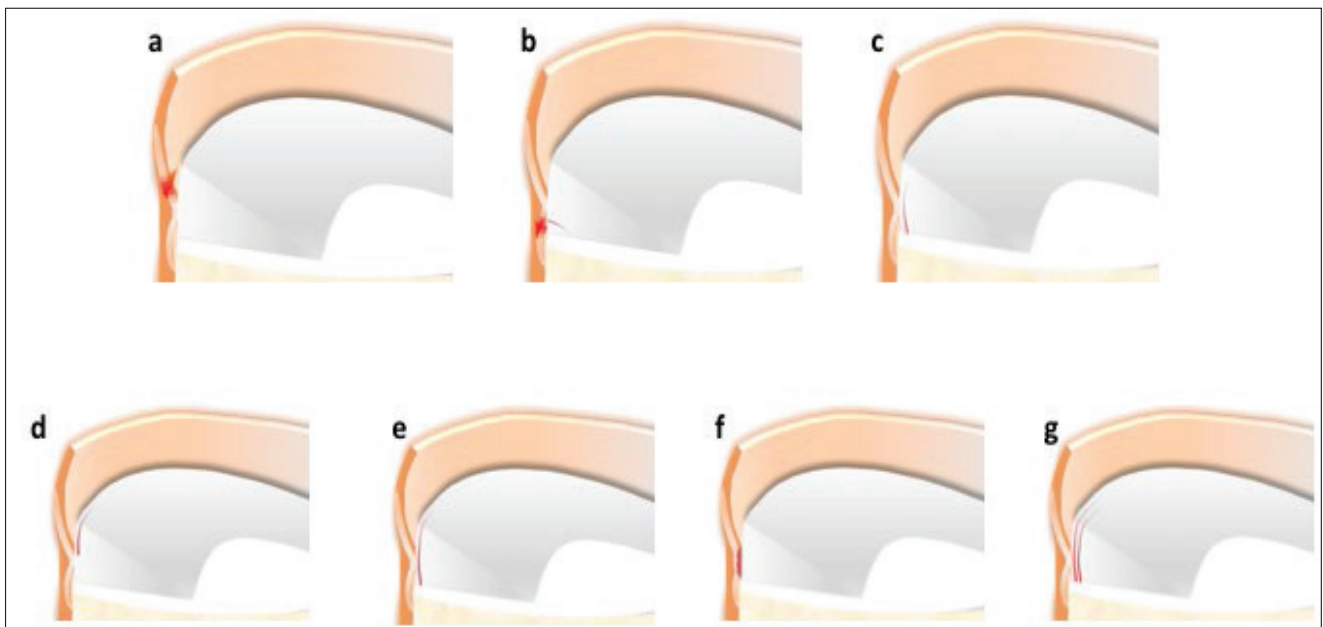


Figure 2. (a) Type 1 ramp lesion illustration, defined as meniscocapsular ligament tear, (b) Type 2 meniscal ramp lesion illustration, defined as partial superior peripheral posterior meniscal horn tear, (c) Type 3A meniscal ramp lesion illustration, defined as partial inferior peripheral posterior horn meniscal tear, (d) Type 3B meniscal ramp lesion illustration, defined as a partial inferior tear affecting the meniscotibial ligament, (e) Type 4A meniscal ramp lesion illustration, defined as complete peripheral posterior horn meniscal tear, (f) Type 4B meniscal ramp lesion illustration, defined as complete meniscocapsular junction tear, (g) Type 5 meniscal ramp lesion illustration, defined as peripheral posterior horn meniscal double tear.

lesions historically have not been consistently identified or well understood. [4-7]

Thaumat et al. [8] proposed a classification of the medial posterior capsular-meniscal lesions. The classification is based on the tear pattern (partial or complete) and its association to a meniscotibial ligament tear. It is divided into 5 types: general ramp lesion, partial superior lesion, partial inferior or hidden lesion, complete tear, and double tear. Grief et al modified this classification by splitting type 3 and 4 in type 3A, 3B, 4A and 4B (**Figure 2**).

Although these lesions are usually associated with an anterior cruciate ligament tear, it remains an under-recognized lesion to many orthopedic surgeons because it is difficult to visualize using standard arthroscopic approaches and cannot be recognized easily on preoperative magnetic resonance imaging (MRI) scans.[4, 7]

However, it is generally considered that arthroscopic evaluation is necessary to completely rule out or accurately make a diagnosis.[3, 9] Diagnosis and treatment of Ramp lesions are important because, if neglected, they can cause anteroposterior instability or injury to the body of the medial meniscus, resulting in early failure of the reconstructed ACL or early osteoarthritis of the knee joint.[10]

While there has been increased interest in diagnosing, treating, and understanding the effects of ramp lesions in the adult orthopedic literature, little information about ramp lesions in pediatric patients currently exists. *Nguyen et al.* [11] found increased medial meniscus tears in pediatric patients with Ramp lesions compared to patients without, *Bernadini et al.* [12] reviewed pediatric ACL reconstruction and found a non-correlated MRI sensitivity of 57% compared to arthroscopic diagnosis, and a positive predictive value of 40%, and *Malatray et al.* [13] had a prospective cohort of pediatric ACL ruptures with a 23% Ramp lesion rate.

We aim to (1) characterize and evaluate the prevalence of ramp lesions in pediatric patients at a major tertiary children's hospital, providing important insights into demographics, diagnosis, treatment and functional disability and (2) evaluate the efficacy of MRI in its diagnosis.

Materials and Methods

With permission from the institutional review board, patients under 18 years old undergoing posterior medial meniscal injuries and anterior cruciate ligament ruptures were reviewed retrospectively from January 2018 to December 2021. Inclusion criteria included patients with a Ramp lesion confirmed on arthroscopy via surgeon notes.

Exclusion criteria included patients over 18 years old, patients that did not have an MRI, and patients that were not treated surgically. 690 patients were identified as having been diagnosed and treated for an ACL tear and/or posterior medial meniscal tear. 105 patients were found to have a medial meniscus ramp lesion at arthroscopy, for

an incidence of 15%. Patient age, sex, initial presentation, physical examination findings, mechanism of injury, pre-operative radiologic findings and treatment were collected and reviewed via electronic medical record.

Arthroscopy surgical technique

Treatment in all cases consisted of arthroscopic suturing with all inside technique and stability testing.

Modified Gillquist portal and maneuver was used to identify the ramp lesion. With the help of arthroscopic hook, the lesion was checked and seen if it was stable or not. A shaver was used to roughen the lesion fragments and the adjacent posterior capsule too. Then the lesion was fixed with all inside technique and the stability of it was tested with the arthroscopic probe.

Data analysis

Descriptive statistics were estimated and reported as means with standard deviation or counts with percentages.

Results

There were 62 females and 43 males, with an average age of 15.3 years \pm 1.5 at the time of diagnosis (Table 1). Mean BMI at the time of injury was 26.0 \pm 5.3. The most common mechanism of injury was sport related (88), followed by falls (6) and jumping (5). 16% (17) of injuries were non-sports related. The most frequent sports involved in injury were basketball (25%), soccer (23%) and football (23%) (Table 1, Graph 1). Injury in these activities was often due to cutting or twisting motions.

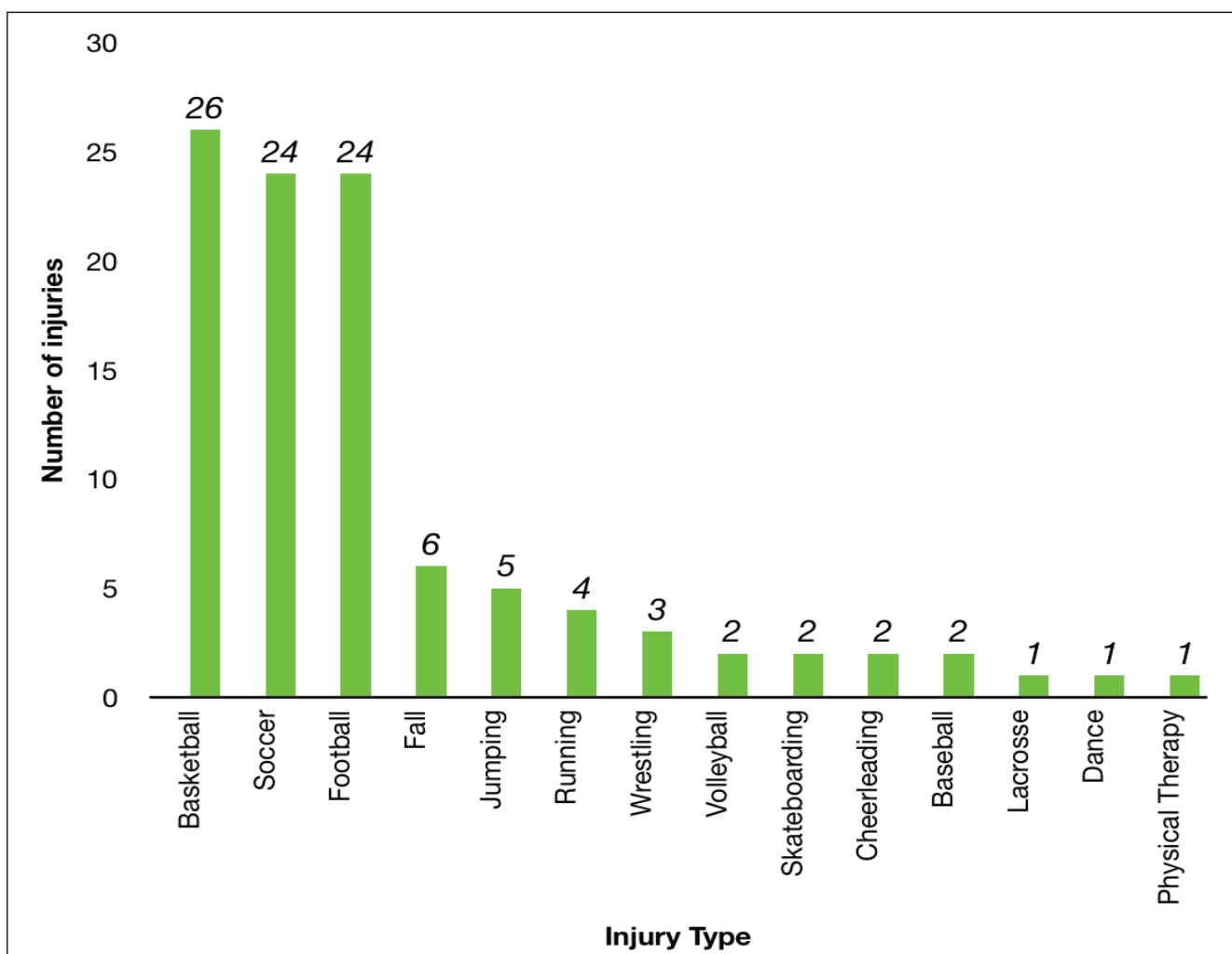
57% (60) of patients presented with tenderness to palpation, 67% (70) had swelling, and on physical exam 50% (53) had a limited range of motion. Referring to MRI reports the associated injury locations were more likely to be in medial compartment (59%) than both medial and lateral compartments (36%) and lateral compartment only (4%). Only three patients had underlying musculoskeletal history pathologies including one with genu varum, one with a history of arthroscopy reduction and internal stabilization procedure for a type I tibial spine fracture 4 years prior to ACLR, and one with avulsion tibial tuberosity 2 years prior to ACLR. All injured were isolated, except one patient with a concomitant ankle sprain.

All cases in our cohort were confirmed ramp lesions through arthroscopy. All patient Ramp lesions were associated with ACL tears. The sensitivity of an MRI in our cohort was 66% (69) There was no significant difference between sex, age, BMI, injury location, tenderness to palpation, swelling, or range of motion between patients that had lesions detected on MRI and patients whose lesions were not detected.

Variables	Counts and Percentages
Sex	Male (62), Female (43)
Race	White (49), Black (42), Asian (4), unable to obtain (10)
Age at Diagnosis (mean)	15.3 ± 1.5
BMI* (mean)	26.0 ± 5.3
Mechanism of Injury	Sports (88), falls (6), jumping (5), running (4), dance (1), PT* (1)
Injury Location (medial vs lateral)	medial and lateral (38), medial only (62), lateral only (4)
Tender to palpation	60 (57%)
Swelling	70 (67%)
Decreased range of motion	53 (50%)
MRI* ramp lesion detection	detected (69, 66%), not detected (32, 30%), suspected (4,4%)
Underlying MSK* pathologies or history	1x acquired genu varum, 1x arthroscopy + ORIF* 4 years prior to diagnosis, 1x idiopathic thoracic scoliosis

*BMI - body mass index; PT - physical therapy, MRI - magnetic resonance imaging; MSK - musculoskeletal; ORIF - open reduction internal fixation.

Table 1. Demographics and Characteristics



Graph 1. Etiology of injury

	Detected on MRI (69)	Not detected on MRI (32)	p
Sex	30 female, 39 male	12 female, 20 male	0.66
Age at Diagnosis (mean)	15.5 ± 1.4	15.0 ± 1.5	0.12
BMI	25.8 ± 5.5	26.2 ± 4.9	0.74
Injury location	medial and lateral (27), medial only (40), lateral only (2)	medial and lateral (10), medial only (19), lateral only (2)	0.61
Tender to palpation	58% (40)	53% (17)	0.67
Swelling	68% (47)	63% (20)	0.65
Range of motion	52% (36)	44% (14)	0.52

Table 2. Lesions Detected Versus not Detected on MRI

Discussion

The diagnosis and treatment of Ramp lesion has been well established in adult populations, but has not been studied as extensively in pediatric populations. In this series of 105 pediatric patients with ACL ruptures, we found ramp lesions in 15% of them. none of our measured patient variables were associated with preoperative MRI diagnosis.[12]

Causes and activities

ACL ruptures, and by extension Ramp lesions, often occur during sporting activities. (cite)

In our cohort, pivoting sports such as basketball, soccer, and football, were most prevalent.

Willinger *et al.* [14] found a 16% incidence of ramp lesions in ACL-injured knees at surgery in professional athletes (mean age of 22.3 years old).

Other studies have shown rates of 9 to 34%. [9, 16-22]

Only 3 studies have reviewed Ramp lesions in a pediatric population after ACL injury; *Nguyen et al.* [11] with a 41% rate in patients aged 10-20 years, *Malatray et al.* [13] with a 23% rate in patients aged 12-18 years, and *Liu et al.* [16] with a 21% rate in patients aged 10-20 years. These incidences are higher than our cohort (15%), but similar to non-pediatric studies.

Diagnosis

A specific test or physical exam finding to detect Ramp lesions does not exist. Further, isolated ramp lesions with no ACL rupture association is rare and not often looked for. [15]

A typical history includes localized pain, with or without swelling that begins directly after trauma and progresses over 2-3 weeks if the patients do not stay in rest. In the context of our study, physical exam findings were not necessarily specific to the Ramp lesions as any findings were confounded by history of ACL rupture.

Our physical exam findings tended to include tenderness to palpation (57%), swelling (67%), and painful or limited range of motion (50%). *Jiang et al.* described a series of

17 isolated Ramp lesions where patients had posteromedial knee pain, limited flexion, medial joint line tenderness, and positive McMurray's tests.[15]

Ramp lesions occur at the attachments of the meniscocapsular ligament and meniscotibial ligament at the middle level of the posterior horn meniscus length.[1] Anatomically, the posterior capsule does not attach directly to the superior portion of the PHMM, providing evidence for the potential location of hidden meniscal ramp lesions when the knee is near full extension.[4]

This hidden area may be responsible for missed diagnoses of ramp tears during preoperative MRI scans, and it further supports the utility of checking this area with a probe and/or viewing the PHMM posteromedially during arthroscopy to confirm or disprove the presence of a ramp lesion at the time of ACL surgery.[13]

In our cohort, MRI sensitivity was 66%. Other reports analyzing the accuracy of MRI for these lesions have ranged from 48-85%, and subsequent arthroscopy for confirmation of diagnosis and treatment is necessary. [1, 9, 11, 12, 14, 17, 19, 20, 23]

Arner et al. [17] had one reviewer out of three with an 84% MRI sensitivity in 90 patients, but had low inter-rater reliability (0.56), while *Kim et al.* [19] had 85% sensitivity in a series of 95 patients.

Because of the difficulty in identifying ramp lesions on standard arthroscopic approaches and defining the level of lesion during arthroscopy, if it is capsular or peripheral menisci, the classification often remains as a general Ramp lesion. [5] There was no documentation of classification in surgery notes in any of our cases.

Treatment

All the patients were treated by arthroscopy with the all inside suture technique [24, 25]

Some reports show good outcomes with trephination and abrasion only, but with a longer return to sport. [12, 26] Most recommend surgical treatment due to risk of osteoarthritis, instability, and a higher chance of ACL re-rupture.[10, 12]

In our series all lesions were treated arthroscopically and tested for stability. Additionally, stabilization carries a theoretical benefit of preventing tear propagation.

Limitations

The study was descriptive. There was no comparison group for the cohort. While this is the largest series on prevalence in pediatric ramp lesions, it is relatively small in comparison to some all-inclusive studies.[2, 16]

There were no MRI scans post-operatively to evaluate healing, nor is this a clinical outcome study.

Conclusion

Ramp lesions had an incidence rate of 15% in children and adolescents with ACL rupture undergoing surgical treatment. Only 66% of lesions were detected on preoperative MRI. Diligent exploration of the posteromedial compartment is necessary during ACL reconstruction to accurately diagnose and repair Ramp lesions in the pediatric population. Lack of treatment may lead to continued instability and risk of complications in these patients.

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The Application of MatriDerm in Soft Tissue Defects with Bone Exposure.

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Abstract

Background: Treatment of patients with post-traumatic severe and chronic wounds poses many challenges. A large number of dermal analogs have been invented in an effort to overcome these challenges. Matriderm®, a biosynthetic dermal analog, is made from bovine collagen and elastin. The aim of our study was to prove the effectiveness of MatriDerm® combined with skin grafting versus skin grafting alone in these difficult-to-heal wounds.

Material and Methods: Twenty-two patients with post-traumatic defects with bone exposure and chronic wounds treated in the Clinic of Plastic Reconstructive and Aesthetic Surgery of the University Hospital “St. George” were included in this prospective study. The mean age of the patients was 58 years. The patients were divided into two groups: the experimental and the control group. The patients in the experimental group received a Matriderm® appliance and a split-thickness skin graft, while those in the control group received only a split-thickness skin graft. All patients gave their informed consent to participate in the study.

Results: The hospitalization period in the experimental group was 3 weeks and 5 days and in the control group 8 weeks. The period of complete healing was shorter in the experimental group patients (5 weeks) compared with control group patients (9 weeks) with a difference reaching statistical significance ($P < 0.05$). Matriderm® enables effective healing and improves elasticity in the treatment of patients with post-traumatic severe and chronic wounds.

Conclusions: With our study, we confirm the evidence of the clinical use of MatriDerm® technology in the healing of soft tissue wounds and prove the effectiveness of combining MatriDerm® and skin grafting for the first time. Moreover, we observed a reduction in wound contraction and an improvement in elasticity, quality of scar tissue, and dermal architecture.

Keywords: Dermal substitute, Post-traumatic wounds, Skin grafting

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Introduction

Post-traumatic wounds with bone exposure and chronic nonhealing wounds can be designated as a silent pandemic affecting a large segment of the world population. It is estimated that 6% of the global population is afflicted by these types of chronic wounds. The International Diabetes Federation predicts that a lower limb is amputated every 30s, globally. One of the most serious complications in post-traumatic wounds is bone exposure, and in metabolic or trophic wounds is the development of local infection with gangrene and subsequent amputation of the lower leg [1].

Damage to this type of wound is in many cases complex and therefore a multifactorial approach is needed [2]. Correction of peripheral vasculopathy, and adequate surgical

treatment of the wound, including control of infection, are the key steps in the treatment of post-traumatic and chronic wounds. If the tissue defect is superficial, a simple wound dressing may be sufficient. However, if the wound is deep enough, with a lesion of adipose tissue, muscle, and bone exposure, it is mandatory to close the wound with a free graft or local/distant flap [3].

Skin grafting is a relatively simple procedure, but there are limitations, including a high probability of graft skin loss and low resistance to friction and pressure. On the other hand, valve surgery is effective and durable in deep ulcers, but has a narrow spectrum of patients and is associated with severe post-operative complications, including flap necrosis. The aim of this study was to investigate the effectiveness of MatriDerm (Skin Health, Billerbeck, Germany), an artificial dermis, compared to a skin graft in the treatment of post-traumatic wounds with bone exposure and chronic difficult-to-heal wounds [4, 5].

Materials and Methods

The study included 22 patients (14 males, 8 females), with a mean age of 58 years (range from 35 to 72 years) with post-traumatic defects with bone exposure and chronic non-healing skin defect and a postoperative follow-up period of 8.8 months (range from 6 to 12 months) treated in the Clinic of Plastic Reconstructive and Aesthetics Surgery of the University hospital “St. George” between 01.2021 and 01.2022. All wounds were localized on the inferior limbs (Table 1).

Characteristics	Patients treated with skin grafts	Patients treated with MatriDerm® and skin grafts
Number of patients	11	11
Sex (male/female)	8/4	6/4
Age	35-72	50-72
Initial size of wounds (cm2)	10-250 cm ²	10-200 cm ²
Wound with bone expose	11	11
Patients with post-traumatic defect	5	3
Patients with chronic non-healing defect	8	6

Table 1. Clinical characteristics of patients.

Exclusion criteria were severe arterial wounds and patients with renal failure and sepsis. In our study, 11 patients were treated with MatriDerm® combined with an autologous skin graft, and 11 patients received only an autologous skin graft. Our protocol for patient selection was based on clinical evaluation, wound examination, swab culture, and instrumental examination (echo-color-

Doppler) of the lower limbs. Each patient was examined for chronic diseases and possible concomitant pathology.

The wound examination included the wound area (cm3), wound bed, wound margins, and the surrounding tissue. Microbial culture was performed to evaluate any microbiological infections and to find the appropriate antibiotic therapy for treatment. Echo-color-Doppler was performed in the lower limbs to achieve a complete evaluation of local vascular circulation.

All procedures were performed in a complete asepsis ambience with general anesthesia. The surgical treatment included debridement (removing all non-viable tissues), controlling infection (based on the results of bacterial culture), and maintaining a balanced moist environment. The curettage of damaged areas and the dermal substitute application in combination with a split-thickness autograft in a one-step procedure (Table 2).

Postoperative evaluation	Patients treated with skin grafts	Patients treated with MatriDerm® and skin grafts
Hospital stay	8 weeks	3 weeks and 5 days
Complete healing period	9 weeks	5 weeks
Completely healed ulcer (%/patients)	60/7	81/9

Table 2. Postoperative characteristics of ulcer.

All patients gave their informed consent to participate in the study.

Material and Methods.

Proper wound bed preparation was performed before the study, including debridement (removing all non-viable tissues), controlling infection (based on the results of bacterial culture), and maintaining a balanced moist environment. Inclusion criteria were type 2 diabetic patients with a chronic foot ulcer, venous wounds, and post-traumatic defects with bone exposure, lasting more than four weeks after appropriate management, wound size bigger than 1 cm2, and formation of healthy granulation tissue after proper wound bed preparation. Exclusion criteria were a wound depth of Wagner grade 3 or a wound with severe vasculopathy [6,7]. After that the 22 patients were divided equally into two groups: a control group (n=11), receiving a skin graft only, and an experimental group (n=11), receiving the MatriDerm® appliance combined with a skin graft.

Surgical technique. In both groups, adequate debridement was performed until healthy tissue was exposed with pinpoint bleeding. After debridement, MatriDerm® was applied, soaked with normal saline, and a split-thickness skin graft was performed in one stage in the experimental group (Fig. 1). Only a split-thickness skin graft was performed in the control group (Fig. 2). Wet-to-

dry compressive dressing was administered until the grafted skin had been taken in both groups. After the grafted skin had been taken, ointment (Bactigras®) and dry dressing with controlled compression were applied daily.

Assessment. For the comparison of the two groups, three factors were measured.

- 1) The length of the hospital stays;
- 2) The length of complete wound healing;
- 3) The number of completely healed patients during the postoperative period for 12 weeks.

Complete healing was defined as complete wound closure without any transudate or exudate from the wound [9]. SPSS ver. 12.0 was used for the statistical analysis.

The data were analyzed with the Chi-square test. Significance was set at a value of $P \leq 0.05$.

Results

A summary of the demographic details of the control and experimental groups, including age, wound size, and wound depth, is shown in Table 1. In 11 patients treated with skin grafting combined with MatriDerm®, we observed complete healing of the wound and 81% epithelialization in 9 patients.

Minimal or absence of skin grafting contracture was observed in these patients.

The percentage of living tissue was evaluated to be 95% of the wounds in patients treated with MatriDerm®

combined with skin grafting, whereas it was almost 70% in the wounds treated with skin grafting alone. In almost all patients treated with skin grafting only, we observed contracture of the graft. The length of the hospital stay was shorter in the experimental group, lasting 3 weeks and 5 days, while in the control group it was 8 weeks. In addition, the time for the wound epithelialization was shorter in the experimental group (5 weeks), than in the control group (9 weeks).

The number of completely healed patients in the 12 postoperative weeks was greater in the experimental group, with 9 patients (93,5%) than in the control group with 6 patients (60.5%) ($P < 0.05$). The elasticity ratio of the affected lesion and contralateral region at the complete wound epithelialization point was higher in the experimental group.

A summary of the outcomes of these factors is shown in Table 2. There was no occurrence of complications, such as a rejection response to the artificial dermis, infection, bleeding problems, or loss of graft skin. Also, during the follow-up period, there was no recurrence in either group.

Case 1: A 52-year-old male with post-traumatic wound with bone exposure on the medial side of the right great toe. Debridement with curettage and VAT (vacuum assisted therapy) was performed primarily, followed by application of MatriDerm® and a split-thickness skin graft. The patient stayed in the hospital for four weeks and the wound epithelialization lasted six weeks (Fig. 1 a, b, c, d, e, f).



Figure. 1(a, b, c, d, e, f). A 52-year-old male patient with post-trauma with bone expose soft tissue defect, at the beginning and end of surgical treatment using MatriDerm® and a split-thickness skin graft.

Case 2; A 72-year-old female with chronic venous insufficiency suffered from an unhealed venous foot ulcer up to 6 months on the anterior part of the right leg after after trauma.

Debridement with excision of wound margins was performed primarily, followed by application of MatriDerm® and a split-thickness skin graft.

The patient stayed in the hospital for two weeks and the wound epithelialization took four weeks. (Fig. 2, a, b, c).



Figure 2 (a,b,c). A 72-year-old female with chronic venous wound treated with MatriDerm® and a split-thickness skin graft.

Discussion

Post-traumatic and chronic wounds with bone exposure is not simply a problem of soft tissue defects; it also degrades the quality of life of patients and can cause complications, such as amputation and sepsis. Therefore, surgical treatment for this severe type of wounds with primary closure, skin graft, and flap application is important [10].

Primary closure is possible only for small wounds, and skin grafting is easy to perform; however, the latter does not take well in deep wounds and has low durability. Flap

application can overcome the limitations of skin grafting; however, it is burdened with the risk of complications, such as flap necrosis, especially in the cases of common diabetes with a poor vascular state and chronic venous insufficiency. In 2000, the use of a collagen–elastin matrix for the treatment of burn wounds in a one-stage grafting model was described by *Van Zuijlen et al.* [11]. This is a highly porous, 1-mm-thick membrane, fully biodegradable, three dimensional, composed of native bovine collagen fibers I and V, coated with elastin hydrolysate derived from bovine ligamentum nuchae in a concentration of three weight-to weight ratio, and the matrices were treated with gamma-irradiation (1000 Gy) and stored at room temperature.

In the past 10 years, dermis, collagen, and elastic fibers have emerged as important components of wound healing. *Cuono et al.* [12], presented a synthesized functional dermal tissue with elastic fiber that had excellent resilience for prevention of scar formation. MatriDerm®, which was used in our study, is a three-dimensional matrix composed of collagen fibrils and elastin fibers for support of dermal regeneration in one stage.

It induces dermis regeneration as a scaffold and decreases scar tissue formation. It also provides optimal dermal wound bed preparation as regenerated skin with extensive formation of rete ridges and capillary loops but with the absence of skin appendages and is ready for relatively thinner subsequent skin grafting [12].

Collagen is obtained from the bovine dermis and contains dermal collagen types I, III, and V. Elastin is obtained from the bovine nuchal ligament by hydrolysis. In addition, MatriDerm® has excellent hemostatic properties and thus reduces the risk of hematoma formation under grafted skin.

In our study, the experimental group treated with MatriDerm® showed a shorter length of hospital stay and length of complete wound closure and showed a higher elasticity ratio of the affected lesion.

We concluded that MatriDerm® induced dermal regeneration and facilitated the graft take. Patients with chronic wounds like diabetic foot ulcers seem to hope for an especially quick return to their daily lives, which was possible in the experimental group. We applied a meshed MatriDerm® and meshed split-thickness skin graft to facilitate graft take [13].

We expect that meshed MatriDerm® would also be effective on wounds with a bleeding tendency, such as those associated with liver cirrhosis or chronic renal failure with dialysis. In our study, elasticity was the most important component for data analysis, considering the predictive factors for recurrence [14, 15] [19].

As we continue to do follow-up with the patients, we expect lower recurrence in the experimental group, given its higher elasticity, than the control group with a lower elasticity. In each patient, the dermal substitute, MatriDerm®, showed positive effects in accelerating the improvement of the quality and the functionality of skin reconstruction.

Dermal substitutes may act as a barrier for vascular ingrowths and hamper diffusion of nutrients by increasing the distance between the wound bed and the graft, for this reason, it was postulated that survival of the overlying skin graft could be at risk after dermal substitution. Furthermore, the skin elasticity parameters of wound areas treated with MatriDerm® were significantly improved in less time when sheet auto grafts were used [12].

The experimental group showed a shorter hospital stay. According to these results, we believe that Matriderm® can be an effective treatment for post-traumatic with bone exposure and chronic non-healing wounds.

Discussion

Wound healing is an evolutionarily conserved complex multi-cellular process that aims at restoring the skin barrier. This process involves coordinated efforts of several cell types including keratinocytes, fibroblasts, endothelial cells, macrophages, and platelets. The migration, infiltration, proliferation, and differentiation of these cells will culminate in an inflammatory response, the formation of new tissue, and ultimately wound closure. This complex process is executed and regulated by an equally complex signaling network involving numerous growth factors, cytokines, and chemokines [17,18]. This has been available in Europe since 2004 (MatriDerm®; Dr Suwelack, Skin and Health Care AG, Billerbeck, Germany).

Conclusions

Our study demonstrates the role of MatriDerm® in combination with skin autologous graft in tissue regeneration and wound closure with a significant reduction in healing time to 15 days in post-traumatic wounds with bone exposure and chronic wounds. On the basis of our clinical practice, we consider MatriDerm® and skin autologous graft as the key element to improve functional and aesthetic outcomes. This association guarantees a temporary barrier with multiple functions: hemostatic, reduction of contracture wound, infection, maintenance of skin elasticity and dermal architecture, and better appearance of the scar. Furthermore, the minimally invasive technique is well accepted by patients with a noteworthy improvement in quality of life along with cost reduction due to the fewer number of medications. In conclusion, our results show that the integration of different disciplines such as cell therapy, bioengineering, and biomaterials sciences is an effective support to successful surgical treatment and definitely healing of post-traumatic with bone exposure and chronic wounds.

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Confirm that none of the Authors has any financial interest in any products and in any other devices or drugs mentioned in this article.

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Ventral Hernias in Kalyana Karnataka Teaching Hospital: A Prospective Study

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Abstract

A ventral hernia is a protrusion of the abdominal viscus through the anterior abdominal wall occurring at any site other than the inguinal and femoral areas and is a common problem encountered by surgeons.

Aims & Objective: Due to the lack of prospective cohorts to determine the natural history of untreated ventral hernias, most surgeons recommend that these hernias be repaired as soon as they are discovered. The purpose of this study was to determine the proportion of ventral hernias occurring in both sexes, various age groups, various risk factors, and complications, as well as their clinical presentations and treatment.

Material and Methods: During the period August 2020 to August 2021 (12 months), a prospective study was conducted at our tertiary care hospital. The study included 50 cases of anterior abdominal hernias excluding groin hernias and posterior abdominal wall hernias. A detailed history and a thorough clinical examination were used to collect data. In the proforma, data was entered, tabulated, and analyzed using statistical software (SPSS 2015).

Results: Ventral hernias accounted for 5% of surgical admissions. Among the ventral hernias, para umbilical hernias were the most prevalent (48%). An infra umbilical midline herniation accounted for 36% of cases, followed by an umbilical region herniation in 18% of cases. Constipation and obesity were found to be the major risk factors. Most defects are small (>2cm). 48% of inlay mesh repairs were made.

Conclusion: 50 cases of ventral hernias were studied in the present study, which was conducted in our tertiary care hospital. Five percent of all admissions to the surgical ward were due to ventral hernias. The females to males ratio was 1:17, and the mean age was 41. The mean total duration for surgery in sublay group was 75.4±9.23 minutes compared to 63.7±10.58 minutes in onlay group, which was statistically significant (p<0.05).

Keywords: hernia, ventral hernia, epigastric, onlay, sublay

Introduction

A ventral hernia is a protrusion of the abdominal viscus through the anterior abdominal wall occurring at any site other than the inguinal and femoral areas and is a common problem

encountered by surgeons [1]. There are different modes of presentations of hernias such as the incidental finding of bulging over the previous surgical scar or symptomatic with pain, vomiting, distension of the abdomen, constipation i.e., signs and symptoms of intestinal obstruction. These defects can be categorized as spontaneous or acquired or by their location on the abdominal wall. Acquired hernias typically occur after surgical incisions and are therefore termed incisional hernias. Epigastric, umbilical, paraumbilical, and incisional hernias constitute a large number of patients whereas the other hernias are rarely seen and form a small amount. Incisional hernia is a common long-term complication of abdominal surgery and is estimated to occur in 3% to 13% of laparotomy incisions [2]. However, its incidence is greater than 23% in patients who have developed an infection in the laparotomy wound [3].

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A ventral hernia is a very common condition presenting to our hospital, so there was a need to study the disease with respect to the various presentations, to gauge the awareness levels of the patients coming to us, and also to determine the best modality of treatment in our set-up.

Thus, the study is being done to know the clinical presentations of ventral hernias, predisposing factors (risk factors) for the development of ventral hernias, different methods of surgical repair of the ventral hernias, complications following surgery, and their follow-up.

Material and Methods

This was a prospective study done at our teaching hospital between August 2020 and August 2021 (12 months). A total number of 50 cases were included in the study. Patients with groin hernias, posterior abdominal wall hernias, and those who did not undergo surgical intervention, and who are not fit for surgery were excluded from the study. Ventral hernias included epigastric, incisional, and umbilical hernias. Data collection included a detailed history and a thorough clinical examination. Patients underwent routine laboratory (CBC, LFT, KFT, BSL) and radiological investigations (Chest X-ray and USG). Patients were operated on with suitable open surgical techniques and followed up for immediate post-operative complications. Data was entered in the proforma, tabulated, and analyzed.

Results

Ventral hernias comprised ~5% of the total number of 1,000 admissions to the surgical ward (from August 2020 - August 2021). In the present study, the youngest patient was 12 years old and the oldest was 76 years old. The mean age at presentation was 47 years. paraumbilical hernia (49%) was the most common variety followed by epigastric hernia (22%) and umbilical hernia (18%). The highest incidence is found in the 41-50 age group.

In our study, the highest number of cases was found to be between 41-50 years of age and the mean age was 47 years. Out of 50 cases, 21 were males and 29 were females. Out of 21 males, 9 cases were of epigastric hernia. Out of 29 cases of ventral hernias in females, 20 cases were of paraumbilical hernia, whereas the next most common type was umbilical hernia (9 cases).

Age	No. of Patients	Percentage [%]
0-10	0	0
11-20	1	2
21-30	5	10
31-40	12	24
41-50	13	26
51-60	10	20
61-70	4	8
71-80	5	10

Table 1. Distribution of data according to Age

	Incidence	Percentage [%]
Male	21	42
Female	29	58

Table 2 Distribution of data according to gender

Size of the defect

The size of the hernia defect at the time of presentation was as follows:

Size of defect	No. of cases	Percentage [%]
<2cms	32	64
2-3cms	12	24
>3cms	6	12

Table 3 Distribution of data according to the size of the defect

It was found that the incidence of complications was more common in patients who presented with small to moderate-sized defects because the narrow neck of the hernia sac would compress the contents leading to irreducibility, obstruction, and strangulation.

Mode of presentation

The complaints which the patients presented in this study are as follows:

COMPLAINT	No. of Cases	Percentage [%]
Swelling with pain	27	54
Swelling	10	20
Swelling with irreducibility	13	26

Table 4 Distribution of data according to Chief complaints

Majority of the patients presented with swelling & Pain over & around the umbilicus or in the line of the scar of previous surgery.

Anatomical sites

In the present study, Paraumbilical hernia was the most common among the ventral hernias with an incidence of 46%. Of these, most occurred in the infra-umbilical region.

ANATOMICAL SITE	No. of Cases
Paraumbilical Hernia – infraumbilical	18
Paraumbilical Hernia – supraumbilical	6
Umbilical Hernia	9
Epigastric hernia	11
Incisional hernia	3

Table 5 Anatomical site distribution

There is a significant association between constipation smoking, obesity, and the occurrence of ventral hernia ($p < 0.001$). Data analysis was done by using the statistical package for social science (SPSS) software version 17 for Windows by using the chi-square test and other parameters. A p -value of less than 0.05 was considered significant.

Duration of surgery

The mean total duration for surgery in sublay group was 75.4±9.23 minutes compared to 63.7±10.58 minutes in onlay group, which was statistically significant ($p < 0.05$)

TYPE OF REPAIR	Operative time (In minutes)
Onlay	63.7
Sublay	75.4

Table 6 Duration of surgery

Post operation stay and drain removal.

A suction drain was put in all cases. Mean drainage duration (4.8±0.99 days vs. 3.5±1.24 days) was low in sublay group compared to onlay group which was statistically significant.

The mean duration of hospital stay postoperatively in sublay group was 4.2±1.51 days, whereas it was 6.7±1.46 days in onlay group, which was statistically significant.

	Duration of Drain (In Days)	Postoperative Stay (In Days)
Onlay	4.8	6.7
Sublay	3.5	4.2

Table 7 Post operation stay and drain removal.

Post Op complications

In the present study, the following complications occurred during the postoperative period. Thus, in the present study, a 6% recurrence rate was observed after 1 year of follow-up.

The wound infection rate was 4%. 3% with onlay repair and 1% with sublay repair. Two patients had marginal suture line necrosis but no wound or mesh infection; necrotic skin was excised and suturing was done.

COMPLICATIONS	No. of Patients
Seroma	3
Wound infection	2
Skin necrosis	2
Recurrence	3

Table 8 Post Operative complications

Discussion:

The incidence of ventral hernia is higher in females because, in multiparous women, the following factors predispose to hernia formation: stretching of the anterior abdominal wall, decreased tone of abdominal wall muscles, and replacement of collagen with elastic fibers. In our study, the incisional hernia was the most common among the hernias, this is comparable to another Indian study [4]. However, *Dabbas N et al.* did a retrospective study of 2389 patients and found that umbilical and paraumbilical hernias were the most common anterior abdominal wall hernia [5]. *Malik AM et al.* found a maximum number of paraumbilical hernias (13%) followed by epigastric hernias and umbilical hernias [6].

Constipation was found to be one of the major risk factors for interfering with wound healing and precipitating incisional hernia, even after a repair. This is comparable to the study of *Ersoz et al.* of the Department of Surgery, Ankara University of Medicine, Turkey [7].

The study evaluated 109 recurrent incisional hernias and found that chronic constipation was the most prominent risk factor associated with late recurrence. In the present study, Incisional hernia was the most common among the ventral hernias with an incidence of 46%. Of the incisional hernias, most occurred in infra-umbilical midline incisions.

In fact, as per literature, the best position for inserting the material has not been conclusively established; but limited studies have shown that meshes implanted on the abdominal aponeurotic layer showed better and early incorporation (higher collagen deposition, capillary density, and cell accumulation) and increased tensile strength reflecting tighter anchorage to the abdominal wall [8, 9, 10].

One European study has shown that onlay technique had significantly more complications as compared to sublay technique [11]. Thus, it can be safely said that based on the above parameters, sublay is a better technique than onlay in terms of placement and overall decreased complications and morbidity [12].

There is a paucity of literature but an experimental study has also shown the superiority of sublay technique, based on different parameters. [13]

Even after long-term follow-up, recurrence rates of around 10% are possible [14].

This is all the more necessary as the world literature is scanty and there is great interest in hernia surgery using mesh these days.

Conclusion:

In the present study of ventral hernias, 50 cases of ventral hernias that were admitted to the Department of Surgery in our Teaching hospital from August 2020 to August 2021 were studied.

Ventral hernia constituted 5% of all admissions to the surgical ward. The mean age was approximately 47 years. Paraumbilical Hernia was the most common variety. 54% of the patients presented with swelling with pain as the chief complaint. 20% of the patients presented with swelling as the chief complaint.

The infra umbilical midline was the most common site for herniation in 36% of cases followed by the Epigastric region in 22% of cases. Obesity and constipation were found to be the major predisposing risk factors. Seroma occurred in 6% of cases. Wound infection occurred in 4% of cases

The mean total time taken for the operation in the 'sublay' group was 75.4±9.23 minutes, compared to 63.7±10.58 minutes in the 'onlay' group; and was found to be statistically significant ($p < 0.05$). The difference in time can be accounted for due to more dissection time needed for creating preperitoneal space. Securing reasonable hemostasis is another burden on time. Ease of operation

is largely subjective (surgeon factor being constant) and depends on individual surgeon's experience, exposure, and planning, quality of assistance, conductive facilities like light, cautery, instruments quality, and sutures, etc.

Apart from recurrence, other postoperative complications like seroma formation and wound infection are attributed largely to extensive dissection and tissue handling during hernia repair.⁸ In the present study, there was slightly more chance of seroma formation in onlay group, which may be due to extensive tissue dissection and increased blood loss.

Duration of hospital stay gives us an indirect indication of the degree of morbidity in terms of postoperative complications. The mean duration in sublay group was 4.2 days, compared to 6.7 days in onlay group; and were found to be statistically significant ($p < 0.05$). On one-year follow-up, the recurrence rate was found to be more in onlay group.

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Staged Crystallized Phenol Treatment in Pilonidal Disease: A Retrospective Cross-Sectional Study.

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Abstract

Background: In recent years, minimally invasive techniques with less tissue excision, rather than surgical treatments including wide tissue excisions, are preferred in the surgical treatment of pilonidal sinus. Crystallized phenol treatment is a widely used minimally invasive method. The aim of this study is to examine the results of applying crystallized phenol in a two-stage manner.

Material and Methods: In this study, demographic information, pilonidal sinus characteristics, and results of crystallized phenol treatment of primary pilonidal sinus patients treated with crystallized phenol at Ankara Yıldırım Beyazıt Education and Research Hospital General Surgery Clinic between January 2016 and July 2021 were retrospectively analyzed.

Results: The average age of 185 patients who underwent phenol treatment for pilonidal sinus was 26.75±6.21 years. 53.2% of the patients were ≤25 years old. 80.5% of the patients were male. 65.0% of all patients had a BMI <30 kg/m². The follow-up period for patients was 31 months (min 6, max 60). The patients had 1-3 pits. In the final evaluation of patients who received crystallized phenol treatment twice, abscesses developed in 3 patients (1.6%) and recurrences occurred in 8 patients (4.3%). A statistically significant relationship was found between age and recurrence (p=0.027) and between BMI and recurrence (p=0.003). The incidence of recurrence increased significantly as the number of pits increased (p<0.001).

Conclusions: In our study, we did not encounter any serious complications with the application of crystallized phenol in two stages. We observed that our patients returned to their routine lives painlessly in the early period and that our recurrence rates were low. Based on our findings, we can say that the application of crystallized phenol as a minimal invasive procedure is still a safe and valid method for the treatment of pilonidal sinus.

Keywords: Pilonidal Sinus, Relapse, Crystallized Phenol Treatment

Introduction

Pilonidal sinus disease (PSD) is a condition characterized by infection of the skin and subcutaneous tissue in the upper part and surrounding area of the structure known as the “congenital natal cleft” or “congenital intergluteal cleft” located between

the two hips [1-3]. Previously thought to be congenital, with increasing evidence, it is now widely believed that PSD is related to hairs in the gluteal cleft and is acquired [4, 5]. Currently, it is accepted that PSD is a chronic condition that can manifest as intermittent symptoms over several years or as acute symptoms [5]. Due to the varying causes of the disease in different patients, treatment management can range from simple incision and drainage to extensive reconstructive procedures after a wide excision [6, 7].

In recent years, as the trend moves towards less invasive surgical methods, the importance of Video-assisted Pilonidal Sinus Ablation (VAAPS) and Endoscopic Pilonidal Sinus Treatment (EPiST) has increased and they have become more prominent [5]. So far, both surgical and non-surgical techniques have been used in the treatment of pilonidal sinus (PSD), but there is still no standard treatment that is widely accepted.

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Although many surgical methods have been performed, the most commonly used methods include excision, excision-primary closure, excision-marsupialization, and excision-flap techniques. Non-surgical methods include depilation, cavity curettage, phenol crystallization (PC) treatment, and laser treatment [6, 8]. However, PC treatment is a widely used conservative method for PSH treatment due to its ease of use and cost-effectiveness (9). In the study results in the literature, it is emphasized that this minimally invasive method is an alternative to surgery because of the short hospital stay of patients, early return to work and daily life, and high patient satisfaction [10, 11]. In addition, it is reported that the recurrence rates are low in PC applications [10, 12].

The basic approach for treatment of pilonidal sinus (PSD) is surgical intervention. However, regardless of the treatment protocol, there is a risk of recurrence for this condition. Therefore, when determining the ideal procedure for PSD treatment, it is preferred that the procedure is simple and cost-effective. This is because the pain levels of these patients should be reduced to a minimum and their quality of life should be improved in their daily lives. The reason why phenol crystallization (PC) treatment is preferred over surgical procedures in PSD is because it is easy to perform and low-cost. The aim of this study is to examine the results of two-stage PC treatment.

Material and Methods

In this study, the demographic information, pilonidal sinus (PSD) characteristics, informed consents, procedure, and results of the PC treatment of primary PSH patients who underwent PC treatment at the General Surgery Clinic of Ankara Dışkapı Yıldırım Beyazıt Training and Research Hospital between January 2016 and July 2021 were retrospectively analyzed based on patient records. Patients who had undergone surgical treatment, developed recurrence, and received PC treatment were excluded from the study.

Crystallized Phenol;

Phenol can be found in liquid or crystallized forms (Figure 1). It is used in the treatment of PSD [13, 14]. The description of the application of liquid phenol into the sinuses through the sinus opening after cleaning the hairs in the sinuses and curettage was first made by Maurice and Greenwood in 1964 [14]. Phenol is colorless at room temperature and is available in liquid and crystalline forms. Phenol is an acidic substance that is present in the composition of various drugs due to its anesthetic and disinfectant effects, which are obtained by adding a hydroxyl group to an aromatic core. It takes on a yellowish color over time when exposed to air. Its specific gravity is 1.07 g/cm³, melting point is 37-41°C, and boiling point is 178-182°C. It dissolves in water and liquid paraffin, but it easily dissolves in alcohol, ether, chloroform, glycerin, carbon sulfide, and alkalis [13].

Application and Treatment Procedure;

The patient was evaluated on the first visit. It was found

that the patients had sinus openings that varied in size from 0.1-4 mm and in number from 1-3. Criteria such as absence of active infection and abscess and not having undergone surgery were sought for the application of CP. The patients were thoroughly informed about the surgical treatment and CP application, and informed consents were obtained. If these were not present, the first application was made. All patients with purulent discharge from the sinus openings were started on oral antibiotics (Amoxicillin and Clavulanic Acid 1000 mg 2x1), and CP was not applied. If there were no problems in the patients called for control 1 week later, CP was applied to them as well.

Patients were taken to a small surgical room. Local anesthesia was given with 3 ml of prilocaine hydrochloride (20 mg/ml) after cleaning the skin surface in sterile conditions (Figure 1). If a patient had multiple sinus openings, the procedure was performed separately for each opening. Then, all sinus orifices were cannulated (Figure 1). The inside of the sinuses was checked for the presence of hair, and the cyst walls were curetted after removing hairs in the cyst with a forceps (Figure 1). Before the procedure, the surrounding skin tissue was protected from the irritant and corrosive effect of the pure crystallized phenol with a topical antibiotic cream (containing Nitrofurazone) by moistening the skin (Figure 1). Approximately 1-2 pieces of CP were applied to each sinus opening, with a size ranging from 0.1 mm to 0.5 mm that could be inserted into each opening (Figure 1). This was done to ensure that CP would melt at body temperature if it came into contact with tissue. Additionally, applying CP in a solid small piece form was preferred to prevent possible complications and the risk of splashing onto the surrounding skin tissue when applied in liquid form.

After the procedure, patients were told they could remove the dressings 24 hours later and take a shower. They were advised to take daily showers and clean the skin area with hair removal cream, and a follow-up appointment was scheduled one week later. If no pathological findings were observed at the follow-up appointment, a second session of CP application was scheduled 21 days later. Patients received two CP applications with a 3-week interval. The final control was performed 4 weeks after the second CP application. The status of patients whose sinuses were checked for closure and found to have no discharge or infection after undergoing two CP treatments and coming for a check-up one month later was considered "healed."

Ethics Committee Approval conducted with the approval of the Ethics Committee of Dışkapı Yıldırım Beyazıt Training and Research Hospital of the Ministry of Health of the Republic of Turkey with the permit number 117-10.

Statistical Analysis

Data was analyzed using IBM SPSS version 22.0 (IBM Corporation, Armonk, NY, USA). Continuous variables were expressed as mean \pm sd and/or median (min-max), and categorical variables were expressed as numbers and percentages. Non-parametric tests were used because numerical variables did not have a normal distribution

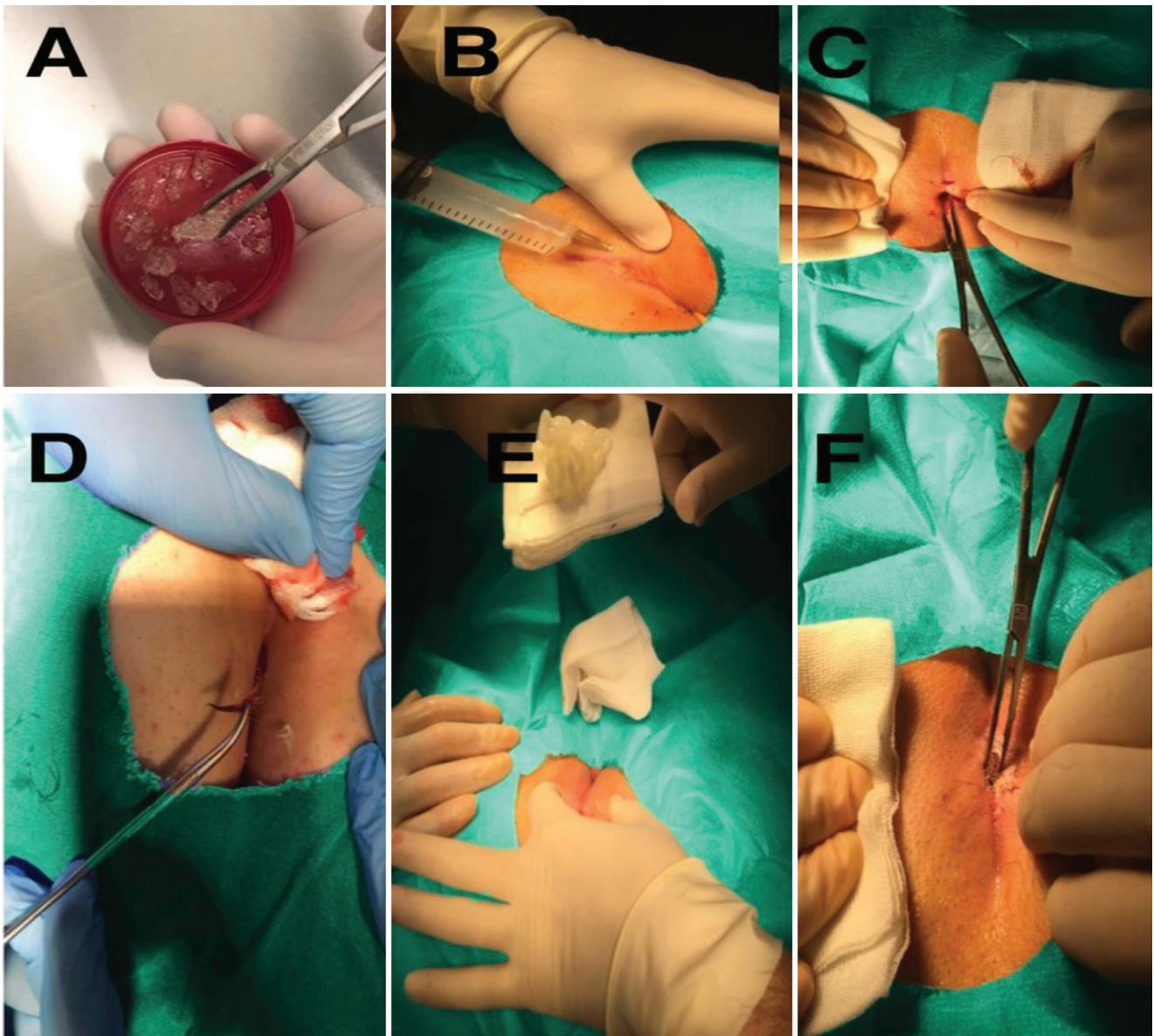


Figure 1. A: phenol in crystalline form, B: application of local anesthesia, C: cannulation and enlargement of the orifice, D: hair removal procedure, E: application of protective cream, F: application of crystalline phenol

according to the Kolmogorov-Smirnov test. The Mann-Whitney U-test was used to examine the differences between numerical variables in two groups and the chi-square test was used to investigate the relationship between two categorical variables.

Results

The average age of 185 patients treated with PSD and phenol application was 26.75 ± 6.21 years. It was seen that 53.2% of the patients were ≤ 25 years old and 47.0% were > 25 years old. 80.5% of the patients were male. 65.0% of all patients had a BMI < 30 kg/m², and the average BMI was 28.72 ± 7.51 kg/m². The median symptom duration was 5 months (min 1, max 15), and the follow-up duration was 31 months (min

6, max 60). 76.8% of the patients described their lifestyle as sedentary due to their professions. 47.6% of the patients were smokers, and 32.4% had a family history of PSD (Table 1).

At the first evaluation during the initial visit, it was found that at least 2 symptoms were present in 34.6% of the patients; 24.3% had abscesses, 22.7% had swelling, 24.9% had pain, and 24.9% had discharge. As a second symptom, swelling was present in 9.4%, pain in 45.3%, and discharge in 45.3% of the patients. 50.8% of the patients had 1 pit count, 44.9% had 2 pits, and 4.3% had 3 pits. In the final evaluation of patients who underwent CP twice, 3 patients (1.6%) developed abscesses and 8 patients (4.3%) had recurrent symptoms. It was determined that 97.8% of the patients had performed local hair cleaning (Table 2).

Descriptive informations		(n)	Percentage (%)
Age (years)	≤ 25	98	%53.0
	> 25	87	%47.0
Gender	Woman	36	%19.5
	Man	149	%80.5
BMI (kg/m ²)	< 30 (Normal)	120	%65.0
	≥ 30 (Obese)	65	%35.0
Lifestyles due to their profession	Ambulatory	43	%23.2
	Sedentary	142	%76.8
Family history	Absent	125	%67.6
	Present	60	%32.4
Smoking	Absent	97	%52.4
	Present	88	%47.6

BMI: Body Mass Index (kg/m²)

Table 1. Descriptive information about patients

When analyzed according to gender, lifestyle due to occupational type, family history, local hair cleaning, and complication status, no significant relationship was found (Table 3). The recurrence rates were 1.0% in patients under 25 years of age and 8.0% in patients over 25 years of age, and a statistically significant relationship was found between age and recurrence status ($p=0.027$).

It was found that the relapse rates were 0.8% in patients with a BMI value <30 kg/m² and 10.8% in those with a

BMI ≥30 kg/m², and there was a statistically significant relationship between BMI and relapse status ($p=0.003$). As the number of pits increased, the relapse rates also increased in a statistically significant manner (1 pit=0.0%; 2 pits=3.6%; 3 pits=62.5%; $p<0.001$). Although the relapse rates in patients who presented with ulcers and discharge (6.7% and 6.5%, respectively) were higher than those who presented with swelling and pain (2.4% and 2.2%, respectively), the difference was not statistically significant ($p=0.680$) (Table 3).

Discussion

Recently, minimally invasive methods that involve the excision of less tissue have been preferred over surgical treatments that include wide tissue excisions in the treatment of PS. CP is widely used in minimally invasive methods today.

The cleaning of hairs within the sinus and subsequent curettage, followed by the application of liquid phenol from the sinus opening, was first described by Maurice and Greenwood in 1964. In the early days of CPT, the procedure was performed under general anesthesia, but it has now become a conservative method performed under local anesthesia on an outpatient basis [14-18].

We also applied the same procedure to our patients.

In order to make the CP procedure easier and more comfortable, it is recommended to enlarge every sinus opening smaller than 3mm.

Enlarging the orifice allows for better observation during all stages of the procedure and prevents early closure of the sinus through granulation and epithelization mechanisms.

Evaluation of the patients	Findings	n	Total(n)	(%)	Total (%)
Symptoms first reported by the patient in the history and detected at the first visit	No symptoms	6	185	3.20%	100.00%
	Abscess	45		24.30%	
	Swelling	42		22.70%	
	Pain	46		24.90%	
	Discharge	46		24.90%	
Symptoms reported secondarily by the patient in the history and detected at the first visit evaluation	Swelling	6	64	9.40%	100.00%
	Pain	29		45.30%	
	Discharge	29		45.30%	
Number of pits determined by the first visit evaluation	1	94	185	50.80%	100.00%
	2	83		44.90%	
	3	8		4.30%	
Detection of the presence of abscess with the last visit evaluation-presence of complications	Absent	182	185	98.40%	100%
	Abscess	3		1.60%	
Detection of recurrence with the last visit evaluation	Absent	177	185	95.70%	100%
	Present	8		4.30%	
Detection of the presence of local individual hygiene (hair cleaning) with the last visit evaluation	Done	181	185	97.80%	100%
	Not done	4		2.20%	

Table 2. Evaluation findings of the patients

Follow-up Criteria	Recurrence (-)		Recurrence (+)		p
	(n = 177)	%	(n = 8)	%	
Age (years)					
≤ 25	97	54.8	1	12.5	0.027*
> 25	80	54.2	7	87.5	
Gender					
Woman	36	20.3	1	12.5	1.000*
Man	142	79.7	7	87.5	
BMI (kg/m²)					
< 30 (Normal)	119	67.2	1	12.5	0.003*
≥ 30 (Obese)	5	32.8	7	87.5	
Lifestyles due to their profession					
Ambulatory	42	23.7	1	12.5	0.683*
Sedentary	135	76.3	7	87.5	
Family history in terms of PSH					
Absent	120	67.8	5	62.5	0.716*
Present	57	32.2	3	37.5	
Symptom (n, %)					
Absent	6	0.56	0	0	0.680**
Abscess	42	23.7	3	37.5	
Swelling	41	23.1	1	12.5	
Pain	45	25.4	1	12.5	
Discharge	43	24.3	1	12.5	
Number of pit					
1	94	53.1	0	0	<0.001**
2	80	45.1	3	37.5	
3	3	1.8	5	62.5	
Local hair removal					
Done	174	98.2	7	87.5	0.163*
Not done	3	1.8	1	12.5	
Complication					
Absent	174	98.2	8	100	1.000*
Present (Abscess)	3	1.8	0	0	

* Fisher's Exact Test, ** Chi-square Test, BMI: Body Mass Index (kg/m²)

Table 3. Follow-up results of the patients

Sinus curettage is typically performed to remove granulation tissue.

In our study, patients had their sinus orifices, which varied in size from 0.1-4mm and number from 1-3, dilated with a cannula. We agree with the views that cleaning all the sinus content enhances the efficacy of phenol application. However, we would like to emphasize the importance of managing bleeding and serous leakage within the sinus. If there is bleeding and serous leakage in the sinus, it is known that CP's chemical cauterization effectiveness can be significantly reduced [19,20].

Hair is made up of proteins, specifically keratin in the form of polypeptides. Fenol, when used at concentrations above 5%, denatures the cellular proteins found in the cell membrane. As a result, the cell membrane and cellular proteins are broken down. It is clear that fenol's chemical

cauterization function can cause burns on the skin if applied in excessive concentrations [14, 15]. Irritant contact dermatitis and superficial cellulitis are the most common complications that arise from fenol application.

To prevent such complications, the perianal area and other non-surgical areas must also be protected, and the area around the pit should be protected with antibiotic cream or vaseline to prevent skin burns [19, 20]. Due to fenol's anesthetic effect, patients feel minimal pain after the procedure. Analgesics can be administered if needed [10, 16].

We also recommended our patients to use Paracetamol 500mg tablets if necessary. The rate of complications from fenol application is reported in the literature as approximately "0-15.2%," and it has been stated that this rate is "at an acceptable level for the effect on quality of life when compared to surgical procedures."

In our study, prior to phenol application, the surrounding skin tissue was protected with a topical antibiotic cream to counter the irritating and caustic effects of pure CP, and no chemical burn effects were detected on the skin during the controls. We also did not observe contact dermatitis or formation of superficial cellulitis in any of our patients.

After CP application, complications such as abscesses and cellulitis are most commonly seen [10]. A chronic abscess can develop via the sinus known as the drainage pathway [9, 20].

The abscess rate has been reported as 12.5% in the studies of *Schneider and colleagues* and 36.6% in the studies of *Dogru and colleagues* [13]. In our study, we detected abscesses in 3 of our patients, but we did not observe hematoma, cellulitis, or bleeding.

We believe that this result is due to effective hair cleaning before the procedure, expansion of the sinus orifice before the procedure, and thorough cleaning and drainage of the cyst cavity.

In the studies found in the literature, the recurrence rates of PSD during the follow-up period of patients range from 0% to 13.9%. In a study conducted by *Patmano and colleagues*, phenol treatment was applied to 64 patients with a single sinus and followed for 6 months, and a total of 6 (9.3%) patients had a recurrence.

Aygen and colleagues treated 36 patients who underwent surgery due to PSD and had a recurrence after the surgery with CP. They reported that 31 patients did not have a recurrence after a single session of CP, but 5 patients had a recurrence. It was stated that they were successfully treated after the second CP was applied [22].

In our study, recurrence occurred in 4.3% [8] of the patients, which is consistent with the literature findings.

In a study conducted by *Sözüer et al.* with 209 patients, the average age was 25.5 and the number of male patients was 4 times higher than the number of female patients, with an average pit number of 2.13. It was stated that nüks was seen in 17 patients after wound healing.

After 12 months of follow-up, a high success rate of 93.7% was achieved with CP application in the treatment of PSD. Also, low recurrence rate and acceptable complication rate were reported [23]. In our study, the average age of patients diagnosed with PSD was 26.75 ± 6.21 .

The recurrence rates in patients under 25 years of age were at the level of 1.0% while the recurrence rates in patients over 25 years of age were 8.0%. A statistically significant relationship was found between age and recurrence ($p=0.027$).

Two studies have been conducted on the treatment of pilonidal sinus with laser epilation.

In one study by *Girgin et al.*, laser epilation was performed on each patient before the first session of CP treatment. 6 to 8 sessions of laser epilation were performed 6 weeks apart and the patients were followed up on average for 24 months, with three-week intervals.

The study found that no recurrence occurred in any of the 42 patients, but the authors emphasized that the number of patients was small and the follow-up period was short, so they could not reach a definite conclusion [24].

In another study by *Ulusoy et al.*, 92 patients with an average age of 28 and pit counts ranging from 1 to 4 were followed up, and it was found that there was a statistically significant effect of hirsutism degree, presence of abscess at the start, and weekly shower count on recurrence.

Patients with recurrence were evaluated and it was noted that patients with 3 or more pits were predominantly affected. It was emphasized that hirsutism degree and pit count were effective factors for recurrence [25].

In a study by *Kaymakçioğlu et al.*, 143 patients were followed for 24 months. The majority of patients were young individuals (70.7%) in the age range of 20-30 years with an average age of 26.3. In the follow-up, 12 patients (8.3%) experienced recurrence, 10 in the same location and 2 in different locations.

The number of pits varied between 1-8. The results of the study showed that age was not a significant risk factor for PSD, but the volume of the sinus tract and the number of sinus orifices were found to be significant factors affecting recurrence.

The study also found that the recurrence rate increased significantly with an increase in the number of pits (1 pit=0.0%, 2 pit=3.6%, 3 pit=62.5%, $p<0.001$).

Aygen and colleagues reported that after multiple applications of CP, a high success rate (91.7%) was achieved in postoperative recurrent PSD. However, there is no consensus on the ideal number of CP applications [22].

The study by *Akkurt et al.* compared the *Karydakias flap technique* with CP in the treatment of sacro-coccygeal localized PSD. In the study, the median number of sinuses was 3 (2-3) and about 3-5 grams of CP was applied to each sinus opening. In the case of cavities that did not close and/or had persistent discharge, CP was applied every 10 days in 3 sessions for 60% of patients and in 2 sessions for 40% of the patients in the phenol group. *Akkurt et al.* concluded that CP is a less invasive alternative treatment option that can be applied before surgical treatment in selected patients [10]. In our study, we applied CP twice and followed up on the patients for 31 months.

We found that recurrence occurred in 8 patients (4.3%) in the final evaluation. We performed surgical procedures on 3 of these patients. Based on the results of our study, we concluded that age, BMI, and the number of pits are effective factors in the occurrence of recurrence after CP.

In a retrospective study where *Bayhan et al.* compared CP and modified Limberg flap procedures, they found that the recurrence rate was higher in the group of patients who underwent CP once (18.9% recurrence rate and 6.8% recurrence rate), however, the recurrence was not statistically significant between the compared groups.

The study also indicated that CP has a high success rate in treating recurrent pilonidal disease after surgery and can be a preferred option. Additionally, the study found that full healing was achieved in 71.87% of patients after a single CP application and in 92.3% of patients after multiple applications [27].

Our study showed a recurrence rate that was consistent

with the literature, as two CP applications were performed. It was stated that there is a strong correlation between the recurrence and high body mass index ($>24,9$ kg/m²) and presence of infection in the surgical area.

The success rate after multiple applications of crystallized phenol was found to be 94.5% [27]. Our study found that the recurrence rate was 0.8% in patients with a BMI value of <30 kg/m² and 10.8% in patients with a BMI ≥ 30 kg/m², and a statistically significant relationship was found between BMI and recurrence ($p=0.003$).

According to history, the "sinus containing hair" in the sacrococcygeal region was first described by *Herbert Mayo* in a female patient in 1833 and was defined by *Dr. Andersson* in the Boston Medical-Surgical Journal in 1847 [10,17]. Despite being first described in a female patient, it is now known to mostly affect young adult males [1-3]. It is two times more common in males than in females [28]. In our study, 80.5% of the patients were males, which is in line with the literature findings.

PSD is a condition that can have negative effects on quality of life due to pain, foul-smelling purulent discharge, and even abscess formation.

Predisposing factors for PSD include male gender, young age (often between the ages of 15-24), family history, Mediterranean ethnicity, deep natal cleft, obesity, hairiness, sedentary lifestyle, poor hygiene, excessive sweating, wearing tight undergarments and clothing. In recent years, it is believed that the accumulation of hair falling from the scalp, back and gluteal regions in the intergluteal sulcus causes PSD. These hairs can penetrate the skin when tight clothing is worn and during prolonged sitting, and reach the subcutaneous tissue, leading to chronic anaerobic inflammation and abscess formation. Additionally, the intergluteal area, where PSD is most commonly seen, is anatomically weaker due to the presence of serous glands. The skin in this area becomes more vulnerable and prone to maceration [29] due to the skin being in an intertriginous area and the opening of the serous glands in this region. In our study, no significant relationship was found between lifestyle due to profession, family history, local hair hygiene, and the presence of complications.

The study conducted by *Kargin et al.* is a cohort study with 20-year follow-up results, which found that the success rate of CP in patients who underwent surgery due to refractory chronic pain syndrome was 71.5% with an average of 2.6 infusions. The success was reported in patients who adhered to the treatment and did not discontinue it.

The patients were followed for an average of 45.8 months and 72.4% of the relapses after CP occurred within the first five years and 97.4% within the first 10 years. The longer the disease duration before treatment, the higher the risk of relapse after treatment was also noted [30].

In our study of 185 patients, 3 (1.6%) developed abscesses and 8 (4.3%) had relapses, indicating a high success rate.

Yirgin et al. reported in their studies on PSD that CP resulted in higher patient satisfaction, shorter hospital stays, and earlier return to daily activities [11]. In a study by *Kayaalp et al.*, it was reported that four relapses were seen in patients who received a single session of CP after a 14-month

follow-up. It was emphasized that a single session of CP is an effective treatment for PSD, with acceptable healing rates, less postoperative pain, and shorter absence from work, and could be considered as an alternative treatment method [31].

The results of our study are in line with the literature that states that the relapse rate increases with an increase in the number of pits [21]. We believe that an increase in BMI can lead to a constant moisture in the intergluteal area, excessive hair accumulation, reduced local hair care, and personal hygiene, which can lead to an increase in relapses. We would like to emphasize that our relapse rate is low. We believe that this result is due to the good cleaning of the cavity from hair and debris before the procedure and that the procedure was two-stage.

According to a literature review conducted by *Doll et al.*, the number of patients affected by PSD has exceeded 40,000 since 2010. It was found that Turkish surgeons contributed the most to the literature on this topic, with 39% of studies on Mediterranean patients and 18% of studies on worldwide patients being published by them. They also reported that there has been a significant increase in knowledge and the number of patients studied in recent years on PSD [32].

Our study has two limitations. First, it is a single center, retrospective study. Secondly, the sample size is moderate compared to published studies. In recent years, when looking at studies, there is also a limitation in terms of the procedure as an intervention. Additional interventions are needed before and after the CP application. Laser epilation, for example, is a good practice due to its hair removal and hair reduction effects. The determination of hair growth level, the identification of the duration of symptoms from the onset and a more detailed examination of lifestyle are becoming increasingly important as evidence of their significance in investigating predisposing factors increases.

Another limitation in our study is that it is not a randomized controlled study, so the surgical treatment options for PSD cannot be compared in terms of complications and recurrence. Finally, as we believe that all preventable predisposing factors should be examined together, the follow-up period in our study is relatively short.

Conclusion

In our study, we did not encounter a secondary serious complication by applying the CP in two stages. We observed that our patients returned to their routine lives painlessly in the early stage and that our recurrence rates were also low. With our findings, we can say that the application of CP for PSD treatment is still a safe and valid method as a minimal invasive intervention. We believe that this application can be preferred by managing with a proper indication and some additional lifestyle changes. Further research in the form of multi-center, large-scale randomized controlled studies to explore all the factors affecting the treatment methods, recurrence, and complication rates may contribute to developing a standardized approach for CP application based on the accumulated evidence-based knowledge.

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Different Pain Types at Coccygodynia and its Relation with Vitamin D Level.

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Abstract

Background: Coccygodynia is a musculoskeletal disease that affects quality of life. The main complaint of coccygodynia is nociceptive and/or neuropathic pain. Vitamin D deficiency has been associated with the development of pain in various diseases.

Aims: In this study we aimed investigate the pain types (nociceptive, neuropathic, mixed) and the relationship between pain types and Vitamin D level in patients with coccygodynia.

Study design: Observational study

Materials and Methods: A total of 54 patients diagnosed with coccygodynia were included. Pain intensity, disability and pain type were evaluated by Visual Analogue Scale (VAS), the Oswestry Disability Index (ODI), and the PainDETECT questionnaire, respectively. All participants had their vitamin D levels measured.

Results: Neuropathic pain was detected in 27.8% of the patients with coccygodynia. Vitamin D was determined to be insufficient or deficient in 81.5% of the patients. A statistical significant correlation was found between neuropathic pain and prolongation of coccygodynia and increased ODI values ($p < 0.05$). The Vitamin D values were determined to show statistically similar distribution in the nociceptive, mixed type, and neuropathic pain groups ($p = 0.532$).

Conclusion: The frequency of neuropathic pain in coccygodynia increases with increasing disability and disease duration. Although vitamin deficiency or insufficiency is common in coccygodynia, it is not associated with the type of pain.

Keywords: Neuropathic pain, Nociceptive pain, Coccyx, Vitamin D deficiency

Introduction

Coccygodynia is a painful clinical condition felt in the coccyx region (tailbone), which increases after a certain period of sitting or standing. [1, 2] The most common cause of coccygodynia is trauma but it may also emerge as idiopathic. [1]

DeAndres et al stated that the type of pain in coccygodynia could be somatic, neuropathic, or mixed type. [3] The chronic inflammatory process that develops following mechanical injury causes a change in the response of neurons over time. [4]

Repeated nociceptive inputs can trigger a long-term increase in synaptic activity and excitability of neurons in the central nociceptive pathways. Neuropathic pain symptoms develop in this condition. [5]

In recent years, Vitamin D has been shown to be responsible for the neurological, hormonal, and immunological effects in the formation of pain, and therefore has an important role in chronic pain. [6] Vitamin D deficiency has been associated with several musculoskeletal pain disorders and neuropathic pain syndromes. [7, 8]

To the best of our knowledge, there are no studies yet that have investigated the role of Vitamin D deficiency in coccygodynia.

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The objective of this study investigate the pain types (nociceptive, neuropathic, mixed), and the relationship between between pain types and vitamin D level in patients with coccygodynia.

Material and Methods

This prospective, cross-sectional study included patients diagnosed with coccygodynia who were consecutively admitted to a Sivas Cumhuriyet University Hospital Physical Medicine and Rehabilitation outpatient clinic between August and December 2021. The diagnosis of coccygodynia was made by a senior consultant based on a thorough medical history, clinical examination, and imaging procedures. Inclusion criteria were patient age in the range of 18- 70 years with coccygodynia, measurement of vitamin 25 (OH) D level and agreement to participate in the study. Exclusion criteria were defined as [1] presence of known polyneuropathy, [2] Diagnoses of diabetes mellitus, renal failure, thyroid disease that may lead to the development of neuropathic pain [3] taking vitamin D replacement therapy, [4] use of any medication that could affect neuropathic pain (such as duloxetine, pregabalin, gabapentin and tramadol), and [5] having received an injection or physical therapy for the treatment of coccygodynia in the last 3 months (Figure I).

A record was made for each patient of age, gender, body mass index (BMI), duration of symptoms, etiology of coccygodynia, pain severity, pain type. BMI was calculated as body weight (kg) divided by squared height (m²).

Serum 25-hydroxyvitamin (25-OHD) levels were measured by using a commercially available

chemiluminescence Immunoassay Kit. Patients were classified as having vitamin D deficiency with 25 (OH) D level of ≤ 20 ng/mL, vitamin D insufficiency with a level of 21–29 ng/ mL, or normal vitamin D with a level of ≥ 30 ng/ mL. [9]

The patients were assessed using a Visual Analogue Scale (VAS), the Oswestry Disability Index (ODI), and the PainDETECT questionnaire.

VAS: The intensity of pain of patients was assessed using the VAS pain score (0–10 cm, with higher scores indicating more pain). Patients' pain intensity at night, pain at rest and pain in active motion were questioned.

ODI: The ODI is used to determine functional level, and comprises 10 items measuring pain severity, personal care, rising from a seated position, walking, sitting, standing, social life, sleep, travel and the degree of pain. The maximum score is 50 points with higher total points indicating a higher level of disability. The total points are converted to a percentage value representing the disability percentage. Validity and reliability studies of the ODI in Turkish were conducted by *Yakut et al.* [10]

PainDETECT: This scale is used to evaluate the presence of nociceptive, neuropathic and mixed type pain. [11] A total score of <12 points is accepted as nociceptive pain with no presence of neuropathic pain. A total score of 13-18 points is indecisive and accepted as mixed type, in which there is a neuropathic component, and when the scores is ≥ 19 points, it is accepted that there is a neuropathic pain component. Validity and reliability studies of the questionnaire in Turkish were conducted by *Alkan et al.* [12]

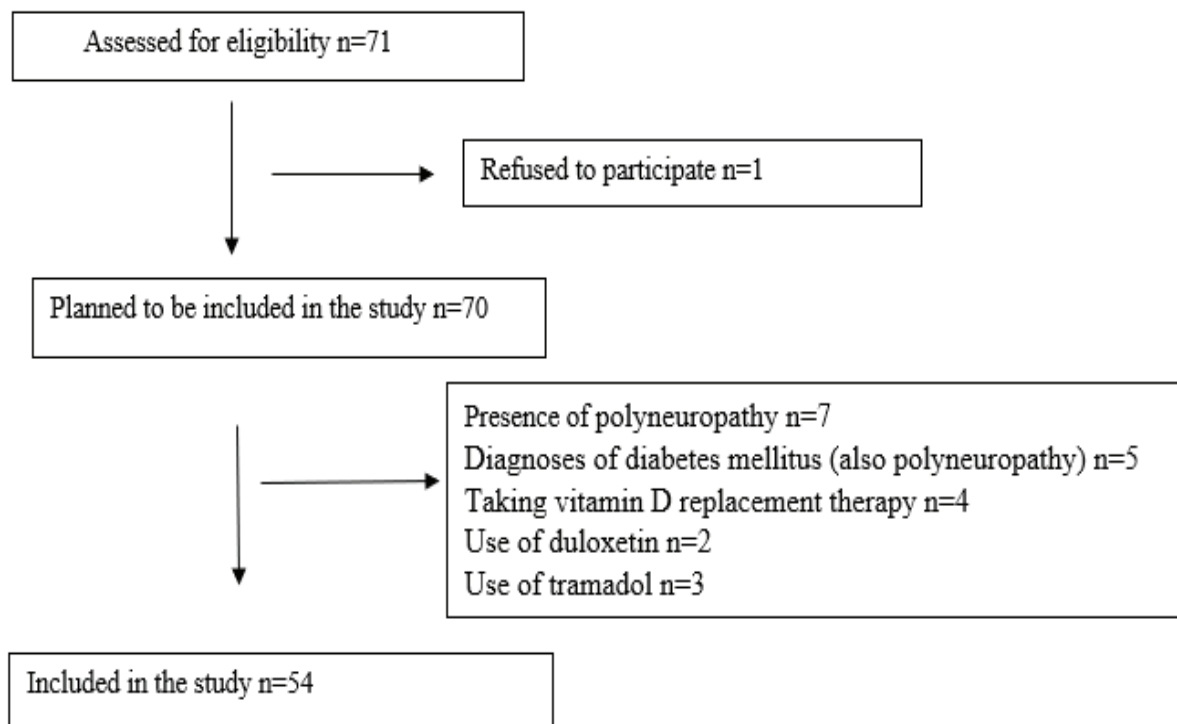


Figure I. Flow diagram of the treatment of coccygodynia

Statistical Analysis

Data obtained in the study were analyzed statistically using IBM SPSS Statistics Standard Concurrent User Vn. 26 software (IBM Corp., Armonk, NY, USA). Descriptive statistics were stated as number (n) and percentage (%) for categorical variables and as mean \pm standard deviation (SD), median, minimum and maximum, and interquartile range (IQR) values for continuous variables. The normal distribution of numerical variables was assessed with the *Shapiro Wilk test*. In the comparisons between the groups, One-Way Variance analysis was applied to variables with normal distribution and *Kruskal-Wallis analysis* was applied to variables not showing normal distribution. When a difference was found between groups as a result of *Kruskal-Wallis analysis*, the *Dunn-Bonferroni test* was used as a multiple comparison test. Relationships between categorical variables were compared with the Pearson Chi-square test exact method. When significance was determined in the Chi-square test, subgroup analyses were made with the *Bonferroni corrected Paired Ratio z test*.

A value of $p < 0.05$ was accepted as statistically significant.

Ethical Consideration

Study procedures were in accordance with the ethical standards of the responsible committee on human experimentation. The study was approved by Sivas Cumhuriyet University Ethics Committee. (2021-06/20) and Helsinki Declaration was taken into consideration. All participants underwent structured interviews and provided written informed consent to participate in this study.

Results

A total of 54 patients were included in the study. Table 1 shows the demographic and clinical characteristics of the patients. In all the patients, coccygodynia was determined as idiopathic or to have developed secondary to trauma. When classified according to BMI, 1 (1.9%) patient was classified as underweight (< 18.5), 10 (18.5%) as healthy weight (18.5-24.9), 24 (44.4%) as overweight (25-29.9), 15 (27.8%) as obese (30-39.9) and 4 (7.4%) as morbidly obese.

The median VAS values were determined as 4.0 (0.0-10.0) when active, 8.0 (4.0-10.0) at rest, and 5.0 (0.0-10.0) at night. The duration of sitting of the patients was determined to be mean 10.0 mins (range, 0-120 mins). According to the PainDETECT classification, neuropathic pain was determined in 15 (27.8%) patients and not in 24 (44.4%) patients. The type of pain was uncertain in 15 (27.8%) patients. The Vitamin D level was determined to be normal in 10 (18.5%) patients, insufficient in 11 (20.4%), and deficient in 33 (61.1%).

The relationships between the variables and the pain types according to the painDETECT scores are shown in

Female/male		47 (87.0)/7 (13.0)
Age, (years)		44.4 \pm 11.8
BMI, (kg/m ²)		29.05 \pm 5.56
Disease duration, (years)		12.8 \pm 11.4
VAS	Active	4.1 \pm 3.8
	Rest	8.1 \pm 1.7
	Night	4.1 \pm 3.7
Duration of sitting, (mins)		19.2 \pm 25.3
painDetect		14.7 \pm 6.7
ODI		42.5 \pm 18.3
25 (OH) D level (ng/mL)		20.51 \pm 13.04

Data presented as mean \pm standard deviation or number (%) BMI: Body mass index,

VAS: Visual Analogue Scale, ODI: Oswestry Disability Index

Table 1: Demographic and clinical characteristics of patients.

Table 2. No relationship was determined between age, BMI, gender, and the neuropathy status ($p=0.678$, $p=0.546$, $p=0.180$, respectively). A relationship was determined between the presence of neuropathic pain increasing the duration of coccygodynia and the ODI ($p < 0.05$). The VAS active values of patients with neuropathic pain were determined to be statistically significantly higher than those of patients with nociceptive pain and mixed type pain ($p < 0.05$). The relationship between neuropathic status and the VAS resting and VAS night values was not found to be statistically significant ($p=0.082$, $p=0.086$). The sitting duration of patients with neuropathic pain was determined to be significantly shorter ($p < 0.05$).

The Vitamin D values were determined to show statistically similar distribution in the nociceptive, mixed type, and neuropathic pain groups ($p=0.532$).

No statistically significant difference was found between the Vitamin D levels according to age, BMI, disease duration, VAS resting, VAS night, sitting duration and ODI values (Table 3).

The rate of Vitamin D insufficiency was found to be higher in male patients than in females.

Discussion

In this study, there was determined to be neuropathic pain in 27.8% of the patients with coccygodynia. Neuropathic pain was seen to be associated with increasing disability, disease duration, pain severity with activity, and shortened sitting duration. In 81.5% of the coccygodynia patients, 25 (OH) D vitamin was determined to be insufficient or deficient. Vitamin D insufficiency and deficiency were not correlated with pain type,

		Pain types			<i>p</i>
		Nociceptive (score ≤ 12)	Neuropathic (score ≥ 19)	Unclear (score 13-18)	
Female, <i>n</i> (%)*		19 (40.4)	15 (31.9)	13 (27.7)	0.180
Male, <i>n</i> (%)*		5 (71.4)	0 (0.0)	2 (28.6)	
Age, years, mean ± <i>sd</i>		46.1±12.3	43.7±12.4	42.7±11.1	0.678
BMI, kg/m² mean ± <i>sd</i>		29.72±5.27	29.28±5.87	27.72±5.83	0.546
Disease duration, <i>M</i>(<i>IQR</i>)		6.5 (8.5) ^a	20.0 (18.0) ^b	9,0 (14.0) ^{ab}	0.036
VAS <i>M</i> (<i>IQR</i>)	Active	8.0 (4.0) ^b	0,0 (5,0) ^a	8.0 (4.0) ^b	0.008
	Rest	9.0 (2.0)	9.0 (2.0)	9.0 (2.0)	0.082
	Night	6.0 (4.0)	0,0 (6.0)	6.0 (4.0)	0.086
Duration of sitting, <i>M</i> (<i>IQR</i>)		15.0 (20.0) ^a	5.0 (10.0) ^b	7.5 (9.0) ^b	0.010
ODI(%), <i>M</i> (<i>IQR</i>)		31.5 (28.8) ^a	60.0 (18.0) ^b	40.0 (23.0) ^{ab}	0.001
25 (OH) D, (ng/mL), <i>M</i> (<i>IQR</i>)		16.85 (13.20)	19.40 (23.90)	13.20 (17.6)	0.549
Vitamin D classification					
Deficiency		15 (62.5)	8 (53.3)	10 (66.7)	0.532
Insufficiency		6 (25.0)	2 (13.3)	3 (20.0)	
Normal		3 (12.5)	5 (33.3)	2 (13.3)	

sd: Standard deviation, *M*: Median, *IQR*: Interquartile range, ^a, ^b show differences between groups. Groups with the same letters are statistically similar.

BMI: Body mass index, *VAS*: Visual Analogue Scale, *ODI*: Oswestry Disability Index

Table 2: Comparison of patients with neuropathy status according to numeric variables

In the current study, females were predominant and more than half of the patients in the sample were obese. BMI is an important factor, and obesity is 3-fold more widespread in patients with coccygodynia than in the normal population. [13] Female dominance is connected to the more posterior localisation of the sacrum and coccyx in females, and being more exposed to trauma during childbirth. [3]

Neuropathic pain is defined by the IASP as pain related to a lesion of the somatosensory system or disease. [14]

Pain in coccygodynia develops from the nerve roots, plexus, and peripheral nerves associated with the coccyx, contractions of the muscles holding the tailbone, and injury

with tissue inflammation around the coccyx and coccygeal joints. [15]

The pathophysiology of pain in coccydynia is similar to that in musculoskeletal diseases. Although nociceptive pain is primarily seen in musculoskeletal diseases, it has been determined to be accompanied by neuropathic pain in recent years. [16]

In a study in which the LANSS neuropathic pain questionnaire was applied to patients with chronic musculoskeletal pain, neuropathic pain was determined in 13%. [17]

Peripheral sensitisation probably develops in

		25 (OH) D level			p
		deficiency	Insufficiency (21-29)	Normal (s ≥ 30)	
Female, n (%)*		30 (63.8)	7 (14.9) ^x	15 (31.9)	0.036
Male, n (%)*		3 (42.9)	4 (57.1) ^y	0 (0.0)	
Age, years, mean ± sd		42.3±12.4	48.1±12.9	47.4±6.9	0.271
BMI, kg/m² mean ± sd		29.9±5.6	28.3±2.5	26.8±7.2	0.285
Disease duration, M(IQR)		11.0 (20.0)	6.0 (6.0)	15.0 (18.0)	0.611
VAS M (IQR)	Active	4.0 (7.5)	3.0 (9.0)	4.5 (9.3)	0.718
	Rest	8.0 (3.0)	9.0 (3.0)	8.0 (3.3)	0.978
	Night	5.0 (7.0)	5.0 (6.0)	5.5 (8.3)	0.949
Duration of sitting, M (IQR)		10.0 (10.0)	10.0 (28.5)	12.5 (10.0)	0.572
ODI (%), M (IQR)		40.0 (22.5)	44.0 (38.0)	51.0 (44.0)	0.808

sd: Standard deviation, M: Median, IQR: Interquartile range; ^x, ^y: shows the statistical difference between female and men

BMI: Body mass index, VAS: Visual Analogue Scale, ODI: Oswestry Disability Index

Table 3: Comparison of patients by Vitamin D Level according to numeric variables

coccygodynia with continuous nociceptive stimulation originating from the coccyx and the muscles and joint holding the coccyx. Continuous nociceptor activation causes an increase in afferent stimuli of the dorsal horn of the spinal cord.

This process induces structural and functional changes throughout the spinal cord and more rostral structures, respectively, and ultimately leads to central sensitisation. [18]

As a result of peripheral and central sensitisation, neuropathic pain components are seen. [18, 19]

The frequency of neuropathic pain was 27.8% in our study. The ganglion impar that formed with the termination of the sympathetic chains in the sacral region is thought to have a role in the development of neuropathic pain in coccygodynia. [2, 3]

Sençan et al [4] reported that sympathetic hyperactivity was caused by chronic irritation of the coccygeal nerve associated with biomechanical changes of the coccyx, and the neuropathic pain in coccygodynia was reduced with ganglion impar block.

They reported that neuropathic pain was determined

with the LANSS questionnaire in 29 of 33 patients with coccygodynia. However, as the patient population in that study comprised cases who had not responded to conservative treatment and it was reported that this may not reflect the true incidence of neuropathic pain. [4]

The higher frequency of neuropathic pain in our study may be due to the fact that the patients did not respond to conservative treatment.

In recent studies, Vitamin D deficiency has been determined to be associated with the etiology of several different chronic painful conditions. [19] Although Vitamin D has been found to be lower in females in various musculoskeletal pain conditions, in the current study a higher rate of Vitamin D deficiency was determined in males. [20, 21]

The relationship between Vitamin D deficiency and symptom severity in chronic pain was determined by *von Kanel et al.* [22] However, the results of the current study showed no relationship between Vitamin D deficiency and pain severity and disability.

In experimental studies, cholecalciferol supplementation with created mononeuropathy was

determined to reduce mechanical hyperalgesia and cold allodynia. [8]

In another study of a rat model with neuropathic pain, cold allodynia and heat hyperalgesia were determined to be reduced with the application of Vitamin D3. [23] In the current study, no relationship was determined between Vitamin D deficiency and neuropathic pain in patients with coccygodynia.

Conclusion

In conclusion, nociceptive and neuropathic pain are seen in coccygodynia. The results of this study demonstrated that the presence of neuropathic pain is associated with disability, pain duration, pain severity with activity, and shortened sitting time in coccygodynia, but is not associated with the Vitamin D level. According to the data obtained in this study, the importance of the type of pain and independent evaluation of the Vitamin D level will be of guidance in providing the necessary medical treatments.

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Conflict of Interest

The authors declare have no conflict of interest. This research received no specific grant.

Author contribution to the study

E. G (concept, design, supervision, resource, materials, data collection and/or processing, analysis and/or interpretation, literature search, writing, and critical reviewing).

H.A.Ü (literature search, writing)

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Influence of Healthcare on the Outcome of the Treatment of Patients with Stoma.

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Abstract

Background: Although stoma is a crucial surgical procedure, this operation has a physical and psychosocial impact on the patient, their habits and quality of life, which they should be properly educated on.

Objectives: The purpose of the work is to analyze the impact of health care, key factors and problems that affect the final outcome of treatment in patients with a stoma, as well as suggestions and guidelines for improvement.

Material and Methods: The results of 10 studies were reviewed including clinical trials, randomized prospective and retrospective studies published between 2011 and 2021.

Results: Education of patients, their families, and medical staff is crucial in improving the quality of life of patients with stoma but also in reducing potential complications of stoma, along with stoma marking. It is also necessary to pay special attention to psychosocial problems in patients, as well as stoma problems in Bosnia and Herzegovina.

Conclusion: More needs to be invested in educating staff, patients and their families about stoma, and integrating stoma patients into society in order to improve their life quality.

Keywords: stoma, complications, quality of life, stoma education

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Introduction

Health care of a patient with a stoma includes professional planning, implementation and evaluation of the specific procedures performed. As the operation can essentially solve the cause of the disease, the nurse/medical technician, enterostomal therapist, will prevent, detect and solve the accompanying problems that the sick person has due to the disease or operation, with planned activities in the field of health care. Continuous professional development of nurses and standardization of the procedures and activities carried out is necessary. In this way, we ensure equality in quality and increase patient safety, related to the performed procedures to which we expose them. The goal of planning the health care of a patient with a stoma is to establish a balance between the realistic possibilities and needs of independent care [1]. The knowledge and skills of healthcare professionals can help improve the quality of life before and after surgery [2].

The aim of the work is; to analyze the impact of health care on the final outcome of treatment in patients who have stoma; to analyze the key factors and problems that influence the outcome of the treatment of people with a stoma; to present proposals for better care of people with a stoma based on the research results

Research methodology

A review of scientific literature published in reference databases (PubMed, Google Scholar, ScienceDirect, Annals of Rehabilitation Medicine, Dabar, ResearchGate, Science Citation Index, CrossRef, Index Copernicus, Icmjer, Reviewer Connect Publons) was performed. It includes clinical trials, randomized prospective and retrospective studies. The research includes studies that were published in English, in the period between 2011 and 2021. The criteria for inclusion in this paper are scientific research studies that are primarily focused on the impact of health care on the outcome of stoma treatment in patients, more precisely on the physical and psychosocial impact, lifestyle habits, quality of life, and the importance of education for patients with stoma. Keywords for the search are the following: stoma patients, stoma education, impact of stoma, quality of life.

Research Results

Using the PRISMA flow diagram, a selection of 10 scientific research papers that meet the set criteria was made. All professional papers with their general characteristics are tabulated below for clarity (table 1).

Discussion

Colon cancer is becoming a growing public health problem. The location of the stoma is an independent risk factor for the development of stoma complications. Preoperative marking of the stoma should be considered to reduce the risk of stoma-related complications [3]. Several retrospective studies have shown that preoperative stoma marking can reduce the rate of complications and enable optimal stoma care for the patient during daily activities [4].

A statistically significant difference was found in the study by *Baykar ZG et al.* where stomal and peristomal complications developed in 40% of stoma patients who underwent emergency surgical interventions, and in 31.1% of stoma patients who underwent planned surgical interventions [5].

Most patients who have developed peristomal skin complications have caregivers and family who are not sufficiently educated to help them with stoma care [6].

Person B et al. shown necrosis usually develops and remains in this form in a small number of patients, from 0.6 to 4.6%, while stoma dehiscence occurs more often, from 7.8 to even 19.5% of patients), with very a small number of those who do not experience severe stoma dehiscence, about 2.2% [7].

It has been shown that early complications are more common after colostomy than ileostomy.

Koc U et al. in their study found the rate of stoma retraction was significantly higher in women than in men (5.9% vs. 2.7%), overall 11.1% in eight dental departments in Turkey [8]. Slightly lower retraction rates were found in 3.2% of patients at the *Turkiye Yuksek Ihtisas Teaching and Research Hospital in Turkey*. Stenosis occurs in some studies from 0.9% to 2.2% [8].

The rate of parastomal hernia in patients in the studies used in this paper is low, ranging from 0.2% to 0.7% [9, 10, 11, 12].

Stoma prolapse was recorded in a small number of patients as well, from 2.7% (11) to 3.2% [13].

The type of stoma, type of operation, surgical technique, preoperative marking of the stoma site and general health of the individual - in addition to preoperative and postoperative follow-up care, appropriate peristomal skin care and patient education - influence the development of complications [14].

Several studies have found that stoma patients faced several problems after stoma creation due to lack of education, preoperative preparation, and postoperative care. Several studies have shown that the rate of stoma complications is lower after ileostomy than after colostomy surgery. [15, 16]

The quality of life of patients whose stoma sites were marked preoperatively was significantly better than that of unmarked patients, their independence parameters were significantly better, and the rate of complications was significantly lower. All these results were significant regardless of the type of stoma. Preoperative marking of the stoma is essential for improving the postoperative quality of life of patients, encouraging their independence and reducing the rate of postoperative complications. [17]

According *Szpilewska et al.* the majority of respondents have limitations in their daily activities (56.43%), while 21.78% of people stated that they do their daily activities better in Poland [18].

Anaraki et al. state that almost half of the patients included in the study, 48% to be exact, were forced to change their clothing style in order to adapt to life with a stoma. Patients with a stoma, for reasons such as the location of the stoma, changes in weight and changes in body appearance, were forced to change their clothing style, which in itself reduced their quality of life.[19]

In a study by *Szpilewska et al.* the majority of respondents stated that their health worsened after the operation, 19.80% of respondents felt that their health had improved, and 23.76% of respondents did not notice a clear change. People spoke similarly about the way to rest after surgery. The frequent occurrence of physical pain after surgery was mentioned by more than 23% of respondents, and 52.47% experienced it sporadically [18].

In the same study, economic conditions worsened for more than 58% of respondents, while others rated them

as unchanged (27.72%) or better (13.86%). Most of the patients reported that they had to change or leave their jobs after the onset of the disease, and that this had a significant impact on their income.

When the person regains his strength, after the end of the treatment and recovery, he can return to his regular activities and jobs that he did before. As many as 12.87% of patients report that they do not feel any limitations in their professional work [18]

When returning to work, one should explain to the employer what a stoma is. Most employers support and understand people with a stoma without any problems. The best way is to talk openly, and this will also help in educating other associates.

Physical jobs such as carrying or lifting heavy loads, and similar heavy jobs are not recommended and should be replaced by lighter ones, which was done by 83.3% of respondents from the study by *Anaraki et al.* [19], because they can cause stoma prolapse or hernia.

While the majority of patients (81.4%) reported being sexually active before stoma surgery, only 33.3% continued to be sexually active after surgery. It was reported that 31.4% of patients were satisfied with sexual activities, and 40.2% of male respondents had problems with erection, according to *Anaraki* [19]. On the other hand, in Poland, 54.45% of people showed a similar or better interest in sex, and 25.74% much less [18].

As many as 82.4% of patients were forced to change their dietary habits after stoma surgery, according to *Anaraki and colleagues.* [19]

Most patients had a change in diet due to gas control problems, but most of them coped with these conditions over time [20].

These results emphasize the need to develop long-term support mechanisms so that patients can better cope and adapt to life with a stoma, while in one study this was measured by an ostomy-specific questionnaire called the Ostomy Adjustment Scale (OAS) [21].

Most patients report that it took them at least 6 months to feel comfortable with daily care and nutrition.

Although most patients get used to this kind of life over time, they have to make sacrifices in the form of adjusting their lifestyle and habits, such as diet, clothing, work, physical activities, etc., all of which affect the individual's personal experience of the quality of life [22].

Patients often become depressed, which is usually more than 50% of patients. Research in Poland states that the respondents stated that after the operation they did not enjoy any kind of entertainment or very rarely and exceptionally - as many as 75.24% [23].

Szpilewska et al in relation to satisfaction with appearance states that 18.81% of people noticed a better appearance after the operation, 56.4% worse, while 24.75% did not notice any change. The majority of respondents accept their illness at an average level (66.33%), scoring from 19 to 29 points on the AIS (Acceptance of Illness

Scale). Not accepting the disease affects women more often (M - 10, F - 21). Men (75.0%) have a better level of acceptance of the disease than women (60.7%). The minimum number of points achieved during the assessment of acceptance of the disease was achieved by a person with a higher education. [18].

People who stated that they have a basic education indicate a much better level of acceptance of their illness. This indicates that there are statistically significant differences between education and the degree of acceptance of the disease, so it can be concluded that education affects the degree of acceptance of the disease. The higher the degree of acceptance of the disease, the better the patients' quality of life [24].

A stoma can affect both the intra and interpersonal aspects of the lives of those who live with it, in a negative and positive way. Consequently, relationships with partners, family members and friendships can be causes of trouble. On the other hand, partners provided support for some, and children were also a source of comfort. A stoma can destabilize one's sense of self, disrupt one's body image, and change one's experience age and sexuality. Other participants were able to use their illness to positively reshape themselves. Disclosing ileostomy status was difficult for some. Intimate and friendly relationships were often questioned due to the stoma status, while other family relationships were largely characterized as supportive [25, 26].

Women described more specific psychological and social problems than men.

Living with an ileostomy also affects relationships with others: partners, friends and family. According to *Smith et al.*, for some, the ileostomy led to the perception or fear of rejection from other people, while the rest of the respondents received support from people in their social circle [27].

Almost 41% of the respondents stated that their relations with their relatives had worsened, and 19.80% experienced an improvement in this area. Statements related to friendships and social contacts are similar: their improvement is indicated by 19.80% and 16.83%, and deterioration by 46.53% and 48.5%, respectively, states *Szpilewska and associates* [18].

Perhaps this is due to the fact that the physical and psychological disorders resulting from a stoma can gradually reduce a person's self-confidence and reduce their social relationships. These factors are often closely related and lead to a certain degree of social isolation [28].

As self-efficacy is an essential component of living with a stoma, appropriate preoperative counseling and postoperative follow-up services for patients and their families are essential to address multidimensional issues including psychosocial and sexual aspects. Furthermore, integration with all related specialties, including psychosocial well-being and sexual health, and the formulation of a stoma support group would be helpful to share their experiences [15].

Because of these results, the main focus should be on the social reintegration of patients with a stoma. Considering the physical obstacles of a stoma, which are mastered over time, patients in most cases consider themselves less valuable, so they often withdraw from social situations, relationships, or avoid them completely, thus leading to isolation.

On the other hand, the closest family and closest social circle of the patient are mostly fully present, which ultimately helps the patient to overcome the psychological effects of the stoma.

Depression, anxiety, disturbed self-image and lack of self-confidence stand out.

Living with a stoma affects the entire aspect of quality of life. The presence of a permanent stoma can affect the quality of life, and a permanent stoma is associated, for example, with poor self-esteem and increased financial worries, although this did not affect the global quality of life.

It is an interesting fact that, although the QOL (Quality Of Life) specific to the stoma was often acceptable, it was still necessary to solve numerous problems related to the stoma. Health quality of life was measured by HRQOL and SF-36 questionnaires and 15D instrument, while QOL was measured by COH QOL Ostomy and Stoma QOL questionnaires [27].

Acceptance of the disease is closely related to the quality of life of stoma patients. Of the group of respondents in Poland who do not accept the disease, 23% showed a poor quality of life. The quality of life at a good level in this group of people is marked with 77%. No one in this group has a very good quality of life.

Among the group of respondents, whose acceptability of the disease is at an average level, up to 93% of people have a good quality of life. 3% answered that they have a bad quality of life, and 4% that they have a very good quality of life. Of the group of respondents who accepted the disease at a good level, 67% pointed out that their quality of life is good. 33% answered that they have a very good quality of life [18].

Problems related to the stoma mentioned included sexual problems, feelings of depression, gas, constipation, dissatisfaction with the appearance, changing clothes and difficulty traveling, feeling tired and worrying about noises from the stoma. Patients with a stoma had more problems in physical functioning, worse ratings of fatigue and loss of appetite, and more problems with self-image and sexual functioning of the body than patients without a stoma [16].

Sexual disorders and feelings of depression were major problems of patients with a stoma, and sexual and psychological consultations can improve the quality of life of patients [14].

Furthermore, the best quality of life was observed in the group of people with the highest level of education (university and high school), while the statistically significantly lowest values were among people with completed or incomplete elementary school [18].

On the other hand, people with higher education received the minimum number of points achieved when assessing the acceptance of the disease, while people who declared primary education indicated a significantly better level of acceptance of their disease. Szpilewska states that there are statistically significant differences between education and the degree of acceptance of the disease, so it can be concluded that education affects the degree of acceptance of the disease [18].

In order to further distinguish whether time, as one of the key predictors of QOL, has an influence on the mentioned problems, all categories were analyzed over time from the creation of the stoma to 8 years after placement. According to the obtained results, people with a stoma have the most problems related to the product, namely the first group who have had a stoma for 6-12 months and the second group of respondents who have had a stoma for 4-8 years. The above can be explained in the first group by fear, lack of knowledge and manual skills and possibly an inadequate choice of stoma device, while the results of the second group can be explained by a loss of will and interest and laxity, as well as security in the existing stoma device without the need and interest in changing the stoma device in terms of novelty available on the market [27].

Analyzing the relationship between the quality of life and the type of stoma, a difference can be observed in all domains of quality of life assessment. People with a colostomy have, on average, higher average scores in the overall QoL score. A particular difference is visible in the spiritual domain [26], while the social subscale had the lowest score. [27].

As mentioned earlier, depression and problems with stoma localization were considered predictors of overall quality of life

The quality of life in patients with a stoma is significantly lower than in patients without a stoma. Adaptation to the new physical condition comes with psychological, social, economic, and these are just some of them [10-18].

As for hospitalization, education can play an important role in its duration. Patients who were included in the already mentioned ERAS program had a significantly shorter number of days of hospitalization compared to patients who were not. The total hospital stay for patients who received a stoma was significantly shorter in the ERAS group, an average of 6 days, with a range of 2 to 21 days, compared to patients who received standard care, an average of 9 days, with a range of 5 to 45 days. Postoperative length of stay was also shorter in the ERAS group, an average of 5 days, with a range of 2 to 12 days, compared to patients who received standard care, an average of 9 days, with a range of 5 to 24 days.

There is also a significant difference in the proportion of patients who developed complications with a stoma, 38% in the ERAS group and 51% in the standard care group [18]. Educational activities aimed at increasing knowledge and focusing on the psychosocial needs of patients can lead to

an increase in the health-related quality of life of patients. When patients with a stoma attend a structured patient education program, it is possible to improve their health-related quality of life compared to patients with a stoma who do not attend the program. Establishment of a structured patient education program aimed at patients with a stoma improved by a specific disease within the framework of health quality of life.

A program that includes interventions aimed at increasing knowledge as well as self-management could benefit from the involvement of lay teachers in addition to health professions teachers. Furthermore, the use of telephone follow-up after hospital discharge can increase patients' health-related quality of life [20].

A study conducted in Taiwan shows that an educational intervention using a multimedia approach, early in the postoperative period, can have a positive effect on the level of knowledge and also promote attitudes and behavior about self-care. Given these results, legislators should consider replacing written information with more detailed multimedia programs as part of postoperative education for stoma patients. For example, multimedia programs have a place in the early education of patients after surgery [7].

Significant changes in health quality of life assessments were most likely a consequence of the beneficial effect of participation in the educational program. One of these studies showed that preoperative education of patients in the patient's home had a significant impact on the acquisition of knowledge of patients about coping with a stoma [13].

Preoperative and postoperative education of patients and their families is important in order to improve the quality of life of patients with a stoma [10, 13]. Entertainment and can adapt them to their abilities [9].

In order to achieve better self-care outcomes, nursing practice with stoma patients should also address perceived barriers to self-care and identify possible coping resources to increase the impact of educational programs [19].

Education of patients with a stoma is a key factor in the quality of life of people with a stoma. It begins with the first visit to the surgeon, and continues with the nurse, and later, if the institution employs one, and the stomatologist [18, 20]. There are even programs in the world that focus on the fastest and most effective recovery after stoma surgery, which have already been shown in some studies to be more effective than the standard care of these patients [18]. Also, modernization of education was recommended, because it also brought better results than standard care [19]. The purpose of education, in addition to adapting to the stoma, is also to reduce the possibility of complications of the stoma, which it also contributes to, as shown by a certain number of studies [2, 3, 6, 13].

There are more than 7,000 people with a stoma in Bosnia and Herzegovina. Unfortunately, their number continues to grow, which is related to the increase in the number of people suffering from bowel, rectal or bladder cancer, as well as ulcerative colitis and Crohn's disease. A stoma changes

life, although in itself it is not an obstacle to a quality life, including a social life and an active sexual life [12, 15].

Obstacles can represent the underlying disease itself, the treatment of which led to the formation of a stoma. After surgery, it seems as if it is impossible to live normally with a stoma, but by gradually accepting the new situation, it is very possible. The patient's quality of life after surgery largely depends on how willing the patient is to cooperate for healing, listen to and practice the dietary instructions received [15]. Also, the quality of life of a patient with a stoma depends on the level at which the patient has adopted the stoma care procedures and accepted lifestyle with a stoma [21].

The importance of the nurse in the care of patients with a stoma is indispensable, and it begins with the diagnosis of the patient, instructions and advice about the disease, therapy, surgical procedure, possible outcomes and quality of life after the procedure. At the same time, the nurse notices and takes care of physical, psychological and emotional problems that occur in the patient, as well as his family, and through effective communication, education and support, he tries to maintain and preserve the dignity of the patient and the quality of his life [22].

The opening of the center in BiH would greatly affect the quality of the education of nurses and certainly bring even better results in the education of patients and their families. Only quality and highly educated healthcare staff can ensure quality education and good acceptance of stoma.

As self-efficacy is an essential component of living with a stoma, appropriate preoperative counseling and postoperative follow-up services for patients and their families are essential to address multidimensional issues including psychosocial and sexual aspects. Furthermore, integration with all related specialties, including psychosocial well-being and sexual health, and the formulation of a stoma support group would be helpful to share their experiences [15].

Through the continuous teamwork of all healthcare professionals, we will increase patient satisfaction with the healthcare provided and improve the quality of life. The importance of all nurses is the education of the general population, that is, the education of the public about stoma, familiarization with stoma and the problems that patients face, and the impact on reducing the stigmatization of patients with stoma [29].

Conclusions

Marking the stoma is important in reducing the complications that can potentially arise due to the placement of the stoma.

Education of patients, their families, and medical staff is crucial in improving the quality of life of patients with a stoma.

Education of patients, their families, and medical staff is extremely important in reducing complications that can potentially arise due to the placement of a stoma.

In addition to physical problems, it is necessary to pay special attention to psychosocial problems in patients with a stoma.

It is necessary to pay more attention to the problem of stoma in Bosnia and Herzegovina.

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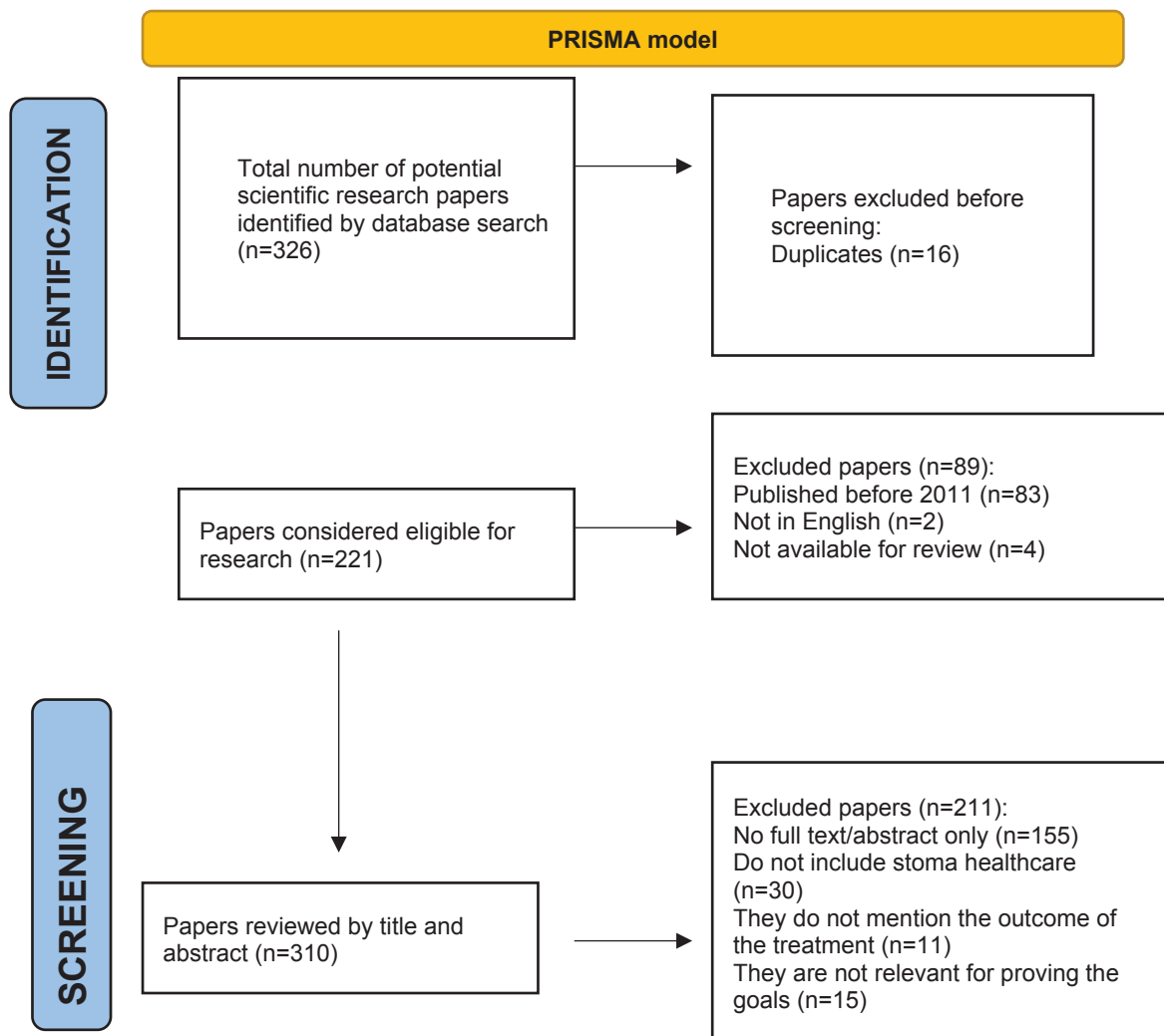
Table 1. All professional papers with their general characteristics

Study number	State	Author/Year/Reference	Name of the study	Type of study	Objectives of the study	Research methods	Results	Conclusion
I	Poland	Szpilewska K., et al.,17, (2018),	Acceptance of disease and the quality of life in patients with enteric stoma	A cross-sectional study	Evaluation of disease acceptance and quality of life of colostomy patients	The study included 101 patients with a stoma performed between February 2015 and February 2016 at the Regional Specialist Hospital in Wrocław. Two anonymous questionnaires were used, i.e. health-related quality of life (HRQoL) and acceptance of illness scale(AiS).	The majority of respondents pointed out the deterioration of the quality of life. The degree of acceptance of the disease among men is 75%, and among women 61%. Social factors that influence the quality of life and acceptance of the disease, namely gender, age, education, job and place of residence.	The higher the level of acceptance of the disease, the better the quality of life of patients with a stoma, and it is necessary to educate patients about their functioning in society.
II	Denmark	Danielson, A. K.,Rosenberg, J., 18, (2014)	Health related quality of life may increase when patients with a stoma attend patient education - a case-control study	Case control study	To investigate the effect of a structured patient education program on health-related quality of life	The study included 50 adult patients who had educational interventions. Health-related quality of life was measured before discharge from the hospital, three months and six months after the creation of the stoma.	A significant increase in HRQoL was detected in the intervention group and no significant change in the control group, with no significant differences between the groups in the period of 3 and 6 months.	When patients with a stoma attend a structured patient education program, it is possible to improve the quality of their health-related lives compared to those who do not attend the program.
III	Denmark	Alenezi, A.N., Mansour, E.A., 9, (2016)	Impact of stoma care education in minimizing the incidence of stoma skin complications	A randomized controlled trial	o Evaluate a structured patient education program on minimizing skin complications in patients with a stoma.	Before discharge, the studied group was given a designed educational program for stoma care. Peristomal skin area was assessed one, three and six weeks after hospital discharge for both groups.	Significant reduction of peristomal skin complications in the study group compared to the control group, even six weeks postoperatively (P=0.028).	Patients with a stoma who attended a structured patient education program have fewer peristomal skin complications compared to those who did not.
IV	Norway	Forsmo, H. M. et al, 4, (2016)	Pre- and postoperative stoma education and guidance within an enhanced recovery after surgery (ERAS) programme reduces length of hospital stay in colorectal surgery	A prospective study	To investigate whether an enhanced recovery after surgery (ERAS) program can reduce hospital length of stay, readmissions and ostomy complications, and improve HRQoL compared with standard education	In a single-center study, 122 adult patients who received a planned stoma were treated either in an ERAS program with extended stoma education (n=61) or standard care with current stoma education (n=61). HRQoL was measured with a generic 15D instrument.	Total hospital stay was significantly shorter in the ERAS education group than in the standard care group (p<0.001). Regarding overall major and minor morbidity, readmission rate, HRQoL, stoma-related complications, and 30-day mortality, the two treatment groups showed similar outcomes.	Preoperative and postoperative stoma education in an enhanced recovery program was associated with a significantly shorter hospital stay without any difference in readmission rates or early stoma-related complications.
V	Iran	Anaraki, F. et al., 14, (2012)	Quality of life outcomes in patients living with stoma	A cross-sectional study	To assess the quality of life of patients with a stoma using a special measuring tool	The City of Hope Quality of Life-Ostomy Questionnaire (COH-QOL) was used in 102 patients to collect demographic and clinical information and to assess quality of life.	70% of patients were dissatisfied with sexual activities, and more than half of them reported depression after surgery. Factors such as the type of stoma, the disease that is the cause of the stoma, depression, the location of the stoma and the change in the style of clothing have significant effects on the total QOL and its subscales (P<0.05).	The findings showed that living with a stoma affects the overall aspect of quality of life. Education of patients and their families is important for improving the quality of life of patients with a stoma. Sexual and psychological consultations can also improve patients' quality of life.

Study number	State	Author/ Year/ Reference	Name of the study	Type of study	Objectives of the study	Research methods	Results	Conclusion
VI	Israel	Person, B. et al., 20, (2012)	The Impact of Preoperative Stoma Site Marking on the Incidence of Complications, Quality of Life, and Patient's Independence	A prospective study	Evaluation of the impact of preoperative stoma marking on patients' quality of life, their independence and the rate of complications.	A validated QOL questionnaire was used in 105 patients who had a stoma created between 2006 and 2008. Complications were recorded during regular postoperative visits, and parameters included demographics, stoma type, marking status, complication rates, QOL, and independence parameters.	52 (49.5%) patients were marked preoperatively, and 53 (50.5%) were not. The QOL of patients whose stoma sites were marked preoperatively was significantly better than unmarked patients ($p < 0.05$), their independence parameters were significantly better, and the complication rate was significantly lower, regardless of the type of stoma.	Marking the stoma before surgery is essential for improving the post-operative quality of life of patients, their independence and reducing the rate of postoperative complications. The role of the enterostomal therapist is very important in pre-operative and post-operative care.
VII	Taiwan	Lo, S. et al., 25, (2011)	Multimedia education programme for patients with a stoma: Effectiveness evaluation	A randomized controlled trial	Evaluation of the effectiveness of a multimedia educational program that deals with knowledge about stoma, attitudes about self-care and behavior in patients with stoma in the postoperative period.	A validated QOL questionnaire was used in 105 pat. who had a stoma created between 2006 and 2008. Complications were recorded during regular postoperative visits, and parameters included demographics, stoma type, marking status, complication rates, QOL, and independence parameters. A total of 102 stoma patients from Taiwan were randomly assigned to a multimedia education program ($n = 46$) and a standard ostomy education program ($n = 56$). The measured outcome variables were knowledge levels, behavior, and attitudes about self-care.	Patients who underwent a multimedia educational program statistically significantly improved their overall self-care knowledge, attitudes, and behaviors compared to those who underwent a conventional stoma education program.	Multimedia packages can improve patient involvement in their stoma care and can improve stoma education, especially in resource-limited healthcare settings.
VIII	Turkey	Koc, U. et al., 19, (2017)	A Retrospective Analysis of Factors Affecting Early Stoma Complications	A retrospective study	Analysis of the frequency of early stoma complications and determine risk factors that can predict stoma complications	Descriptive statistics were used to analyze patient and surgical variables, as well as short-term (30-day) outcomes of 462 consecutive patients who underwent ostomy surgery between January 2008 and December 2012.	The incidence of short-term complications was 28.4%. Complication rates were highest in patients who had malignant disease, a colostomy, or a stoma located in the left lower abdominal quadrant, while the latter was an independent risk factor for the development of early stoma complications.	Rates of early stoma complications are higher in patients with malignant diseases, after colostomies and permanent stomas. The location of the stoma is an independent risk factor for the development of stoma complications, and preoperative marking should be considered to reduce the risk of stoma complications.
IX	Turkey	Baykara, Z.G. et al., (2014)	A multicenter, retrospective study to evaluate the effect of preoperative stoma site marking on stomal and peristomal complications	A retrospective study	Assessment of the effect of preoperative stoma marking on postoperative stomal and peristomal complications	A one-year retrospective and descriptive study included 748 patients from eight stomatology units in Turkey. Data on patients were obtained from patient records, extracted and analyzed.	Stoma/peristomakomplikacionsu se razvilekod 248 (33,2%) osoba. Stopakomplikacijabila je većakodpacijena-tačijemjestostomeni-jeoznačenonegokodonihči-je je mjestostomeoznačeno (22,9% i 46%, respektivno; $P < 0,001$).	Patients whose stoma location was not assessed and marked preoperatively, regardless of the type of surgery, had a significantly higher rate of postoperative complications than patients who underwent preoperative marking of the stoma site.

Study number	State	Author/ Year/ Reference	Name of the study	Type of study	Objectives of the study	Research methods	Results	Conclusion
X	India	Davis, D et al., (2020)	Impact of stoma on lifestyle and health related quality of life in patients living with stoma: A cross sectional study	A cross-sectional study	Determining the quality of life and the impact of stoma on the patients' lifestyle at the gastroenterology department of the Tertiary Care Center in South India during 2018	55 patients were included in the study, following the sequential sampling technique. Data was collected using City of HopeQOL questionnaires that had questions to assess the quality of life from four subdomains including physical, psychological, social and spiritual aspects.	The average QOL score of the subjects was 4.13 ± 1.07 . Patients achieved relatively good results in physical (5.68 ± 1.76) and spiritual (4.32 ± 1.36) domains, but the result of the sociological (2.85 ± 1.3) domain was very low. Patients with permanent stoma had significantly better results than temporary ones ($P=0.04$).	The average QOL score is significantly low and living with a stoma affects the overall aspect of quality of life. As self-care is necessary, appropriate preoperative counseling and postoperative services for patients and their families are essential, as is the formation of support groups.

Diagram 1. PRISMA model



Bedside Ultrasonographic Assessment of the Optic Nerve Sheath Diameter to Assess Intracranial Pressure in Patients Given Ketamine in Emergency Department

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Abstract

Background: There is an ongoing debate if ketamine exerts any effect on intracranial pressure (ICP). ICP can be evaluated noninvasively by means of optic nerve sheath diameter (ONSD) measurement. In the present study, we aimed to determine if ketamine has any perceivable effect on ICP using ONSD.

Material and Methods: In this single-center observational study, we prospectively enrolled patients who were admitted to the ED and received intravenous ketamine for induction, analgesia, procedural sedation for any procedure (ie, fracture reduction, laceration repair, pacemaker implantation). ONSD was used to rate ICP changes noninvasively both before and after ketamine application.

Results: There were a total of 75 patients with a mean age of 59.8 ± 20.5 years. The majority of patients were applied Procedural Sedation (53.3%). In patients who were administered ketamine for induction, the median ONSD before and after ketamine were 5.10 (IQR: 1) mm and 5.00 (IQR: 1.30) mm, respectively. There occurred no significant diameter change ($p=0.832$). In patients who were administered ketamine for analgesia, the median ONSD 3.70 (IQR: 0.40) mm and 3.65 (IQR: 0.23) mm prior to and after the procedure, respectively. There occurred no significant diameter change ($p=0.549$). In patients who were administered ketamine for procedural sedation, the median ONSD before and after the procedure were 4.05 (IQR:0.67) mm and 3.97 (IQR: 0.69) mm, respectively. This time, however, ONSD was significantly reduced after ketamine administration ($p=0.001$).

Conclusions: In this patient population, ketamine did not cause any incremental effect on ONSD, a surrogate marker of ICP.

Keywords: Intracranial pressure; ketamine; sedation; ultrasound; optic nerve

Introduction

In the emergency care setting, ketamine is the most commonly employed drug for the purposes of procedural sedation, rapid sequence intubation (RSI), and analgesia [1]. An anesthetic agent that possesses dissociative properties, ketamine antagonizes central N-methyl-D-aspartate receptors but leaves protective airway reflexes, spontaneous respira-

tions, and cardiovascular tone relatively intact [2]. Praised by such favorable overall side effect profile, however, there is ongoing debate if it elevates intracranial pressure (ICP) [3, 4]. During 70s, when first case series had been published, it was suggested that ketamine has an untoward effect of suddenly elevating ICP among patients with impedance to cerebrospinal fluid (CSF) circulation. Fortunately, however, this effect was not observed in those with unimpeded CSF flow [4]. Hence, Green *et. al.* [5] suggested that ketamine should not be avoided in procedural sedation, RSI, and analgesia in the ED, provided that the patient has no hydrocephalus.

Elevations in ICP are best reflected by invasive ICP monitoring [6]. Nevertheless, invasive ICP measurement can cause catastrophic hazards, including bleeding and infection, and the clinical condition of some patients may not be suitable for this method [7]. Thus, preferably bedside techniques that allow safe, simple, rapid, noninvasive, and reproducible ICP monitoring should be introduced into clin-

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ical practice [8]. Thanks to its steep learning curve, rapid, noninvasive, bedside nature, and reproducible results, ultrasonography (USG) has been widely utilized in the emergency departments (ED) worldwide [9]. It is used to evaluate abdominal, thoracic, cardiac cavities as well as bone, soft tissue, and eye in the ED [10, 11]. Ocular USG has been recently introduced and widely utilized to measure ONSD to determine ICP increase [12, 13].

Subarachnoid space is in direct continuation with the space beneath the optic nerve sheath and above the nerve; this explains the increase in the diameter of the retrobulbar sheath as a reflection of increased ICP (9,12). This expansion can be readily detected by B-scan USG (14).

It is a applicable method for unstable patients in the emergency room, intensive care unit (ICU) and remote care facilities [15]. Studies conducted so far on the effect of ketamine on ICP have utilized invasive techniques.

In the present study, we investigated whether ketamine would increase ICP by measuring ONSD both before and after ketamine administration using bedside USG, a noninvasive technique, in patients who received ketamine in the ED. To our best knowledge, this is the first study of its kind in the literature.

Materials and Methods

Study design

This study was an observational study conducted in a single center in a prospective fashion between September 2021 and May 2022. It was approved by the local ethics committee at Health Sciences University Antalya Training and Research Hospital (02 September 2021, No:2021-259).

Data collection

This study included patients who were admitted to the ED and received ketamine for induction, analgesia, procedural sedation for any procedure (i.e., fracture reduction, laceration repair, pacemaker implantation). There was no specific age limit for study entry. All participants or their relatives gave informed consent for study participation. The following exclusion criteria were used to exclude subjects: eye and orbital diseases, optic nerve tumors, orbital mass, history of neurosurgical procedures, history of head trauma, and refusal of the study participation.

Study Protocol

The following demographic and clinical data of the patients were collected: age, sex, type of the procedure (induction, procedural sedation, analgesia), initial ketamine dose, any maintenance ketamine dose, and timing of ketamine application. Simultaneously with the ONSD measurements, vital signs were also measured and included the following: heart rate, blood pressure, respiratory rate, oxygen saturation (SpO₂), Glasgow Coma Scale (GCS) score. The patient outcomes in the ED (discharge, hospital admission, ICU admission, death) were recorded on a pre-prepared Study Form.

After the decision was made by the ED Physician to administer ketamine after initial evaluation, bedside ONSD measurement was done. Another physician, namely the treating physician, performed IV ketamine administration after determining the medication dose and timing. ONSD was measured 1 to 2 minutes before and 10 minutes after a single dose of 0.5–2 mg/kg IV of racemic mixture of ketamine. Because ketamine has a short duration of action (~10 minutes), no other treatment was administered, nor drug change made for a 10-minute waiting time [16].

ONSD Measurement

After the principle emergency physician performed a clinical assessment of all patients, they all underwent bedside USG examination according to the study protocol. The USG examinations were carried out by 4 emergency physicians working in the ED, who had at least 2-year experience in USG and were certified for basic USG and advanced USG including ONSD assessment. Briefly, ONSD measurement was performed with the patient in supine position with both eyes shut, and a small volume of ultrasound gel was applied on both eyelids.

This was followed by determining the site of the optic disk using a 7.5 MHz linear ultrasound probe (Mindray Medical, Germany). First, both eyes were examined both vertically and horizontally; then, the optic disk was directly visualized. As stated elsewhere, ONSD measurement was carried out both in transverse and sagittal planes, from a point that was 3 mm proximal to the optic disk. ONSD was measured in reference to the width of the hypoechoic area used as a guide (Figure 1). Two separate measurements in terms of millimeter (mm) were taken from both the coronal and longitudinal planes and averaged to yield the mean ONSD value.



Figure 1. ONSD Measurement technique: transverse measurement of optic nerve, at a site 3 mm proximal from the optic disk, with closed eyelids.

Statistical Analysis

Study data were analyzed with SPSS (Statistical Package for the Social Sciences) 23.00 for Windows statistical software package (version 23.0; SPSS, Chicago, IL). Descriptive data included number (n) and percentage (%) of patients,

and interquartile range (IQR) for continuous variables. Fischer’s Exact Test was used to compare categoric variables. The distribution of continuous variables was tested using Kolmogorov-Smirnov test. Sign test was used for the comparison of the continuous variables in two dependent groups; Mann-Whitney U test was used to compare continuous variables between two independent groups. A p value of less than 0.05 was considered statistically significant.

Results

This study enrolled a total of 75 patients who were administered ketamine in the ED. Forty-four (58.7%) of them were male and 31 (41.3%) were female. Their mean age was 59.8 ± 20.5 years. Their comorbidities included HT in 42.7% (n=32) patients, DM in 22.7% (n=17), CAD in 17.3% (n=13), COPD in 10.7% (n=8), malignancy in 10.7% (n=8), CVD in 9.3% (n=7), and CRD in 6.7% (n=5). An analysis of their vital signs revealed a mean SBP of 120.93 ± 30.0 mmHg, mean DBP of 71.64 ± 19.3 mmHg, mean pulse rate of 95 ± 24.2 bpm, mean SpO2 of $93.74\% \pm 9.3\%$, and mean respiratory rate of 17.73 ± 5.9 breaths per minute. The demographic and clinical characteristics of the study population were shown on Table 1. The initial ketamine dose

Variable	% (n)
Sex	
Male	58.7% (44)
Female	41.3% (31)
HT	42.7% (32)
DM	22.7% (17)
CAD	17.3% (13)
COPD	10.7% (8)
Malignancy	10.7% (8)
CVD	9.3% (7)
CRD	6.7% (5)
	Mean \pm SD
Age	59.8 ± 20.5
HR	95 ± 24.2
SBP	120.93 ± 30.0
DBP	71.64 ± 19.3
SpO2	93.74 ± 9.3
RR	17.73 ± 5.9
Initial ketamine dose (mg/kg)	1.0 ± 0.4
Participants who received a second ketamine dose	12 (16%)
Second ketamine dose (mg/kg)	0.7 ± 0.1

Note: Data are presented as n (%), mean \pm SD, or median [IQR]. HR, heart rate; SBP, systolic blood pressure; DBP, diastolic blood pressure; RR, respiratory rate; SpO2, pulse oximetry. HT: hypertension, DM: diabetes mellitus, CAD: Coronary artery disease, COPD: chronic obstructive pulmonary disease, CVD: Cerebrovascular disease, CRD: chronic renal disease

Table 1. Demographic and clinical characteristics of the study population

administered was 1.0 ± 0.4 mg/kg. Twelve participants received a second ketamine dose of 0.7 ± 0.1 mg/kg given 10 min after the first dose.

The indications of administration of ketamine in the ED included induction in 30.7% (n=23) patients, procedural sedation in 53.3% (n=40), and analgesia in 16% (n=12) (Table 2).

Ketamine Indication	% (n)
Induction	30.7% (23)
Procedural Sedation	53.3% (40)
Analgesia	16% (12)
Total	100% (75)

Table 2. Ketamine Indication

An analysis of ONSD measurements carried out before and after ketamine administration showed that the minimum and maximum ONSD values before ketamine administration were 3.30 mm and 7.40 mm; after ketamine administration, the minimum and maximum ONSD values were 3.30 mm and 7.15 mm. ONSD measurements before and after ketamine administration were shown in Figure 2 and Figure 3.

An analysis of the pre-procedural and post-procedural bedside ONSD measurements revealed that among patients who received ketamine for induction, pre-procedural median ONSD was 5.10 (IQR:1) mm and post-procedural ONSD was 5.00 (IQR:1.30) mm, and the difference was not statistically significant (p=0.832). Among those who received ketamine for analgesia, the corresponding values were 3.70 (IQR:0.40) mm and 3.65 (IQR:0.23) mm, and the difference was again statistically non-significant (p=0.549). Among those who received ketamine for procedural sedation, the corresponding measurements were 4.05 (IQR:0.67) mm, and 3.97 (IQR:0.69) mm, and the difference between the two measurements was statistically significant (p=0.001) (Table 3).

Ketamine indication	ONSD		p value
	Pre-procedural ONSD value (IQR)	Post-procedural ONSD value (IQR)	
Induction	5.10 (1.0) mm	5.0 (1.3) mm	0.832
Procedural Sedation	4.05 (0.67) mm	3.97 (0.69) mm	0.001
Analgesia	3.70 (0.40) mm	3.65 (0.23) mm	0.549

ONSD: Optic nerve sheath diameter, IQR: Median interquartile range, mm: Millimeter

Table 3. Pre-procedural and post-procedural bedside ONSD measurements of patients who received ketamine

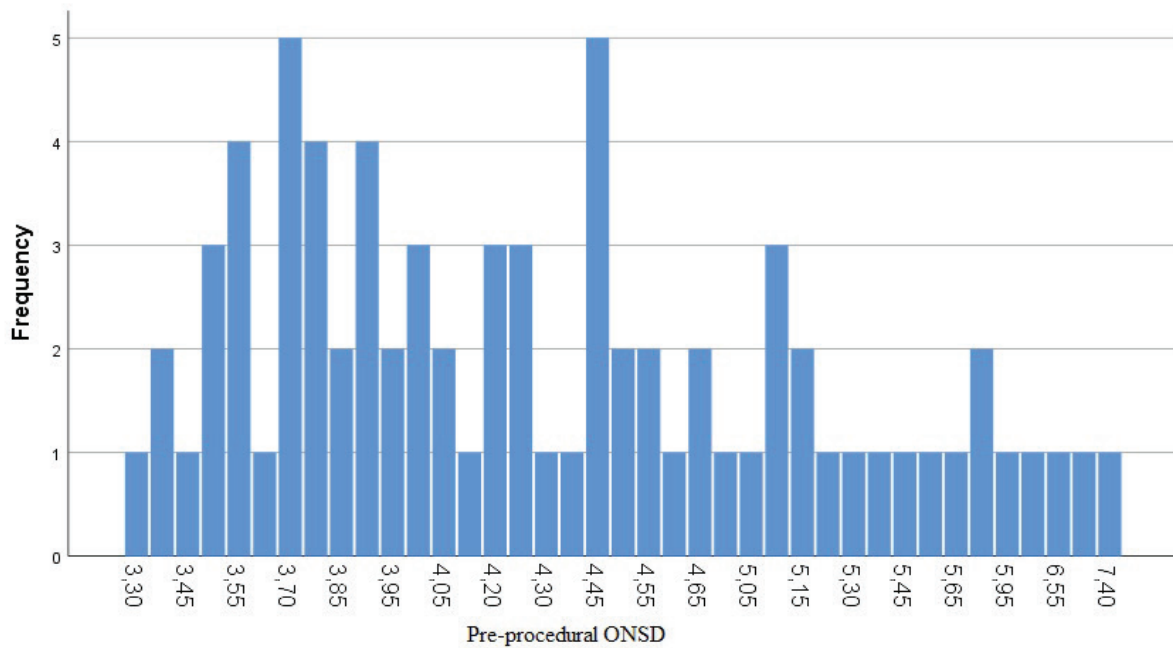


Figure 2. Pre-procedural ONSD measurements

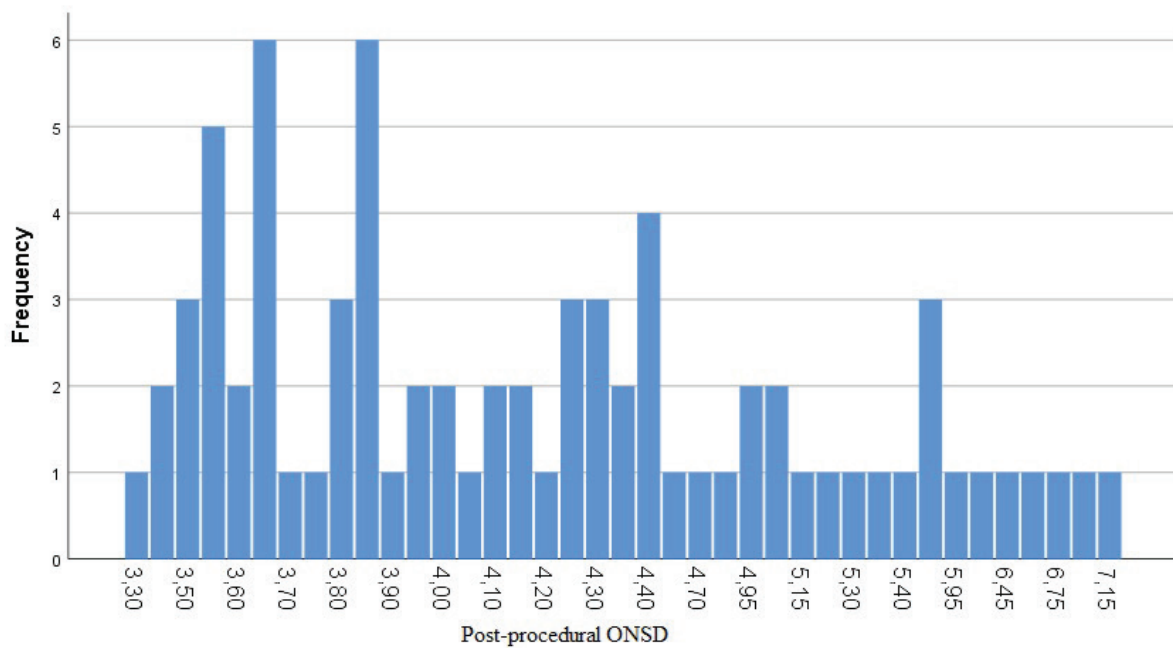


Figure 3. Post-procedural ONSD measurements

An analysis of patient’s outcomes revealed that 29.3% (n=22) of patients were discharged from the emergency department; 16% (n=12) were admitted to hospital; 53% (n=40) were admitted to ICU; and 1.3% (n=1) died (Table 4).

Patient Outcome	% (n)
Discharge from ED	29.3% (22)
Hospital admission	16% (12)
ICU	53.3% (40)
Dead	1.3% (1)

Table 4. Patient Outcomes

Discussion

Early ketamine studies have implicated its use with temporary increments in ICP [17]. Initially, *Shapiro et al.* [18] reported temporary ICP increase independent of alterations of partial pressure of oxygen (PaO₂) or partial pressure of carbon dioxide (PaCO₂). It was suggested that ICP increase is probably dependent on cerebral blood flow swings. These early observations have caused hesitancy among physicians about the use of ketamine in patients with neurological conditions for a long time. Although several publications have challenged this notion, precluded use of ketamine for patients with neurological conditions has remained a norm. In contrast to this widespread belief, a systematic review of 16 articles involving 127 adults refuted ICP increase in patients with atraumatic brain conditions receiving ketamine [19]. Furthermore, a more recent systematic review of 11 studies dealt with the issue and stated that while only slight ICP increase was observed in two of the studies, two other small studies actually reported a decrease in ICP after ketamine application [20]. In all of these studies ICP measurements have been carried out using invasive methods. Nevertheless, invasive ICP monitoring is not free of complications; bleeding, infections and other potentially dangerous complications may develop, and not all patients are suitable for undergoing invasive ICP monitoring [9].

ONSD measurement with POCUS is considered a safe, noninvasive tool for rapid determination of ICP and can be readily performed at bedside, allowing earlier implementation of appropriate therapy [18]. We also investigated if ketamine used for various indications in the ED increased ICP using ONSD measurement, a noninvasive tool. We have come across no study in the literature that specifically studied ICP changes using ONSD measurements in patients who received ketamine.

We observed no significant changes regarding ONSD between pre-procedural and post-procedural measurements in patients who received ketamine for induction and analgesia ($p=0.832$ and 0.549 respectively). In patients who received ketamine for procedural sedation, on the other hand, there was a significant difference between pre-procedural median ONSD and post-procedural median ONSD (4.05 (IQR: 0.67) mm vs 3.97 (IQR: 0.69) mm, $p=0.001$).

Our study results suggest that, let alone increasing ICP, ketamine actually reduced ICP in a statistically significant manner when administered for procedural sedation ($p=0.001$). Ketamine interferes with the presynaptic catecholamine uptake and its effect starts within 30 seconds. It then rapidly enters the central nervous system owing to its high lipophilic character (distribution half-life of 10 min) [21, 22]. Its usual dose is between 1 and 5 mg/kg/h [22]. We also administered ketamine at a dose range of 0.5-2 mg/kg. Additionally, 12 patients needed an extra dose of ketamine.

Our study results can be generalized to ED patients for a number of reasons. First of all, our study population included a wide range of age groups admitted to ED in daily

routine. Secondly, we used an initial ketamine dose that is conventionally used for anesthesia induction, analgesia and procedural sedation. Thirdly, our patients were administered more than one ketamine dose. Despite the fact that our study made no observation about ketamine's effects in settings where cerebral autoregulation was pushed to its limits, it still provides valuable information about ketamine monotherapy's effects on ICP, both in adults and children. Our study is the first to provide an insight on ketamine's effect on ONSD.

Conclusions

An overview of the results of our analyses using ONSD, a noninvasive bedside tool, suggest that ketamine is a medication that does not cause any increase in ICP when given for various indications in the ED. There is a need for future studies to specifically investigate ketamine's effects on ONSD when administered for a range of indications in the ED.

Author Contributors

FY, EA and BB performed data acquisition. FY, EA, CK, IT, IB and EDA contributed to study concept and design, analysis and interpretation of the data, drafting of the manuscript, critical revision of the manuscript for important intellectual content, and statistical expertise.

Declaration of conflicting interests

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Informed consent

All patients provided written informed consent prior to study participation.

Ethical approval

This study was initiated in the ED of a tertiary hospital following ethics committee approval.

Availability of data and materials

All materials taken from other sources (including our own published writing) were clearly cited.

Human rights

Our work does not infringe on any rights of others, including privacy rights, and intellectual property rights. There is no human rights violation in our manuscript.

Abbreviations:

RSI - Rapid Sequence Intubation; ICP - Intracranial Pressure; CSF - Cerebrospinal Fluid; USG - Ultrasonography; ED - Emergency Departments; ONSD - Optic Nerve Sheath Diameter; SpO₂ - Oxygen Saturation; GCS - Glasgow Coma Scale; ICU - Intensive Care Unit; IQR - Interquartile

Range; SPSS - Statistical Package for the Social Sciences; HR - Heart Rate; SBP - Systolic Blood Pressure; DBP - Diastolic Blood Pressure; RR - Respiratory Rate; HT - Hypertension; DM - Diabetes Mellitus; CAD - Coronary Artery Disease; COPD - Chronic Obstructive Pulmonary Disease; CVD - Cerebrovascular Disease; CRD - Chronic Renal Disease; PaO₂ - Partial Pressure of Oxygen; PaCO₂ - Partial Pressure Of Carbon Dioxide;

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Pulmonary Rehabilitation for Chronic Lung Diseases

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Abstract

Chronic Obstructive Pulmonary Disease (COPD) is now the main cause of disability in the developed world. The advance of COPD is related to increasing breathlessness, disability and periodic hospitalizations. An aging population in the developed world and increasing cigarette consumption in developing countries expand the global impact of this condition. The disorder associated with COPD leads to a decrease in physical activity and failure of functional independence.

The aim of this study was to evaluate the effects of PR in patients with normal exercise capacity on health-related quality of life and exercise capacity.

The mean FEV1/FVC was $59.4 \pm 14.1\%$, and the mean FEV1 was $64.8 \pm 23.0\%$ as expected. Most topics had mild to moderate COPD. The P_{Imax} and P_{Emax} were normal. These subjects had no previous participation in home-based or hospital-based PR. All the subjects had normal maximal $\dot{V}O_2$ and work rate before PR.

After PR there were still considerable improvements in maximal $\dot{V}O_2$ (mean increase of 101.3 mL/min, $p < 0.001$) and work rate (mean increase of 8.2 watts, $p < 0.001$). Ventilation, heart rate, and mean blood pressure were constant following PR. The maximum oxygen pulse at maximum exercise was significantly increased with PR ($p < 0.02$). The SpO2 and end-tidal PCO2 at peak exercise did not significantly improve after PR.

Although dyspnea scores at rest were low and did not improve significantly with PR, dyspnea at end-exercise was significantly improved after PR ($p = 0.01$). PR should be the responsibility of the clinical management of patients with COPD, even for those with normal exercise capacity. However, the benefits of disease progression, hospitalization, and survival for these patients remain unknown.

The main role in the management of any chronic disease, including lung disease, is to improve the quality of life (QL) in patients.

Conclusion; Although strongly recommended by scientific societies pulmonary rehabilitation programs still need to be more widely implemented. PR programs have shown a high level of evidence of benefits in chronic respiratory patients, particularly those with COPD.

Keywords: pulmonary rehabilitation; COPD; exercise capacity, lung diseases

Introduction

COPD is now the main cause of disorder in the developed world. The advance of COPD is associated with increasing breathlessness, disability, and periodic hospitalizations. An aging population in the developed world and the increase in cigarette consumption in developing countries compound the universal impact of this condition [1, 2].

The disability associated with COPD leads to a reduction in physical activity and loss of functional independence. The disability may not develop in COPD

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until there has been an irreversible loss of lung function. Treatment concentrated on regressive airflow obstruction is frequently ineffective and therapeutic strategies are better aimed at decreasing symptoms and reducing disability. Pulmonary rehabilitation has been demonstrated to reduce disability in COPD [3, 4]. Pulmonary rehabilitation intends to improve symptoms, disability, and handicaps in patients with COPD and significantly improve whole functional independence.

Evidence of benefit for pulmonary rehabilitation was secured. Randomized controlled trials have repeatedly shown increased exercise performance and improved health outcomes [5, 6].

Recent NICE guidelines for COPD management emphasize the importance of pulmonary rehabilitation as part of an integrated multidisciplinary approach. At the same time, it is recognized that the delivery of pulmonary rehabilitation services in the UK and other developed countries is poor and currently serves only a minority of people with disabling lung disease. The general rule is that pulmonary rehabilitation programmes should be designed around individual needs [4]. This is usually limited to individual prescriptions for exercise training intensity and usually includes brisk walking or static cycling [7, 8].

A natural extension of this principle is that highly individualized training directed at the individual's expressed functional goals improves pulmonary rehabilitation outcomes. More specifically, it can be hypothesized that goal-directed exercise in pulmonary rehabilitation improves measures of daily activities and domestic functioning [9, 10].

The need to assess individualized pulmonary rehabilitation was emphasized in the GOLD guidelines. However, no studies have been conducted on pulmonary rehabilitation in individuals. Assessing domestic functions and daily activities is an emerging science.

A self-report scale of domestic functioning was developed for use with COPD patients and is known as the Functional Status Scale. These consist of a planned list of daily tasks that patients are asked to use to assess their current level of functioning. Less attention has been paid to the use of individualized measures of functional status in pulmonary rehabilitation. Individualized measurements allow patients to assess only those daily activities that they consider relevant. The aim of this study was to investigate the effects of PR on health-related quality of life and exercise performance in patients with normal exercise capacity.

Material and Methods;

Subject Selection

Forty-five subjects with COPD and normal exercise capacity were engaged in our outpatient clinic, from August 2020 to March 2022. They met the following inclusion criteria: a diagnosis of COPD based on the GOLD staging of the disease¹⁰; normal exercise capacity with maximal oxygen uptake (VO₂) of 85% by incremental cardiopulmonary

exercise test; stability from exacerbations with no worsening of respiratory symptoms (i.e., dyspnea, chest tightness, and cough); no increase in the use of rescue medication; no unscheduled visits due to COPD worsening for at least 3 months¹³; and capacity to mobilize individually.

The exclusion criteria were the use of oral corticosteroids; history of other lung diseases, including pneumoconiosis, bronchiectasis, pulmonary tuberculosis, primary pulmonary hypertension, pulmonary embolism, interstitial lung disease; and orthopedic, neurologic, or cardiovascular impairment that might deliver the subject unable of completing the exercise training.

Measurements

Physiologic parameters were charged by spirometry, respiratory muscle strength testing (maximal inspiratory pressure [$P_{I_{max}}$] and maximal expiratory pressure [$P_{E_{max}}$]), and cardiopulmonary exercise test before and after PR. The HRQL and dyspnea symptoms were assessed by the St George's Respiratory Questionnaire (SGRQ) [14] and dyspnea scores.

Pulmonary Function Test

Pulmonary function tests for measurement of FEV₁ and FVC were generated by spirometry), following the standards of the American Thoracic Society and European Respiratory Society. The best flow-volume loop was applied in the final data analysis. Knudson made reference equations for FEV₁ and FVC based on the normal populations available.

Respiratory Muscle Strength

The $P_{I_{max}}$ and $P_{E_{max}}$ were estimated using a standard mouthpiece and a direct dial pressure gauge.

$P_{I_{max}}$ was measured at residual volume, and $P_{E_{max}}$ at total lung capacity, according to procedures already described. The $P_{I_{max}}$ and $P_{E_{max}}$ were measured several times, and after 4 or 5 attempts, a plateau of values then showed relatively little variability ($\pm 10\%$ of reading). The highest values for $P_{I_{max}}$ and $P_{E_{max}}$ were registered.

Pulmonary Rehabilitation

All subjects participated in a 12-week, 2-session per week, outpatient-based PR program. In each session, formal education, including breathing retraining, correct use of medications, and self-management skills, was given independently. After the education, the exercise training with lower limb cycle ergometer exercise was practiced. Exercise demonstrations were 40 min, and exercise intensity targets were set at high intensity, with 75–100% of the maximal VO₂ observed in the pre-PR incremental exercise test. Sessions were nearly monitored by a rehabilitation therapist.

We monitored work rate, SpO₂, heart rate, dyspnea scores, and leg fatigue during every exercise training session. During the period of PR, these subjects were not allowed to perform the exercise by themselves at home.

Results

The clinical characteristics and lung function of these subjects with COPD are shown in Table 1.

The mean FEV₁/FVC was 59.4± 14.1%, and the mean FEV₁ was 64.8± 23.0% as predicted. Most subjects had mild to moderate COPD. The P_{Imax} and P_{Emax} were normal. These subjects had no previous participation in home-based or hospital-based PR.

VARIABLES	VALUES
Age, yrs.	69 ±9.8
BMI	24.2±4.9
COP Dstage n, (%)	
I mild	11 (22.7)
II moderate	24 (54.0)
III severe	10 (23.3)
IVvery severe	0
P _{Imax} , cm H ₂ O	67.2±24.4
P _{Imax} , % of predicted	72.5±23.7
P _{Emax} , cm H ₂ O	107.3±29.2
Treatment	
Theophylline	34 (75.0)
Inhaled long-acting muscarinic antagonists	26 (57.0)
Inhaled long-acting b antagonist + corticosteroid	20 (44.0)
Oral corticosteroid	0

Table 1- Baseline characteristics of patients with COPD and normal exercise capacity

Changes in HRQL with Pulmonary Rehabilitation

Table 2 shows the SGRQ scores, total symptoms, activity and impact before, and after PR.

There were significant improvements in all domains of SGRQ (all p<0.001). The mean changes of scores of all domains were more than 4 units, which was associated with clinical importance.

Changes in Lung Function and Respiratory Muscle Strength with Pulmonary Rehabilitation

There were no significant changes in pulmonary function test results (FEV₁, FVC, and FEV₁/FVC) after 12 weeks of PR. However, respiratory muscle strength (P_{Imax} and P_{Emax}) was significantly improved (p<0.05).

Changes of Exercise Capacity, Cardiorespiratory Function and Dyspnea with Pulmonary Rehabilitation

All the subjects who participated had normal maximal V̇O₂ and work rate before PR. After PR there were still important improvements in maximal V̇O₂ (mean increase of 101.3 mL/min, p <0.001) and work rate (mean increase of 8.2 watts, p<0.001). Patients with COPD are frequently less active in daily life than healthy older adults [13, 14].

In addition, inactivity is related to poor functional status and a higher risk of hospital admissions and mortality [15, 16]. It appears clear that COPD patients would be more physically and socially active after PR.

Despite there is currently no strong evidence that patients translate the benefits achieved from PR into a more active lifestyle in real life. Ventilation, heart rate, and mean blood pressure were constant following PR. The maximum oxygen pulse at maximum exercise was extremely increased with PR (p<0.02).

Variables	Before Pulmonary Rehabilitation	After Pulmonary Rehabilitation	Mean Difference	P
FEV ₁ /FVC, %	59.4 ± 14.1	61.5 ± 15.0	2.1	.34
FEV ₁ , L	1.29 ± 0.47	1.33 ± 0.46	0.04	.46
FEV ₁ , % predicted	64.8 ± 23.0	66.7 ± 22.3	2.0	.42
FVC, L	2.24 ± 0.79	2.21 ± 0.66	−0.03	.75
FVC, % predicted	88.3 ± 34.5	87.7 ± 32.0	−0.6	.87
P _{Imax} , cm H ₂ O	68.1 ± 25.7	75.9 ± 24.0	7.8	.02
P _{Imax} , % of predicted	73.6 ± 25.6	82.5 ± 22.2	8.9	.02
P _{Emax} , cm H ₂ O	109.4 ± 30.5	121.4 ± 37.3	12.0	.03
P _{Emax} , % of predicted SGRQ scores	65.2 ± 20.7	71.5 ± 20.4	6.3	.04
Total	39.8 ± 16.3	28.6 ± 16.0	−12.4	< .001
Symptoms	47.8 ± 23.9	35.5 ± 25.9	−7.8	.03
Activity	50.6 ± 18.7	42.8 ± 18.2	−12.5	< .001
Impact	31.2 ± 20.1	18.7 ± 15.3	−11.1	< .001

Values mean ± SD; PImax = Maximum Inspiratory Pressure; PEmax = Maximum Expiratory Pressure; SGRQ = St George's Respiratory Questionnaire

Table 2 - Effects of Pulmonary Rehabilitation on Pulmonary Function Tests, Respiratory Muscle Strength, and Health Related Quality of Life

The SpO₂ and end-tidal PCO₂ at peak exercise did not significantly affect after PR. Albeit dyspnea scores at rest were low and did not change significantly with PR, dyspnea at end-exercise was significantly improved after PR ($p=0.01$). Lately published the first meta-analysis was recently published examining the effect of exercise training on measures of physical activity. This meta-analysis pointed out that supervised exercise training confers a significant but small effect on physical activity. The principal limitation of the meta-analysis was that the majority of the evolved studies did not use the same method to measure physical activity; furthermore, it is well known that questionnaires and pedometers are an inadequately sensitive means of detecting changes in physical activity in this particular clinical (slow walking) population [17, 18].

When the authors concluded only those studies that practiced a multisensory accelerometer to measure physical activity, they reached improvements that are more significant in physical activity [19]. Accelerometers or activity monitors are small devices carried on the arm, leg, or waist that measure energy expenditure, movement pattern, and body position over a period of time (24 hours to 7 days) and maintain objective measurements of daily life activity. Two parameters appear to be essential to enhancing physical activity in COPD patients after PR: the frequency of supervised exercise training and the duration of the program. Surely, in the meta-analysis [20], the studies that proposed an exercise-training regimen of three times per week demonstrated a significant increase in physical activity, in contrast with those that offered exercise only two times a week.

Also, in a study measuring physical activity with an accelerometer, it was shown that a 6-month, supervised exercise training program was demanded to obtain a significant effect on physical activity, while three months was shown to be insufficient. This is constant with the recent concept that 6 months are needed for most people to change their behavior [21]. The recording of unplanned daily physical activity provides a new dimension in the patient assessment that goes beyond any measurement of physiological capacity. Daily activity and the completion of domestic tasks are more important for the patient than an improvement in the 6-minute walk test, total CRQ score, or maximal load accomplished during ergo spirometry. Thus, clinicians should take into account what people actually do (e.g., walking, climbing stairs, dressing, etc.), rather than what they are able of doing since it is the natural level of physical activity that seems to best complete the prognostic benefit [22].

Conclusion

Although strongly recommended by scientific societies pulmonary rehabilitation programs still need to be more widely implemented. PR programs have shown a high level of evidence of benefits in chronic respiratory patients, particularly those with COPD.

Personalized pulmonary rehabilitation programs should be considered for COPD patients of all stages, who have respiratory symptoms and/or who have an intolerance to physical effort although optimal pharmacological treatment. PR has certainly been shown to provide beneficial effects on dyspnea, improvement in muscle strength and endurance, improvement of psychological status, reduction of hospital admissions, and improvement of HRQoL in COPD patients, with a gradual increase in daily physical activity and autonomy.

Successful PR, therefore, requires behavioral changes. The mechanism of benefits of PR should be addressed. To realize this, patients' skills and adherence may be promoted if they are enrolled in longer, comprehensive programs comprising interactions with a multidisciplinary team offering support, counsel, encouragement, and coaching. These changes rest on the following: exercise training; psychosocial support; nutritional intervention; self-management; and education, as well as pacing and energy conservation strategies, all of which are planned for motivated COPD patients. Then, PR embodies a very significant and safe therapeutic option that aims to reverse the systemic manifestations of COPD and which, along with pharmacological therapy, can be used to obtain optimal patient management, leading to a favorable change in the daily life of our COPD patients. Therefore, with the increasing burden of COPD patients in the world, there is an urgent need for advocacy with the concerned authorities, for a more general reimbursement of PR programs worldwide.

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Abbreviation; COPD - Chronic Obstructive Pulmonary Disease; NICE - National Institute for Health and Clinical Excellence; PR - Pulmonary Rehabilitation; VO₂ - Maximal Oxygen Uptake; P_{Imax} - Maximum Inspiratory Pressure

P_{Emax} - Maximum Expiratory Pressure; SGRQ - St George's Respiratory Questionnaire; FEV₁ - Forced Expiratory Volume in 1 s; FVC - Forced Vital Capacity; HRQOL - Health-Related Quality of Life

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MRI in Evaluation of Rectal Cancer pre- and post-Chemo-Radiation Treatment.

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Abstract

Rectal cancer is associated with a high risk of metastases and local recurrence; local recurrence rates after surgical treatment being up to 32%. An accurate local staging at the time of initial diagnosis is therefore very important. Magnetic Resonance Imaging (MRI) is already established as an accurate tool for the preoperative staging of rectal cancer and has resulted in marked improvements in staging accuracy.

Material and Methods: This study used MRI in comparing the morphologic features of rectal cancer before and after 8 weeks of chemo-radiation treatment (CRT) and to correlate the post treatment MRI appearances with the histological findings in resected tumors. 45 patients with histo-pathologically proven rectal adenocarcinoma received standardized 8 weeks chemo-radiation therapy and subjected to MRI before and after treatment for clinical staging. A correlation between pathological response and MRI findings was done.

Results: The MRI diagnostic accuracy to diagnose T2 is 74.2% with relatively low specificity (64.7%). The diagnostic accuracy of MRI in evaluation of stage T3 and T4, the MRI sensitivity was 96.2% however of low specificity 26.3%. The diagnostic accuracy was 66.7%. Additionally, in evaluation of T2 stage, the sensitivity of MRI was very low 27.3% and specificity relatively high 94.7%. Diagnostic accuracy was 70%.

Post RCT, based on downstaging after CRT, the sensitivity of MRI to show no tumor was very low 0% with diagnostic accuracy 88.9%. However, to evaluate stage T2, the sensitivity was 84.6% with low specificity 66.7% and the diagnostic accuracy was 74.2%.

Conclusion: MRI had an accuracy average of 81.6% in T stage and 68.9% in N stage in re-staging rectal tumors after CRT. Over-staging results of majority of the inaccuracy. The statistical agreement between post-CRT MRI and the pathologic staging involving T and N stages was not satisfactory. In view of the above, Post CRT, restaging rectal cancer remains a challenge.

Keywords: Rectal cancer, Pre and post chemo-radiotherapy. MRI.

Introduction

Colorectal cancer is remarkably common, representing the fourth leading cause of cancer mortality and the second most common malignancy worldwide, with nearly

1 million newly diagnosed cases each year [1, 2]. Of all the colorectal cancers, rectal cancer (RC) comprises over one third of the cases [1,3], and is associated with a high risk of local recurrence and metastases. Local recurrence rates after surgical treatment of RC could reach 32% [4], mostly due to the incomplete resection of the tumor [5,6], and the circumferential safety of resection [7,8]. Therefore, an accurate local staging of RC at the time of initial (preoperative) diagnosis is crucial.

High spatial resolution MRI is an established reliable tool for the preoperative staging of RC [4], that has markedly improved the staging reliability [5]. MRI also delineates the relationship between the tumor and the mesorectal fascia, which represents the circumferential resection

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margin (CRM) in the surgical excision process [6]. An involved CRM is when the tumor extends to within 1 mm of the meso-rectal fascia [6]. Patients with stage T3 or T4 disease or disease involving the potential CRM on MRI are offered chemo-radiotherapy [6]. CRT followed by resection has proved to reduce the postoperative recurrence rate [6].

The MRI and Rectal Cancer European Equivalence (MERCURY) Study evaluated the survival of patients who underwent initial surgery vs preoperative CRT and surgery [8]. The study found that post-CRT, MRI evaluation of the tumor regression grade (TRG) corresponded to the disease-free survival, overall survival and prognosis; and that post-CRT MRI assessment of potential CRM involvement provided prognostic information on the risk of local recurrence [8]. Furthermore, both post-CRT MRI T-staging and TRG assessments were significantly correlated with the pathologic T stage; and the pathologic T stage in turn was strongly correlated with the overall and disease-free survival and local recurrence [8]. MRI's power to forecast good and poor responses after pre-operative CRT enables the further modification of the treatment [9].

The literature reveals several knowledge gaps. First, not many studies assessed the accuracy of pre-surgery MRI findings with the final outcomes and survival. In addition, the ongoing development of the MRI technology in terms of increased resolution and better techniques mean that MRI findings could translate into better forecast of outcomes and survival, as recommended by Kevin et al 2019 [10]. These considerations were the motivations to undertake the current study.

Therefore, this retrospective study bridges this knowledge gap to compare pre-surgery MRI findings of RC with post-surgery histopathology findings of the resected tumors as a gold standard. The specific objectives were to compare, at two time points (before and after 8 weeks of CRT), the:

1. Morphologic characteristics of RC as outlined by MRI vs histopathology
2. Staging features of RC outlined by MRI vs histopathological findings

Material and methods

Forty-five patients with histo-pathologically proven rectal adenocarcinoma received standardized 8-week CRT and subjected to MRI before and after treatment for clinical staging. A correlation between pathological response and MRI findings was done.

This is a retrospective and prospective study that includes 45 patients, 39 of them with biopsy-proven stage III and IV rectal adenocarcinoma who received

standardized 8 weeks CRT. Lower stages of rectal cancer were used to examine the MRI accuracy and not exposed to CRT treatment. The indications for CRT were biopsy-proven locally advanced rectal cancer. In this regard, a locally advanced rectal cancer patient will be selected on the basis of clinical staging MRI findings of a high likelihood of circumferential resection margin involvement and hence possibility of inadequate immediate resection.

Informed consent was obtained from all patients after full explanation of the technique of MRI which is noninvasive, without any risk approved till now. Privacy of all patients' data is guaranteed.

Exclusion criteria included patients without available histopathology results.

Radiological evaluation: Computed tomography (CT) to exclude pulmonary and abdominal metastasis of all patients. MRI: All cases underwent MRI examination in the Radio diagnosis Department (Hamad Hospital and Rumela hospital) using a machine (Siemens 1.5 Tesla) with abdominal surface coil. All patients were positioned in the supine position. The following sequences are used, axial, sagittal and coronal T2WI. Axial cuts with fat saturated fast spin-echo T2WI and TIWI were obtained. Also, axial, sagittal and coronal T1WI were taken immediately after a manual intravenous injection of 0.1 mg of Gd-DTPA/kg of body weight (Dotarem). Patients were asked to do breath-holding techniques to the extent tolerable.

Results

The sample size comprised 45 (82.2%) males and 8 (17.8%) females. Mean age of the sample was (22.5 years) and the range was 29. In terms of location, the majority of lesions were in the upper and mid rectum.

General characteristics:

High rectal tumors comprised nearly half (48.9%) the sample, followed closely by mid rectal tumors (46.7%) while low rectal tumors were rare (4.4%). (High rectal tumor: > 15 cm from the anal verge; Mid rectal tumor: 10-15 cm from the anal verge; Low rectal tumor: within 5-10 cm from anal verge).

MRI show lower diagnostic accuracy to differentiate mucinous and non-mucinous rectal tumors, 47.7%. This value was in post-chemo-radiotherapy with low specificity 33.3%.

Also, pre chemotherapy diagnostic accuracy of MRI was low 46.5% and low specificity 29.6%.

Post CRT, MRI in evaluation of lymph nodes involvement, sensitivity was 84.6%, diagnostic accuracy 68.9% however low specificity 47.4%.

Morphology Features	Pre CRT			Post CRT		
	MRI	HP	P	MRI	HP	P
	N (%)	N (%)		N (%)	N (%)	
Tumor						
Histologic grade						
Well differentiated	—	9 (20)	—	—	9 (20)	0.000
Moderately differentiated	—	28 (62.2)	—	—	28 (62.2)	
Poor differentiated	—	8 (17.8)	—	—	8 (17.8)	
Type			0.003			0.003
Not Mucinous	12 (26.7)	27 (62.8)		14 (31.8)	27 (61.4)	
Mucinous	33 (73.3)	16 (37.2)		30 (68.2)	17 (38.6)	
MRI post contrast						
Washout			—			0.002 ^a
No washout	16 (35.6)	—		32 (71.1)	—	
Washout	29 (64.4)	—		13 (28.9)	—	
Enhancement			—			< 0.001 ^a
Enhancement	45 (100)	—		40 (88.9)	—	
No Enhancement	0 (0)	—		5 (11.1)	—	
Diffusion WI			—			< 0.001 ^a
Not restricted	2 (4.4)	—		25 (55.6)	—	
Restricted	43 (95.6)	—		20 (44.4)	—	
Lymph nodes						
Intramesorectal lymph nodes						
Uniformity			—			0.002 ^a
Uniform	13 (28.9)	—		30 (66.7)	—	
Heterogeneous	32 (71.1)	—		15 (33.3)	—	
Regularity			—			0.008 ^a
Regular	16 (35.6)	—		31 (68.9)	—	
Irregular	29 (64.4)	—		14 (31.1)	—	
Extramesorectal lymph nodes						
Uniformity			—			0.45
Uniform	9 (20)	—		9 (20.0)	—	
Heterogeneous	10 (22.2)	—		36 (80.0)	—	
Regularity			—			—
Regular	11 (24.4)	—		—	—	
Irregular	8 (17.8)	—		—	—	
Non exist	26 (57.8)	—		—	—	

—: not applicable; ^a comparison of pre vs post CRT MRI values

Table 1. Comparison of morphologic features of MRI vs histopathology (HP) before and after CRT

Table 1: shows the comparison of morphologic features of MRI vs histopathology before and after CRT. Histologically, most cases of rectal cancer where the moderately differentiated (62.2%), with the well differentiate and poorly differentiated adenocarcinoma were a minority (20% and 17.8% respectively). 100% of cases showed enhancement in Pre CRT, however restricted diffusion was in 95.6% of Pre CRT cases.

Staging Features	Pre CRT			Post CRT		
	MRI	HP	P	MRI	HP	P
	N (%)	N (%)		N (%)	N (%)	
Tumor T staging			0.000			0.395 ^b
Stage 0	0 (0)	4 (8.9)		1 (2.2)	4(8.9)	
Stage 1	0 (0)	3 (6.7)		1 (2.2)	3 (6.7)	
Stage 2	6 (13.3)	12 (26.7)		20 (44.4)	13 (28.9)	
Stage 3	31 (68.9)	21 (46.7)		17 (37.8)	19 (42.2)	
Stage 4	8 (17.8)	5 (11.1)		6 (13.3)	6 (13.3)	
CRM involvement by tumor			—			0.012 ^a
Not involved	28 (62.2)	—		—	37 (82.2)	
Involved	17 (37.8)	—		—	8 (17.8)	
CRM involvement by lymph nodes			—			—
Not involved	12 (26.7)	—		—	—	
Involved	33 (73.3)	—		—	—	
Anal sphincter involvement			—			1.000 ^a
Not involved	32 (71.1)	—		—	32 (71.1)	
Involved	13 (28.9)	—		—	13 (28.9)	
EMVI			—			0.021 ^a
Not involved	31 (68.9)	—		—	39 (86.7)	
Involved	14 (31.1)	—		—	6 (13.3)	
Peritoneal reflection involvement			—			0.022 ^a
Not involved	30 (66.7)	—		—	33 (73.3)	
Involved	15 (33.3)	—		—	12 (26.7)	
Metastases			—			—
M1	3 (6.7)	—		—	—	
M0	42 (93.3)	—		—	—	
Involved Mesorectal LN			—			0.392 ^b
N0	9 (20)	—		32 (71.1)	26 (57.8)	
N1	20 (44.4)	—		10 (22.2)	16 (35.6)	
N2	16 (35.6)	—		3 (6.7)	3 (6.7)	
Involved Extramesorectal LN			—			—
Yes	19 (42.2)	—		—	—	
No	26 (57.8)	—		—	—	

—: not applicable; ^a comparison of pre-CRT MRI vs post CRT HP values; ^b comparison of pre-CRT MRI vs post CRT MRI values; EMVI: extra mural venous invasion; LN: lymph node.

Table 2. Comparison of staging features of MRI vs histopathology before and after CRT

Table 2 displays the staging correlation between the results from post-CRT MRI and pathology. According to the results of the pre-CRT MRI staging for T status, 31 patients (68.9%) had advanced T3 tumors, 8 (17.8%) patients had T4 tumors with adjacent organ invasion, and 6 (13.3%) patients had T2 tumors. For initial N status, 36 (80%) patients had positive lymph node and 9 (20%) patients had negative lymph node.

The pathological results demonstrated that 19 (42.2%) of the cases had T3, 13 (28.9%) T2, 6 (13.3%) T4 and 4 cases (8.9%) no tumor found. However, the data from post-CRT MRI indicated that 20 (44.4%) of the patients had T2 tumor.

T stage	Sen	Spec	PPV	NPV	LR+	LR-	Diagnostic Accuracy
T2	75%	29.6%	38.7%	66.7%	1.07	0.84	46.5%

Sen: sensitivity; Spec: specificity, PPV: positive predictive value; NPR: negative predictive value; LR+ likelihood ratio positive; LR-: likelihood ratio negative.

Table 3: Pre CRT MRI accuracy indices compared with pre-CRT biopsy for stage T2 Tumors

Variable	Sen	Spec	PPV	NPV	LR+	LR-	Diagnostic Accuracy
T3+T4	96.2%	26.3%	64.1%	83.3%	1.31	0.14	66.7%

Sen: sensitivity; Spec: specificity, PPV: positive predictive value; NPR: negative predictive value; LR+ likelihood ratio positive; LR-: likelihood ratio negative.

Table 4: Pre CRT MRI accuracy indices compared with pre-CRT biopsy for stage (T3+T4)

The diagnostic accuracy of MRI in evaluation of the T3 and T4, the MRI sensitivity was 96.2%, however low specificity 26.3%. The diagnostic accuracy was 66.7%.

Variable	Sen	Spec	PPV	NPV	LR+	LR-	Diagnostic Accuracy
T2	27.3%	94.7%	75%	69.2%	5.18	0.77	70%

Sen: sensitivity; Spec: specificity, PPV: positive predictive value; NPR: negative predictive value; LR+ likelihood ratio positive; LR-: likelihood ratio negative.

Table 5: Accuracy of MRI in diagnosing T2 in reference to biopsy findings.

In evaluation of T2 stage, the sensitivity of MRI was very low 27.3% and specificity relatively high 94.7%. Diagnostic accuracy was 70%.

T stage	Sen	Spec	PPV	NPV	LR+	LR-	Diagnostic Accuracy
T2	70.6%	33.3%	40%	64.3%	1.06	0.88	47.7%
T3	84.6%	66.7%	64.7%	85.7%	2.54	0.23	74.2%
Intra-mesorectal LNs (N1+N2)	84.6%	47.4%	68.8%	69.2%	1.61	0.32	68.9%

Sen: sensitivity; Spec: specificity, PPV: positive predictive value; NPR: negative predictive value; LR+ likelihood ratio positive; LR-: likelihood ratio negative.

Table 6: Post CRT MRI and Post CRT Biopsy accuracy indices.

Post RCT, stage T3 tumor, the sensitivity was 84.6% with low specificity 66.7% and the diagnostic accuracy was 74.2%. In other words, the MRI the diagnostic accuracy to diagnose T3 is 74.2% with relatively low specificity (66.7%).

Lymph Node staging	MRI pre-CRT	MRI post CRT	0.000
N0	9 (20.0)	32 (71.1)	
N1	20 (44.4)	10 (22.2)	
N2	16 (35.6)	3 (6.7)	

Table 7. MRI and intra-mesorectal lymph nodes correlation

MRI in evaluation of intra-mesorectal lymph nodes pre- and post-CRT revealed significant statistical correlation.

Discussion:

In regional advanced rectal cancer, surgical treatment only may not be sufficient as relatively high local recurrence rate [11, 12]. Preoperative CRT has been proven to regress the size and regress the tumor stage, augmenting the chance of sphincter preservation, reduction of the local recurrence rate or distant metastasis and improve survival rate [13, 14]. Good responders or pathological complete response (pCR) patients have a better outcome in comparison with poor responders [14, 15].

On the background of these results, either an observation approach for pathological complete response or non-conventional surgery (i.e., local excision) for better response has been assumed [16], although safeness of the approaches after CRT is remains questionable. So, accurate preoperative restaging after CRT is crucial to determine the optimal treatment plan for irradiated cancer rectum, especially in cases with good response to CRT, fear of surgical risk or radical operation refusal [16, 17].

MRI has been commonly used for preoperative assessment of rectal cancer, proven to be highly accurate in the initial disease staging [18, 19, 20]. However, when used for restaging after CRT, MR imaging are far less accurate as a result of limited ability to differentiate visible residual tumors from nonmalignant tissue, such as fibrosis, rectal wall thickness, and inflammatory infiltration induced by neoadjuvant therapy, so that the extent of local rectal tumor may be either overestimated or underestimated [15, 21, 22, 23].

A recent systematic review and meta- analysis showed that MRI restaging after CRT showed poor mean sensitivity (50.4%) [23]. Unsatisfactory accuracy had also been reported by other investigators with 47-52% for T staging and 64- 68% for nodal staging, by using MRI in irradiated rectal cancer [15, 21].

In our study, the overall diagnostic accuracy for T restaging was 46.5% and low specificity 29.6%. This was comparable to the study of *Shufang Zhan et al*, 2015 [24].

Overstating of T0–T2 results in most of the inaccuracy. In our study, sensitivity of MRI in T2 was 27.3% only.

Cases with pathologically confirmed good response to CRT, namely Stage 0–I, and up to 91.7% (11/12) were overestimated, with a poor 8% sensitivity and an acceptable 84% specificity. Moreover, MRI barely discovered 18.2% (4/22) of the cases with pCR, with a poor 18% sensitivity and an excellent 100% specificity. When it comes to T stages after CRT, only 4 out of 25 (16%) patients with ypT0 were correctly identified, whereas over-staging occurred in 11 cases as ycT2 and in 10 cases as ycT3. Moreover, 20.5% (9/44) of the patients considered to be node-negative at post-CRT MRI, proved to have nodal metastases by histopathology.

For nodal restaging with MRI, the overall accuracy was 63.8%, whereas 26.6% of the cases were over-staged and 9.6% were under-staged. These results were similar with

previous reports [15,21, 25]. Yet, the much better accuracy rate was reported by *Cho et al.*, with 67% for T stage and 75% for N stage [26].

On the one hand, when considering local excision in good responders or observation strategy for pCR, MRI provided limited value which should be taken into consideration based on these findings. On the other hand, in view of the excellent 100% specificity in predicting pCR, observation strategy could be considered in cases with pCR, anxiety for surgical risk or refusing the radical operation.

Our study excluded 8 patients with histologically proven rectal mucinous tumors, taking into consideration the tendency to increase the inaccuracy rate in staging because of high signal intensity after CRT which could result in difficulty in differentiating true tumor mass from mucin remained in place. However, this exclusion criterion seemed not to contribute to an increased diagnostic performance.

Kappa statistics revealed poor concordance in both T ($k=0.156$) and N staging ($k=0.289$) after preoperative CRT in this study. [23]

The presence of nodal involvement is an important prognostic indicator for oncologic outcomes. Up to now, there is no imaging modality that can precisely evaluate the lymph node status, and the optimal criteria to define nodal involvement have also not been established.

The criterion of a metastatic LN on MRI applied in this study was defined as axes >0.5 cm in diameter, which is the most used in similar studies [25]. Its overall accuracy was 63.8%, whereas 26.6% of the cases showed over-staging and 9.6% under-staging. Kappa statistics revealed poor concordance in N staging ($k=0.289$) after preoperative CRT.

Previous studies had reported similar results [27, 28]. However, the size criterion was not very reliable for accurate assessment; even lymph nodes smaller than 5 mm had also been reported to contain tumor [29]. Few studies had shown improved sensitivity with the use of irregular borders or signal homogeneity [27, 30]. A new development of an ultrasmall superparamagnetic iron oxide as a lymph node contrast material has been shown to increase the accuracy for detection of nodal metastases after CRT, but this agent has not been approved in Europe [31].

In the present study, considering nodal metastasis, a moderate 58% sensitivity and acceptable 74% specificity were observed. What should be kept in mind is that a negative MR imaging of nodes is not equivalent of no metastasis, because of limited utility of this method to identify micro metastases within the lymph nodes.

In summary, with the poor agreement in staging between MRI after CRT and histopathological findings, we suggest that radical surgical approach should be performed, regardless of the result of MR imaging after neoadjuvant therapy [15], unless a new imaging modality is developed to achieve considerably improved accuracy in clinical practice. However, for cases with pCR, fear of surgical risk or refusing radical operation, an observation strategy could be considered in view of the excellent 100% specificity of MRI in predicting pCR. Certainly, this study has some

limitations: firstly, its retrospective nature might result in inaccuracies, and secondly, the relatively limited number of patients could potentially lead to bias.

Conclusions

MRI had an accuracy average of 81.6% in T stage and 68.9% in N stage in re-staging rectal tumors after CRT. Over-staging results of majority of the inaccuracy.

The statistical agreement between post-CRT MRI and the pathologic staging involving T and N stages was not satisfactory. In view of the above, Post CRT, restaging rectal cancer remains a challenge. In addition, MRI is in satisfactory to diagnose pCR. Therefore, the surgical plan before treatment should not be changed unless a new modality is used to achieve high accuracy in clinical practice. However, for those patients with pCR, intolerance or refusing radical operation, observation plans should be recommended owing to MRI's high specificity to predict pCR.

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Evaluation of ALK, EGFR and PD-L1 Mutations in Pulmonary Carcinomas through Immunohistochemistry.

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Abstract

Introduction: Lung cancer, with about 2.2 million new cases and 1.8 million deaths, is the second most commonly diagnosed cancer and the leading cause of cancer death in 2020. Immunohistochemistry (IHC) now is used not only to diagnose and classify lung tumors into subtypes, but also to determine the eligibility of patients for different molecular-targeted therapies.

Objectives: Study of ALK, EGFR and PD-L1 mutations in Pulmonary Carcinomas through immunohistochemistry examinations to help determine the prognosis and cases that may benefit from target therapy. Detection of possible links between ALK, EGFR, PD-L1 and other variables such as age, sex, histological entity and degree of tumor differentiation.

Materials and Methodology: The study is retrospective and includes 266 patients diagnosed with lung cancer who underwent biopsy at the American Hospital in the period 2016-2020. Tissues obtained were subjected to IHC examination using antibodies against factors EGFR, ALK, PD-L1, etc.

Results: The study showed that out of 266 patients, 24% of lung cancer cases are females and 76% are males. The average age was 61.8 years. No statistically significant relationship was found between ALK, PD-L1 and EGFR with variables such as age, gender and degree of differentiation of adenocarcinomas. No significant link was found between ALK and PD-L1 and the histological entity, but a significant link was found between EGFR and histological type of pulmonary carcinomas.

Conclusions: Lung cancer is one of the most common cancers, found mainly in men, but also in women. Nowadays, IHC helps not only to diagnose lung cancer, but also to determine patients who can respond to target therapy and their prognosis. Therefore, the use of IHC to detect ALK, EGFR, PDL-1 mutations and their links to patient characteristics is becoming increasingly necessary.

Keywords: Lung cancer, Immunohistochemistry (IHC), ALK, PD-L1, EGFR

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Introduction

Lung cancer, with about 2.2 million new cases and 1.8 million deaths, is the second most commonly diagnosed cancer and the leading cause of cancer death in 2020. [1, 2]

IHC now is used not only to diagnose and classify lung tumors into subtypes, but also to determine the eligibility of patients for different molecular-targeted therapies. Anaplastic lymphoma kinase (ALK) is a transmembrane protein, member of the insulin receptor tyrosine kinase family (RTK).

ALK rearrangements occur in 3–7% of NSCLC (Non-Small Cell Lung Cancer) with EML4 (echinoderm microtubule-associated protein-like 4) as the most common fusion partner. [3, 4, 5]

They are more common in young people, patients who have never smoked or light smokers, and patients with adenocarcinoma. ALK inhibitors available for the treatment of ALK-rearranged lung tumors, include crizotinib (first generation ALK inhibitors), ceritinib and alectinib (Second-generation ALK inhibitors in the post-crizotinib setting). [6, 7] Epidermal growth factor receptor (EGFR) is a transmembrane tyrosine kinase receptor which belongs to the HER family. It has an extracellular ligand binding domain, a transmembrane domain, and an intracellular domain (tyrosine kinase). The two most common mutations that account for greater than 85% of all EGFR gene mutations are in-frame deletions in exon 19 (LREA deletions) and substitution in exon 21 (L858R). [8, 9]

EGFR mutations predict the benefits of anti-EGFR therapies, especially tyrosine kinase inhibitors (TKIs). Erlotinib and gefitinib are orally active, selective EGFR-TKIs that produce objective response rates in about 10% of advanced non-small cell lung cancer (NSCLC). [10, 11]

Programmed death-ligand 1 (PD-L1) is a type 1 transmembrane protein that belongs to the B7 ligands family and may be expressed both on hematopoietic cells (dendritic cells, macrophages, mast cells, T-cells and B-lymphocytes) and nonhematopoietic cells (endothelial, epithelial and tumor cells). [12, 13]

PD-L1 expression is used as a biomarker that predicts which patients are most likely to respond to anti-PD-1/PD-L1 therapies. Some of these therapies which are approved in treatment of lung cancer are pembrolizumab (anti-PD-1), Nivolumab (anti-PD-1) and atezolizumab (anti-PD-L1). [14, 15]

Materials and Methodology

1. Immunohistochemical analysis

We examined paraffin-embedded tissue sections using the following primary antibodies: TTF-1, CK-7, CK-20, Ki67, etc. According to the above indicators and other immunohistochemical markers, we classified lung cancer into adenocarcinoma, squamous carcinoma, adeno-squamous carcinoma, small cell carcinomas (SCLC), etc. ALK, EGFR, PD-L1 mutation analysis were made following guidelines of International Association for the Study of Lung Cancer (IASLC). [16, 17, 18]

ALK positivity was confirmed using Ventana IHC, which is based on a specific monoclonal antibody (D5F3) and was combined with a signal amplification system. ALK positivity was defined as strong granular cytoplasmic staining (any percentage of positive tumor cells) in the tumor cells; otherwise, the sample was deemed ALK negative. EGFR mutation analysis was made using the following major antibodies: DEL specific monoclonal antibody (pre-diluted, clone SP111, Ventana) specific monoclonal antibody L858R (pre-diluted, SP125 clone, Ventana) and the tEGFR antibody (1: 100, clone SP9, Spring Bioscience, Pleasanton, CA). EGFR positivity was based on membrane

and / or cytoplasmic staining, as follows: 0, without staining or pale staining in <10% of tumor cells; 1+, weak staining in ≥ 10% of tumor cells; 2+, moderate staining in ≥ 10% of tumor cells; 3+, strong staining in ≥ 10% of tumor cells. For PD-L1 mutation analysis PharmDx PD-L1 IHC 22C3 was used. A minimum number of 100 tumor cells are required to consider a valid example for its evaluation in formalin-fixed paraffin-hardened tissues (FFPE) using the mouse 22C3 monoclonal clone. PD-L1 was considered positive when a membrane staining (partial or complete) of ≥1% tumor cells was seen.

2. Statistical analysis

Our study is retrospective type and includes 266 patients diagnosed with lung cancer that underwent biopsy at the American Hospital in the period 2016-2020. The obtained data are presented in the form of graphs and tables. Statistical analysis of data is performed in the statistical program Chi-Square and Crosstab. Significance is denoted by P. Significant in our study was considered value of P <0.05, while value of P > 0.05 was considered not significant.

Results

The study involves 266 patients of whom 203 (76.3%) are male and 63 (23.7%) females. Of the 266 patients surveyed, only in 201 of them age is known. Referring to these 201 patients it resulted that 5% of them were ≤ 40 years old, 33% were between 41 and 60 years old and 62% were over 60 years old. The average age was 61.85 with a standard deviation (Sd) = 10.145.

Age	No. of cases	% of cases
≤ 40 years old	10	5
41-60 years old	67	33
>60 years old	124	62
Total	201	100

Table 1: Age of the participating sample.

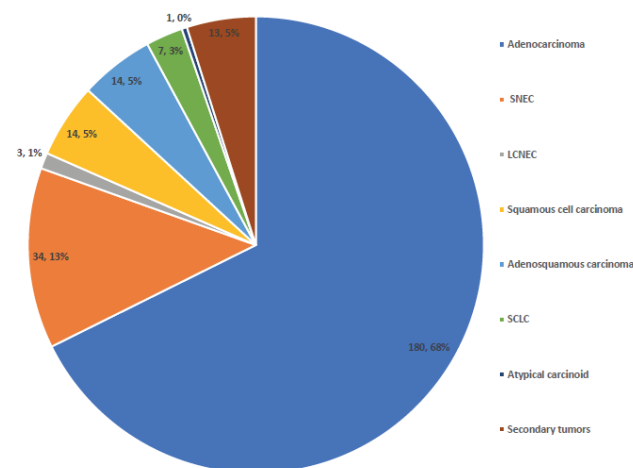


Table 2: Frequency of histological type

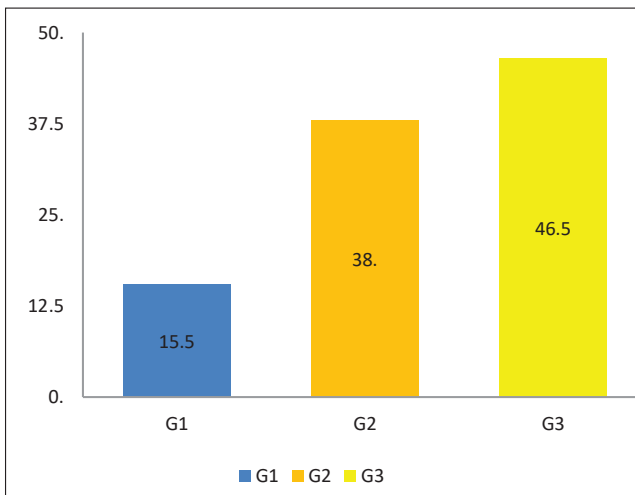


Table3: Grades (%) of adenocarcinoma

From the data obtained according to the histological type of carcinomas, it resulted that out of 266 patients 67.7% were adenocarcinomas, 12.7% were small cell neuroendocrine carcinomas, 1.1% were large cell neuroendocrine carcinomas, 5.3% were squamous cell carcinomas, 5.3% are adenosquamous carcinomas, 2.6% were small cell carcinomas (SCLC), 0.4% were atypical carcinoids and 4.9% were secondary tumors. From the 180 patients in our study diagnosed with Adenocarcinoma, only 155 of them had the grade of differentiation confirmed. It turned out that in these 155 patients, 15.5% were Grade 1, 38% were Grade 2 and 46.5% were Grade 3

Frequency according to ALK: In 178 cases studied 6 patients (3.4%) are positive and 172 patients (96.6%) are negative. Frequency according to EGFR: In 266 cases studied 50 patients (18.8%) are positive and 216 patients (81.2%) are negative. Frequency according to PD-L1: In 112 cases studied 39 patients (34.8%) are positive and 73 patients (65.2%) are negative.

Limitations of the study

Our study is retrospective and does not follow the dynamics of cases, to see the prognosis of patients and to extract data on the survival of patients according to the stage of the disease at the time of diagnosis and benefits from the treatment scheme chosen. Data were lacking in some patients. There were also cases when immunohistochemistry examinations for ALK and PDL were missing due to the absence of Antibodies. Our study includes a small number of cases and we must consider that the Chi-square test is very sensitive to the size of sample. Thus, in a small sample we may not have detected a significant relationship even if it actually exists.

Discussion

The results of our study showed that ALK is not related to gender, but is related to age. Positive cases belonged mainly to middle age, while in old age there were far fewer positive cases. Also, in our study the only histological type, ALK positive, were Adenocarcinomas. No significant relationship was found between ALK and the degree of differentiation of adenocarcinomas. In all three degrees of adenocarcinomas predominated a negative ALK. These data are consistent with the existing literature. The study failed to find statistically significant links between EGFR and gender and age, with EGFR negativity predominating in both variables. A statistical correlation was found between EGFR and histological type where positive cases with adenocarcinoma and adenosquamous carcinoma predominate. No significant association was found between EGFR and adenocarcinoma grade, but it turned out that grade II and III had more EGFR positive cases, unlike another study done in California where EGFR positive resulted more in first and second grade [19]. This incompatibility can be explained by the small number of patients with grade I adenocarcinoma included in our study, with different population characteristics or differences in technique used. Our study found no significant association between PD-L1 and gender, with both male and female predominant negative cases. PD-L1 had no significant relationship with age in our study, but it turned out that positive cases predominated in the age group over 60 years. Histological types were mostly negative. No significant association was found between PD-L1 and the degree of Adenocarcinoma. It should be taken in consideration that in addition to the small number of patients included in the study, knowledge about the expression of PD-L1 in lung cancer is still deficient, so further studies should be performed to determine whether there is a link between PD-L1 and these variables.[20]

Conclusions

Lung cancer is one of the most common cancers, found mainly in men, but also in women. Nowadays, IHC helps not only to diagnose lung cancer, but also to determine patients who can respond to target therapy and their prognosis. Therefore, the use of IHC to detect ALK, EGFR, PDL-1 mutations and their links to patient characteristics is becoming increasingly necessary.

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The Origin of Pilonidal Sinus Disease – 10 Wrong Theories and one Recent Discovery.

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Abstract

Introduction: In the last two centuries, many theories have been proposed to explain the origin of pilonidal sinus disease (PSD) – congenital and acquired.

Materials and Methods: A PubMed literature review was conducted and looked at different proposed theories on the origin of PSD; this overview was then compared to research results from more recent studies.

Results: Initially it was postulated, that PSD was of embryonic origin. This however changed during World War II as more 78.000 American soldiers were diagnosed and treated for PSD. Thereafter, the perception of the origin of PSD changed to an acquired one. New data has shown that short hair fragments, which have fallen from the scalp may be the origin of PSD – therefore disproving the theory of folliculitis and fatty gland obstruction.

Conclusion: These new findings may explain why recurrences/new diseases occur within follicle-free areas – such as scars and without any preceding infection. This may aid in the prevention of PSD.

Keywords: Pilonidal sinus disease, genesis, Prevention, short hair fragments.

Original article, no submission or publication in advance or in parallel

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Introduction

Pilonidal sinus disease (PSD) was first described 186 years ago as a “lump” in the lower back region of a captain’s young son. [1]. Despite being injected with silver (Ag) and mercury (Hg) solutions¹, healing was dismal. A small

¹ In the past, mercury was used in several forms for antimicrobial purposes. Some of the most common forms of mercury-based disinfectants were as follows:

1. Mercury (I) chloride (Hg₂Cl₂): Also known as mineral calomel, was a widely used antiseptic and disinfectant in the 19th and early 20th centuries as well as in the treatment of syphilis. It was used to treat wounds, as a preservative for biological specimens, as a disinfectant for medical and dental instruments, and to rid the body from “impurities”. It frequently caused accidental poisonings.
2. Mercury (II) chloride, mercury bichloride (HgCl₂): This form of mercury was commonly used as an antiseptic and as a topical treatment for skin conditions.
3. Mercury (II) oxide, mercuric oxide (HgO): Mercury oxide was used as a disinfectant for air and surfaces, and was also used as a component in some cosmetics and soaps. It is a highly toxic substance which can be absorbed by inhalation of aerosol, by ingestion or through skin.

nest of hair was discovered by the physician and thereafter removed – this resulted impressive healing. Most common theories at that time were as follows:

Congenital theories postulated

As this disease occurred in the midline, it was consecutively thought that pilonidal sinus was an acquired disease.

In 1860, *Luschka* postulated that a pilonidal sinus was a remnant of the embryonic preen gland in human beings [2]. In 1878, *Féré* proposed, that a pilonidal sinus developed between 3rd and 6th embryological week in utero, when the neural tube and skin ectoderm close in the midline[3]. Through faulty closure, skin remnants like hair follicles would be transferred into the depth, allowing hair to grow and develop into larger hair nests.

In 1882, *Lannelongue* described a ligament between the pilonidal sinus area and the coccyx[4]. As the body grew, the distance between skin and coccygeal bone increased. The idea was, that ligament traction would generate a small concave area, which would finally develop into PSD.

Other scientists like *Madelung* (1885) suggested, that a pilonidal sinus was a “error in nature” where insufficient resorption of the in-utero human tail had occurred [5]. *Tourneaux* (1887) blamed remnants of neuro-cutaneous tracts for the formation of pilonidal sinuses [6].

Congenital theories answered

As time passed on, the embryological theories were subsequently disproven. Answering *Luschka* with his preen gland theory, the preen gland is only seen in birds and not in mammals[2]. The faulty closure theory with the inclusion of hair follicles in the depths would have been proven by histology by identifying hair follicles – which could never be seen. Only loose hair without follicles could be seen in the pilonidal sinus cavities until now. Caudal traction as a reason for developing PSD would have been very evident in the very tall people; this has proven not to be true. If the faulty resorption of the human tail would be a reason for PSD, a pilonidal sinus would be seen from birth on. In reality, pilonidal sinuses mostly arise new in previous healthy people during puberty. Neurocutaneous tracts, as proposed by *Tourneaux*, have never been seen in histology.

Acquired theories postulated

As World War II passed by, more than 78.000 American soldiers were diagnosed with PSD between 1941 and 1945 [7], and a further 530.701 between 1944 and 1951, as reported by *Buie* 1952 [8]. As the US Army was the first army to introduce mechanized warfare with the introduction

of Jeeps, PSD was immediately attributed to driving in cars, hence coining the name “Jeep’s Disease”-[9].

Patey and Scarff (1946) believed, that bumpy rides on hard seats led to hair being suctioned into small gluteal injuries [10]. In 1953, *Hueston* proposed that obstruction and infection of hair follicles to be responsible - hair with its complete root would lodge itself into a deeper skin area [11]. As *Palmer* in 1959 realized, PSD was more common during puberty [12]. As increased muscle development is typical during puberty, he proposed gluteal traction onto the skin to be the main reason for invagination and pilonidal sinus development. The most unconventional theory until now was from *Ahmad* (2005), who proposed that “*wrong sexual thoughts*” would activate special sweat glands in the gluteal area, which would lead to a PSD [13].

Acquired theories answered

Regarding *Buie’s* “Jeep’s disease” and related driving of cars – it became evident post World War II, that marching soldiers had the same pilonidal incidence as driving soldiers; so “Jeep’s disease” was observational bias, as during war, young male soldiers tend to be in close quarters, therefore being prone to PSD [14].

The suction theory of hair by *Patey and Scarff* seemed appropriate, but did not answer the question of anatomical region: most gluteal muscle and most of suction is generated close to the anus, where the intergluteal fold is deepest [15]. But PSD does not arise here; in contrast, a pilonidal sinus in close proximity to the anus is very rare [16]. Most cases of PSD arise cranial to the intergluteal fold and in the proximal third of the intergluteal fold, where the intergluteal fold is shallow.

The obstruction and infection of hair follicles as proposed by *Hueston* in 1953 is just a nice theory and never been observed. These obstructed follicles resulting in hair moving into the deeper skin from here, especially as the hair with a root is large and blunt tipped, therefore impeding movement into deeper tissues. Furthermore, 1/5th of the PSD cases is seen in women.

The large majority of them don’t have any telogenic hair present in the upper third of the intergluteal fold or above; so, there is no hair from here to be inflamed or to move into the skin. Furthermore, pilonidal sinus is seen in scars and areas without any hair follicle.

This shouldn’t be possible due to *Hueston* and his obstruction/folliculitis theory. Gluteal traction of hair follicles, as *Palmer* proposed, should generate most of the PSD in sporty people, who develop a larger and more powerful gluteal muscle. In fact, we see the opposite: less cases of PSD in sporty people.

Commenting briefly on the proposal of *Ahmed* (2005) - there are no special sweat glands found in the buttocks. PSD patients sweat less than average individuals [17, 18], have the similar testosterone levels as other people, and their sexuality is adequate in relation to their pubertal age behavior [19].

While being widely used in the past, mercury is now known to be highly neurotoxic and not used anymore for inner application. Instead, better and more efficient alternative wound disinfectants such as PVP-iodine, chlorhexidine, silver sulfadiazine, etc. are used. Nowadays, thiomersal (sodium salt of an organic mercury compound) is still used as a preservative in cosmetic and pharmaceutical products.

The most likely reason for Pilonidal Sinus Disease

So, if we see a PSD more often in some families, in people that have been excised largely before and around puberty: What are the reasons for that acquired disease with an obvious family trait?

Bosche, et al. proved that the pilonidal sinus nests contained between 0 and 403 loose hairs; and on light microscopy they discovered that 75% of the hair in the pilonidal sinus were without root [20]. Most of the hair was cut at one or both sides, and the mean length of the hair in the sinus nest was less than 1 cm [20].

They additionally proved that stronger hair was significantly more present in PSD patients when compared to normal patient population [21]. Scientific forensic biologists from the Munich Police could successfully prove that most of the hair in the nest resembled hair from the head, and not from the intergluteal region [22]. In fact, occipital hair was present in this region immediately at the end of any haircut, despite regular protective measurements [23].

Interestingly, *Gosselink* – using Electron microscopic methods - could depict hair just entering the skin in 2017, thus proving that sharp hair with “right” directional scales was the culprit, that penetrated into deeper skin [24, 25]. Ruptured hair, as well as hair with its root, are too large and too bulky at the end to enter the skin, which could be demonstrated by *Bosche* [20].

Consequences of the short hair fragment genesis of PSD – an outlook

What are the wider reaching consequences of this new findings related to sharp hair fragments being the culprit of PSD?

- We have to think about how to reduce the amount of sharp hair fragments being present in the intergluteal fold. Wet haircuts are better than dry haircuts; and scissor cuts are better than machine cuts, as they produce less sharp hair fragments.
- The hairdresser gowns and other protective measures have to be improved.
- Every male should have a shower after going to the hairdresser, washing out the small hair fragments between neck and gluteal muscles area.
- In patients with lots of hair growing in the intergluteal area, depilation treatment of the intergluteal area can be of use. Intergluteal hair is able to catch and hold sharp hair fragments from the top; it keeps them in the intergluteal fold. As longer this sharp hair fragments stay in the intergluteal fold, as larger is their change to be drilled into the skin through intergluteal movements when walking. Regular use of depilatory cream and razor depilation adds 50% to the postoperative recurrence rate, as proven by *Petersen and others* [26]. Today laser depilation seems to be the best way to enable a long-term depilation needing no further compliance than the 5-10 sessions. Laser depilation works best in dark haired patients, which are more prone to PSD.

- In term of future research, we need to identify the persons at risk, the ones that have a family history of PSD or who have 2-5 years’ earlier disease than others. Shampoos or formulas need to be developed which may permanently soften the hair, with the effect of lesser short hair injections. Could a protective spray covering the intergluteal skin prevent further injections of hair in the glabella/intergluteal region? Alternatively, a skin treatment which improves penetration resilience of the skin to the small hair fragments could theoretically lead to the same positive effects. Until now, perforation resilience of the skin has not been investigated so far, which is an interesting area of research. Another research topic which will be published on soon will tell us if the glabella sacralis region just above the intergluteal fold has major influence of the amount of hair entering the intergluteal fold.

There are numerous questions to be answered. One hundred- and ninety-years following Mayo’s findings, there is reason to be optimistic that PSD prevention can be improved within the next 10 years.

Conclusion

These new findings may explain why recurrences/new diseases occur within follicle-free areas – such as scars and without any preceding infection. This may aid in the prevention of PSD.

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Comparative Analysis of Knee Replacement Surgery who follow up by Physical Therapy and Intra-articular Steroid Injections for Obese Patients

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Abstract

Knee osteoarthritis (KOA) is the most common chronic articular disease, and its prevalence has doubled since the mid-20th century. It affects 16% of the adult population over 50 years of age in the post-industrial era [1].

Obesity is one of the only modifiable risk factors for both incidence and progression of Osteoarthritis (OA).[2]

Although OA was previously regarded as a disease of the elderly, its development starts much earlier than originally thought, and OA is ranked among the top 20 diseases in the 40–45 years age group [3].

This review aims to provide a comprehensive analysis of the outcomes of knee replacement surgery following up physical therapy, versus intra-articular steroid injections for obese patients (BMI >30)

The study design employed in this review is narrative, and articles published after 2010 from PubMed were considered for inclusion. The review examines the impact of each intervention on the complete regain of knee function in this specific population.

Through the analysis of relevant studies, this review seeks to inform clinical decision-making and guide the management of obese patients with knee osteoarthritis.

Conclusion. Based on the reviewed literature, knee replacement surgery appears to offer a better chance of achieving complete regain of knee function in obese patients (BMI >30) undergoing physical therapy compared to intra-articular steroid injections. However, the findings are limited by the availability of studies and the heterogeneity in the research methodologies.

Keywords: knee osteoarthritis, knee replacement, knee corticosteroid injection, physical therapy

Introduction

Obesity, defined as having a body mass index (BMI) greater than 30, is a prevalent health concern that affects millions of individuals worldwide. [4]

There has been a significant global increase in obesity rate during the last 50 years. Obesity is defined as when a person has a body mass index [BMI (kg/m²), dividing a

person's weight by the square of their height] greater than or equal to 30, overweight is defined as a BMI of 25.0-29.9. Being overweight or obesity is linked with more deaths than being underweight and is a more common global occurrence than being underweight.[4]

Obesity is a well-recognized global epidemic. The WHO estimates from 2008 indicate that more than 1.4 billion adults are overweight and, of these, more than 200 million men and 300 million women are obese¹. The trend is worrying: over the past 30 years, worldwide obesity has more than doubled.[5]

Among its many associated health complications, obesity significantly impacts musculoskeletal health, leading to increased stress on weight-bearing joints such as the knee. As a result, obese individuals commonly experience knee osteoarthritis, which can severely impair their mobility and overall quality of life.[6]

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The implications for the musculoskeletal system include both degenerative and inflammatory conditions, with the greatest burden resulting from osteoarthritis (OA) [5].

OA is a clinical syndrome of joint pain and dysfunction caused by joint degeneration, and affects more people than any other joint disease. Currently, nearly 10 per cent of the population is affected and the prevalence increases with age.[7]

Knee OA can be classified on clinical criteria alone (including pain, age, stiffness, crepitus, bony tenderness and bony enlargement), which make up the inclusion criteria for most clinical trials in this field. For patients with advanced knee osteoarthritis, knee replacement surgery is a commonly recommended intervention to alleviate pain and restore function.[8]

However, the presence of obesity adds complexity to the surgical procedure and subsequent recovery process. [9]

The pain and decreased function associated with OA place a major burden on communities as well as health and social care systems; hip and knee OA are leading causes of disability worldwide.

Treatment modalities for OA can be broadly divided into conservative and surgical.[10]

Obese patients undergoing knee replacement surgery often face challenges such as increased surgical risks, delayed wound healing, and difficulties in rehabilitation due to excess weight-bearing. Therefore, it is crucial to evaluate the outcomes and effectiveness of interventions for this specific population.[11]

Conservative therapies include supportive nonpharmacological therapy, systemic pharmacological therapy and localized intra-articular (IA) therapies delivered directly into the affected joint. [12]

Intra-articular injection of Corticosteroids (CS) is perhaps the most common conservative approach in the treatment of knee OA. The rationale behind its use relies on its immunosuppressive activity in the knee joint acting at different levels of the inflammatory cascade. In particular, it acts by blocking the synthesis of pro-inflammatory signalling molecules, such as interleukin 1 (IL-1), leukotrienes, prostaglandins and catabolic proteins such as metalloproteinases. These combined actions may be accountable for the pain relief observed in patients treated with CS. [13]

Intra-articular steroid injections have emerged as an alternative treatment option for knee osteoarthritis, offering pain relief and potentially delaying or avoiding the need for surgery. These injections deliver corticosteroids directly into the knee joint, reducing inflammation and providing temporary relief. While they are considered less invasive than surgery, their long-term efficacy and ability to promote complete regain of knee function in obese patients undergoing physical therapy remain uncertain. [13]

The primary aim of this review article is to compare the outcomes of knee replacement surgery followed by physical

therapy to those of knee replacement surgery followed by intra-articular steroid injections and physical therapy in obese patients (BMI >30). Specifically, we seek to evaluate which intervention leads to a better chance of achieving complete regain of knee function.

Understanding the differential effects of these interventions on obese patients' knee function will provide valuable insights for healthcare professionals involved in their management.

By comparing surgical and non-surgical approaches, we can contribute to informed decision-making, ensuring that patients receive the most suitable treatment option tailored to their specific needs.

Additionally, it may pave the way for further research in this area, focusing on refining existing interventions and exploring innovative approaches to optimize knee function restoration for this vulnerable patient population.

Methodology:

A comprehensive literature search was conducted using PubMed, considering articles published after 2010. The search strategy employed relevant keywords such as "knee replacement surgery," "obese patients," "BMI >30," "physical therapy," "intra-articular steroid injections," and "regain of knee function." The inclusion criteria for articles were as follows: (1) studies comparing knee replacement surgery and intra-articular steroid injections in obese patients (BMI >30); (2) studies that assessed knee function outcomes; (3) studies published in English; and (4) articles published after 2010. After evaluating the search results, relevant articles were selected for inclusion in this review.

Discussion:

A total of 10 articles were selected for inclusion in this review. The studies encompassed various study designs, including prospective cohort studies, randomized controlled trials, and retrospective studies. The selected articles evaluated the outcomes of knee replacement surgery and intra-articular steroid injections in obese patients (BMI >30) undergoing physical therapy.

The studies consistently reported that knee replacement surgery resulted in significant improvements in knee function, pain reduction, and patient-reported outcomes. [14, 15]

Patient-report measures of physical function provide useful information related to patients' perceptions of physical function, but there is a burgeoning body of evidence that suggests patient-reports fail to capture the actual change in functional performance after Total knee arthroplasty TKA[16]. Objective measures such as range of motion, strength, and functional tests consistently showed improvements following knee replacement surgery. [17]

Few studies have included both pre-operative and post-operative assessments of physical function using both

patient-report and performance-based measures of physical function. Even fewer include acute assessment coupled with adequate follow-up after TKA [18]

Subjective measures, including pain levels and patient-reported outcomes, also demonstrated favorable results after surgery.

Improvements in patient-report often correspond strongly with improvements in patient's report of pain [19].

Patients who have advanced knee OA and subsequent TKA have difficulty discriminating pain from their ability to perform functional tasks. The assessment of physical function beyond the acute recovery phase is key as patients' outcomes normally do not stabilize until at least 6 months after surgery [17]

On the other hand, the evidence regarding the efficacy of intra-articular steroid injections was limited and inconclusive. Initiating treatments with either corticosteroid or hyaluronic acid injections was not associated with reduced symptoms compared to non-users over two years in patients with knee OA. [20]

While some studies reported short-term pain relief following injections, there was insufficient evidence to support long-term functional improvement. The studies highlighted the need for further research to establish the long-term effectiveness of intra-articular steroid injections in obese patients undergoing physical therapy.[21]

Overall, the findings suggest that knee replacement surgery offers a better chance of achieving complete regain of knee function in obese patients (BMI >30) undergoing physical therapy compared to intra-articular steroid injections. Obesity had a negative effect on progress during the CPM protocol, which commenced immediately after surgery and continued until discharge.[22]

However, it is important to note that the evidence is limited by the availability of studies and the heterogeneity in research methodologies. Further well-designed studies are needed to provide more robust and conclusive evidence on the comparative outcomes of these interventions in this specific population.

The findings from the selected studies suggest that knee replacement surgery leads to significant improvements in knee function, pain reduction, and patient-reported outcomes in obese individuals.[23]

The surgery is effective in restoring knee function and enhancing the quality of life in this specific population. In contrast, the evidence regarding the efficacy of intra-articular steroid injections is limited and inconclusive, with some studies reporting short-term pain relief but insufficient evidence of long-term functional improvement.[24]

Conclusion:

Based on the reviewed literature, knee replacement surgery appears to offer a better chance of achieving complete regain of knee function in obese patients (BMI >30) undergoing physical therapy compared to intra-articular steroid injections.

However, the findings are limited by the availability of studies and the heterogeneity in the research methodologies. Further well-designed studies are needed to provide more robust evidence on this topic.

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CASE REPORTS

Scrotal Kaposi's Sarcoma in HIV-negative Patient: A Case Report and Review of the Literature.

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Abstract

Background: Kaposi's sarcoma (KS) is an indolent angio-proliferative tumor proliferation with spindle cells originating from endothelial and immune cells infected with human herpes virus type 8. (HHV-8: also known as Kaposi sarcoma herpes virus [KSHV]). HHV-8 was identified as the causative agent of KS. This virus is present in 95-98% of cases with KS. Kaposi's sarcoma was first described by a Hungarian dermatologist 1872 named Moritz Kaposi.[1]

The lesions are characterized by the proliferation of spindle cells of endothelial origin, which present different degrees of abnormal vascularization, inflammatory infiltrates, and fibrosis. Kaposi's Sarcoma (KS) is a malignancy that generally affects the skin, and can be systemic with internal organ involvement. It originates from the vascular endothelium. KS's relationship with human immunodeficiency virus (HIV) infection is well known.

In this article, we will present a 73-year-old male patient with 3 purple scrotal lesions up to 0.5 cm in size.

Conclusion; Kaposi's sarcoma of the scrotum in a negative patient is a rare pathology. However, in cases of scrotal lesions that last over time, a differential diagnosis should be made and Kaposi's sarcoma should be taken into consideration. Also, a screening for other accompanying lesions, especially a detailed examination of the gastrointestinal tract is important in cases of Kaposi's sarcoma of the scrotum.

Keywords: Kaposi's Sarcoma, Human herpes virus, HIV, Scrotal Kaposi

Introduction

Kaposi's sarcoma (KS) is an indolent angio-proliferative tumor proliferation with spindle cells originating from endothelial and immune cells infected with human herpes virus type 8.

(HHV-8: also known as Kaposi sarcoma herpes virus [KSHV]). HHV-8 was identified as the causative agent of KS. This virus is present in 95-98% of cases with KS. Kaposi's sarcoma was first described by a Hungarian dermatologist in 1872 named Moritz Kaposi.[1]

The lesions are characterized by the proliferation of spindle cells of endothelial origin, which present different degrees of abnormal vascularization, inflammatory infiltrates and fibrosis. Red blood cells and hemosiderin deposits give the lesions their purplish appearance. Spindle

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cells are infected with HHV-8. HHV-8 encodes for a number of genes that induce proliferation, cytokine production and angiogenesis thus contributing to tumor pathogenesis. Kaposi's sarcoma has a variable clinic from minimal mucocutaneous lesions to extensive organ involvement. The skin lesions are classically characterized by macules, plaques and nodules that are of a purple, red, blue, dark brown or black appearance. Penile KS is relatively common, while isolated scrotal KS has rarely been seen.[2] In this article, we will present a 73-year-old male patient with 3 purple scrotal lesions up to 0.5 cm in size.

Case report

In this case report we will address a 73-year-old male with 3 dark-colored nodular scrotal lesions with a diameter of 0.3, 0.5 and 0.4 cm (Figure 1). The lesions appeared 2 years ago and during this period they were treated several times



Figure 1. Macroscopic appearance of the lesion.

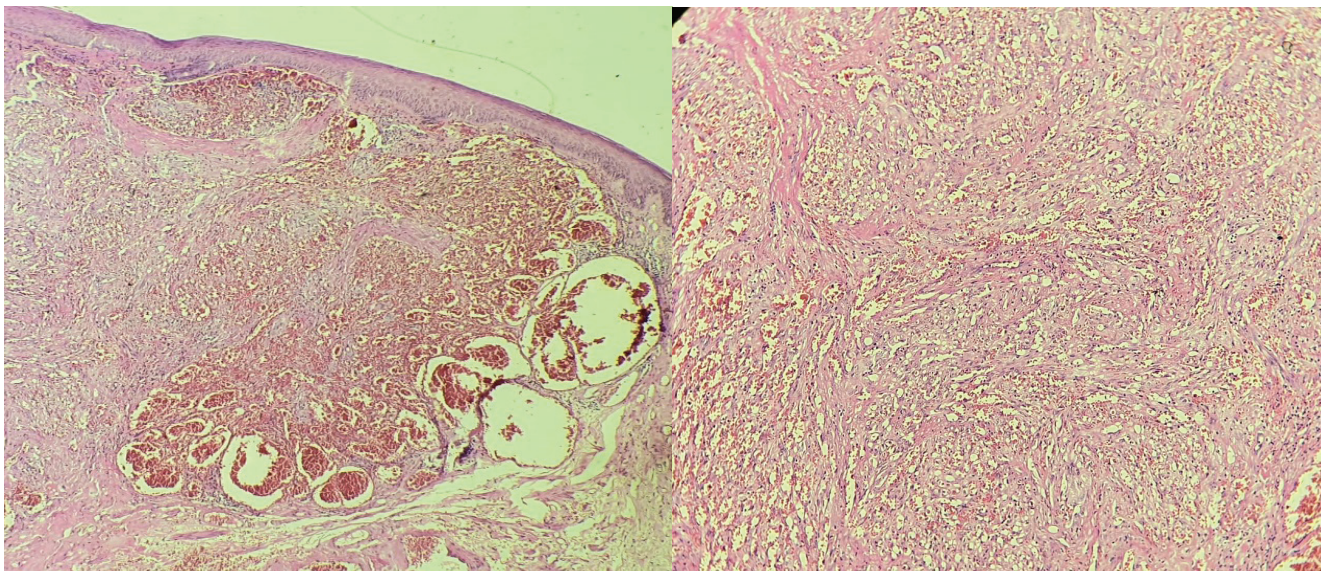


Figure 2. The view in Hematoxylin-Eosin Staining

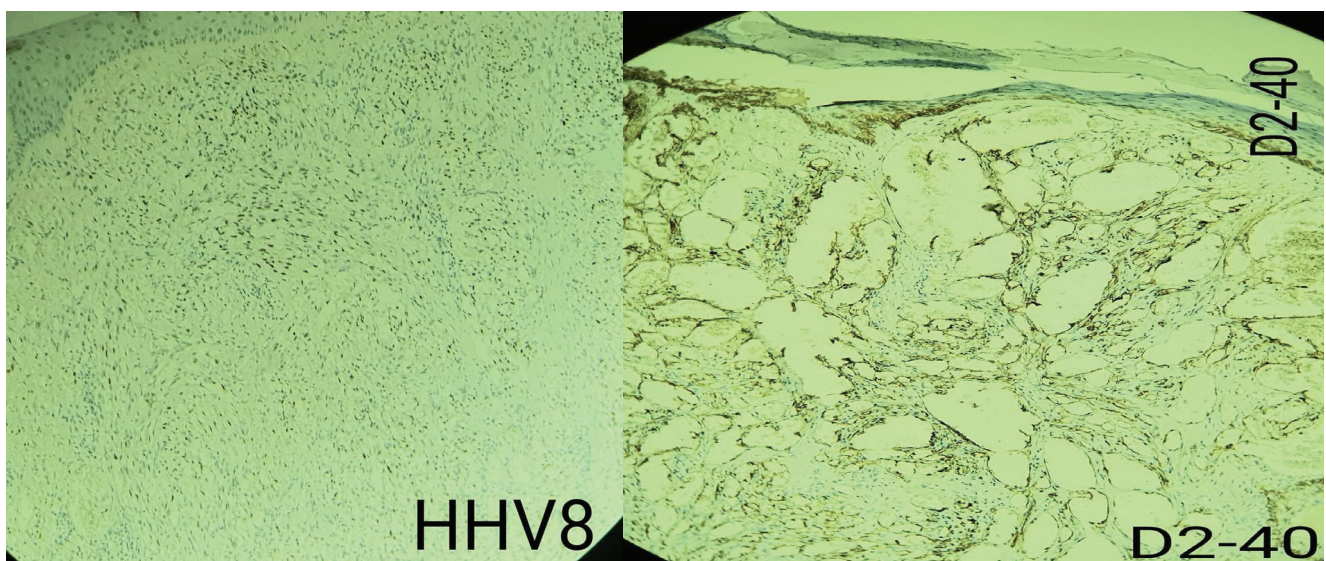


Figure 3. Immunohistochemistry. HHV8 (+++), D2-40 (+++)

by a dermatologist with local agents but without results. The patient is diagnosed with diabetes mellitus type 2, hypertension and also with rheumatoid arthritis for which has been treated with immunosuppressors (Methotrexate). No other similar lesions were seen in other part of the body. Routine laboratory tests were all normal. After the failure of treatment with conservative methods, surgical excision of the lesions was performed. The excision of the lesions was performed with spinal anesthesia and the material is sent for histopathological examination. In the Hematoxylin – Eosin staining the lesion make it easier to see different parts of the cell under a microscope.

Also, the immunohistopathological examination are performed and the lesions are: HHV8 (+++), D2-40 (+++), CD34 (+-), Ki67 20 %, MelanA (---), S100 (---). (Figure 3). In this way the diagnosis of Kaposi Sarcoma is established. The patient underwent a total body CT and also a gastric endoscopy. The results of these examination are normal and no regional lymphadenopathy was observed. The serological tests for HIV, HbsAg, anit-HCV, TPHA and VDRL were negative.

After surgery the patient was follow - up for any recurrence. No local recurrence or systemic lesions was observed during last year of follow up.

Discussion

Kaposi's sarcoma is caused by an uncontrolled proliferation of spindle cells which are thought to originate from endothelial cells. Regardless of their heterogeneity, the tumor consists of HHV-8 genetic material with immunohistochemical markers of endothelial, spindle and lymphoid cells. [3]

Previous molecular studies suggested that Kaposi's Sarcoma originated from a single clonal cell rather than a multifocal origin. However, a current study with data from 98 patients with primary cutaneous Kaposi's Sarcoma analyzing HHV-8 viral DNA in tumors showed that approximately 80% of tumors originate from multiple cell-independent tumors.[4]

Kaposi sarcoma may be caused by HHV-8 (KSHV) with stimulation by autocrine and paracrine growth factors secreted by the spindle cells themselves as well as the supporting network of mononuclear and endothelial cells. Coinfection with HIV may create a more aggressive course, which is mitigated by effective antiretroviral therapies. Indeed, the risk of Kaposi sarcoma development is amplified 500-10,000 times in patients coinfecting with KSHV and HIV.[5]

In summary, complex immune dysregulation is the center theme for the pathogenesis of Kaposi sarcoma. This includes cellular immunity defects,[6, 7] humoral immunity defects and abnormalities of vascular endothelial growth factor. Apparent overlapping mechanisms for upregulation of multiple pathways produce the malignant phenotype.

Kaposi Sarcoma is characterized by few or widespread multifocal, brown-violescent or dark red patches and papules, plaques and/or deep nodular skin lesions. Its

classical form is often seen in older male patients of Mediterranean or Ashkenazi descent and it is localized in the mucocutaneous tissues, more commonly affecting the lower extremities and feet with its nodular lesions and presents as a clinical entity rarely showing visceral involvement. [8] In the genital region, cases of penile involvement are more frequent, while Kaposi's sarcoma of the scrotal region in HIV negative patients is very rare and only a few cases have been reported in the literature. From our search in the English literature, it appears that the first case of Kaposi's sarcoma in the scrotal region was first described by *Iyas S et al.* in 1976 [9].

Cases with Kaposi's sarcoma of the scrotal region in HIV negative patients after our research results: *Ozmen H et.al* in 2014 [10], *Bayoumi M E et.al* in 2018 [11], *Yenice M G et.al* in 2018 [12], *Al Aboud D et.al.* in 2022 [13].

This means that our case is the sixth case of scrotal Kaposi's Sarcoma in HIV negative patient reported in English literature.

Cases of involvement in the organs of the gastrointestinal tract, according to a Greek study, are high in Kaposi's Sarcoma cases, therefore screening with endoscopic examination is recommended. [14].

The diagnosis of Kaposi's sarcoma is an immunohistopathological diagnosis, therefore the role of the pathologist is very important. Kaposi's sarcoma goes through several stages: 1. Patch stage, 2. Plaque stage, 3. Tumor (nodular) stage. [15, 16].

In the examination with immunohistochemistry, Kaposi's Sarcoma is positive for: HHV8, CD34, CD31, D2-40 and negative for: SMA, Desmin, Cytokeratins, S100, MelanA, HMB45.

The differential diagnosis should include: angiosarcoma, hobnail hemangioma, spindle cell hemangioma, Kaposi form hemangioendothelioma, which are HHV8 negative. [17, 18, 19].

Conclusion

Kaposi's sarcoma of the scrotum in a negative patient is a rare pathology. However, in cases of scrotal lesions that last over time, a differential diagnosis should be made and Kaposi's sarcoma should be taken into consideration. Also, a screening for other accompanying lesions, especially a detailed examination of the gastrointestinal tract is important in cases of Kaposi's sarcoma of the scrotum.

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CASE REPORTS

The Key Role of Splenectomy in Fever of unknown Origin which Resulted to be B-cell primary Splenic Lymphoma.

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Abstract

Background: The term ‘fever of unknown origin’ (FUO) was first introduced by Petersdorf and Beeson in 1961, and it is defined as recurrent fever >38.3°C, lasting for >3 weeks, remaining undiagnosed after 1 week of in-hospital evaluation. The etiologies of classic FUO include mainly infections, malignancies, non-infectious inflammatory diseases, and miscellaneous causes, while some cases remain undiagnosed. Primary splenic lymphoma (PSL) is a rare malignant lymphoma. In many cases, splenectomy is the treatment of choice for massive splenomegaly.

Case presentation: A 54-year-old woman presented with a history of high fever up to 39°C, sweating, fatigue, and weight loss for one month. She had been treated by her family physician with antibiotics (cephalosporin) for 10 days but without improvement. On admission, the patient had palpable splenomegaly but no palpable lymphadenopathy. The patient had increased markers of inflammation. The indicators of autoimmune disease were all negative. Screening for specific infectious diseases and the blood cultures all came out negative. Abdominal computerized tomography (CT) revealed an enlarged spleen. The splenectomy was performed and the spleen was sent for histological analysis. Meanwhile, the patient was subject to a complex treatment. Histological and immunohistochemical analysis confirmed the diagnosis of diffuse large B-cell non-Hodgkin lymphoma with diffuse red pulp infiltration. Afterward, the patient underwent systemic chemotherapy.

Conclusion: We strongly suggest that clinicians should have a high index of suspicion for malignancies in cases with FUO. Sometimes splenectomy can be the key to solving the problem.

Keywords: fever of unknown origin, primary splenic lymphoma, splenomegaly, splenectomy.

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Background

The term ‘fever of unknown origin’ (FUO) was first introduced by *Petersdorf and Beeson* in 1961 based on an analysis of 100 cases, and it was defined as recurrent fever >38.3°C, lasting for >3 weeks, remaining undiagnosed after 1 week of in-hospital evaluation. [1]

The etiologies of classic FUO mainly include infections, malignancies, non-infectious inflammatory diseases, and miscellaneous causes, while some cases remain undiagnosed. [2, 3] Primary splenic lymphoma (PSL) is a rare malignant lymphoma with an incidence of ~1% among patients with non-Hodgkin lymphoma (NHL), although the spleen is involved in approximately half of the cases of Hodgkin’s disease and one-third of NHLs as part

of systemic disease. PSL is a lymphoma that originates in the spleen and is confined to this area for a few months, followed later by its appearance in another location. Massive splenomegaly is indicated by spleen weight exceeding 1000 g and largest spleen dimension greater than 20 cm. [4] Based on the literature data, we can say that splenectomy is the best solution in massive splenomegaly. Splenectomy is not only a diagnostic procedure, but also a therapeutic choice for splenic lymphoma. [5]

Case Report

A 54-year-old woman presented with a history of fever up to 39°C, sweating, fatigue and weight loss for one month. She had been treated by her family physician with antibiotics (cephalosporin) for 10 days but without improvement. On admission the patient had palpable splenomegaly but no palpable lymphadenopathy. The patient had increased markers of inflammation: Fib 656 mg/dl (normal 200-400), ERS= 65 mm/h (normal <16), PCR 57 mg/l (normal <5), LDH 760 U/L (normal 125-220), ALP 289 U/L (normal 40-150) Protein electrophoresis: albumin 51.6% (56-68), alfa1 globulin 4.7% (2-4), alfa2 globulin 15.1% (6-11), beta globulin 11.1% (8-14), gamma globulin 17.5% (9-18). The indicators of autoimmune disease came all negative. Screening for specific infectious diseases including tuberculosis, viral infections such as HIV, cytomegalovirus, Epstein-Barr virus (EBV) was negative. The blood cultures were negative. Abdominal computerized tomography (CT) revealed massive splenomegaly (21cm), lymph nodes in the spleen hilum, without hepatomegaly or other concerns. (Fig 1) Splenectomy was performed, and spleen was sent for histological analysis. Histological and immunohistochemical analysis confirmed the diagnosis of diffuse large B-cell non-Hodgkin lymphoma. The normal tissue structure of the spleen appears to be replaced by a lymphoid cell population (CD45 +) of the centroblastic type with differentiation B (CD20 +, CD79 +); the tumor cells have an increased mitotic index, infiltrate the red pulp diffusely causing extensive tumor necrosis; the cells were negative for CKMNF, CD3, CD5, BcL6, BcL2, Cyclin D1, CD30, CD10, CD15, CD23; the cells were positive for

CD20, CD79. Ki-67 labeling index was 80-85%. Afterwards the patient underwent systemic chemotherapy.

Discussion

We decided to publish this case to show the connection between infectious diseases and other pathologies, and to highlight the importance of the collaboration between the Infectious Diseases Specialist and other Specialists.

Fever is the most important groundwork of the infectious disease specialist's job, but not always fever is of an infectious origin, as other pathologies might be often hidden behind them. We can say that one of the causes of fever is malignant pathologies. In one of their studies *Stamatis P Efstathiou et al*, showed that malignancies are one of the causes of FUO in 30.4% of cases. [6]

But also, within malignancies, different pathologies occupy different places. Among the neoplastic causes of FUO, malignant lymphomas are the most common. [7]

Primary Splenic Lymphoma (PSL) is a rare neoplasm of the spleen. The spleen may be the primary site of the lymphoma, or it may be a component of disseminated lymphomas. PSL is generally presented as B cell non-Hodgkin lymphoma. Our patient presented with a history of fever >39°C, sweating, weight loss for one month.

These are signs and symptoms described in literature. The most common presenting symptoms of PSL are fever, malaise, left upper quadrant pain, weight loss and night sweats. [1]

Abdominal computerized tomography (CT) performed on our patient showed massive splenomegaly (21cm), lymph nodes in the spleen hilum, without hepatomegaly or other concerns.

However, we say that the CT does not confirm the diagnosis since splenectomy is what confirms the diagnosis and prevents splenic rupture. This was the best solution since the splenic biopsy has a very high morbidity as a result of procedural hemorrhage or pneumothorax as a procedural complication. In many cases, splenectomy is the treatment of choice for massive splenomegaly. [4]

After the splenectomy procedure, we performed a spleen biopsy that confirmed the diagnosis of diffuse

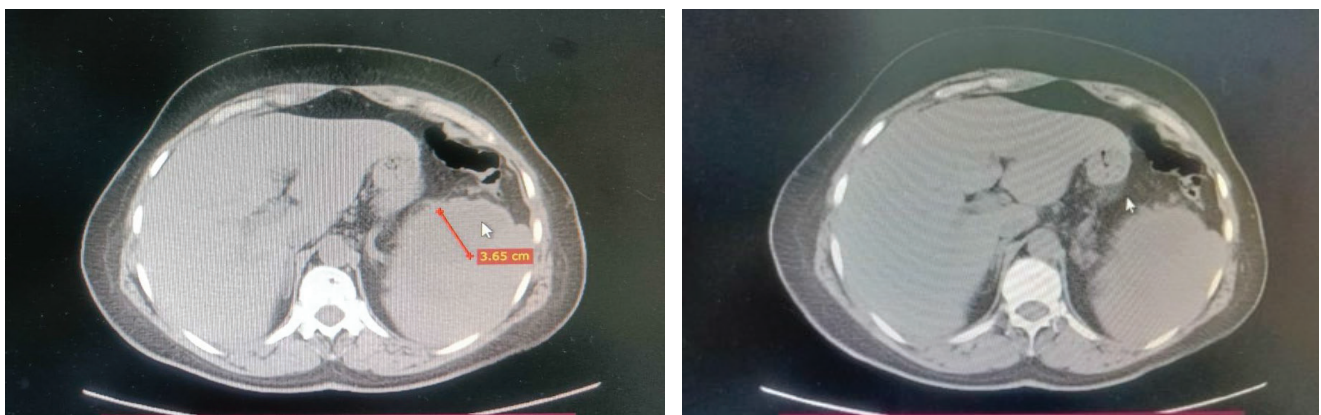


Figure 1. Lymph nodes in the spleen hilum

large B-cell non-Hodgkin lymphoma. Finally, our patient underwent systemic chemotherapy procedures.

Conclusion

We suggest that clinicians should keep a high index of suspicion for malignancy in cases with fever of unknown origin. We can also say that splenectomy can be the key to solving the case although the operative risk in massive splenomegaly is too high.

List of abbreviations: *FUO* - fever of unknown origin; *CT* – computed tomography; *PSL* – primary splenic lymphoma; *NHL* – non-Hodgkin lymphoma

Ethics approval and consent to participate; Not applicable.

Consent for publication; Written informed consent was obtained from the patient for the publication of this case report and any accompanying images. A copy of the written consent is available for review by the Editor-in-Chief of this journal.

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Chylothorax Management four Years post Spine Surgery: A Successful Conservative Treatment.

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Abstract

Background: Chylothorax is a pathological condition associated with a high mortality and morbidity rate. The first observation of chylothorax associated with thoracic vertebral injury was documented by Krabbell in 1885. Since then, several cases have been described in the literature.

Non-traumatic chylothorax several years after spine surgery is a rare condition. We described a case of a patient who sustained a thoracic spine fracture-dislocation and presented with a right sided chylothorax as a late complication to his thoracic spine trauma. A right thoracentesis was performed, providing partial relief of respiratory symptoms. The collected fluid was sent to the laboratory for further examination. Biochemical analysis of the milky pleural fluid confirmed the suspicion of chylothorax, with elevated levels of triglycerides and lymphocytes. These findings supported the diagnosis of chylothorax.

Conclusion: Non-traumatic chylothorax occurring several years after spine surgery is a rare condition, and there is limited literature available on this particular pathology. The diagnosis can be simplified through laboratory examination of the milky fluid. Conservative treatment is typically the approach of choice in the majority of cases, involving total parenteral nutrition and the insertion of a chest tube into the chest cavity, followed by chemical pleurodesis.

Keywords: Thoracic fracture; Trauma; Chylothorax

Introduction

Chylothorax is a rare condition characterized by chyle leakage into the pleural space due to thoracic duct damage within the lymphatic system [1-3]. It typically occurs on the right side and presents as a pleural effusion. Diagnosis involves measuring cholesterol and triglyceride levels in the pleural fluid [4].

Complications of chylothorax include malnutrition, immunosuppression, and respiratory distress.[3] Treatment approaches range from conservative to aggressive, depending on the clinical scenario [4]. Malignancy accounts for approximately 50% of cases [5], while iatrogenic disruption of the thoracic duct during surgery, blunt trauma, and spine trauma contribute to about 25% of cases [6].

However, chylothorax associated with vertebral fractures appears relatively rare or underreported. In this case report, we present a patient with chylothorax following an anterior fracture of the T11 vertebra, resulting from vertebral plate dislocation.

Literature Review

A PubMed search was conducted (filters: English language, human subjects, up to October 2022) using the terms “chylothorax,” “chyle leakage,” and “thoracic duct injury.” The search yielded 24 articles on spinal trauma, 30 articles

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on spine injury, and 25 articles on spinal injury. Among the 98 articles obtained, the following exclusion criteria were applied: nontraumatic chylothorax, articles reporting iatrogenic chyle leakage as a complication of anterior/ anterolateral spine surgery, purely descriptive technical articles focusing on anatomical nuances, articles providing a general overview of chylothorax as a consequence of chest and/or abdominal trauma, and articles discussing cases of polytraumatized patients with spinal fractures and multiple thoracic and/or abdominal posttraumatic injuries where the exact cause of chylous leakage cannot be determined. Ultimately, 21 articles describing chylothorax cases associated with spine fractures were selected.

Case Presentation

A 55-year-old male with paraplegia was admitted to our hospital due to symptoms of dyspnea, cough, and chest pain.

A CT-scan indicated the presence of a right-sided pleural effusion (Fig.1.). Four years prior to admission, the patient experienced a severe accident resulting in significant motor impairment of the lower extremities. A CT scan revealed a fracture between the T10 and L1 vertebrae. Subsequently, he underwent surgical intervention involving transpedicular T10-L1 screw-rod fixation. Following the surgery, the patient has remained disabled with paraplegia.

Diagnosis of Chylothorax

A right thoracentesis was performed, providing partial relief of respiratory symptoms. The collected fluid was sent to the laboratory for further examination. Biochemical analysis of the milky pleural fluid confirmed the suspicion of chylothorax, with elevated levels of triglycerides (473 mg/dL) and lymphocytes (94%). These findings supported the diagnosis of chylothorax.



Figure. 1 Axial contrast computer tomography of patient's thoracic cavity demonstrating the right-sided chyle accumulation

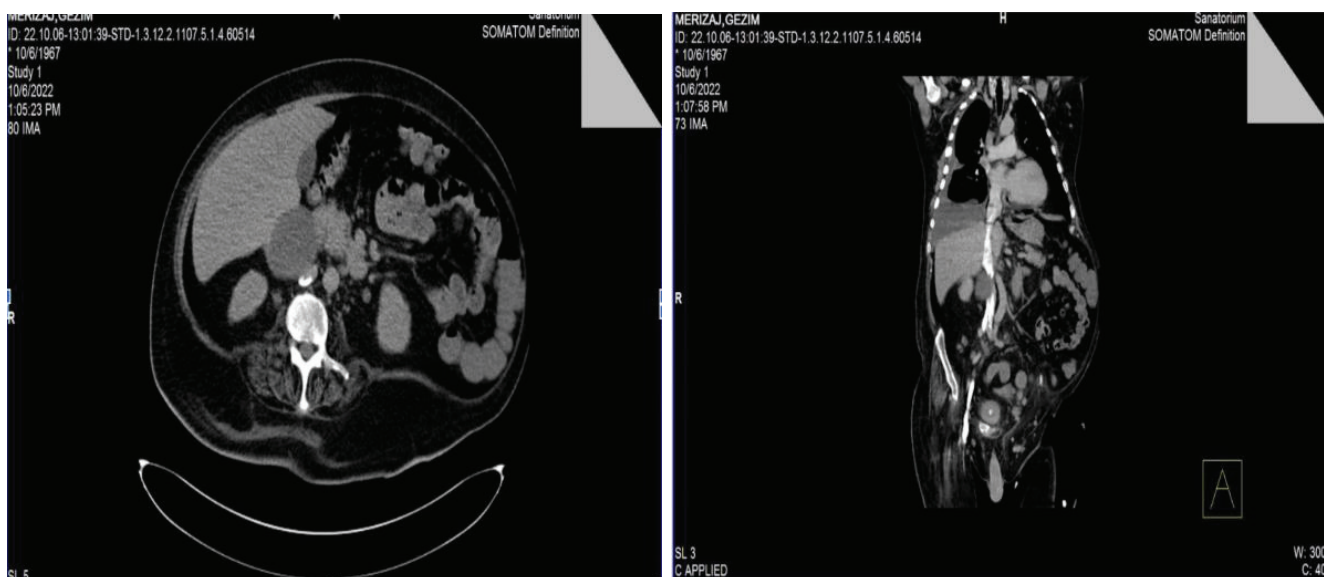


Figure. 2 Axial contrast CT scanner and sagittal view of patient's abdominal cavity demonstrating cystic mass in caudal lobe with "effect mass" on IVC.

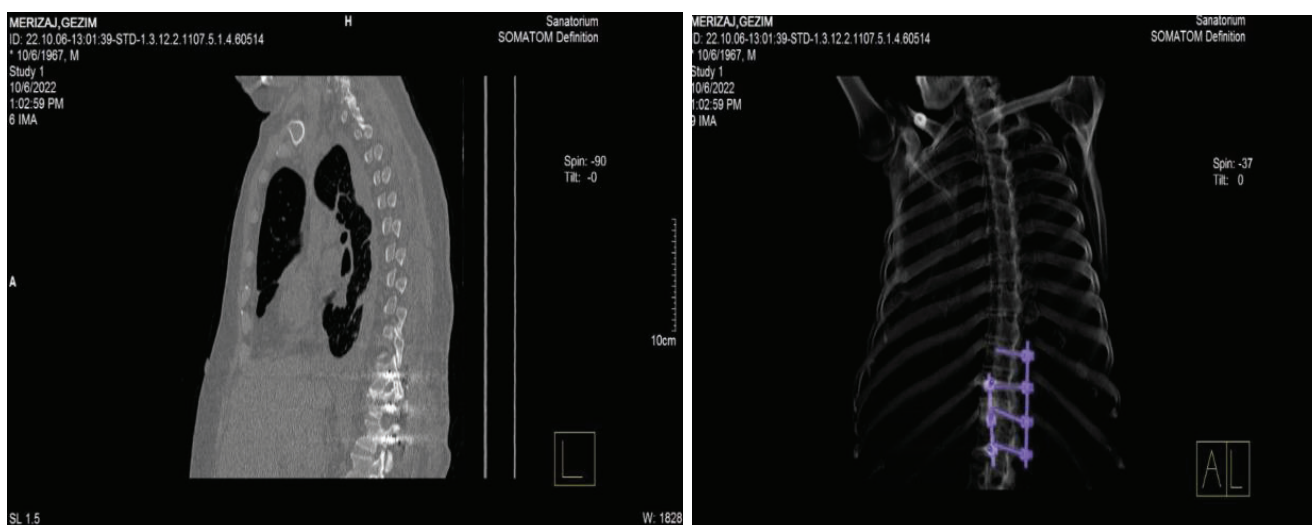


Figure 3 A thoraco-abdominal CT scan revealed an anterior fracture at the L1 vertebra and dislocation of the screw-rod.

Radiological Images

A thoraco-abdominal CT scan revealed an anterior fracture at the L1 vertebra and dislocation of the screw-rod (Fig.3.). Additionally, a cyst measuring 75x60mm was observed in the caudal lobe of the liver, causing a mass effect on the inferior vena cava (IVC) as shown in Fig. 2. Furthermore, the CT scan confirmed the presence of right pleural fluid.

Chest Tube Placement and Pleurodesis Regimen

The patient underwent a chest tube thoracostomy procedure along with bed rest, total parenteral nutrition, and maintenance of electrolyte balance. After three days of interrupted feeding, the chyle flow rapidly decreased from approximately 1500 ml to less than 70 ml. Chemical pleurodesis was performed using povidone iodine, which was injected into the pleural cavity through the chest tube. Following the injection, the chest tube was clamped for two hours. During this period, the patient engaged in light exercise, such as gently rolling in bed, to facilitate the diffusion of the solution throughout the pleural cavity. After two hours, the chest tube was released. Chest X-ray and thoracic echo performed after the chest tube drainage procedure did not indicate the presence of pleural effusion. On the 5th postoperative day, the patient consumed a meal consisting of 50 grams of butter, and no pleural effusion was observed. Subsequently, the pleural drain was removed from the chest cavity, and the patient was discharged home in good condition.

Discussion

Chylothorax is a pathological condition associated with a high mortality and morbidity rate. [7].

The first observation of chylothorax associated with thoracic vertebral injury was documented by *Krabbell* in 1885. [8, 9]

Since then, several cases have been described in the literature. Typically, chylothorax is noted immediately to several days after the occurrence of the injury. However, in our case, chylothorax was identified four years after the injury, which is a rarely documented phenomenon. Chyle extravasation in chylothorax can occur through two major mechanisms [1, 2].

It can result from direct trauma to the lymphatic vessels in the chyle pathway or from occlusion of the thoracic chyle duct. Clinical manifestations of chylothorax include hypovolemia due to significant chyle loss, dyspnea, malnutrition resulting from the loss of proteins, fats, and vitamins, as well as electrolyte imbalances.[10]

A clinical suspicion of chylothorax arises when milky or white fluid is drained from the thorax. However, it is important to note that this classical appearance can also be observed in pseudo chylothorax.[11]

Various diagnostic approaches can be employed to confirm the presence of chylothorax. Lymphangiography can help identify the site of chyle leakage or blockage. [12]

Thoracentesis and laboratory analysis of the pleural fluid can provide further diagnostic evidence based on the presence of chylomicrons. [11]

Recently, near-infrared fluorescence imaging of the thoracic duct and scintigraphy using SPECT/CT with orally administered ^{123}I -betamethyl-*p*-iodophenyl-pentadecanoic acid (^{123}I -BMIPP) have shown promise in revealing chylous leakage [13].

The management of traumatic chylothorax primarily involves conservative treatment, which includes chest drainage, chemical pleurodesis, total parenteral nutrition (TPN), and a medium-chain triglyceride diet. This approach has been supported by numerous authors and has yielded satisfactory results in terms of reducing chyle production within a few days to 3-4 weeks. [14]

In some cases, administration of octreotide has shown positive outcomes for patients.[15] Surgical intervention

should only be considered if chyle production does not decrease after the second or third week of conservative management.[16] The aim of surgical treatment is to ligate the thoracic duct, a procedure that has been performed in a few documented cases in the literature.

Conclusion

Non-traumatic chylothorax occurring several years after spine surgery is a rare condition, and there is limited literature available on this particular pathology. The diagnosis can be simplified through laboratory examination of the milky fluid. Conservative treatment is typically the approach of choice in the majority of cases, involving total parenteral nutrition and the insertion of a chest tube into the chest cavity, followed by chemical pleurodesis.

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Fournier's gangrene in Patients Operated for Hemorrhoidal Prolapse in the Surgical Emergency Department.

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Abstract

Fournier's gangrene (FG) is a well known often fatal fasciitis of the pelvic floor following ano-rectal, urologic and gynecologic infections. Although rarely it is described as a complication of operative anal procedures and predisposing factors such as diabetes, alcoholism, immune-defects and consumptive diseases.

Current literature only briefly mentions the potential risk of FG after such a common surgical procedure. However, devastating complications occur more often than expected. This catastrophic complication without a predisposing factor is discussed along with a review of the literature.

The objective of this article is to provide updated and relevant information regarding the recognition, diagnosis and management of FG, from the general surgeon to the emergency department.

This article refers to two complicated cases of Fournier's gangrene. The patients underwent emergency surgical intervention with the diagnosis of hemorrhoidal prolapse with rectal bleeding and accompanying anemia...

Conclusion; The gold standard for treatment was found to be a combination of surgical debridement, broad-spectrum antibiotics, and the administration of intravenous fluids. Further, patient survival was found to be directly related to the time from diagnosis to treatment when they underwent surgical debridement.

The General surgeon must be vigilant for this condition and be aware of risk factors, prognostic indicators, and proper treatment protocols to recognize FG early and initiate appropriate management.

Keywords: Fournier's gangrene, necrotizing fasciitis, emergency department

Introduction

Fournier's gangrene is a serious inflammatory pathology with a very high risk to life. It is also known as necrotizing fasciitis or acute necrotizing inflammation. [1, 2]

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It was first described in 1764 by Baurienne and in 1877 by Avicenna. [3]

The precise definition was later given by Jean Alfred Fournier, a Parisian venereologist. It affects older males more than females. [4]

The incidence is 1.6 males per 100,000 inhabitants. Cases have also been observed in children. It is mainly localized in the perianal and perineal areas and often involves the genital area as well. [5] The clinical presentation is characterized by fever, pain, foul odor, necrosis, and subcutaneous crepitus, rapid progression, and general deterioration leading to multiorgan failure. [6]

The cause of gangrene is a result of thrombosis of the blood vessels localized in these areas. There is still no exact cause for this pathology. The infectious and inflammatory process spreads quickly along the Dartos, Colles, and Scarpa's fascias, allowing for the early involvement of the

abdominal wall. [7]

Many studies suggest that the causes may be anorectal infections, genitourinary infections, and various anorectal interventions. [8]

These infections can compromise the immune system, allowing toxins and enzymes from microorganisms to cause necrosis. The origin of the microorganisms appears to be from the digestive tract (30%-50%), the genitourinary tract (20%-40%), and the skin (20%). [9]

Microbial cultures have revealed both aerobic and anaerobic microbes. The synergy between the microbes is a crucial factor in this pathology. [10]

The most common associated pathologies are diabetes mellitus, hepatic cirrhosis, malignant pathologies, obesity, and immunodeficient patients. [11]

Since 1950, more than 1,800 cases for study have been reported in English language medical literature. This disease occurs worldwide and, although it is recognized more frequently among male adults, has been identified also among women and children. Treatment usually consists of the surgical removal (debridement) of extensive areas of dead tissue (necrosis, necrotic) and the administration of broad-spectrum intravenous antibiotics. Surgical reconstruction may follow where necessary.

This article refers to two complicated cases of Morbus Fournier. The patients underwent emergency surgical intervention with the diagnosis of hemorrhoidal prolapse with rectal bleeding and accompanying anemia.

First Patient

Patient A.N., 59 years old, presented to the surgical emergency department with a diagnosis of active hemorrhoidal prolapse with rectal bleeding. He reported a 7-year history of hemorrhoidal disease, and in the past two months, rectal bleeding had become almost daily. No accompanying pathology was found during rectoscopy. Occasionally, the patient used oral therapy with daflon 500mg. Blood tests showed: red blood cells - 3,780,000 10⁶/mL, hemoglobin - 8.9 g/dl, leukocytes - 6.40 10⁹/mL. Blood group - 0 (Rh+). Biochemical analysis was within normal limits. Urine analysis showed 30-35 leukocytes per field and 9-10 red blood cells per field. The only accompanying diseases were prostatitis, left kidney calculi, and previous urinary tract infections.

After consultation with the anesthetist, a Milligan-Morgan hemorrhoidectomy was performed under spinal anesthesia. During the hospital stay, the patient was treated with fluids, oral metronidazole, ciprofloxacin, intravenous omeprazole 40 mg, subcutaneous enoxaparin, and analgesics. The patient started an oral liquid diet immediately after the spinal anesthesia wore off. The patient was discharged from the hospital in good condition 48 hours after the surgery. After leaving the surgical clinic, the patient was recommended a high-fiber diet, local toilet with potassium permanganate, oral ciprofloxacin 500 mg, subcutaneous enoxaparin, and analgesics.



Figure 1. First Patient after surgery

Six days after the surgery, the patient presented to the emergency department with unbearable pain in the anal area, a temperature of 38.8 degrees Celsius, pallor, profuse sweating, fatigue, fecal incontinence, a pulse rate of 112 beats per minute, and a rhythmic pattern. Locally, edema of the perianal area, crepitus, intraanal necrosis, and extension towards the scrotal area with foul-smelling and dark-colored secretions were observed. The anorectal examination was very painful. Rectoscopy revealed a dark purple mucosa in the anal area with clearly demarcated necrotic zones, extending about 2 cm above the dentate line.

The patient was transferred to the intensive care unit where a urinary catheter was placed. Intravenous therapy with fluids, electrolytes, imipenem, metronidazole, gastroprotective agents, and analgesics was initiated. Blood tests performed upon arrival at the hospital showed the following deviations: red blood cells - 3,620,000 10⁶/mL, hemoglobin - 8.3 g/dl, leukocytes - 4.3 10⁹/mL, SGOT - 46 U/L, SGPT - 56 U/L, PCR - 7 mg/L. Viral tests were negative.

Abdominal ultrasound showed edema of the perineum, perianal edema, thickened rectal walls up to 1 cm, air bubbles in the perianal and perirectal soft tissues, and minimal fluid in both scrotums. The patient underwent surgery under general anesthesia 6 hours after arriving in the emergency department. Initially, six deep elliptical incisions were made, four perianal and two in each scrotum. The necrotic tissue was then excised until the borders of healthy macroscopic tissue were reached. These borders were considered the zone where there was no necrosis and red blood was visible. The procedure was mainly performed with scissors and cold bistoury, with very limited use of electrocautery. Suture with 3-0 vicryl was used in two moments. Attempt was made to achieve perfect hemostasis. The wounds were treated with oxygenated water and 0.9% physiological saline after excision.

Finally, the wounds were covered with compresses soaked in 2% lidocaine gel and chlorhexidine acetate. After the surgery, the patient continued the initiated therapy,

adding subcutaneous enoxaparin and human albumin. Intravenous therapy lasted for 12 days and was discontinued two days after the patient became afebrile.

The operative wounds were treated three times a day with isotonic saline solution, oxygenated water, and 5% betadine solution every 8 hours. Necrotomy was performed twice at the patient's bedside. Oral fluid, liquid diet, and hyperprotein diet started 7 hours after the operation. On the 15th day after the second intervention, the beginning of wound granulation was evident, the secretion from the wounds decreased, there was no foul odor, the patient was afebrile, active, with a pulse rate of 87 beats per minute, leukocyte count resulted in 9.20 10/ml, erythrocytes - 3,780,000 per mL, hemoglobin - 8.3 g/dL. Biochemical analyses were within normal limits. On the 23rd day, the patient was discharged from the hospital in good condition. It was recommended that the wound be treated daily by the respective nurse, and a high-fiber, hyperprotein, and fluid-rich diet was advised.

Epithelialization of the wounds was completed after 95 days. After wound epithelialization, the patient reported two complaints: urinary urgency and occasional incontinence of gas and liquid stools.

Second Patient

Patient M.S, 66 years old, is transferred to the surgical emergency department from the endocrinology ward. The patient was previously diagnosed with non-insulin-dependent diabetes mellitus (type 2), arterial hypertension, and morbid obesity. He had been on oral therapy with metformin and antihypertensive medication for three years.

For the past six years, he has been undergoing conservative therapy for hemorrhoidal disease and constipation. In the past week, significant rectal bleeding and hemorrhoidal prolapse during defecation were daily occurrences.

In the last 24 hours, rectal bleeding and hemorrhoidal prolapse have occurred outside the act of defecation. Anorectal examination in the surgical emergency department reveals prolapsed hemorrhoids with active bleeding. The anal canal was tamponaded with a sponge



Figure 2. Second Patient after surgery

Deviations in the blood tests performed upon arrival at the surgical emergency department show: erythrocytes - 3,910,000 per mL, hemoglobin - 11.1 g/dL, blood glucose - 205 mg/dL.

Arterial blood pressure is 150/91 mm/Hg, and the body mass index is 36 kg/m². After consultation with the anesthesiologist, the patient underwent surgery 4 hours after presenting to the surgical emergency department.

The Milligan-Morgan procedure was performed with the help of spinal anesthesia. Postoperative therapy includes two liters of fluids, flagyl, ciprofloxacin, omeprazole, enoxaparin, oral antidiabetic therapy, and intravenous analgesics. Oral feeding commenced immediately after the recovery of motor block. The patient stayed in the surgical clinic for 48 hours and was transferred to the endocrinology clinic without early postoperative complications.

The surgeon recommended a high-fiber diet, local wound toilet with potassium permanganate, oral ciprofloxacin 500 mg, subcutaneous enoxaparin for 10 days, antidiabetic therapy, and paracetamol. On the eighth postoperative day, the patient reports a temperature of 37.6 degrees Celsius, pulsating and burning pain in the anal and perianal area, perianal itching, difficulty urinating, anorexia, abdominal discomfort, and putrid secretions in the wound dressing.

The pain radiates posteriorly to the sacrum and anteriorly to the scrotum. Locally, there is evident extensive perianal cellulitis spreading posteriorly and anteriorly. No signs of necrosis are observed on the skin. Crepitus is detected along the cellulitis area, and the skin appears reddish and inflamed. Only at the site of the operative wound are necrotic hemorrhoidal bridges evident. A rectoscopy is performed under anesthesia, revealing that the anorectal mucosa has a dark reddish color. This area extends approximately 4 cm above the dentate line.

There is a strong foul odor. The following abnormalities were detected in the laboratory examinations at the surgical emergency department: erythrocytes - 3,810,000 per mL, hemoglobin - 10.8 g/dL, leukocytes - 3.90 10/mL, blood glucose - 490 mg/dL. The pulse rate was 112 beats per minute, and the blood pressure was 105-79 mm/Hg.

The blood type is group 0 (Rh-). An abdominal CT-scan with intravenous contrast revealed the presence of air bubbles in the subcutaneous perianal area with wide spread, double-layered walls of the rectum, disruption of the subcutaneous adipose tissue structure, and free fluid in both testicular sacs. In these conditions, the patient was transferred to the intensive care unit for monitoring and preparation for intervention.

A urinary catheter was inserted. Fluid therapy and intravenous imipenem were initiated. The intervention took place 4 hours after arrival in the emergency department. With the help of general anesthesia, eight wide elliptical incisions were made: four perianal incisions, two scrotal incisions, and two anococcygeal incisions. Necrotomy was performed until macroscopically healthy tissue margins were reached. Electrocautery was used sparingly.

The intervention was performed with the help of a retractor and cold bistoury. The wounds were covered with gauze soaked in chlorhexidine acetate and lidocaine gel. After the surgery, the patient was treated with three liters of fluid, imipenem, flagyl, omeprazole, subcutaneous enoxaparin, insulin, and antihypertensive medication. An oral fluid diet rich in fiber and protein started 6 hours after the intervention.

The operative wounds were treated three times a day, every 8 hours, with isotonic saline solution, abundant oxygenated water, and 5% betadine solution. On the 14th day, the patient felt better and was active. The temperature has normalized. Blood glucose level is 140 mg/dL. Erythrocytes count is 3,880,000 per mL. White blood cells count is 9.20 10/mL. Blood pressure is 150-86 mm/Hg, and pulse rate is 89 beats per minute. Locally, the wounds continue to have secretions, but without a strong odor. During this period, necrotomy was performed 8 times at the patient's bedside.

On the 14th day, insulin was replaced with metformin, flagyl and imipenem were discontinued, and intravenous ciprofloxacin was started. The patient was discharged from the hospital on the 30th day after the second intervention. Laboratory analyses showed: erythrocytes count - 3,980,000 per mL, white blood cells count - 9.50 10/mL, blood glucose - 170 mg/dL, blood pressure - 150-80 mm/Hg. Other biochemical analyses were within normal range.

During the patient's stay in the surgical ward, they lost 10 kg of body weight. The wounds were closed 4 months after discharge from the hospital.

Discussion

Both cases mentioned above are rarely reported in the literature. FG is a serious surgical problem with high mortality and morbidity, still there is a male predominance [10].

Vick R et al. have written that there are so many predisposing factors described by various authors as seen in literatures. Out of them, diabetes, old age, alcoholism, obesity, paraplegia, and renal insufficiency are commonly seen. However, it is interesting to note that in almost 30% to 50% cases no definite predisposing factor is found [13].

Agranulocytosis is mentioned as a cause in one reported case [14].

Fournier's gangrene is described as a synergistic polymicrobial infection of the soft tissues in the perineal area. This synergy is believed to be the cause of the spread of inflammation, pronounced edema, and progressive necrosis. Anorectal infections, genitourinary infections, and traumatic wounds are referred to as the most common causes of Fournier's gangrene. [10]

Inflammatory anal pathologies, malignant tumors of the sigmoid and rectum, perforated diverticulitis, rectal trauma, acute transverse appendicitis, and transanal procedures are thought to be contributing factors to the development of the pathology. [15]

Chernyadyev SA et al. [16] note that the cause of Fournier's gangrene can be established in 95% of cases; the disease usually occurs because of infectious processes of the urogenital tract, anorectal area, or skin of the genitals. Fournier gangrene develops commonly in immunocompromised patients with diabetes, obesity, and malignant neoplasms. *Kincius et al.* [17] who conducted a study among patients with Fournier's gangrene found a high proportion of people with diabetes mellitus. Also, our cases was with non-insulin-dependent diabetes mellitus (type 2), arterial hypertension, and morbid obesity.

Yoshino et al. [18] described the case of an anal fistula in a patient with type 2 diabetes mellitus, resulting in an abscess of pararectal tissue complicated by Fournier gangrene.

Cases of Fournier's gangrene have been reported even after minimal interventions in the anal canal. In the literature, only one case has been reported as complicated with Fournier's gangrene following hemorrhoidectomy.[19]

Fournier's gangrene is usually associated with pathologies that reduce the immune system's powers. These include diabetes, malignant pathologies, renal insufficiency, malnutrition, cirrhosis, AIDS, corticosteroid users, and dialysis patients. Both patients we referred to had accompanying pathologies. [20, 21]

Patient A presented with anemia and recurrent urinary infections. Patient B had diabetes and obesity. These comorbidities affect the patient's immune system.

The Fournier's gangrene rate due to proctological procedures is extremely rare.[22]

However, in the literature, necrotizing perineal soft tissue infections after anal dilatation, hemorrhoidal band ligation, and open hemorrhoidectomy, which require radical debridement, have been described. [23]

Although hemorrhoidectomy is a common surgical procedure, the appearance of FG is unpredictable.[24]

The most important point in the treatment of this extremely severe pathology is the early diagnosis. Diagnosis is usually made by physical examination. Perineal necrotizing fasciitis is clinically characterized by, severe perineal pain and high fever. In the early phase of FG, clinical findings may be indistinguishable from other soft tissue infections such as erysipelas or cellulitis, but the presence of indeterminate borders and sensitivity outside of the affected area is in favor of FG. [25]

Early diagnosis and aggressive surgical intervention with broad-spectrum antibiotics can reduce mortality in FG. [26]

We surgically treated the patients after resuscitating them with fluids and broad-spectrum antibiotics, aiming to normalize the parameters as much as possible.

The second intervention was performed under general anesthesia to avoid the complications of spinal anesthesia.

The second intervention in both patients was performed with the help of retractors and cold scissors. Electrocautery was used very sparingly. Vicryl 3-0 sutures were occasionally used.

The incisions were wide and elliptical in shape.

The removal of all the devitalized tissue is important to stop the progress of the infection and simultaneous elimination of systemic effects of toxins and bacteria [27].

Necrectomy was performed aggressively, aiming to reach the level of healthy tissue in terms of color and arterial blood supply.

Hemostasis was attempted to be as close to perfect as possible. Antibiotic therapy should be regulated in double or triple combinations to include broad-spectrum agents for possible pathogens as soon as possible, without antibiogram result [28, 29]

During their stay in the surgical clinic, the patients were treated three times a day, every 8 hours, with ample oxygenated water, 5% Betadine solution, physiological saline, and Flagyl solution. Every day, temperature, pulse, blood pressure, and diuresis were evaluated.

A suggested regime would include a third-generation cephalosporin or broad-spectrum penicillin, gentamicin, metronidazole, or clindamycin [30].

Every 4 or 5 days, laboratory and biochemical analyses were performed. As soon as necrosis spread was observed, it was excised. Fluid and protein balance were maintained not only intravenously but also orally. Early diagnosis and timing of the first debridement is an important determinant of mortality. [31, 32]

The patients were allowed to eat through the mouth 5 or 6 hours after the intervention. The patients were mobilized 48 hours after the intervention. We followed the course of releasing incisions with aggressive necrectomy during the intervention. The second intervention was performed with the help of endotracheal anesthesia. This anesthesia method was chosen to prevent infection. Local treatment three times a day accompanied by necrectomy was also a significant advantage in the path to recovery.

Other surgical techniques are referred to when the pathology progresses and biochemical, laboratory parameters, and the general condition of the patient do not stabilize. Temporary colostomy technique is recommended in such cases. It was not necessary in our two cases. The presentation of the patients in a relatively short time also led to their early diagnosis.

On the other hand, the assessment of the overall condition, resuscitation, correction of biochemical and vital abnormalities, and the initiation of broad-spectrum antibiotic therapy are believed to have influenced the good postoperative course after the second intervention. Microbiological studies show that *Pseudomonas aeruginosa* predominates over other microbial strains in Fournier's pathology.

Hakkarainen TW et al. shown that medical intervention revolves around the initiation of empiric broad-spectrum antibiotics while awaiting culture sensitivities. Antibiotic therapy has historically involved triple therapy in covering gram-positive, gram-negative, and anaerobic organisms associated with Fournier gangrene. These typically include

staphylococcus, streptococcus, coliforms, *Pseudomonas*, *Bacteroides*, *Clostridium*, and possibly yeast. The combination of a third-generation cephalosporin, aminoglycoside, penicillin, and metronidazole, has classically been used as triple therapy antibiotic coverage. Antibiotic therapy typically requires a duration of at least two weeks. [33, 35]

It is thought that this strain is also the cause of leukopenia in the preoperative period. The synergistic activity of aerobic and anaerobic microbes enables the release of exotoxins and enzymes such as collagenase, heparinase, hyaluronidase, streptokinase, and streptodornase. All these elements lead to tissue destruction and the spread of inflammation. Aerobic microorganisms cause complement fixation and platelet aggregation. Anaerobic microorganisms produce heparinase and collagenase. Park et al. [34], in an analysis of factors related to mortality from necrotizing soft tissue infections, found that patients with a high body mass index or abnormal leukocyte, C-reactive protein and platelet counts reflecting the severity of the infectious process or impaired renal function have an unfavorable outcome.

Both of these factors contribute to microvascular thrombosis, resulting in necrosis of soft tissues. On the other hand, impairment of phagocytic activity in necrotic tissues leads to rapid spread of infection. Inflammation spreads along fascial planes, usually limited by the Colles' fascia of the perineum. Inflammation can spread to the scrotum, penis, and anterior abdominal wall. Testicular involvement indicates widespread inflammation, including retroperitoneum.

Urogenital infections progress posteriorly along the Buck's and Dartos fascia. Anorectal infections begin and spread in the perianal and anorectal areas. [1]

The severity index of the pathology depends on temperature, respiratory rate, pulse, blood pressure, and sodium level in the blood. [36]

It is reported that when this index is greater than 9, the mortality rate reaches 73%. In addition to the risk factors for each patient, the fact that the Milligan-Morgan technique in patients with large hemorrhoidal prolapse causes significant wounds and local necrosis should not be overlooked.[37]

It is still inconclusive whether a change in surgical technique would have an impact on the non-appearance of this severe postoperative complication. In both cases, leukopenia, anemia, and mild alterations in biochemical parameters are evident.

Conclusion

The gold standard for treatment was found to be a combination of surgical debridement, broad-spectrum antibiotics, and the administration of intravenous fluids. Further, patient survival was found to be directly related to the time from diagnosis to treatment when they underwent surgical debridement.

The General surgeon must be vigilant for this condition and be aware of risk factors, prognostic indicators, and proper treatment protocols to recognize FG early and initiate appropriate management.

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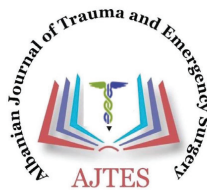
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AJTES

Albanian Journal of Trauma and Emergency Surgery

EDITORIAL POLICY

Scope and Mission

Albanian Journal of Trauma and Emergency Surgery (AJTES) that comes out two times a year, peer-reviewed and open-access international journal. The journal is the official scientific publication of the is the official publication of the Albanian Society for Trauma and Emergency Surgery (ASTES) Tirana, Albania. The language of the journal is English.

AJTES was founded in 2017 for the first time and publishes scientific articles that aims to promote interest, knowledge, and quality of care in emergency and trauma surgery. Its mission is to open an interdisciplinary forum that allows for the scientific exchange between basic and clinical science related to pathophysiology, diagnostics, and treatment of traumatized patients. The journal covers all aspects of clinical management, operative treatment, and related research of traumatic injuries and health care research, conducted in all fields of medicine and health care, as well as interesting case reports and clinical images, invited reviews, invited medical education papers, editorials, opinions and viewpoints, comments and letters to the Editor. The structure of each edition of the publication comprises section categories determined by the Editor and reflects the views of the Editorial Board.

AJTES encourages academicians, researchers and specialists of different medical and health care fields from all over the world to publish their valuable research in all branches of medicine and health care.

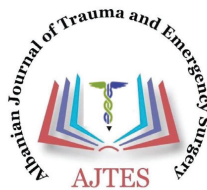
The journal's aim is to publish original articles with high scientific and ethical quality.

The Editorial Board of the *AJTES* and the Publisher adhere to the principles of the International Council of Medical Journal Editors (ICMJE), the World Association of Medical Editors (WAME), the Council of Science Editors (CSE), the Committee on Publication Ethics (COPE), the US National Library of Medicine (NLM), the World Medical Association (WMA), the US Office of Research Integrity (ORI), the European Association of Science Editors (EASE), and the International Society of Managing and Technical Editors (ISMTE).

AJTES permits and encourages authors to post items approved for publication from the journal on personal websites or institutional repositories both prior to and after publication, while providing bibliographic details of the publication in *AJTES*. All articles are also available in PDF format on our website <https://journal.astes.org.al/> and can be downloaded free of charge.

The *AJTES*'s mission is to distribute and expand worldwide good quality research, focused primarily on the medical and health care problems of the European and not only.

AJTES is open to publication for all the authors that comply with the scientific and ethical requirements of the journal. All manuscripts submitted for publication are strictly internally and externally peer reviewed for their originality, methodology, scientific relevance, quality, ethical nature and suitability for the journal. A similarity check is performed on all manuscripts submitted. All the articles published at *AJTES* will be fully accessed online. The open-access publication fee for this journal is EUR 200 for full-length articles and EUR 150 for case reports.



Submission of a manuscript implies that the submitted work has not been published before (except as part of a thesis or report, or abstract); that it is not under consideration for publication elsewhere; that its publication has been approved by all co-authors. If and when the manuscript is accepted for publication, the author(s) still holds the copyright and retains publishing rights without restrictions. Authors or others are allowed to multiply article as long as not for commercial purposes. For the new invention, authors are suggested to manage their patent before published.

Ethics

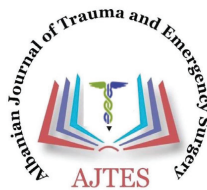
AJTES is committed to the highest standards of research and publication ethics. All submitted manuscripts are screened for plagiarism in order to detect instances of overlapping and similar text. The editors will act in accordance to the relevant international rules of publication and research ethics (COPE guidelines, WAME resources, WMA policies and ORI) if any ethical misconduct is suspected.

The journal recommends an approval of the research protocols by an ethics committee in accordance with international agreements “WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects (last updated: October 2013, Fortaleza, Brazil)”, “Guide for the care and use of laboratory animals (8th edition, 2011)” and/or “International Guiding Principles for Biomedical Research Involving Animals (2012)”. This approval is required for all experimental, clinical and drug trial studies. For articles concerning experimental research on humans, a statement should be included that informed consent of patients and volunteers was obtained following a detailed explanation of the procedures that they may undergo. The journal may request a copy of the Ethics Committee Approval received from the relevant authority. Informed consent must also be obtained for case reports. More details on the ethical principles of the journal may be found at the “Ethical Guidelines” and the “Instructions to Reviewers” pages. All reference for the ethical issues must be mentioned at the method section of the article.

Conflict of interest policy

The AJTES’s editorial review process is in accordance with the Good Editorial Practice set by international editorial organizations (WAME, COPE). WAME indicates that “conflict of interest exists when an author, reviewer, or editor in the publication process (submission of manuscripts, peer review, editorial decisions and communication between authors, reviewers and editors) has a competing interest that could unduly influence his or her responsibilities (academic honesty, unbiased conduct and reporting of research and integrity of decisions or judgments) in the publication process”.

The AJTES requires that each author, reviewer, and editor must disclose to the editor-in-chief any conflict of interest related to family, personal, financial, political or religious issues as well as any competing interest outlined above at the WAME’s definition. Whether or not a conflict of interest and financial support exist, they must be declared at the Conflict of Interest Statement (signed and approved from all the authors) as well as at the end of the manuscripts (Conflict of Interest Statement, before the Reference Section). If a reviewer or an editor has a conflict of interest and/or believes that it is not appropriate to be a reviewer, or an editor for a given manuscript, the reviewer or the editor should resign from the assignment. The AJTES editorial board members may also submit their own manuscripts to the journal. However, they cannot take part at any stage on the editorial decision of their manuscripts. They will be treated like any other author and if any, final acceptance of such manuscripts can only be made by the positive recommendation of at least two external reviewers. Authors should not contact any of the editorial executive or scientific board members during the review process. All necessary information regarding the process of a manuscript will be regularly provided from the editorial office via the official e- mail addresses. The names of the handling editor and the reviewers are not disclosed to the author(s). Due to the AJTES’s double-blinded review principles, the names of authors and reviewers are not known to each other. Please refer to



the “conflict of interest statement and copyright form” section below for the conflict of interest declaration for authors. For a conflict of interest statement for reviewers, please refer to the “Instructions to Reviewers” page.

INSTRUCTIONS FOR AUTHORS

AJTES is based on independent and unbiased double-blind and peer-reviewing principles. Only unpublished papers that are not under review for publication elsewhere can be submitted. The authors are responsible for the scientific content and the ethical compliance of the material to be published. *AJTES* reserves the right to request any research materials on which the paper is based. It is highly recommended that all manuscripts must be checked from a native English speaker with experience in Scientific English writing. The executive editorial board is committed to a rapid publishing process. The authors will be kept informed about all the stages of the reviewing process.

Manuscript formatting

The manuscript format must follow the guidelines described below that are in accordance with the ICMJE (Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals - updated in August 2013 - <http://www.icmje.org/icmje-recommendations.pdf>). The manuscript must be submitted to the following address: ajtes.editor@gmail.com

Papers that do not comply with the format of the Journal and submission requirements will be returned to the author for correction without further review.

General Format

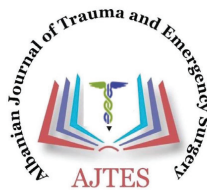
The manuscript should be typed in a Microsoft Word™ file, single-column format, double-spaced with 2.5 cm margins on each side, and 11-point type in Times New Roman font.

All abbreviations must be defined the first time they are used and should be displayed in parentheses after the definition. Abbreviations should be limited to those defined in the AMA Manual of Style, current edition. Authors should avoid abbreviations in the title and abstract and limit their use in the main text.

Decimal points should be used in decimals throughout the manuscript. Measurements should be reported using the metric system according to the International System of Units (SI). Consult the SI Unit Conversion Guide (New England Journal of Medicine Books, 1992). An extensive list of conversion factors can be found at <http://www.unc.edu/~rowlett/units>. For more details, see:

http://www.amamanualofstyle.com/oso/public/jama/s_i_conversion_table.html.

When a drug, product, hardware, or software is mentioned within the main text product information, it should include the name of the product, the producer of the product, and the city or the country of the company. It should be provided in parenthesis in the following example format: “Examination BIO- AUTO analyzer (Beckman-Coulter, New Jersey, NJ, USA)”.



Article Type

Identification of the article type is the first step of manuscript preparation and submission. The article type dictates the rules that should be followed, including formatting and word limits of the manuscript. The main categories of article types are outlined below:

Original Article: Original contributions are manuscripts containing substantial novel research. These articles can include randomized controlled trials, observational (cohort, case-control or cross-sectional) studies, diagnostic accuracy studies, systematic reviews, and meta-analyses, non-randomized behavioral and public health intervention trials, experimental animal trials, or any other clinical or experimental studies. Abstracts must begin on a separate page and should not exceed 300 words.

Abstracts should be structured with the following subheadings: *Background, Aims, Study Design* (case-control study, cross-sectional study, cohort study, randomized controlled trial, diagnostic accuracy study, meta-analysis and systemic review, animal and in vitro experimentation, non-randomized study in behavioral sciences and public health, etc.), *Methods, Results, Conclusion, and Keywords*.

The main text should be structured with the following subheadings:

Introduction, Material and Methods, Results, Discussion, Conclusions, Acknowledgments, Conflict of Interest statement, Authorship contribution, References, Tables, and Figure Legends.

The main text should not exceed 4500 words, excluding the abstract, references, tables, and figure legends. There should be a maximum of 100 references.

Review Article. A review article is an article that summarizes the current state of understanding of a particular topic. A review article surveys and summarizes previously published studies, rather than reporting new facts or analysis.

Review articles are sometimes referred to as survey articles or, in news publishing, summary articles.

Academic publications that specialize in review articles are known as review journals.

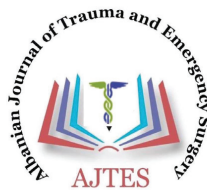
Review articles learn about:

- *Main people who were/are working in a field*
- *Recent major advances and discoveries*
- *Significant gaps in the research*
- *Current debates*
- *Ideas on where the research might go next.*

Review articles in journals analyze or discuss research previously published by others, rather than reporting new studies results. An expert's opinion is valuable, but an expert's assessment of the literature can be more valuable. When reading individual articles, readers could miss features that are apparent to an expert clinician-researcher. Readers benefit from the expert's explanation and assessment of the validity and applicability of individual studies.

Literature reviews provide a summary of what the authors believe are the best and most relevant prior publications.

Systematic reviews determine an objective list of criteria, and find all previously published original papers that meet the criteria; they then compare the results presented in these papers.



Some journals likewise specialize in the review of a field; they are known as review journals.

The concept of “review article” not need to do peer-reviewed or is non-peer-reviewed.

Abstracts must begin on a separate page and should not exceed 350 words.

Abstracts should be structured with the following subheadings: *Background, Aims, Methods, Results, Conclusion and Keywords*.

The main text should not exceed 4500 words, excluding the abstract, references, tables, and figure legends. There should be a maximum of 20 tables and/or figures and 150 references.

Commentaries articles:

are usually by invitation only, are short, narrowly focused articles that are usually ordered by the journal. These articles are generally not reviewed.

A comment generally takes one of two forms:

- The first form aims to highlight one or more exciting research articles or clinical trials recently published in a journal or other one, to discuss specific issues within a subject area, rather than across the field, and to explain the clinical implications of the article rather than new findings in context. Opinions are welcome as long as they are based on fact.
- The second form is more editorial in nature and includes an aspect of an issue that is relevant to the purpose of the journal. Examples of this type of comment could be a discussion on the impact of new technology on research and treatment or a discussion on peer review changes or grant application procedures and their effect on research. By their nature, the second form of comment is less common. Comments are usually commissioned by well-known experts in a particular field, and authors are asked to provide a balanced summary of the field, to cover only the work that has been published (or is still in print at the time of writing), and not to discuss and mention mainly their work or that of their close colleagues.

Abstracts must begin on a separate page and should not exceed 250 words.

Abstracts should be structured with the following subheadings: *Background, Aims, Methods, Discussion, Conclusion, and Keywords*.

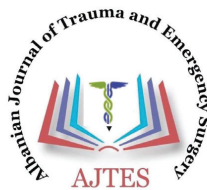
Commentaries articles must be a maximum of 2000 words and have a maximum of 40 references. Typically, do not contain pictures or tables. For more information click here <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4789530/>

Perspective articles; have an important role in academic research. They stimulate further interest in presented topics within the reader audience.

They are different from other types of articles because they present a different take on an existing issue, tackle new and trending issues, or emphasize topics that are important but have been neglected, in the scholarly literature.

In some scientific fields, they bridge different areas of research that the journal publishes, while in others they bring new issues and ideas to the forefront. In general, their role is to enlighten a general audience about important issues.

It gives researchers the opportunity to contribute to their discipline in different ways, while at the same time enhancing their own professional work.



A perspective article is a way for young researchers to gain experience in the publication process that can be often arduous and time-consuming. It can be a way in which they learn from the publication process while they are working on their original research articles that often take years to complete.

In the case of experienced researchers, provides them at least two distinct benefits:

- The first, it allows them to step back and reflect on a significant issue that they may know a lot about, but that they have never had the time to address.
- The second benefit is that the researcher gets the opportunity to give their own authorial voice to a published article that will reach a wide audience.

Before one decides to write and submit a perspective research article to an academic journal, it is important to become familiar with the article's expectations of the target journal.

Although academic journals hold a similar definition and purpose of a perspective article, there are differences in the technical requirements each journal has. When it comes to the length of the perspective article, some journals have strict limitations while others allow articles to vary the length within a given range. The perspective article has a limitation of 2,500, with defined reference and figure limits. Abstracts must begin on a separate page and should not exceed 250 words.

With respect to the structure of the perspective article, journals define their expectations in different terms. The perspective article emphasizes the structure of the article, requiring sections such as the *abstract, introduction, topics, and conclusion*.

Opinion articles allow readers of a newspaper to voice their thoughts and ideas on topics ranging from local happenings to international controversy. Most opinion articles are about 1500 words long, with a professional tone. If you want to try your hand at writing an op-ed, you can learn to choose a compelling topic, write an effective draft, and finish off your op-ed like a professional editor. The perspective article emphasizes the structure of the article, requiring sections such as the *abstract, introduction, topics, and conclusion*. Abstracts must begin on a separate page and should not exceed 250 words.

The latest articles discuss the current or recent news of general interest (the problem of the day) or of a specific topic (of interest to the general public and its results are quite welcome). A final article may include randomized and non-randomized (complete and partial) of scientific data in the interest of a local, national, regional, continental, and global study. The Latest articles emphasize the structure of the article, requiring sections such as the *abstract, Background, Aims, Study, Methods, Results, Discussions, and Conclusion*.

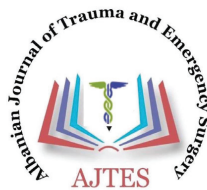
The main text should not exceed 4500 words, excluding the abstract, references, tables, and figure legends. There should be a maximum of 20 tables and/or figures and 100 references.

Abstracts should be structured with the following subheadings: *Background, Aims, Study, Methods, Results, Conclusion, and Keywords*. Abstracts must begin on a separate page and should not exceed 250 words.

Short Report:

Short reports or short communications are short versions of research, applications, or work in progress limited to 1500 words. These articles can include clinical or laboratory work, collected case reports of scientific significance, etc.

Abstracts must begin on a separate page and should not exceed 250 words.



Abstracts should be structured with the following subheadings: *Background, Aims, Study, Methods, Results, Conclusion, and Keywords*.

The main text should be structured with the following subheadings: *Introduction, Material and Methods, Results, Discussion, Conclusions, Acknowledgments, References, Tables, and Figure Legends*. The main text should not exceed 1500 words, excluding the abstract, references, tables, and figure legends. There should be a maximum of 8 tables and/or figures and 25 references.

Invited Review or Medical education articles: Invited review and Medical education articles are comprehensive analyses of specific topics in medicine, which are written upon invitation due to the extensive experience and publications of authors on the review subjects. They can also be articles focused on clinical teaching and guidelines.

All invited review articles will also *undergo peer-reviewing prior to acceptance*. Review articles must not exceed 5000 words for the main text (excluding references, tables, and figure legends) and 250 words for the unstructured abstract. A review article can be signed by no more than 6 authors and can have no more than 50 references.

Case Report: Interesting cases demonstrating new findings can be reported. Cases should be unique, representing a diagnostic or therapeutic challenge, and having a learning point for the readers.

Abstracts of case reports should mainly include information about the case and should be limited to a maximum of 250 words.

The abstract must begin on a separate page and should be structured with the following subheadings: *Background, Case Report, Conclusion, and Keywords*.

The main text of case reports should be structured with the following subheadings: *Introduction, Case Report, Discussion, Acknowledgments, and References*.

Case reports must not exceed 1500 words (excluding references, tables, and figure legends).

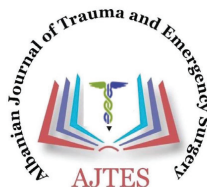
Case reports can be signed by no more than 6 authors and can have no more than 15 references and 6 figures or tables. It is highly recommended that the Case reporting must follow the CaRe (Case Report) guidelines.

Clinical Reasoning: Clinical reasoning represents rational thinking through the various aspects of patient care to better define the medical strategy regarding the diagnosis and/or treatment of a clinical problem in a specific patient. Conducting a physical exam, taking a medical history, ordering complimentary exams, and describing safe and effective treatment are necessary steps in gathering clinical data from a patient before engaging in the process of clinical reasoning. The latter represents a critical thinking process about all the important clinical information using personal skills and abilities often achieved from the experience.

This article type is intended to help clinicians think differentially and take the next step which determines the best course of action to take based on what is known or what can reasonably be hypothesized from clinical data.

The authors are encouraged to present clinical cases from their experience which has generated a real diagnostic dilemma.

The first section, case presentation, should include the patient's complaints as well as historical and clinical data enough to present an initial differential diagnosis.



The second section, complementary exams, is dedicated to pertinent and necessary complementary examinations according to previous topographic and clinical differential diagnosis.

In the third section, the authors should present all steps (surgery, biopsy, pathological exam) needed in defining the final diagnosis.

A supplementary section should include an overview of the final diagnosis.

The maximum lengths of the text and the references should not exceed 2500 words and 30 references, respectively. No abstract is required.

Clinical Image: The journal publishes original, interesting, and high-quality clinical images having a brief explanation (maximum 500 words excluding references but including figure legends) and of educational significance. The figure legend should contain no more than 100 words.

It can be signed by no more than 5 authors and can have no more than 5 references and 2 figures or tables. Any information that might identify the patient or hospital, including the date, should be removed from the image.

An abstract is not required with this type of manuscripts.

The main text of clinical images should be structured with the following subheadings: Case, and References.

Letter to the Editor: Letters in reference to a journal article must not exceed 600 words (excluding references). Letters not related to a journal article must also not exceed 600 words (excluding references). An abstract is not required with this type of manuscripts. A letter can be signed by no more than 5 authors and can have no more than 5 references and 2 figures or tables.

Other: Editorials, reviewer commentaries, book reviews, reports on publication, and research ethics, Opinions and View-Points are requested by the Editorial Board.

A summary of the article type's characteristics is given in the table below.

Article Type	Limit of				
	Word	Abstract word	Reference	Author	Tables/Figures
Original Article	4500 ¹	300 ⁴	100	None	20
Review Article	4500	350	150	6	20
Commentaries articles	2000	250	50	6	-
Perspective articles	2500	250	40	2	2
Latest articles	4500	250	100	10	20
Invited Review	5000 ¹	250	50	6	6
Case Report	1500 ¹	250 ⁵	15	6	6
Clinical Image	500 ²	N/A	5	5	2
Letter to the editor	600 ³	N/A	5	5	2
Clinical reasoning	2500 ³	N/A	30	5	3
Short report	1500	250 ⁴	25	4	8

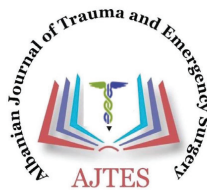
¹ This should not include the abstract, references, tables or figure

² This should include the figure

³ This should not include the

⁴ Should be structured with the following subheadings: Background, Aims, Study Design, Methods, Results, Conclusion, and Keywords.

⁵ Should be structured with the following subheadings: Background, Case Report Conclusion, and Keywords.



Preparation and submission of a manuscript

All manuscripts should be submitted via email to the following address: ajtes.editor@gmail.com; ajtesjournal@gmail.com

The submission should be divided into SEPARATE files in the following order:

1. *Cover Letter (separate file)*. <https://drive.google.com/file/d/1pKueirCkP2-DNd6RsY5Lk-NzQOBjQnKO/view?usp=sharing>
2. *Authorship Contributions, Copyright Transfer, and Conflict of Interest Statement Form (separate signed file)*.
<https://drive.google.com/file/d/1IVGYfpvqsXruNwFeKothDX0zt2WGiXxb/view?usp=sharing>
https://drive.google.com/file/d/1_53doLRgxRlp1kVbiyYVh9XDLzaDtjv_/view?usp=sharing
<https://drive.google.com/file/d/1hB-5WsprQAiwsqWNiL4Yqrr0Zkm2tf-I/view?usp=sharing>
3. *Manuscript (Title page, Abstract page, main text, references, tables, and figure legends)*.
4. *Figures (if applicable)*.

1. Cover Letter

The cover letter addressed to the Editor in Chief from the corresponding author, should include:

the article title and type of article he/she is submitting (for example original article, case report, review article, or clinical image).

The corresponding author should briefly summarize why their work is a valuable addition to the scientific literature. Furthermore, there should be a statement that the manuscript has not already been published, accepted, or under simultaneous review for publication elsewhere.

AJTES does not accept multiple submissions and duplicate submission. For manuscripts that have been presented orally or as a poster, this must be stated on the title page with the date and the place of the presentation.

An example of a cover letter can be found on the journal's webpage (AJTES Cover Letter). <https://drive.google.com/file/d/1pKueirCkP2-DNd6RsY5Lk-NzQOBjQnKO/view?usp=sharing>

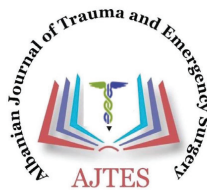
2. Authorship Contributions, Copyright Transfer and Conflict of Interest Statement Form

This is a statement of scientific contributions and responsibilities of all authors.

The form is available for download at the journal's webpage. <https://journal.astes.org.al/>

The ICMJE recommends that authorship has to be based on the following 4 criteria:

- *Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work.*
- *Drafting the work or revising it critically for important intellectual content.*
- *Final approval of the version to be published.*
- *Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.*



A contributor should meet all four criteria to be identified as an author. If a contributor does not meet all four criteria, he/she should be acknowledged in the acknowledgments section of the manuscript. All authors must sign the corresponding declaration.

For more details please refer to the ICMJE's definition of the role of authors and contributors at <http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html>

AJTES recommends that the author ranking in the authorship list has to follow the importance of the contribution of the individual co-authors in the study, with the exception of the last author who is generally the author group coordinator or leader and whose contribution is comparable with the first author.

The authors must state in the section dedicated to the Author Contribution Form and in the main text (before the Reference section) if they have agreed for another ranking order (for example authors A.B and C.D. have an equal contribution to this study, etc).

The specific contribution of each author must be stated at the end of the manuscript, before the references.

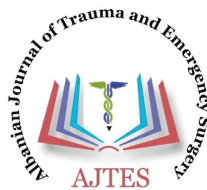
All contributing authors must sign the **Authorship Contributions, Copyright Transfer, and Conflict of Interest Statement Form** and submit it through the submission system during submission. Please see Authorship Contributions, Conflict of Interest Statement and Copyright form for detailed information regarding "Acknowledgement of Authorship, Exclusive Publication Statement, Conflict of Interest Statement, and Transfer of Copyright Agreement".

Please refer to the "conflict of interest policy" for more information. <https://drive.google.com/file/d/1hB-5WsprQAIwsqWniL4Yqrr0Zkm2tf-I/view?usp=sharing>

1 - Manuscript must contain: Title Page (separate page)

This should include:

- a) The complete manuscript title (no more than 150 characters).
<https://drive.google.com/file/d/1YzknUnqHJR9NWah39QOe6gWfUfX1nj3/view?usp=sharing>
- b) The running head (no more than 50 characters).
- c) Word counts for the abstract and text (the text word count does not include references, tables, and figure legends).
- d) The number of references and the number of figures and/or tables.
- e) All authors' full names.
- f) Detailed affiliations and e-mail addresses (all authors should meet the ICMJE's requirements for authorship – see details at "author contribution form"). <http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html>
- g) The name, address, telephone and fax numbers, and email address of the corresponding author.
- h) Key-words: (3 to 6 key-words) from the list provided in Index Medicus under "Medical Subject Heading (MeSH)". <https://www.nlm.nih.gov/mesh/meshhome.html>
- i) Information about where and when the study has previously been presented.



Abstract Page (separate page)

Original articles, invited review articles, and case reports should include an abstract on a separate page.

Abstracts for original articles and short reports should be structured with the following subheadings: *Background, Aims, Study design, Methods, Results, and Conclusion.*

Abstracts for case reports should be structured with the following subheadings: *Background, Case Report, and Conclusion.*

Abstracts for review articles should not be structured. *Clinical images, clinical reasoning, Editorials, Letters to the Editor, and Commentaries or Opinions/Viewpoints* should not contain an abstract.

Main document

The main document should include the main text, acknowledgments, conflict of interest disclosure, authorship contribution description, references, tables, and figure legends, in that order.

Main text

The main text should be structured according to the article type, as described in the Article Type section above.

Acknowledgments

All contributors who do not meet the criteria for authorship (ICMJE: authorship and contributorship: <http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html>) should be mentioned in this subheading.

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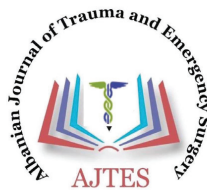
Statement about specific author contribution at the study (including concept, design, supervision, resource, materials, data collection and/or processing, analysis and/or interpretation, literature search, writing, and critical reviewing).

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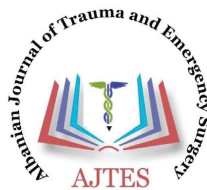
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Tables should be presented within the main document and after the reference list. All tables should be referred to within the main text and they should be numbered consecutively in the order they are referred to within the main text. A descriptive title should be provided for all tables and the titles should be placed above the tables. Abbreviations used in the tables should be defined below the tables (even if they are defined within the main text). Tables should be created using the “insert table” command of the word processing software and they should be arranged clearly to provide an easy reading.



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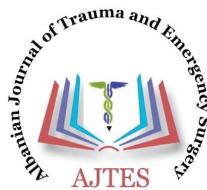
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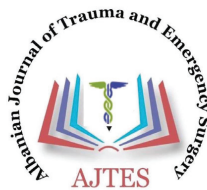
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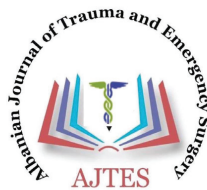
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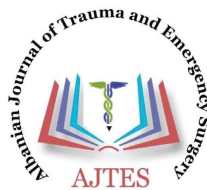
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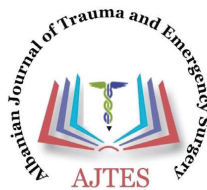
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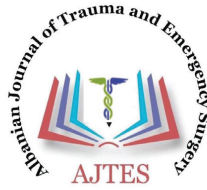


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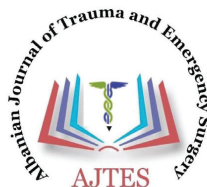
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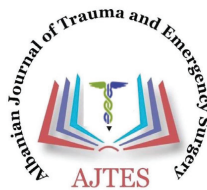
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- Start online registration:** September 01, 2023.
- Abstract acceptance notification:** October 25, 2023
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