Acta Balneologica

CZASOPISMO POLSKIEGO TOWARZYSTWA BALNEOLOGII I MEDYCYNY FIZYKALNEJ
JOURNAL OF THE POLISH BALNEOLOGY AND PHYSICAL MEDICINE ASSOCIATION

TOM LXIV	NUMER 6 (172)/2022	DWUMIESIĘCZNIK	LISTOPAD-GRUDZIEŃ
TOM LXIV	NUMBER 6 (172)/2022	BIMONTHLY	NOVEMBER-DECEMBER

Aluna Publishing

Acta Balneologica

WYDAWCA/PUBLISHER:
Wydawnictwo Aluna
ul. Przesmyckiego 29
05-510 Konstancin Jeziorna
www.actabalneologica.pl

KOORDYNATOR PROJEKTU/
/PROJECT COORDINATOR:
MEDDOM PRESS
tel. 604-208-453
barbadom@wp.pl

OPRACOWANIE GRAFICZNE/
/GRAPHIC DESIGN:
Piotr Dobrzyński
www.poligrafia.nets.pl

PRENUMERATA/SUBSCRIPTION:
prenumerata@wydawnictwo-aluna.pl

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REVIEW ARTICLE/PRACA POGLĄDOWA

Physical Procedure in Temporomandibular Joint Dysfunctions. Clinical Study

Postępowanie fizykalne w dysfunkcjach stawu skroniowo-żuchwowego. Badania kliniczne

DOI: 10.36740/ABAL202206101

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SUMMARY

Aim: Temporomandibular joint dysfunction is a common and difficult clinical problem. To present the use of physical therapy in patients with temporomandibular joint dysfunctions.

Materials and Methods: The paper presents the etiopathogenesis and clinical presentation of temporomandibular joint dysfunctions as well as patient cases and describes physical therapy in joint dysfunction, including the methods and equipment used to perform the procedures.

Conclusion: The paper stresses the importance of physical therapy in the treatment of temporomandibular joint dysfunctions. Physical therapy is a crucial part of treatment in patients with temporomandibular joint dysfunctions.

Key words: temporomandibular joint, dysfunction, treatment

Słowa kluczowe: staw skroniowo-żuchwowy, dysfunkcja, leczenie

Acta Balneol, TOM LXIV, Nr 6(172);2022:495-502

INTRODUCTION

Dysfunctions of the temporomandibular joint (TMJ) and the other parts of the masticatory organ affect 15% to 23% of the population. Patients experience headache, migraines, pain in the frontal and temporal region, otalgia, dizziness, impaired balance, unspecified toothache, shoulder and back numbness, light sensitivity, cheek pain, and limited TMJ mobility. Important risk factors include emotional stress, deleterious habits, poorly fitting dental prostheses or dental fillings and crowns, malocclusion, and injuries. Temporomandibular joint dysfunctions (TMDs) develop unnoticed by the patient and initially do not cause any constant symptoms [1-10].

AIM

To present the use of physical therapy in patients with temporomandibular joint dysfunctions.

MATERIALS AND METHODS

The temporomandibular joint (TMJ) is a structurally, biomechanically, and functionally complex system consisting of bones, muscles, ligaments, and teeth controlled together by the central nervous system (CNS). The TMJ is responsible for several activities that are necessary to live and function, namely mastication, initial digestion, swallowing, speaking, breathing, and expressing emotions. The joint is composed of three main skeletal parts, or bones; these are the mandible, the maxilla, and the temporal bone, which connects the mandible with the rest of the skull. The TMJs are symmetrical, but any movement in one joint results in movement in the other. The mandibular fossa of the temporal bone and the mandibular head form the articular surfaces of the TMJ; however, these structures do not come into direct contact with each other, but are separated by an articular disc. The articular disc helps the articular surfaces meet their metabolic requirements (as they have no blood supply of their own) and reduces friction during joint movement. The TMJ is innervated by the trigeminal nerve and its blood supply is provided by the superficial temporal artery (external carotid artery), the middle meningeal artery, and the internal maxillary artery.

The active part of the masticatory organ consists of the following muscles: the masseter, the temporal muscle, the medial pterygoid, and the superior and inferior lateral pterygoid. The TMJ is also directly activated by the digastric muscle as well as the neck and shoulder girdle muscles, which stabilise the position of the head.

The TMJ is additionally protected by a joint capsule. The capsule is sac-like and fairly loose, allowing the mandibular

head to move from the mandibular fossa to the articular tubercle when the mouth opens and preventing synovial fluid loss. The articular capsule exists thanks to the capsular ligament.

Ligaments are passive structures that do not actively participate in joint function; their role consists in restricting movement at the end ranges of motion. The TMJ has the following ligaments: the lateral ligament, the stylomandibular ligament, and the sphenomandibular ligament. There are collateral ligaments inside the TMJ, namely the medial and lateral discal ligaments, which attach the lateral and medial edge of the articular disc to the lateral and medial pole of the condylar process.

The TMJ is a compound joint with an extremely complex structure and function. As the two TMJs are connected to the same bone (mandible), they must always function together, even though each joint is capable of individual movement. The inferior articular cavity (the condyle-disc complex) is responsible for joint rotation; the superior articular cavity (between the disc and the articular surface of the temporal bone) is responsible for translation (e.g. when the mandible moves forward).

The structure of the joint does not ensure its stability; the stability is only provided by the muscles that elevate the mandible. Even at rest, resting muscle tension is maintained. Joint dislocation is prevented due to an increased intraarticular pressure, caused by the mandibular head being pressed against the articular disc and the disc being pressed against the mandibular fossa.

The TMJ allows for movement in three directions:

1. Mandible protrusion and retrusion (gliding movement between the articular surface of the tubercle on the temporal bone and the articular disc, rotation between the articular disc and the surface of the mandibular head).
2. Mandibular depression and elevation (opening and closing of the mouth). These combine gliding movement in the superior articular cavity (from the mandibular fossa to the top of the tubercle) with hinge movement in the inferior articular cavity (rotation of the mandibular head on the inferior surface of the articular disc).
3. Lateral (mastication) movements. The mandibular head travels to the mandibular fossa in one joint; at the same time, the mandibular head of the contralateral joint travels with the articular disc onto the articular tubercle.

Any description of the TMJ biomechanics should mention the concept of centric relation. Since teeth are not flexible, abnormal occlusion sends signals to the nervous system responsible for the masticatory organ and the system takes action to ensure a stable position of the mandible. Unfortunately, this process may usually be accompanied by functional abnormalities of the masticatory organ system structures, including for instance excessive muscle tension.

FUNCTIONAL DISORDERS OF THE TEMPOROMANDIBULAR JOINT

The classification described by Okeson is currently the most commonly used system. The author divided TMJ disorders as follows:

1. Functional muscle disorders (local muscle soreness, protective co-contraction, myofascial pain, myospasm, chronic myalgia).
2. Functional TMJ disorders (disorders of the mandibular head-articular disc complex, excessive mobility).
3. Chronic restricted mandible opening.
4. Developmental disorders.

The body may respond to functional muscle disorders in different ways. The first and most common response consists in the development of a protective co-contraction. Patients experience it as muscle fatigue after exercise.

The next stage of functional muscle abnormalities is associated with myofascial pain, which is local pain accompanied by the presence of trigger points (dense, painful, and tight regions of muscle fibres surrounded by normal tissue).

All these abnormalities are characterised by the presence of two main symptoms, namely pain and functional impairment.

Internal disorders of the mandibular head-articular disc complex function are usually accompanied by acoustic symptoms produced in the joint. These sounds may be divided into two types, crepitation and clicking, caused by articular disc and mandible deviation; friction in the joint indicates degenerative changes [11-13]. Early clicks suggest the onset of TMD, while sounds produced later during movement suggest a chronic disorder.

Disorders of the mandibular head-articular disc function may develop in three different ways. Disc displacement with reduction occurs when the disc is displaced anteriorly and/or medially (for instance as a result of ligament damage). When the mouth opens, the condyle moves over the posterior edge of the articular disc later than it is supposed to. TMJ abduction typically shows movement with deviation (lateral displacement towards the locked joint); once the joint is unlocked (reduction), the deviation resolves. Disc displacement without reduction means complete anteromedial disc displacement. When examined, patients with this type of disorder have difficulty fully opening their mouth; the movement it very painful (range of motion is 25-30 mm), with hard resistance at end of range as the mouth opens. Lateral movements towards the affected joint are normal, but movements in the other direction are restricted and may be painful.

The third type of disorder consists in excessive articular disc mobility (hypermobility). Patients have acoustic symptoms during joint movement, but pain is not always present. The range of motion in the joint is normal.

In the second group of disorders, the articular surfaces of the TMJ are not properly aligned. This group includes such disorders as:

- shape abnormalities (associated with abnormal articular surfaces), always with movement impairment at the same time;
- adhesions (temporary sticking of the articular surfaces, both in the inferior and superior articular cavity);
- subluxation occurs in the absence of any other joint abnormalities and is caused by the structure of the articular surfaces of the patient's joint;

– disc dislocation; patients are unable to close their mouth after abduction. The articular disc travels posteriorly as far as possible with respect to the mandibular head. The condition usually occurs after a prolonged dental procedure or excessive yawning. Patients complain of pain and inability to close their mouth.

TMD ASSESSMENT AND TREATMENT

Patients should receive dental and orthodontic treatment, physical therapy, orthopaedic, ENT, and psychological treatment, and speech therapy. The treatment methods may be divided into reversible, conservative treatment (e.g. splints, physical therapy), initiated earlier, and irreversible treatment, which is usually used when the conservative methods have not been effective. There are functional tests that allow for an approximate assessment of the degree of temporomandibular joint dysfunction.

A test is conducted to measure the muscle strength of the latissimus dorsi, which is mainly responsible for upper limb extension and adduction. During the test, the patient is in an upright position, with the upper limb in internal rotation and the dorsum resting on the hip. A kg against resistance test is performed in a way that allows the patient to perform a movement with their mouth closed. The patient then swallows several times, opens and closes their mouth, and again performs extension and adduction with mouth open; limb strength is compared. If no difference in strength is detected, the TMJ complex is normal; if a difference is found, it may suggest a joint dysfunction.

The use of an individually prepared rehabilitation programme helps restore normal TMJ function in patients with TMD (Table 1).

TMJ ASSESSMENT

The examination uses disposable objects (wooden tongue depressors, paper rulers, disposable gloves) and measures ranges of motion as well as its quality and the presence of pain.

TMJ range of motion test:

Patient opens their mouth as far as possible; a special ruler is used to measure the distance between the lower and upper incisors. The normal range is 45-50 mm of abduction.

Lateral abduction: ranges of motion to the right and left are measured with a disposable paper ruler, assessing the distance between the medial line of the maxilla and mandible during maximum lateral abduction to the right and left. The result should be up to approximately 8-10 mm.

The test assesses whether the mandible is (vertically) depressed evenly and monitors the joint for any asymmetrical movements of the mandible and the presence of pain; asymmetrical mandibular depression is assessed.

TMJ examination also includes muscle pain assessment by palpation. Two muscles are assessed, the temporal muscle and the masseter, both of which can be accessed directly by the examiner.

The test is performed at the same time on both sides. During the test, the patient is asked to rate the pain they experience on a scale from 0 to 3, where 0 means no pain,

Table 1. TMJ physical examination report

	Test	Parameter value	Normal range
1	Max abduction: - max abduction value - pain during examination - asymmetrical movements	 - millimetres (mm) - present (0) absent (B) - direction (right/left/absent)	 - 45-50 mm - absent - absent
2	Lateral abduction: - value of abduction to the right - value of abduction to the left - pain during movement - asymmetry during movement	 - millimetres (mm) - millimetres (mm) - absent present - absent present	 - 10 mm - 10 mm - absent - absent
3	Palpation: - temporal muscle - masseter	0 - no pain 1 - uncomfortable pressure 2 - considerable discomfort/pain 3 - presence of reflexes that clearly cnfirm pain (e.g. lacrimation)	No pain
4	Muscle tests - superior lateral pterygoid/ m.inferior lateral pterygoid/m. medial pterygoid	Pain (B)/No pain (BB) during the following tests - patient opens their mouth widepatient protrudes the mandible with resistance applied by the examiner - patient clenches their teeth - patient bites down on a wooden tongue depressor	No pain (BB)
5	Teeth clenching/grinding	Present (0)/absent (B)	Absent (B)
6	Acoustic symptoms (clicking/crepitation)	Present (0)/absent (B)	Absent (B)

1 means uncomfortable pressure, 2 means considerable discomfort/pain and 3 means the presence of reflexes that clearly confirm pain (e.g. lacrimation).

TEMPORAL MUSCLE

Starting position: the test is performed with the patient in a supine position and with their head in an intermediate position.

Anterior portion: the examiner's hands are placed along the muscle fibres above the zygomatic arch.

Intermediate portion: examination of the region directly above the TMJ and above the zygomatic arch (mostly fibres on the lateral side of the skull).

Posterior portion: examination above and behind the ear (mostly horizontal fibres) (Figure 1).

Figure1. Palpation of the anterior portion of the temporal muscle

The masseter. Starting position: the test is performed with the patient in a supine position, with their head in an intermediate position. Two fingers are placed along the muscle on the superior and inferior insertion. The fingers are first placed bilaterally on the zygomatic arches directly under the TMJs, and then move down along the muscle fibres (Figure 2).

Due to their location, and due to the difficult access to the muscles on palpation, the superior and inferior lateral pterygoid muscles and the medial pterygoid muscles are assessed indirectly using muscle tests.

Medial pterygoid muscle: contraction – teeth clenching – clenching with pressure on a tongue depressor, stretching – maximum opening of the mouth.

Figure 2. Palpation of the masseter

Inferior lateral pterygoid muscle: contraction – patient protrudes chin with resistance, stretching – teeth clenching – teeth clenching with pressure on a tongue depressor.

Superior lateral pterygoid muscle: contraction – teeth clenching – clenching with pressure on a tongue depressor, stretching – teeth clenching – teeth clenching with pressure on a tongue depressor (Table 2).

Assessment for acoustic symptoms in the TMJs, including a) teeth clenching/grinding. b) acoustic symptoms – crepitations during mandibular movement, examined with a stethoscope.

TMJ dysfunctions. Passive stretching of the abductors. The patient opens their mouth as wide as possible, the examiner passively increases the range of motion using his/her thumb and index finger. This must not be painful for the patient; the movement should be careful (Figure 3).

Myofascial release of the masseter. Transverse release: the patient is in a supine position, the examiner's thumb and index finger move down from the zygomatic bone and along the entire muscle. Longitudinal release: two or three fingers are placed at the insertion point of the masseter; pressure is applied and the fingers move towards the medial region of the face (Figure 4 and 5).

Temporal muscle treatment: depending on the examination findings, temporal muscle relaxation is performed for the portion of the muscle that requires it. The treatment is repeated 10 times.

Table 2. Algorithm to identify the painful structure

	Medial pterygoid	Inferior lateral pterygoid	Superial lateral pterygoid
Wide opening of the mouth	Pain	Slight pain	No pain
Protruding the mandible with resistance applied by the examiner	Slight pain	Pain	No pain
Teeth clenching	Pain	Pain	Pain
Biting down on a wooden tongue depressor	Pain	No pain	Pain

Figure 3. Passive stretching of the abductors of the mandible

Figure 4. Transverse release of the masseter

Figure 5. Longitudinal release of the masseter

Myofascial treatment of the lateral pterygoid:

The patient is in a supine position. The therapist's fingers are placed behind the mandibular angle; the patient is asked to perform retrusion with isometric tension for 10 s and relaxation with an exhalation. The treatment is repeated 10 times during one session (Figure 6).

Figure 6. Lateral pterygoid treatment

Medial pterygoid treatment: the patient is in a supine position and is asked to perform mandibular depression inferiorly and laterally, in the direction of the stretched muscle; tension is maintained for 10 s and followed by relaxation. The isometric tension is repeated 10 times (Figure 7).

Figure 7. Medial pterygoid treatment

TMJ mobilisation. The patient is in a supine position, with the therapist standing sideways to the patient, on the side contralateral to the joint being mobilised, with the thumb placed at the level of the lower molars and the other fingers on the mandibular body. The other hand (index and middle finger) is placed on the condylar pole (to control the movement in the joint). A little force is applied downwards to achieve distraction (distraction duration 1 s); the procedure is repeated 6 times for each joint (Figure 8).

CLINICAL CASES

Ankylosis is defined as joint stiffness resulting from disease or injury. Early TMJ ankylosis leads to the abnormal development of the facial skeleton as well as difficulty breathing, eating, and maintaining oral hygiene (Figure 9).

The patient was an 18-year-old male with left TMJ ankylosis and the following symptoms: restricted mandibular abduction (to 11 mm), malocclusion, and facial asymmetry (Figure 10).

Figure 8. TMJ mobilisation

Figure 9. Case 1. TMJ ankylosis

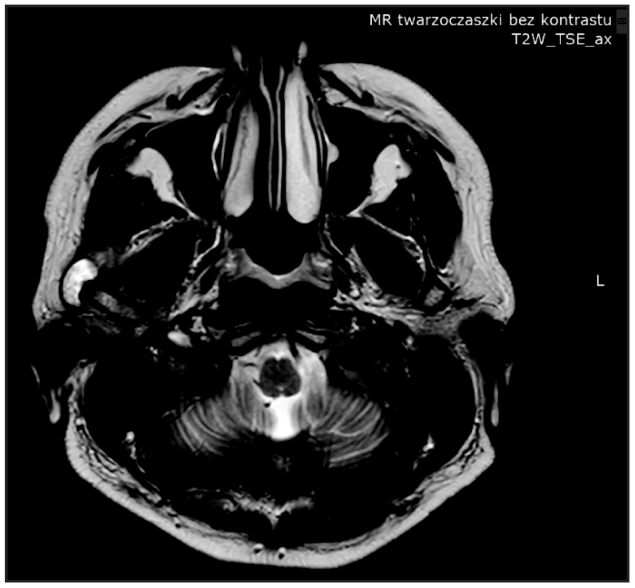

Figure 10. Case 2. Synovial chondromatosis of the TMJ (MRI).

Synovial chondromatosis is a mild, chronic, progressive pathology consisting in follicular hyperplasia of joint cartilage.

The patient was a 46-year-old male with a 2-year history of right TMJ pain and restricted mandibular abduction. The symptoms were associated with mandibular injury.

TMD treatment is difficult. First, it has to reduce and eliminate pain and functional impairment of the masticatory system. Patient compliance is very important in the treatment process. Deleterious oral habits should be eliminated; patients should not chew gum, eat hard foods, or open their mouth wide while yawning.

- various relaxation techniques are recommended to reduce stress levels in everyday life;
- so-called mouth guards placed between the upper and lower teeth at night are recommended to protect from teeth grinding and to reduce masticatory muscle tension;
- orthodontic treatment for malocclusion; teeth occlusion analysis is necessary and muscle deprogramming should be performed to help the muscles "get used" to a new situation and reduce tension;
- patients with degenerative changes, where the surface of the mandibular head becomes uneven and sharpened and its movement is altered, undergo physical therapy in the form of ultrasound therapy with phonophoresis, laser therapy, and shockwave therapy [13-15].

Ultrasound therapy uses mechanical vibrations with a frequency of 800 and 2400 kHz, produced by ultrasound transducers. They have mechanical (tissue micromassage), thermal, and physicochemical effects on tissue; they reduce pain and muscle tension, improve blood supply, and decrease inflammation. The recommended dose of ultrasound therapy in the treatment of TMJ arthropathy is 0.4-0.6 W/cm^2, with a procedure duration of 3-4 minutes. The treatment is often combined with non-steroidal anti-inflammatory drugs.

Extracorporeal shockwave therapy (ESWT) uses shockwaves generated by an electrical pulse and focused by thousands of small crystals in the applicator head. The machine produces shockwaves of compressed air. The shockwaves penetrate tissues up to 4-7 cm. The pressure in the tissues reaches 2-5 bar and the waves are applied at the frequency of 1-22 Hz. The procedures improve tissue metabolism and blood supply, increase collagen production, reduce muscle tension, and eliminate pain.

The treatment starts with f=5-10 Hz in 2-4 sessions with 3-day intervals, with the following settings: shockwave transmitter diameter 15 mm, 2000 pulses, pressure 3-4 bar, frequency 5-10 Hz (Figure 11 a, b).

High Intensity Laser Therapy

This therapy uses infrared wavelengths. A photomechanical wave is generated in the tissues, which increases metabolism, eliminates pain, has anti-inflammatory effects, reduces oedema, dilates blood vessels, stimulates DNA synthesis through phytohemagglutinin stimulation, increases fibroblast activity, activates phagocytosis, and eliminates inflammation.

Pulse frequency is set at 1 to 100 Hz, treatment duration is calculated based on total energy and power, and the energy is supplied in J (Figure 12 a, b).

Figure 11a,b. Shockwave therapy procedure, equipment

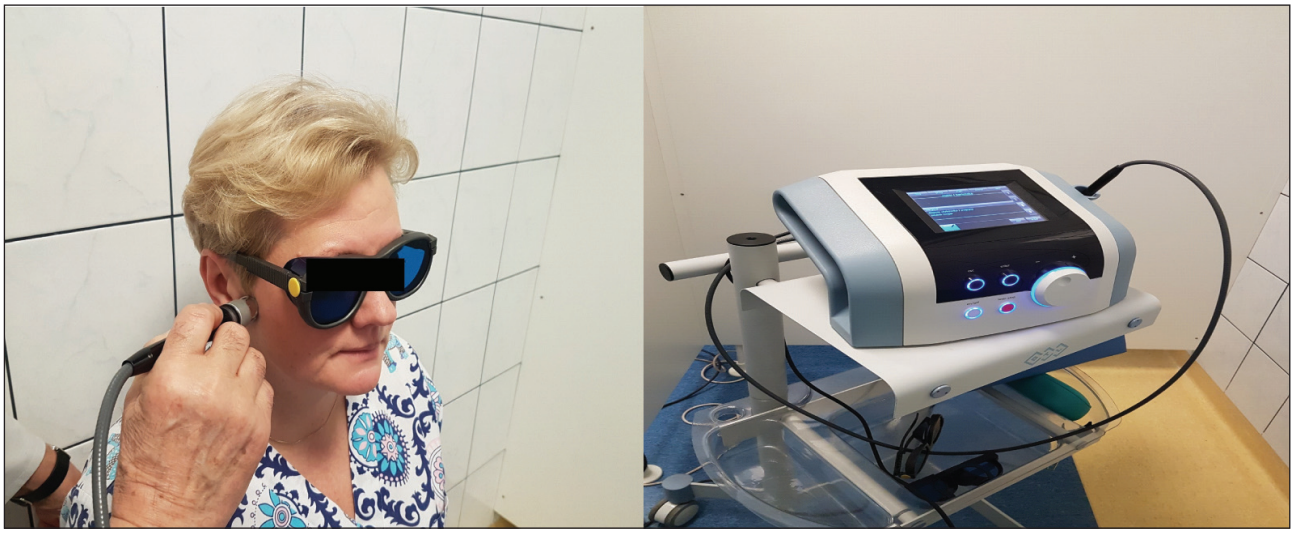

Figure 12 a,b. Laser therapy procedure, equipment

DISCUSSION

Temporomandibular joint dysfunctions affect almost a third of patients and constitute one of the three main problems in dental medicine, the other two being dental caries and periodontal disease. Their symptoms are not specific, which makes the diagnostic work-up difficult; history-taking, a manual examination, imaging (CT, Doppler), and the use of a face-bow and articulator are required. Non-invasive therapy is possible once the exact position of the maxilla and mandible with respect to the axis of mandibular rotation in the joint has been determined, together with the extent and degree of the vertical dimension of occlusion. 3D CT diagnostic imaging reveals TMJ and cervical spine abnormalities.

Doppler ultrasound allows for examining TMJ movements. The use of a face-bow and articulator is important in the diagnostic work-up of TMJ disorders and helps determine the exact position of the maxilla and mandible with respect to the axis of mandibular rotation in the joint and perform non-invasive treatment.

In the case of TMDs, manual therapy is focused on muscle relaxation and the reduction of myofascial tension. Physical therapy methods, such as ultrasound therapy, laser therapy, cryotherapy, and shockwave therapy, play an important role in the treatment of these disorders; they help eliminate pain and reduce the increased muscle tension. Patients are instructed to do relaxation exercises aimed at stress reduction and autotherapy and to perform their scheduled exercises at home.

CONCLUSIONS

Physical therapy is crucial in the treatment of temporomandibular joint dysfunctions.

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Conflict of interest:
The Author declare no conflict of interest

Received: 18.03.2022
Accepted: 10.11.2022

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A – Research concept and design, B – Collection and/or assembly of data, C – Data analysis and interpretation, D – Writing the article, E – Critical review of the article, F – Final approval of article

Info

On behalf of the Editorial Board and the Publisher of Acta Balneologica – the official journal of the Polish Society of Balneology and Physical Medicine (published since 1905), we cordially invite you to the new website www.actabalneologica.eu where, among others, we publish open access articles. We would like to remind you that Acta Balneologica is indexed in the Web of Science (ESCI) as well as EBSCO databases, has 20 MEiN points, and has the permanent patronage of the Rehabilitation Committee of the Polish Academy of Sciences.
At the same time, we encourage you to visit and like the Acta Balneologica profile on Facebook. facebook.com/actabalneologica. There, we place posts in the field of health resort medicine. And we will share information about treatment methods available in health resort stations.
A natural consequence of our activities in the field of health resort medicine has been the establishment of the Polish Society of Health Resort Patients in 2019. You can find out more about the goals, tasks, and methods of operation of this Society on the website www.uzdrowiskowi.pl.
You can also download the membership declaration here.

Systemic Cryotherapy in the Treatment of Autistic Children

Krioterapia ogólnoustrojowa w leczeniu dzieci autystycznych

DOI: 10.36740/ABAL202206102

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SUMMARY

Aim: Autistic disorders in children cover three developmental areas: social interaction, communication development disorders, and repetitive behavioral repertoire. Autistic children are a group resistant to therapeutic intervention due to their imapired contact with the environment, but the correction and compensation of disturbed functions through the interaction of motor and seems to be the most important goal of therapy.

Materials and Methods: The study group consisted of 57 students of two special schools diagnosed with autism (age 6-16 (AVG 10 +/- 6), whose parents consented to participate in the research program, this 12 (21%) girls and 45 (79) %) boys. Fine and gross motor skills were assessed. The assessment of fine motoricity included the evaluation of the functions of individual parts of the body: throwing and catching a large ball, throwing tennis balls accurately into the basket while sitting on a chair, standing, lying on a mattress, pedalling on a stationary bike, performing unassisted squats, lifting the knees high in a standing position,unassisted jumping on a baton and kicking a volleyball. Large motor activity (change of place) included: walking up the stairs holding on to the handrail, stepping back and forth,going through the tunnel, walking on a ramp inclined at an angle of 45, traversing an obstacle course made of soft rollers of different sizes with the help of another person. After a two-week break, the subjects received a series of 10 treatments temperature at a temperature of - 110°C, each treatment lasting 2 minutes. The treatments took place once a day from Monday to Friday, excluding Saturdays and Sundays. After each treatment, the patient exercised for 1 hour in accordance with the previous results of fine and gross motor skills.

Results: 1 child (10 entries) completed a full series of treatments. Other children: - 9 entries - 1 child, - 8 entries - 2 children, - 4 entrances - 2 children, - 3 entries - 1 child, - 2 children refused to continue the procedure after 30 seconds, - 2 child refused to enter the cryochamber.

Conclusions: 1. It seems that cryogenic therapy should not be used in autistic children due to safety and the amount of work involved in preparing and conducting the procedures. 2. Parents' attitudes towards the disease and their child's treatment options make it difficult to cooperate and plan the therapy.3. In adult high-functioning autistics being treated at ZUL there is a very good tolerance of the procedure.

Key words: systemic cryotherapy, autistic child, therapy, fine and gross motor skills

Słowa kluczowe: krioterapia ogólnoustrojowa, dziecko autystyczne, terapia, mała i duża motoryka

Acta Balneol, TOM LXIV, Nr 6(172);2022:503-506

INTRODUCTION

Autism is one of the most serious and holistic disorders of human development [1, 2]. There are many different theories about the causes of autism, hence different classifications with significant discrepancies [3-5].Many doctors and researchers of this disease believe that the cause of its formation is the malfunctioning of the central nervous system, the greater the damage to the brain, the more severe mental retardation and the greater likelihood of autism. Numerous studies of autistic individuals reveal evidence of the occurrence and chronic insufficiency of cerebral circulation, oxidative stress, neurotransmitter abnormalities, loss of toxin detoxification, abnormalities of the bacterial flora, lack of immune regulation and others [6, 7].The American Autism Society reports that 1 in 166 people are affected with mild, moderate or severe autism (1:166). According to the Autism Europe data, 0.6% of the European Union population is affected by autism, which is approximately 5 million people (2009 estimate) [8].European statistics show that autism affects boys 4 times more often than girls. The AUTYZM-POLAND agreement

assumes a lower ratio of 1:1000, which means that there are about 38,000 people-with autism,living in Poland including about 10 thousand children and adolescents. According to the data of the Ministry of National Education, 15553 students had a diagnosis of autism in 2015, and in 2019 their number increased to 26143. There are many different theories regarding the causes of autism. Many researchers believe that the essence of this disease is a malfunction of the central nervous system [9, 10]. It is believed that the following factors may cause the disease: biological, environmental, resulting from disturbances in the course of metabolic reactions [11]. So far, no cure has been found for this disease, it lasts for life [12].

Organising the therapy with a child is determined by the current needs of the child and its environment. Careful observation allows the selection of an appropriate method in establishing contact between the therapist and the child and understanding it. Finding and harmonizing the activities of school counselors, psychologists and physiotherapists can stimulate or inhibit a child's hypersensitivity or hypersensitivity. The diagnostic basis is always a medical and psychological examination, but the determination of fine and gross motor skills and the work of the kinesiotherapist with a child may give even better results, which is confirmed by studies [13-15].Adding physiotherapeutic treatments to it, if possible, may help, but as the presented studies have shown, not always the selected ones. Treatments with the use of physical factors have been used in children before, unstable organism is subject to various environmental systems [16]. Cold treatment consists in lowering tissue temperature in the form of local and total treatments [17, 18].

Treatment with cold includes many methods of different effects: cold water, ice, easily evaporating liquid substances, gel compresses, cryogel, cold dressings, cooling gas, cold air blowing, thermoelectric cooling. Low temperatures in the human body trigger local and general, physiological defense reactions of the body [19].Initially, there is a contraction of blood vessels and a decrease in body temperature within the skin and subcutaneous tissue. After the procedure blood vessels dilate and blood flow increases. The action of cold improves oxygenation and nutrition of tissues, faster removal of metabolic products, including inflammatory mediators such as histamine, serotonin and prostaglandins, reduces inflammatory reactions, leads to faster wound healing, and improves the appearance and color of skin. Cryogenic temperatures act on receptors and nerve conduction, including blocking severe pain stimuli. It increases the concentration of ß-endorphin, the strongest endogenous analgesic factor [20].The direct effect on the receptors and the reduction in nerve conduction, result in a reduction in muscle tension without deterioration of their strength or even their increase, after the procedure, it is obligatory to undergo kinesiotherapy [21].An important systemic effect of systemic cryostimulation is an increase in immunity. There are no reports in the scientific literature on the use of systemic cryotherapy in children. Local cooling has been proposed to combat spasticity in children with cerebral palsy [22].The use of low temperature treatments has been found to be effective in relieving pain in children, especially in acute conditions [23].

The beneficial effects of cold compresses in post-exercise headache in children have been confirmed [24]. Ice packs have been used for intramuscular injections to reduce pain [25]. In neurological patients and especially in children and adolescents with cerebral palsy, improved mood and increased spontaneous motor activity and decreased spasticity have been noted after systemic cryotherapy [26, 27].

MATERIALS AND METHODS

The research was carried out at the Department of Treatment Improvement of the Central Clinical Hospital of the Ministry of the Interior and Administration in Warsaw. The study group consisted of 57 children diagnosed with autism aged 6-16 years (AVG 10 years and 6 months +/-). Fine and gross motor skills were examined before and after a series of 10 treatments in the cryochamber. Before starting the project, the physiotherapists got to know the essence of autism and the management and use of special techniques when a child is, for example, aggressive. The "Applied Behavioral Analysis in therapeutic work with people with autism" course organized by the Polish Association for Behavioral Therapy has been completed. There were lectures at an integrated school on systemic cryotherapy for parents of autistic children, teachers, school counselors and psychologists dealing with these children. Parents declared that they would like to use systemic cryostimulation with their children (it was possible). Physiotherapists had 6 meetings with children at school, they carried out an examination of fine and gross motor skills in children who were to use it. The respondents got acquainted with therapists, 2 physiotherapists for each child were appointed, following the observations and suggestions of psychologists and school counselors. Organisational arrangements were made, the first familiarization with the hospital and the procedure was established. The psychologists and school counselors prepared the Cars and Chat scales and prepared for the research. The first group of autistic children visited the Healing Improvement Center together with their parents and caregivers – in order to get to know the new place, the dates of meetings were set. The condition for starting the research was always the presence of the child's parent or a caregiver during the procedure, in order to eliminate quickly undesirable behaviors or new ones that arose. Each child had a diary in which physiotherapeutic observations were recorded for a psychologist or school counselor. Only 3 people from the group of 20 agreed to continue the research. Parents were guaranteed free transport and systemic cryotherapy treatments, with the children of course. The next step was to prepare another group at another integration school on the same principles. The treatment is preceded by a medical examination at the Rehabilitation Centre after a referral from the child's physician (first contact or a specialist). Unfortunately, the parents did not say everything about their children's health before, especially about taking medications, especially neuroleptics. 57 students diagnosed with autism were qualified for the study, after eliminating contraindications to cryotherapy, 30 children were qualified for cryotherapy, with 11 children finally taking part in the procedures in the cryochamber. Two physiotherapists were

reassigned to each child due to the specific nature of the disease (in case one of them was absent). An individual exercise programme adapted to the child's abilities was established. The examination of an autistic child is difficult, it requires the selection of measurement and analytical methods, as well as concentration of the researchers. Physiotherapists did not predict certain behaviors, they were bitten, scratched, beaten and bruised.Physical activities included fine and gross motor skills, exercises were frequently changed to stimulate the nervous system and quest autonomy. Efforts were made for the therapist to protect, sometimes and to help as little as possible. Locomotion exercises included: cycling, kicking a ball and an obstacle course made of soft elements was built. It required walking over obstacles, deliberately placing the feet in the indicated place, performing a haemostatic step and walking on a ramp as well as climbing and descending stairs. The agility exercises included: rolling, crawling, throwing balls and bags into a basket, and throwing and grabbing a large ball and giving it to the physiotherapist.

During each visit, blood pressure was measured and compared with the measurements taken in healthy and training children at two Warsaw schools in the same age range, the studies did not show any differences. It was planned to use an inactive cryogenic chamber, then a vestibule with a temperature of -60°C. The children lay down on the floor, took off their clogs, banged their heads against the walls of the rooms. It was determined established that some children, unfortunately, couldn't benefit from the procedure due to these reactions. One child completed a series of 10 treatments in a cryochamber at -110°C, other 3 had more than half of the series and three had less than half of the series. Two children refused to continue the procedure after 30 seconds, and other two refused to enter the cryochamber. In the boy who completed a series of 10 treatments in the cryogenic chamber with a temperature of -110°C and a stay for 2 minutes, no undesirable new behaviors and the appearance of new ones were noticed.

The test results did not improve motor skills. The child knows all the streets of Warsaw with their topography. He surprised with phenomenal memory. He rode a stationary bike for 15 minutes after the procedure, exercised his feet due to his flat feet, and was very fond of the obstacle course. The huge cooperation with the mother, who took an active part in the classes, resulted in such an effect. The success of the results was also influenced by external situations, the room, the equipment, the therapists and their personalities. The question should be asked about the meaning and necessity of successful systemic cryostimulation therapy with kinesiotherapy. The less cooperation between the caregivers, the worse the results. In order to implement this programme, the child must be prepared in terms of basic motor factors. Movement is a very important element for handicapped children, it seemed that the combination with cryotherapy would increase its effectiveness.

RESULTS

The cooperation of many people from various fields of medicine gives good therapeutic effects to autistic patients, an indispensable element is the involvement of their caregivers. Fine and gross motor kinesiotherapy skills applied in these children in combination with systemic cryostimulation did not change. After applying a series of 10 treatments, no new undesirable behaviors appeared in the autistic boy. When applying certain physical procedures, particular attention should be paid to the level of intellectual disability. It seems that appropriate and effective methods should still be searched for, with probably less preparation effort.

CONCLUSIONS

1. The use of systemic cryostimulation did not affect the appearance of undesirable new behaviors in an autistic child.
2. A series of 10 systemic cryotherapy treatments did not improve fine and gross motor skills in the child.
3. In order to implement the therapeutic programme, the child must demonstrate basic, specific motor activities.
4. An important element of the therapy is the cooperation of the child's caregivers – the smaller it is, the worse the results are.

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Conflict of interest:
The Authors declare no conflict of interest

Received: 18.03.2022
Accepted: 10.11.2022

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Info

POLISH ASSOCIATION OF HEALTH RESORT PATIENTS

On the initiative of Professor Irena Ponikowska, the Polish Association of Health Resort Patients was established in 2019. The Association aims to integrate patients using health resort treatment, increase the availability of health resort treatment for subjects in need, improve the quality of services provided in the health resort treatment sector, cooperate with doctors and health resort treatment facilities, and involve in patient education.

Each member of the Association will be able to benefit from discounts in fees for stay and treatment, during commercial stays in selected health resort treatment facilities, and take part in conferences, workshops, and consultations organized by the Association.

Natural and legal persons may be members of the Association. Membership in the Association for natural persons is free, whereas legal persons may become supporting members.

We invite both patients and companies operating in the field of health resort medicine to work together.

Please visit the website of the Association udrowiskowi.eu where you will find more information as well as a declaration of joining the Association.

The Board of the Polish Association of Health Resort Patients

Balneotherapy and Health-related Quality of Life in Adults with Knee Osteoarthritis: a Prospective Observational Study Into a Real Clinical Practice Condition

Balneoterapia i jakość życia związana ze zdrowiem wśród dorosłych z chorobą zwyrodnieniową stawów kolanowych: prospektywne badanie obserwacyjne rzeczywistego stanu praktyki klinicznej

DOI: 10.36740/ABAL202206103

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SUMMARY

Aim: To analyze the influence of balneotherapy applied in conditions of real clinical practice in Fitero's Thermal Station (Spain) on HRQoL in adults with KOA.

Materials and Methods: This was a prospective observational study conducted under conditions of real clinical practice with a 9-month follow-up. The individuals were beneficiaries of the Spanish social thermalism programme. A total of 10 sessions were prescribed, individually, considering the clinical situation and preferences of each participant. In all cases, 10 bath sessions were administered, along with other techniques. The clinical assessments were conducted before initiating the balneotherapy and 1, 3, 6 and 9 months after. The main variable was HRQoL (Euroqol 5D-5L; WOMAC). The statistical analysis was performed by intention to treat.

Results: The study included 71 users. At 6 months, improvements were found in the following dimensions of the WOMAC questionnaire: pain (24.47%), stiffness (30.75%) and functional capacity (26.66%) ($p<0.05$). Pain and anxiety/depression showed statistically significant differences in the EQ 5D-5L throughout the study.

Conclusions: HRQoL in KOA would improve with the Balneotherapy, prevailing the effects for up to 6 months. The absence of adverse effects and the ease of completing the treatment provided by the Spanish social thermalism system make this treatment feasible.

Key words: knee osteoarthritis, balneology, quality of life, balneotherapy, chronic disease.

Słowa kluczowe: choroba zwyrodnieniowa stawu kolanowego, balneologia, jakość życia, balneoterapia, choroba przewlekła

Acta Balneol, TOM LXIV, Nr 6(172);2022:507-516

INTRODUCTION

Knee osteoarthritis (KOA) is a chronic articular pathology that affects 20-25% of the adult population [1, 2] and, specifically in Spain, its prevalence is estimated to be 20-30%, depending on age [3,4]. The care and management of this disease poses a considerable burden in terms of direct, indirect, personal and social costs [5-9]; in fact, it has been estimated that the yearly direct costs of people with KOA can be up to twice as high compared to those of people without KOA [10]. Considering the increase in life expectancy [4] and that the prevalence of this disease increases with the aging of the population, KOA can be regarded as a first-order problem.

KOA is characterized for producing pain, stiffness and limitation of joint mobility, affecting health-related quality of life (HRQoL), which is influenced by factors such as age, gender, BMI, physical activity level, psychological state, socioeconomic state and education level [11]. The care and management of KOA require a multidisciplinary approach that includes surgical, pharmacological and non-pharmacological treatments. Among the non-pharmacological treatments, there seems to be consensus on recommending therapeutic exercise programmes (both ground and aquatic training), the reduction of body weight in overweight individuals and the application of educational measures about the disease [12, 13].

Balneotherapy is defined as the therapeutic use of natural mineral water or its derivatives (gases and peloids) with different ways of application (bathing or drinking) [14, 15]. It is widely used in Europe, with different studies supporting its efficacy on degenerative pathologies of the locomotor system as one of its main indications [16]; moreover, spas are very suitable environments to perform multidisciplinary health interventions and education activities [17]. However, it is rarely included in clinical guidelines, and it only appears in the recommendations of the Osteoarthritis Research Society International (OARSI) for individuals with multiple-join arthrosis with comorbidities [12], and in the consensus document created by experts following the Delphi method in Italy [18].

Multiple clinical studies that use different types of mineral waters, peloids or combinations of both have assessed HRQoL in individuals with KOA, and such studies have been analysed in systematic reviews and metaanalyses [19-22] that report on the effect of these treatments. Furthermore, in vitro and animal studies have shown an anti-inflammatory, antioxidant, chondroprotective and immunosuppressant effect at the cellular level [23], and its action may be due to a combination of mechanical, thermal and chemical factors [24]. However, few studies have been conducted under real clinical practice conditions. Unlike clinical trials, which are carried out in controlled environments and include homogenous groups of patients, real clinical practice studies are performed in non-selected patients. This type of studies would provide additional evidence to clinical trials.

AIM

The aim of the present study was to analyse the influence of balneotherapy applied in real clinical practice conditions in Fitero´s Thermal Station on the HRQoL of adults with KOA.

MATERIALS AND METHODS

STUDY DESIGN

We conducted a single-group prospective observational study under conditions of real clinical practice at Fitero's Thermal Station (Navarra, Spain) between May 2018 and February 2020, with a 9-month follow-up. The study was registered at ClinicalTrials.gov (NCT03952897), approved by the Clinical Research Committee of the Toledo Hospital (Reg. 14/07/2017), and complies with the principles of the Declaration of Helsinki, the rules of Good Clinical Practice and the legal requirements established for this type of studies.

PARTICIPANTS

The study sample was recruited among the users of Fitero's Thermal Station that benefited from the social thermalism programme of the Spanish Ministry of Health, Consumer Affairs and Social Welfare, who were from all over the Spanish territory. The sample consisted of men and women of 60-80 years of age, diagnosed with knee osteoarthritis according to the criteria of the American College of Rheumatology [25, 26], with the prescription of a 10-day balneotherapy treatment, and who were capable of filling up the questionnaires and giving their informed consent. The study excluded the individuals who had carried out a balneotherapy within 6 months prior to the intervention, and those who were planning to do it within the following 6 months.

The participants were recruited at the doctor's office of Fitero's Thermal Station by consecutive sampling during the months of May 2018, and in May 2019.

PROCEDURES AND INTERVENTION

The study was carried out in Fitero's Thermal Station, whose water is hyperthermal, highly mineralized, chlorinated-sulfated-sodic-calcic and radioactive [27] (see water composition in Table 1).

The physician of the thermal station prescribed the balneotherapeutic treatment to each participant individually, considering their clinical situation and preferences.

In all cases, 10 sessions of balneotherapy were prescribed, which included bath (15 minutes at 38°C) and other techniques. The latter varied between cases and included circular shower (15 min at 38°C), jet (10 min at 40-42°C), steam bath (15 min at 45°C and 100% humidity) and mobilization in the swimming pool (20 min at 32-34°C).

After the physician gave the treatment prescription, subjects were asked to participate in the study and sign the informed consent.

Table 1. Physical and chemical characteristics of the mineral water of Fitero's Thermal Station (Spain)

Temperature (˚C)			46.2
Conductivity at 25˚C (µS cm^{-1})			7200
pH			6.3
Residual dry matter at 180˚C (mg/L)			4915
ANIONS			
	mg/L	mEq/L	% meq
Cl^-	1481.6	41.797	58.17
F^-	1.0	0.052	0.07
HCO_3^-	109.8	1.800	2.50
CO_3^{2-}	0.0	0.0	0.0
NO_3^-	0.0	0.0	0.0
SH^-	0.0	0.0	0.0
SO_4^{2-}	1355.0	28.211	39.26
CATIONS			
	mg/L	mEq/L	% mEq
Na^+	955.0	41.544	58.27
K^+	31.8	0.825	1.16
Li^+	0.3	0.046	0.06
Ca^{2+}	432.7	21.593	30.29
Mg^{2+}	88.5	7.281	10.21
Sr^{2+}	0.0	0.0	0.0
Fe total	0.2	0.008	0.01
DILUTE GASES			
CO_2 (mg/L)			24.8
SH_2 (mg/L)			0.0
Rn^{222} (Bq/L)			100

The assessments (A) were performed immediately before starting the balneotherapy (day 0: A0) through a personal interview and the post-treatment assessments, via telephone, at months 1 (A_1), 3 (A_2), 6 (A_3) and 9 (A_4). In all cases, the same member of the research team was in charge of conducting the evaluations. Moreover, when the stay at the thermal station finished, the completion of the prescribed treatment was verified, as well as possible incidents.

OUTCOME MEASURES

The main outcome variable was the HRQoL obtained through the Euroqol 5D-5L questionnaire [28] and the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) [29], which had been validated in Spanish to be self-administered or administered through interview or phone call.

EuroQol 5D 5L: it is an instrument used to evaluate HRQoL in general populations. It assesses 5 dimensions of HRQoL: mobility, self-care, the capacity to perform acitivities of daily living, pain/discomfort, and anxiety/depression. The score of the items ranges from 1 (absence of problems) to 5 (presence of extreme problems). The answers to these dimensions provide a state of health from which the EuroQol index is calculated.

Furthermore, the perception of the individual toward his/her health state on the day when the questionnaire is completed was evaluate using the EQ-5D visual analogue scale (EQ-5D-VAS), which scores from 0 to 100, with 0 being the worst possible state and 100 the best. The estimated minimal important differences of the EuroQol index is 0.15 [30].

The Western Ontario and McMaster Universities Arthritis Index (WOMAC) is a specific questionnaire of the lower limb to evaluate HRQoL in individuals with knee and/or pelvis arthrosis. It consists of 24 questions scored from 0 (no, without difficulty or no symptom) to 4 (unable to engage in activities or extreme symptoms). Physical function, pain and stiffness are assessed by 17, 5 and 2 questions, respectively. From a total achievable score of 96 points, a lower score indicates less severe symptoms or physical disability. The minimal important differences estimated for the pain and function subscales of WOMAC are 12/100 and 13/100, respectively [30].

Furthermore, identifying, sociodemographic and clinical variables were recorded, as well as variables related to the balneotherapeutic treatment. In the follow-up assessments, the participants were also asked about variations in their pharmacological treatment, the possible surgical treatment of KOA, and the appearance of new diseases, accidents or hospitalizations.

SAMPLE SIZE

We calculated the minimum sample size needed to detect a difference equal to or higher than 0.1 in the EQ-5D index, assuming a standard deviation of 0.2 [31], and accepting an error of $\alpha = 0.05$ and a risk of $\beta = 0.2$ in a bilateral test. Assuming follow-up losses of 30%, the minimum sample size required was considered to be 52 individuals. The sample size was estimated using the EPIDAT v.4.2 statistical software.

STATISTICAL ANALYSIS

To minimize the possible bias from loss of patients in the follow-up, we performed an intention-to-treat analysis, giving the worse value obtained in each measurement to the participants that abandoned the follow-up.

The continuous variables were described using the mean and standard deviation, after verifying that they had a normal distribution, according to the Kolmogorov-Smirnov test. The dichotomous or polychotomous variables were described by their percentage with respect to the group.

The 5 answer levels of the EQ 5D-5L questionnaire were dychotomised into "no problems/problems", as is recommended by the EQ-5D-5L User Guide [32], and they were analysed using Mc Nemar's test for repeated measures.

The variations in the scores of VAS-EQ, EQ Index and the three dimensions of WOMAC along time were evaluated through ANOVA of repeated measures, using the Bonferroni correction for multiple comparisons. Similarly, we analysed the possible differences in subgroups according to age, sex, employment situation, social class, education level, BMI, date of KOA diagnosis and pharmacological treatment conducted. The results are presented as mean difference, confidence interval and p-value.

All those values with p-value < 0.05 were considered statistically significant. The statistical analysis of the data was performed using IBM® SPSS® Statistics 23 software.

RESULTS

Of the 5,898 users registered in the thermal station during the recruitment period, 4,479 had been diagnosed with knee arthrosis and were thus evaluated for eligibility. Of these, 1,359 did not meet the age criteria, 2,217 had followed another balneotherapeutic treatment within the previous 6 months, 831 had one scheduled within the following 6 months, and 1 user refused to participate in this study. Finally, 71 participants were included in the study. During the follow-up period, 20 participants were lost: 5 in the first month, 3 in the third month, 6 in the sixth month and 6 in the ninth month. All participants included in the study completed the balneotherapeutic treatment (Figure 1).

The baseline sociodemographic and clinical characteristics of the 71 participants of this study are shown in Table 2. The average age of the participants was 71.22 years (SD: 5.26). Regarding sex, 64.8% of the participants were women. Married was the predominant civil status (78.9%), and almost all participants were retired (97.2%). With respect to education level, 40.9% had a high school diploma or higher, and the predominant social class was IV, i.e., skilled worker (28.2%). The average BMI was 27.47 Kg/m^2 (SD: 2.90). In 76.1% of cases, KOA had been diagnosed over 5 years before the study and 35.21% were under a pharmacological treatment for arthrosis.

ANALYSIS OF HRQOL
EUROQOL 5D-5L

Table 3 shows the frequencies and proportions of responses by dimensions and grouping the levels based on

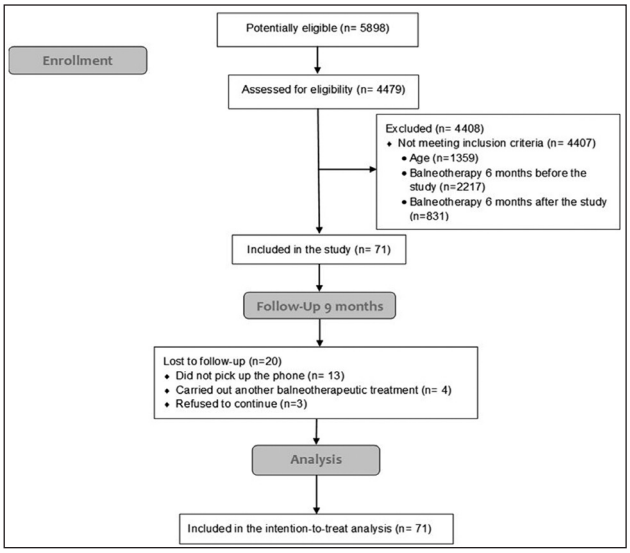

Figure 1. Flow chart of participants in the study

Table 2. Baseline characteristics of the individuals included in the study

VARIABLES	Total (n=71)
Age x̄ (SD)	71.22 (5.26)
Sex n (%)	Men: 25 (35.2) Women: 46 (64.8)
Marital status n (%)	Single: 6 (8.5) Married: 56 (78.9) Widow: 9 (12.7)
Employment situation n (%)	Retired: 69 (97.2) Unemployed: 1 (1,4) Active: 1 (1.4)
Social class n (%)	I - 7 (9.9) II - 8 (11.3) III - 12 (16.9) IV - 20 (28.2) V - 6 (8.5) VI - 11 (15.5) Missing data: 7 (9.9)
Education level n (%)	Primary incomplete: 9 (12.7) Primary complete: 27 (38.0) Secondary first stage: 5 (7.0) A level/VT: 18 (25.4) University degree: 11 (15.5) Missing data: 1 (1.4)
BMI (Kg/m^2) x̄ (SD)	27.47 (2.90)
KOA diagnosis date (years) n (%)	< 5: 15 (21.1) >5: 54 (76.1) Missing data: 2 (2.8)
Pharmacological treatment of KOA n (%)	Yes: 25 (35.21) No: 46 (64.78)

x̄: mean; SD: standard deviation; BMI: body mass index; KOA: knee osteoarthritis.

the presence or absence of problems of the EuroQol 5D-5L. The responses disaggregated into the five levels are gathered in the supplementary material (Proportion of responses by level of severity for EQ-5D-5L dimensions at baseline and at follow-up, Figures 3-7). As can be observed, the number of individuals without pain increases along the follow-up time, being statistically significant up to the ninth month. Similarly, the number of patients without anxiety/depression increases significantly up to the third month. No improvement was detected in the perception of the health state measured with VAS-EuroQol or in the EQ Index (Table 4).

WOMAC

The 3 dimensions of the WOMAC questionnaire improved significantly up to the sixth month in all cases, except for pain at 3 months, whose improvement was not significant, although it was close to significance (p= 0.079) (Figure 2). At 1 month after the end of the treatment (follow-up A1), the percentage of improvement with respect to the baseline value were 29.51% for pain, 43.61% for stiffness, and 37.41% for general functional capacity. At 6 months after the end of the treatment (follow-up A3), these percentages were 24.47%, 30.75% and 26.66%, respectively (Table 5).

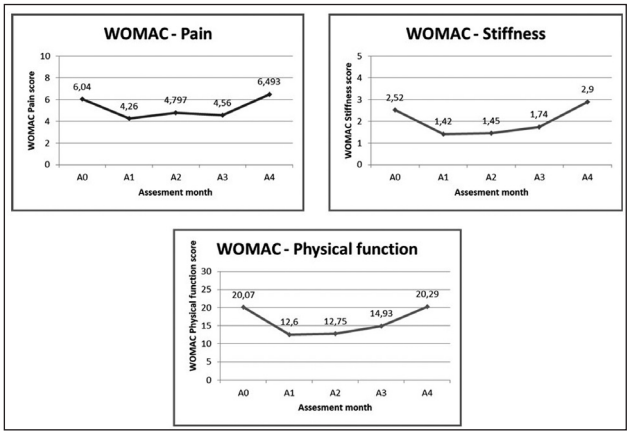

Figure 2. Scores of the WOMAC dimensions throughout the study

QUALITY OF LIFE, ANALYSED BY SUBGROUPS

In the HRQoL subgroup analysis of the perception of the health state measured with VAS-EuroQol, the EuroQol index and the pain, stiffness and physical capacity dimensions of WOMAC, no differences were found based on sex, age, education level, social class, KOA diagnosis date, BMI or pharmacological treatment.

DISCUSSION

In this study, we evaluated HRQoL in individuals with KOA at 1, 3, 6 and 9 months after a balneotherapeutic treatment, under real clinical practice conditions, in Fitero's Thermal Station (Spain), finding improvements in all the dimensions of the WOMAC questionnaire, and an increase in the number of patients who did not present pain in the EQ 5D-5L questionnaire, which prevailed for 6 months after the treatment. During the revisions, the participants were asked about variations in the pharmacological treatment, surgical treatments, accidents, hospitalisations and visits to the ER, which were minimal and did not seem to influence the results.

The sociodemographic characteristics of the sample were similar to those of other studies on KOA, balneotherapy

Table 3. Responses by dimensions of the EuroQol 5D-5L questionnaire

DIMENSIONS of the EQ 5D -5L	Level	A_0	A_1	A_2	A_3	A_4
MOBILITY	No problems	29(40.8%)	29(40.8%)	32(45.1%)	23(32.4%)	19(26.8%)
n (%)	Problems	42(59.2%)	37(52.1%)	31(43.7%)	34(47.9%)	32(45.1%)
SELF-CARE	No problems	59(83.1%)	61(85.9%)	57(80.3%)	49(69.0%)	41(57.7%)
n (%)	Problems	12(16.9%)	5(7.0%)	6(8.5%)	8(11.3%)	10(14.1%)
ACTIVITIES OF DAILY LIVING	No problems	46(64.8%)	48(67.6%)	47(66.2%)	43(60.6%)	27(38.0%)
n (%)	Problems	25(35.2%)	18(25.4%)	16(22.5%)	14(19.7%)	24(33.8%)
PAIN	No problems	2(2.8%)	13(18.3%)*	19(26.8%)*	13(18.3%)*	12(16.9%)*
n (%)	Problems	69(97.2%)	53(74.6%)	44(62.0%)	44(62.0%)	39(54.9%)
ANXIETY/ DEPRESSION	No problems	46(64.8%)	57(80.3%)*	57(80.3%)*	47(66.2%)	41(57.7)
n (%)	Problems	25(35.2%)	9(12.7%)	6(8.5%)	10(14.1%)	10(14.1%)

** P< 0.05; A0: baseline assessment; A1: assessment at 1 month; A2: assessment at 3 months; A3: assessment at 6 months; A4: assessment at 9 months.*

Table 4. Comparison of the results of the VAS-EuroQol and EQ Index during the follow-up

	A_0 Mean (SD)	A_1-A_0 Mean dif. [CI95%] p	A_2-A_0 Mean dif. [CI95%] p	A_3-A_0 Mean dif. [CI95%] p	A_4-A_0 Mean dif. [CI95%] p
VAS-EuroQol	74.014 (13.539)	-2.085 [-7.469 a 3.299] p=1.000	-6.324 [-13.487 a 0.839] p =0.127	-7.099 [-14.195 a -0.001] p=0.05	-4.718 [-10.318 a 0.881] p=0.171
EQ Index	0.769 (0.128)	0.029 [-0.018 a 0.077] p= 0.794	0.048 [-0.003 a 0.100] p=0.079	-0.039 [-0.115 a 0.036] p=1.000	-0.149 [-0.243 a -0.054] p<0.001

VAS: Visual Analogue Scale; Statistical significance when p value is < 0.05; SD: standard deviation; Mean dif.: mean difference; A0: baseline assessment; A1: assessment at 1 month; A2: assessment at 3 months; A3: assessment at 6 months; A4: assessment at 9 months.

Table 5. Comparison of the results of the WOMAC dimensions during the follow-up

	A_0 Mean (SD)	A_1-A_0 Mean dif. [CI95%] p	A_2-A_0 Mean dif. [CI95%] p	A_3-A_0 Mean dif. [CI95%] p	A_4-A_0 Mean dif. [CI95%] p
WOMAC-PAIN (0-20)	6.044 (2.687)	-1.783 [-2.816 a -0.749] p<0.001	-1.246 [-2.561 a -0.068] p=0.076	-1.478 [-2.638 a -0.319] p=0.004	0.449 [-1.622 a 2.521] p=1.000
WOMAC-STIFFNESS (0-8)	2.521 (1.584)	-1.099 [-1.683 a -0.514] p<0.001	-1.070 [-1.776 a -0.365] p<0.001	-0.775 [-1.499 a -0.050] p=0.028	0.380 [-0.761 a 1.522] p= 1.000
WOMAC-PHYSICAL CAPACITY (0-68)	20.077 (9.271)	-7.477 [-11.498 a -3.456] p<0.001	-7,323 [-11.856 a -2.790] p<0.001	-5.138 [-9.450 a -0.827] p=0.01	0.215 [-5.586 a 6.016] p=1.000

Statistical significance when p value is < 0.05; SD: standard deviation; Mean dif.: mean difference; A0: baseline assessment; A1: assessment at 1 month; A2: assessment at 3 months; A3: assessment at 6 months; A4: assessment at 9 months.

and quality of life [33-37], and the sample size, despite the 20 losses at 9 months, was enough to detect the changes. An intention to treat analysis was used to control possible biases and follow-up losses.

The initial HRQoL of the individuals (0.769) obtained in the EQ index was lower compared to the one obtained in the national health survey for the Spanish population with arthrosis, arthritis or rheumatisms (0.908) [38] and higher than that obtained in a different study that analysed the EQ index in a Spanish population with KOA (0.544) [39]. This could be because the national health survey includes all age groups and different rheumatic pathologies without specifying the area of affectation, as well as to the fact that the study of García-Perez et al. included individuals from traumatology and rheumatology. Thus, the latter may correspond to cases with a worse evolution of the disease, whereas the individuals who participate in the social thermalism programme must request it personally, which implies willing to move from home during the course of the programme and being self-sufficient.

Several meta-analyses have reported on the benefits of balneotherapy on the improvement HRQoL in KOA

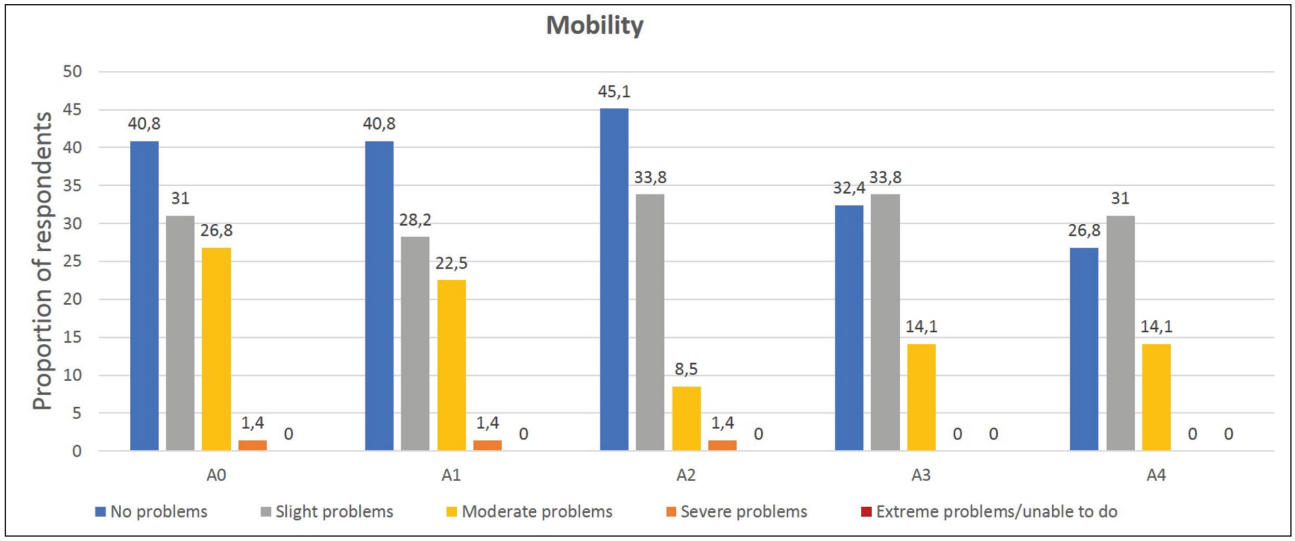

Figure 3. Proportion of responses by level of severity for EQ-5D-5L dimensions at baseline and at follow-up

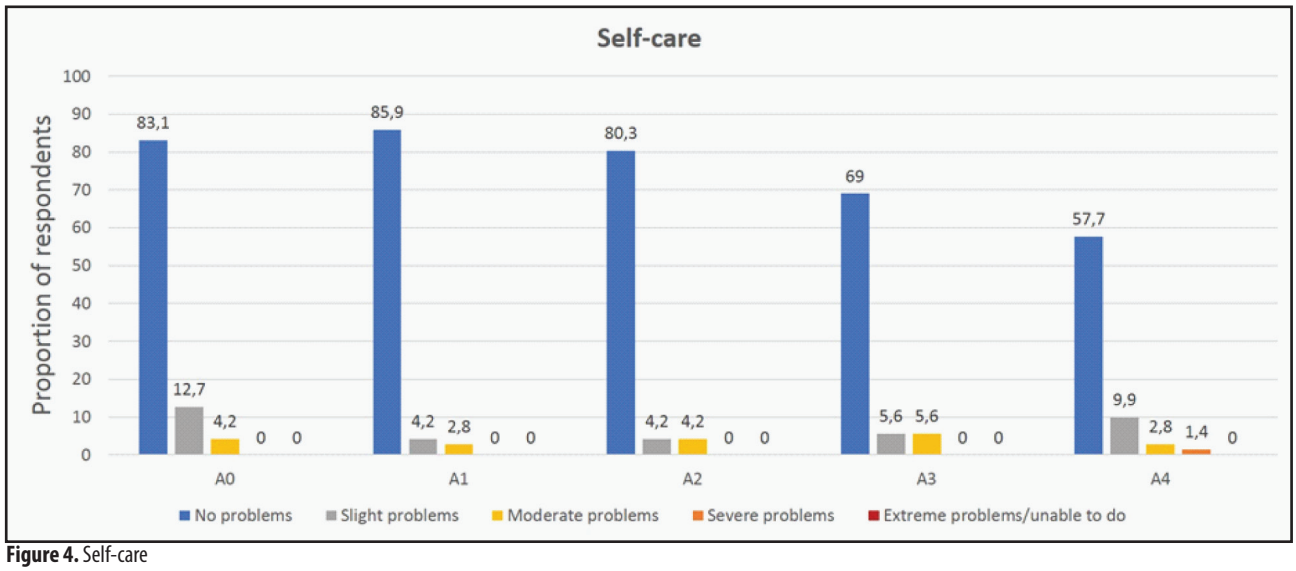

Figure 4. Self-care

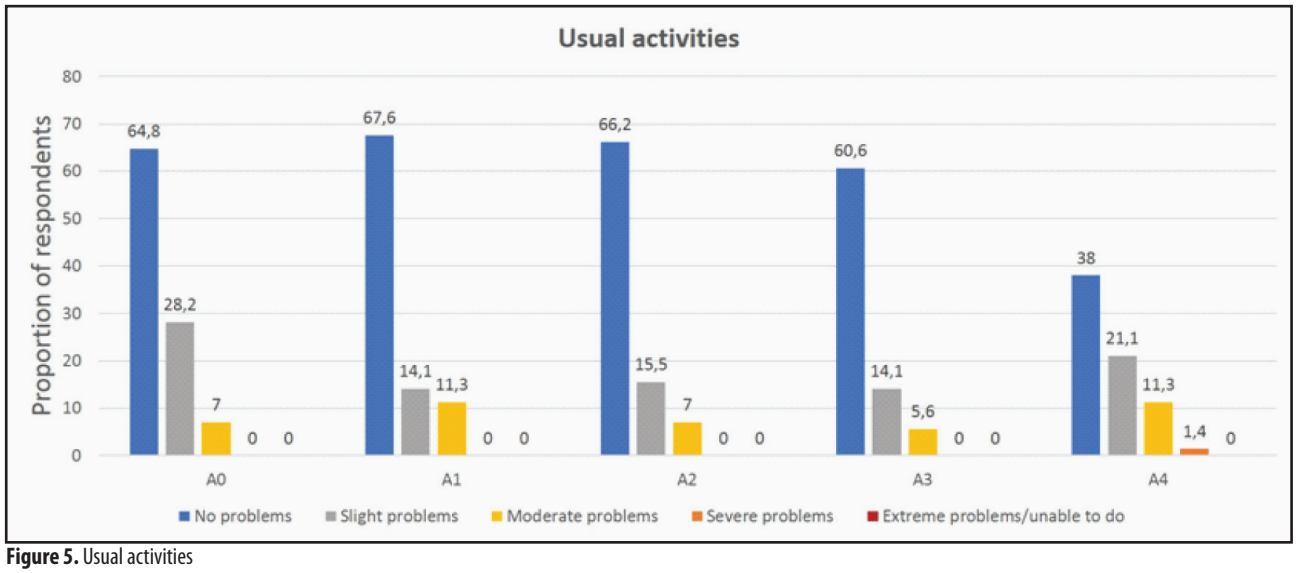

Figure 5. Usual activities

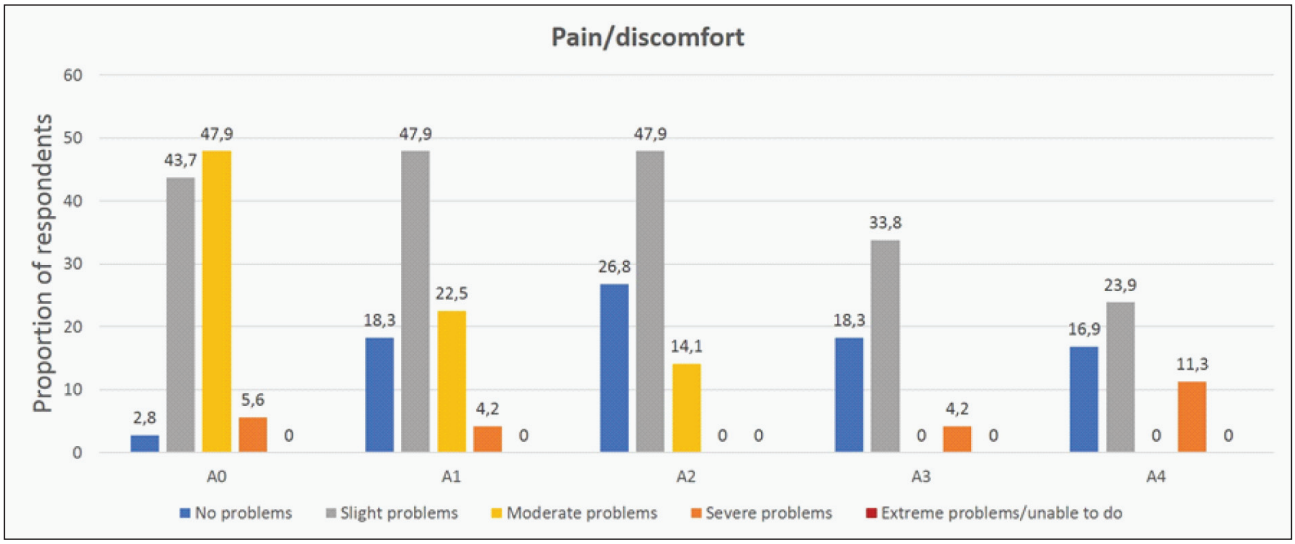

Figure 6. Pain/discomfort

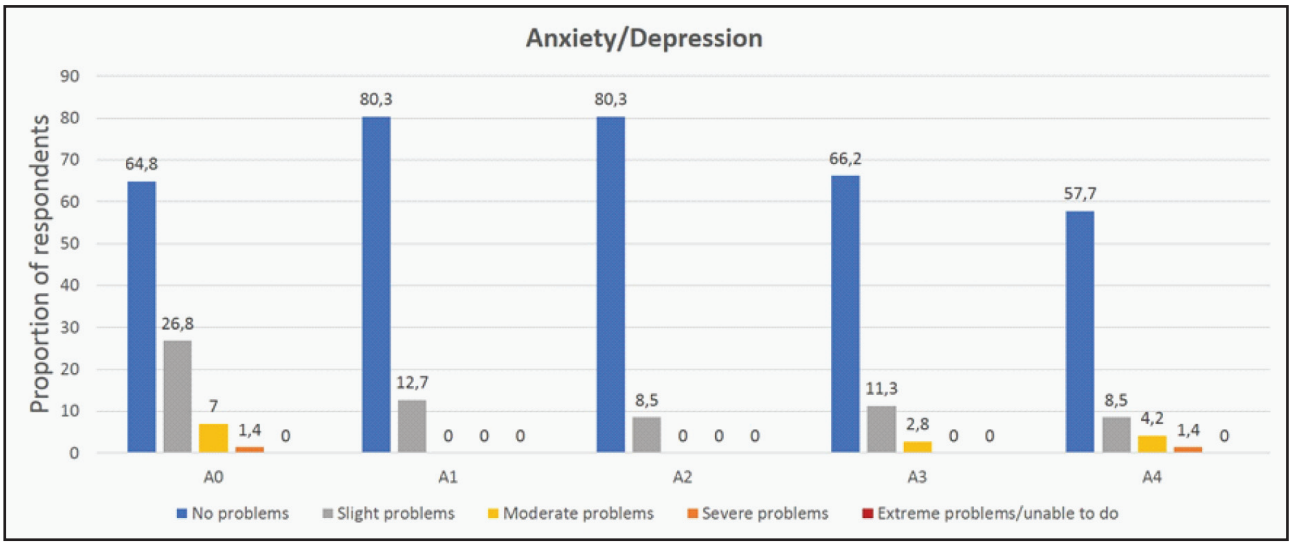

Figure 7. Anxiety/depression

patients [21, 22]. In the present study, statistically significant improvements were obtained [40], in the 3 subscales of the WOMAC questionnaire. These improvements reached the clinically relevant minimum change [30], and they were similar to those obtained in the intervention groups of several published randomised controlled clinical trials [20, 34, 35, 41], prolonging the detected effect, as in other studies, for up to 6 months [37, 42, 43].

Significant differences were not found in the EQ Index; however, considering that a statistical analysis by intention to treat was conducted and the Bonferroni correction was used, the actual values should be slightly better.

The dimensions of the EuroQol 5D-5L questionnaire that showed improvement were pain and anxiety/depression. Several studies support the effect of balneotherapy on anxiety and chronic pain [44, 45]. However, to the best of our knowledge, there are no studies to date that provide similar results about the state of anxiety/depression in KOA patients, nor can we explain this effect, although in the classic texts of medical hydrology [46-48] radioactive waters seem to be indicated in depressive states, due to their regulatory action on the neurovegetative tone, and this effect could also be related to the characteristics of the thermal station environment [24]. It would be interesting to delve into the knowledge of the influence of balneotherapy on the state of mind.

Few studies have used chlorinated [49, 50] or radioactive water [51] in KOA, which are predominant in Fitero's Thermal Station. As in the present work, these studies show statistically significant improvements on pain and physical condition, which prevail for at least 6 months.

The mechanisms of action of this type of water are poorly known. The studies conducted to date on radon therapy in humans associate them with an antioxidant effect and on the immune response [52], an anti-inflammatory effect [53], an analgesic effect [54] and a modulatory effect on bone metabolism [55]. Regarding the mechanisms of action of

chlorinated water, they are known to act through cellular osmosis, being capable of activating/inhibiting apoptosis and cell necrosis, participating in mechanotransduction mechanisms through ion channels, and they could be involved in multiple biological processes [56].

The main limitations of this study were the absence of a control group, which does not allow knowing the real size of the effect on HRQoL, the number of participants lost during the follow-up and the possible modifications of the pharmacological treatment, which were gathered as a dichotomous variable (yes/no).

It would be interesting for future studies to delve into the mechanisms of action of radioactive water and analyse its possible effect on emotional and mental state.

CONCLUSIONS

Despite the limitations of this study, considering that both the characteristics of the sample and the obtained results are similar to those obtained in the intervention groups of other RCTs, we can conclude that HRQoL in KOA can be improved with the treatment at Fitero's Thermal Station, and this effect could prevail for at least 6 months.

Considering the absence of adverse effects and the ease of treatment completion offered by the Spanish social thermalism system, the application of balneotherapy seems to be viable in the treatment of KOA.

The study was registered on May 24, 2019, at ClinicalTrials.gov (NCT03952897).

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Conflict of interest:
The Authors declare no conflict of interest

Received: 12.04.2022
Accepted: 25.10.2022

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Info

V SPOTKANIE EKSPERTÓW FIZJOTERAPIA-ORTOPEDIA-REUMATOLOGIA

Ramowy program:
1. Ból przewlekły - nowa jednostka chorobowa
2. Terapia ukierunkowana na potrzeby pacjenta.
3. Przełożenie badań naukowych na praktykę w gabinecie

Spotkanie Ekspertów to wyjątkowa inicjatywa, która od 5 lat dostarcza naukowych doznań na najwyższym poziomie. Inicjatywa, która tworzy unikalną przestrzeń do skonfrontowania różnych idei, swobodnej wymiany poglądów i doświadczeń, wypracowania nowych rozwiązań pomiędzy najwybitniejszymi specjalistami ze swoich dziedzin z kręgu fizjoterapii, ortopedii, reumatologi i nie tylko. Tematem tegorocznego spotkania wybitnych polskich i zagranicznych ekspertów będzie szeroko rozumiana problematyka bólu przewlekłego i jego leczenia. Istotą spotkania będzie podkreślenie roli współpracy lekarza i fizjoterapeuty w podnoszeniu skuteczności proponowanych procedur i oddziaływań medycznych, skróceniu czasu niepełnosprawności pacjenta oraz poprawie jego jakości życia

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Effectiveness of Vascular Balneotherapy in the Treatment of Chronic Venous Disease (CVD)

Skuteczność balneoterapii naczyniowej w leczeniu przewlekłej choroby żylnej

DOI: 10.36740/ABAL202206104

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SUMMARY

Aim: Inside the "Antica Querciolaia" Thermal Station, located in the municipality of Rapolano Terme (Siena), there is a well, called "Well 5 – Cold Bath", from which gushes a homeothermic alkaline bicarbonate-sulphate mineral water, considered suitable for thermal use with venous vascular address. The main endpoint of the study was to demonstrate the effects of vascular balneotherapy with thermal mineral water on classical symptoms, such as edema and quality of life of patients with chronic venous disease in the lower limbs, while the secondary endpoint was to verify the efficacy and tolerability of vascular balneotherapy carried out in predefined vascular paths and with a standardized protocol.

Materials and Methods: In the double-blind, randomized controlled study, 60 patients with chronic venous disease of the lower limbs were enrolled in the first three stages of the CEAP classification. The patients were divided into two equivalent groups: "Balneotherapy Group", treated with baths in thermal mineral water from "Well 5 – Cold Bath" and venoactive drug therapy and "Control Group" which only took drug therapy in an equivalent dose and duration.

Results: The results of the study show a clear improvement of the "Balneotherapy Group" compared to the "Control Group" in the treatment of chronic venous disease of the lower limbs, concerning both the primary and secondary endpoints set by the study.

Conclusions: Our findings show the undoubted efficacy and excellent tolerability of vascular balneotherapy in the treatment of chronic venous disease of the lower limbs.

Key words: chronic venous disease, balneotherapy, quality of life, edema

Słowa kluczowe: przewlekła choroba żylna, balneoterapia, jakość życia, obrzęk

Acta Balneol, TOM LXIV, Nr 6(172);2022:517-522

INTRODUCTION

There are many people affected by venous problems, in fact, only in Italy, venous disease is one of the first causes of pathology, with very high percentages of the population (between 30 and 50%, with prevalence in women) suffering from veins varicose or related diseases [1].

Diseases of the veins of the lower limbs, often of multiple origin (varices, venous thrombosis, angiodysplasias, etc.), all lead to venous insufficiency, understood as the inability of the venous system to perform its functions effectively. Venous insufficiency can therefore also be established for non-venous causes in the strict sense, but it can also be caused by non-vascular factors, such as muscular or orthopedic diseases of the lower limbs [2, 3].

Many patients with chronic venous disease (CVD) of the lower limbs are treated in Europe with different forms of physical therapy in water and a considerable number of doctors and patients believe in the beneficial effect of these methods [4, 5], but still today there are relatively few clinical trials demonstrating these results [6, 7]. In Italy, physical treatments in water for patients with CVD include from simple thermal baths to vascular balneotherapy, which is mainly based on a bath with thermal water (at a temperature between 26° and 30°C) associated with an active walk, with immersion of the lower limbs only, along pre-established vascular paths [8]. The observed benefits could only be attributed to the mechanical effects of the water, but thermal specialists believe that the type of mineral water used adds particular therapeutic properties, even if the clinical relevance of the available data is not yet fully clear [9].

AIM

Inside the "Antica Querciolaia" Thermal Station, located in the municipality of Rapolano Terme (Siena), there is

a well, called "Well 5 – Cold Bath", from which gushes a homeothermic alkaline bicarbonate-sulphate mineral water, with fixed residue at 180° greater than 1g/l, (analysis conducted in 2011 by Prof. Salvatore and in 2015 by Prof. Trifuoggi, both of the Chemistry Department of the University of Naples Federico II) considered suitable, on the basis of a bibliographic analysis conducted by the investigating doctors, for thermal use with venous vascular address. The need to verify the validity of vascular balneotherapy with this type of water in the treatment of chronic venous disease led us to develop a study protocol for this type of pathology, also considering that the NHS has recognized chronic phlebopathies as pathologies admitted to the group of those who find real benefit from the thermal treatment [9]. The main endpoint of the study was to demonstrate the effects of vascular balneotherapy with thermal mineral water, captured by the "Well 5 – Cold Bath" located within the same thermal station as indicated above, on classical symptoms, such as edema and quality of life of patients with chronic venous disease in the lower limbs. While the secondary endpoint was to verify the efficacy and tolerability of vascular balneotherapy carried out in predefined vascular paths and with a standardized protocol.

MATERIALS AND METHODS

In the double-blind, randomized controlled study, 60 patients, with a mean age of about 63 years (range 27-80 years), affected by chronic venous disease of the lower limbs were enrolled starting from June 2018. In all patients the venous pathology was therefore classified with a reference CEAP class [1-10] and in the case of a different class between the two limbs, only the limb affected by the greater one was taken into account, then, if in the same class, it was considered the more edematous of the two, finally the right one was considered by convention. The venous echocolordoppler of the lower limbs was used to define the nature of the venous pathology (primary or secondary), recording the morphology, the functionality of the valves, the presence or absence of pathological refluxes in the veins of the deep and/or superficial circulation, as well as the incompetence of perforating veins, all applying the classification criteria of Nicolaides [11]. All patients affected by CVD were admitted to the study, according to the CEAP classification and on the basis of a venous Doppler ultrasound examination of the lower limbs, performed by the specialist doctor. Only patients with CEAP stage up to class 3 were admitted to the study, while all patients enrolled in other research protocols, who had undergone thermal treatment in the previous twelve months or who had undergone sclerotherapy, surgical treatment were excluded from the study or pharmacological for CVD in the month prior to the start of the study. All patients affected by:

- Venous ulcer in active phase or other dermatological pathology in progress;
- DVT or SVT in the acute phase;
- Fontaine stage III arteriopathy;
- Decompensated diabetes or arterial hypertension;
- Recent onset cardiovascular disease (within six months);
- Serious pathologies affecting the haematopoietic, renal and hepatic systems;
- Neoplastic diseases in progress or diagnosed in the last three years.

After verifying the enrollment and obtaining the signature of the informed consent of the patients, I was randommised 1:1, through a computerized table of randomization numbers, into two groups: "Balneotherapy Group", treated with baths in thermal mineral water of the "Well 5 – Cold Bath" and drug therapy, in double daily oral administration, for forty-four days, with sulodexide and "Control Group" that took only the drug therapy indicated in an equivalent dose and duration. The collection of anamnestic and clinical data performed during the initial visit highlighted the presence of some concomitant pathologies to CVD. In particular, in the "Balneotherapy Group" eleven patients had arterial hypertension well compensated with antihypertensive drugs, one patient with non-insulin-dependent diabetes mellitus under control with oral antidiabetic drugs, three with hypercholesterolemia controlled with statins, five with diffuse osteoarthritis and finally two with prostatic hypertrophy in targeted drug therapy. While, in the "Control Group", nine patients with arterial hypertension were identified, two with non-insulin-dependent diabetes mellitus and four with hypercholesterolemia, all well compensated by suitable therapies. In the "Balneotherapy Group" 23 females were enrolled (76.6%), while in the "Control Group" 19 (63.3%). The age range was between 27 and 80 years in the first group and between 35 and 76 years in the second, but the average was approximately equivalent. Regarding the CEAP classification, all patients of both groups were symptomatic and were classified, according to their clinic (Table 1). Patients were enrolled on the report made by the General Practitioners of various areas adjacent to medical resort, because it was absolutely essential that patients continue to reside in their homes and carry out their normal daily activities, in order to avoid the placebo effect due to the stay in a thermal environment, as suggested by the most recent works of international literature, but also to eliminate daily and annoying movements for the patient enrolled in the study. The patients reported by the General Practitioners, as established in the design of the research program, made an appointment directly at the reception of the thermal establishment and carried out the visit for enrollment at the phlebological clinic of the same establishment, in order to verify, by the doctor examining specialist, the already indicated criteria for inclusion and exclusion from the study. The thirty patients affected by CVD of the lower limbs of the "Balneotherapy Group" were treated, in fact, with a cycle of vascular balneotherapy with a standardized protocol, comprising a cycle of twelve treatments, lasting twenty minutes each, performed at a daily rhythm (except for two days of interruption between the fifth and seventh day to avoid the onset of the thermal crisis) based on thermal balneotherapy in predisposed vascular paths. This path

consisted of two long pools (about 10 meters) side by side, about 70 cm deep and equipped with water at different temperatures: the first with alkaline bicarbonate-sulphate mineral waters from the "Well 5 – Cold Bath" of the "Antica Querciolaia" (about 27°C) and the other with ordinary water (about 22°C) [1]. Furthermore, both pools of the paths had a disconnected bottom, covered with large rounded pebbles, which force the patient to train both balance and walking posture, in fact this bottom, by pressing on the plantar arch, performs a squeezing function on the "insole vein of Lejars ". The two pools, parallel but not communicating, also oblige the patient to go up and down some steps at the end of the vascular corridors [2, 3]. These patients were also prescribed orally, in double daily administration, a venoactive drug with sulodexide. While the thirty patients with CVD of the lower limbs of the "Control Group" were only administered orally the same drug of the other group, in an equivalent dosage and duration. However, patients in this group were placed on a waiting list for a subsequent vascular balneotherapy treatment at the end of the study, for purely ethical reasons. The cycles of vascular balneotherapy, as well as the necessary specialist visits, were provided by the thermal station completely free of charge, therefore without charges for both patients and the NHS. For the study, a personal card was used for the collection of demographic data (with pathological and remote phlebological anamnesis), evaluation of clinical efficacy and quality of life tests. During the first and last checks, the following parameters of efficacy and tolerability of the treatment were considered:

- Evaluation of the six main symptoms of the lower limbs of venous origin (pain, heaviness, mania, itching, burning, night cramps) according to a VAS scale from 0 to 5;
- Measurement of the circumference of the ankle (point B), of the calf at maximum circumference (point C), and of the thigh root (point G) with the SIGVARIS measurement system and the height of each point measured from the heel (so as to repeat the measurement in exactly the same place);
- Overall judgment of the doctor and the patient on the efficacy and tolerability of the therapies performed, expressed as excellent, good, fair and insufficient;
- Investigation into the onset of any side effects, their severity and the search for a possible link with the therapy in progress;
- Administration of the SF-12 survey for QoL [12, 13].

All patients underwent the initial visit (T0), with venous Doppler ultrasound examination of the lower limbs and compilation of the medical record (inclusion in the study), an intermediate visit at the end of the cycle of twelve treatments (T1), with only measurement of the circumferences foreseen in the study, and a final visit (T2), one month after the end of the vascular balneotherapy cycle and compilation of the medical record with all the final evaluation parameters, performed by a specialist doctor other than the recruiter. For the VAS scale we obtained cumulative scores for each symptom by multiplying the number of patients who had reported a certain score by the corresponding score value and then adding all the results. At this point we obtained an individual mean score (VMI) by dividing the cumulative score by the total number of patients in each of the two groups. A statistical analysis on these parameters was deliberately not conducted, as they reflect a semi-quantitative evaluation of predominantly subjective symptoms. The statistical evaluation was instead calculated on the basis of the results obtained from the quality of life test, in fact the corresponding values of the two groups were compared on the means of the t-Student test for paired and/or independent data, depending on the case. The analyzed data were expressed as the mean + or - the standard deviation and the comparisons were made with a t-Student test for comparative data between T2 and T0 (All processing was performed through the GraphPad Prism 5.03 software). Furthermore, the differences in the behavior of the two groups of the values at T2 and T0 of the measurements of the circumferences of the points established by the study (B, C, G) were compared as the average of the measurements in centimeters and the corresponding improvement percentage.

RESULTS

The two groups of patients in baseline conditions were adequately homogeneous for comparison and all selected patients finished the planned study period. Positive family history for venous disease was present in 66.6% of patients, while 23.3% had undergone saphenectomy or minor surgery (seven patients in both groups). A sclerosing therapy was performed in seven patients of the "Balneotherapy Group" against four of the "Control Group", while only in two cases of the first group and three in the second had a previous history of superficial venous thrombosis been found. No patient in either group had previously suffered from deep vein thrombosis or skin ulcer. At the final visit (T2), one month after the end of the treatments, the individual mean assessment (VMI), obtained with the VAS scale, for pain decreased from 2.23 to 0.81 in the "Balneotherapy Group" and from 2.30 to 1.32 in the "Control Group", that of the heaviness from 4.20 to 1.54 in the first group and from 4.16 to 1.96 in the second, finally for the mania from 1.90 to 0.52 in the first and from 1.99 to 0.88 in the second group. No significant changes were found with respect to other

Table 1. Distribution of patients (n° and %) according to the CEAP classification

C= Clinic	Balneotherapy Group (%)	Control Group (%)
Symptomatic	30 (100)	30 (100)
C1: Telangectasias	6 (20.1)	7 (23.4)
C2: Saphenous veins	8 (26.6)	5 (16.6)
C3: Edema	16 (53.3)	18 (60.0)

Table 2. Quality of Life Test Assessment (SF-12)

		Balneotherapy Group (n=30)			Control Group (n=30)		
		T0	T2	p	T0	T2	p
Physical Activity	Mean	81.90	82.50	n.s.	81.80	85.00	n.s.
	s.d.	16.57	23.75		27.04	30.08	
Role and Physical health	Mean	51.92	78.84	0.003	45.45	79.54	0.005
	s.d.	34.58	26.16		21.84	24.54	
Physical Pain	Mean	52.19	65.84	0.026	52.18	57.09	n.s.
	s.d.	21.07	21.21		10.90	16.45	
General health	Mean	59.00	61.23	n.s.	64.81	58.00	n.s.
	s.d.	13.47	12.54		09.92	14.25	
Vitality	Mean	61.15	61.73	n.s.	64.82	58.00	n.s.
	s.d.	20.75	20.29		15.30	16.63	
Social Activities	Mean	61.05	72.59	0.005	45.45	50.09	0.018
	s.d.	24.57	21.21		11.55	11.30	
Role and Emotional State	Mean	53.84	82.05	0.005	39.39	69.69	n.s.
	s.d.	37.80	28.65		35.97	40.70	
Mental health	Mean	66.92	70.92	n.s.	60.09	65.81	n.s.
	s.d.	14.29	15.07		16.40	17.83	

Table 3. Evaluation of edema as a change in cm and % of improvement

		Balneotherapy Group (n=30)			Control Group (n=30)		
		T0	T2	cm	T0	T2	cm
Point B	Mean	23.60	20.83	- 2.76	23.22	21.51	- 1.71
	%		11.74			7.36	
Point C	Mean	36.16	33.96	- 2.19	36.29	34.91	- 1.38
	%		6.08			3.80	
Point G	Mean	54.76	53.33	- 1.43	54.69	53.97	- 0.72
	%		2.61			1.31	

Table 4. Secondary endpoint evaluation

	Balneotherapy Group (n=30)			Control Group (n=30)		
	Discreet	Good	Excellent	Discreet	Good	Excellent
Clinical Effectiveness	1	12	17	9	15	6
%	3.3	40.1	56.6	30	50	20
Tolerability	1	14	15	12	17	1
%	3.3	46.7	50	40	56.7	3.3

required symptoms, such as itching, burning and nocturnal cramps. While for the QoL results, both the perception of "role and physical health "and "social activities" improved in both study groups, while the assessment of "physical pain" significantly improved only in the "Balneotherapy Group", as well as that relating to the "role and emotional state". On the other hand, no significant changes were found in all the other parameters evaluated (Table 2). Edema, intended as a measurement in cm of points B, C and D of the lower limbs, improved significantly in both study groups, even if the one associated with balneotherapy had a greater percentage of improvement than the control one (Table 3).

Finally, as regards clinical tolerability, of the thirty patients treated with vascular balneotherapy, only one patient presented the asymptomatic appearance of bruising to the right lower limb on the fourth day, which did not require any drug treatment or the need to stop treatment. In both groups, minor side effects were reported, in a total of 6% of cases, affecting the gastrointestinal system, such as heartburn and mild epigastralgia, certainly due to oral drug therapy administered. An insufficient judgment on the secondary endpoints was not detected in either of the two study groups, while a good-excellent judgment on the clinical efficacy of the treatments implemented was expressed in 96.7%

of patients treated with balneotherapy and by 70% of the "Control Group". As regards the judgment on tolerability, the profile was still clearly in favor of balneotherapy for which a good-excellent judgment identical to the previous one was always reported, against only 60% of the cases of the other group (Table 4).

DISCUSSION

The results of the study have shown a sure efficacy of vascular balneotherapy with bicarbonate-sulphate alkaline calcium mineral water from "Well 5 – Cold Bath" of the "Antica Querciolaia" thermal station in the treatment of chronic venous disease of the lower limbs. This method was carried out with a standardized protocol, comprising a cycle of twelve treatments, lasting twenty minutes each, performed at a daily rate, based on thermal balneotherapy in prepared vascular paths. This therapeutic modality has an immediate and persistent beneficial effect over time on the classic symptoms of chronic venous disease and on edema of the lower limbs, the main target of this pathology [14, 15]. In fact, in this regard, the data collected relating to the measurements of the specific circumferences of the lower limbs appear suggestive, which confirms not only the net reduction of edema immediately, but also in the final control after one month, which obviously cannot be attributed to an effect of drug therapy alone [16]. Similar considerations deserve the data derived from the SF-12 processing, in fact this questionnaire represents a sensitive evaluation tool that allows you to obtain numerous information relating to the area of interest and the psychophysical conditions of the subject under examination. The significant improvement, persistent over time, recorded with the results of this questionnaire, administered at the beginning and at the end of the study, for the "Balneotherapy Group", therefore represents the clear demonstration of the effectiveness of this practice on the various aspects that characterize venous pathologies. In fact, it is widely demonstrated by scientific studies that the hot-cold alternation to which the lower limbs are subjected intensely stimulates the circulatory tone of the venous walls, thus favoring a better tissue trophism, in addition to the physical activity of walking, it promotes venous emptying of the limbs. lower legs, the development of the calf muscles and the articular motility of the ankle and knee, all characteristics of extreme importance in influencing the course of venous disease over the years, preventing many of the complications that it can cause [17-18]. Therapeutic actions therefore derive from the simultaneous exploitation of the physical action of massage by the water during walking on a disconnected bottom, together with the therapeutic active ingredients of the thermal water used [19].

CONCLUSIONS

Failure to detect side effects such as to interfere with the treatment allow to consider the tolerability of vascular balneotherapy with alkaline calcium bicarbonate-sulphate mineral water from "Well 5 – Cold Bath" in the treatment of chronic venous disease of the lower limbs to be considered excellent. This feature is of extreme importance for a therapeutic modality that is intended to be used by a predominantly elderly population such as the varicose one. Moreover, many of the patients treated with balneotherapy in the study were carriers of other concomitant pathologies, yet they proved to tolerate any stress caused by this therapeutic method well [20].

Therefore, our findings show the undoubted effectiveness and excellent tolerability of vascular balneotherapy with alkaline calcium bicarbonate-sulphate mineral water from "Well 5 – Cold Bath", located inside the "Antica Querciolaia" thermal station in the municipality of Rapolano Terme (Siena), in the treatment of chronic venous disease of the lower limbs, at least in the first three stages of the CEAP classification, with a significant improvement in the quality of life of patients undergoing this therapy.

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Conflict of interest:
The Authors declare no conflict of interest

Received: 12.05.2022
Accepted: 15.10.2022

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A – Research concept and design, B – Collection and/or assembly of data, C – Data analysis and interpretation, D – Writing the article, E – Critical review of the article, F – Final approval of article

The Effectiveness of Rehabilitation Program After Hybrid Osteosynthesis in Ankle Joint Unstable Injuries

Skuteczność programu rehabilitacyjnego po hybrydowej osteosyntezie niestabilnych uszkodzeń stawu skokowego

DOI: 10.36740/ABAL202206105

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SUMMARY

Aim: To develop a rehabilitation protocol for patients with the unstable ankle joint injuries by doing comparative analysis between HSEF functional results and the traditional method.

Materials and Methods: The study was performed on 61 patients with the unstable ankle trans- or supra-syndesmotic fractures. Patients were divided into two equal groups where I = main and II = control due to the age, distribution and disorders. 10 patients from the group I were operated using HSEF, the other 51 were selected for the traditional osteosynthesis (plate and positioning screw). For the monitoring of osteosynthesis quality was used The Foot and Ankle Disability Index (FADI) scale. Nonparametric statistical analysis was completed using Statistica 13.0 computer software.

Results: After application of HSEF method authors of this paper created original rehabilitation protocol. Limitations in the rehabilitation process (e.g., not weightbearing) on 42±3 day in the control group II caused a significant gap in the results of ankle joint functional recovery. On day 56±3, the main group I overreached the control group II by 1.5 ($p3<0.001$). With each FU 1-3 of the main group I, the total sum of points according to FADI (subscale of sports activity) steadily increased by 5, and with FU 3 on the 56±3 day, reached 16 points. Positive quantitative dynamics in scores were the characteristic of patients from both groups (advantage of the group I was insignificant (by 2 points) ($p4<0.001$)), although none of them reached the normal (32 points) at the final term (FU 4).

Conclusion: Provided results proved the effectiveness of the developed rehabilitation protocol. It enhanced patients recovery up to 1-2 weeks.

Key words: hybrid osteosynthesis, unstable ankle joint fractures, rehabilitation program, assessment of ankle joint stability, plate and position screw stability

Słowa kluczowe: hybrydowa osteosynteza, niestabilne złamania stawu skokowego, program rehabilitacyjny, ocena stabilności stawu skokowego, stabilność śrub i płytek

Acta Balneol, TOM LXIV, Nr 6(172);2022:523-528

INTRODUCTION

The "gold standard" for syndesmosis stabilization is rigid fixation with a positioning screw [1]. Open reduction and internal fixation method with plate and positioning screw is effective in 79,8% cases of ankle fractures [2]. In 70% of all patients occurs posttraumatic osteoarthritis [3]. Hybrid osteosynthesis is an alternative method of ankle joint injuries stabilization [4]. It allows to improve functional results of a surgical treatment [5].

Young people often get high-energy ankle injuries during their participation in various sport activities [3]. Appropriate treatment and rehabilitation play significant role in returning to both daily living activities and sports [6]. It is especially difficult to diagnose and treat patients with unstable bone fractures and distal syndesmosis injuries.

Ankle joint functional recovery depends on the length and rotational ability mechanism of the fibula. The systematic review shows the importance of fibular fracture osteosynthesis but there are discussion regarding the optimal intervention and particular method of the operation procedure (e.g. plate or intamedullary nail fixation) [7-9].

Dystal tibio-fibular syndesmosis (DTFS) contains ligaments, which wide DTFS is just up to 1 mm during the normal

gait. DTFS also takes part in the stability of the ankle joint and its damage causes joint instability in 18-45% of all cases [10, 11]. Domestic damage of syndesmosis occurs in 1-18% of cases [12]. Incidentally, high-energy sport injuries lead to syndesmosis disruption in up to 32% of cases [13]. Postponed DTFS fracture treatment leads to early osteoarthritis of ankle joint [14], prolongation of the pain syndrome during gait cycle, and long-term functional limitations in sport activity [15, 16]. Thus, the "gold standard" for syndesmosis stabilization is rigid fixation with a positioning screw drilled through 2 corticals of fibula and at least 1 cortical of tibia [1]. Consequently, the normal physiological motions between the tibia and fibula are abolished. Such type of fixation requires screw removal in 6-8 weeks after the first surgery with purpose to avoid the occasional break under the repetitive strain induced by the movement when the ankle is loaded [17]. The elastic synthesis differs from the rigid one in the method of DTFS fixation by elastic tapes and endobatons. The essence is a preservation of physiological motions in DTFS during the healing process [18, 19]. Therefore, fixation integrity of ankle joint structures during a recovery period is crucial for biomechanical stability.

Hybrid osteosynthesis is an alternative method for ankle joint injuries stabilization [4]. We propose the original method of a lateral column stabilization with an intramedullary blocking nail and restoration of a syndesmosis with an elastic TightRope® system (type of a suture button) [20]. Such a hybrid stable-elastic fixation (HSEF) allows to improve functional results of surgical treatment [5]. Accordingly, the biomechanical ankle joint stability structures are the main factors in the healing process of such injuries [21].

Rather complicated to get effective treatment results by updating the surgical method only. Important phase is also the postoperative rehabilitation [22]. In the scientific publications there is also limited evidence of rehabilitation protocols where the comparison of advantages and disadvantages after hybrid osteosynthesis in athletes is presented [23].

AIM

To develop a rehabilitation protocol for patients with unstable ankle joint injuries by doing comparative analysis between HSEF functional results and the traditional method of fibula osteosynthesis with a positional screw for syndesmosis.

MATERIALS AND METHODS

The study was performed on 61 patients with unstable ankle trans- or supra-syndesmotic fractures. The majority of patients – 45 (73.8%), were engaged in active sports: football, volleyball, tennis, running, etc. There were 15 (24.6%) females, 46 (75.4%) males. The age of patients was from 21 to 60 years. The average age of patients in the main group I was 45.9±9.6 years. In the control group II – 43.9±11.0 years. Distribution of patients by age was categorized into two groups 21-44 and 45-59 years respectively. Patients of the main group I were divided into 70 / 30% with a dominance of young people. Approximately the same distribution 60,8/39,2% was in the control group II.

All patients with unstable bone fractures and syndesmosis damage were divided into two groups according to a method of treatment: the main group I consisted of 10 patients who were randomly selected to be operated using HSEF: fibula synthesis with an intramedullary nail, syndesmosis – with an elastic band on endobatons.

The control group II consisted of 51 patients, who were randomly selected for the traditional osteosynthesis (plate and positioning screw) of the fibula fracture. The screw had to be removed 6-8 weeks after the surgical intervention. In the 8th week the functional load was initiated.

After the surgical intervention recovery with purpose of the proper monitoring of the quality of osteosynthesis we used The Foot and Ankle Disability Index (FADI) scale. The scale contains a Subscale of particular Sports Activities such as running, jumping, landing, quickly stopping, standing, executing lateral movements, doing low-energy exercises, performing exercises with patient's own technique, and doing sports for a long period of time. Points in the scale were corresponded to 4 – no difficulties, 3 – minor difficulties, 2 – moderate, 1 – difficult, and 0 – inability. Results of the clinical evaluation were done during follow-up examinations (FU) on 14 ± 3 (1), 42 ± 3 (2), 56 ± 3 (3), and 168 ± 3 (4) days from the moment of surgical intervention.

RESULTS

After the detailed analysis of familiar rehabilitation protocols, we created the original one [24, 25]. With the aim to present advantages of the original HSEF method, we propose Table 1 where we compare traditional and our original protocol.

Analysis of FADI scale shows positive perspective for post-operative recovery in the main group (Table 2).

Distinction is due to the rehabilitation protocol defined as the "turbo" mode of recovery. Patients of the control group II were unable to fully load the extremity. Precondition for starting of the rehabilitation program was early activation during the first week when the dressing was changed. During Phase 1 (FU1), the range of ankle-foot up and down movements of the operated limb was-fully achieved.

Rehabilitation exercises for patients from the main group I during the 1st week consisted of passive movements in ankle and no weightbearing of lower extremity, tapping the heel on a hard surface – "vibration massage". Therefore, with each FU 1-3 of the main group I, the total sum of points according to the FADI (subscale of sports activity) steadily increased by 5, and with FU 3 on the 56±3 day, it reached 16 points. It is interesting to emphasize that for the patients of the control group II, rapid increase in the recovery of ankle joint in the "turbo" mode was noted up to 11.0 points at FU 3.

Patients from the main group I were allowed to perform light sport activities (except jogging and jumping) from day 42±3 (FU 2), while patients from the control group II were advised to avoid any weightbearing of the ankle joint due to the risk of positioning screw fracture (Figure 1).

Limitations in the rehabilitation process on 42±3 day in the control group II caused a significant gap in results of

Table 1. Comparison of the rehabilitation protocols after surgical treatment of unstable trans- and supra-syndesmotic fractures

After traditional osteosynthesis method (with plate and positioning screw)*		After HSEF	
FU week	**Actions**	**FU week (day)**	**Actions**
1	- Operated limb should be elevated for 23 hours per day. - Ice (vascutherm or ice bag) under the knee to reduce swelling and pain. - Movement of the toes. - Hip and knee in a physiological position.	1 23 hours per day From 1-2 days From 3-5 days By the end of the week	In a supine position: - Operated limb should be elevated - ice (vacuterm or ice bag) over the ankle joint, to reduce swelling -Immobilisation of the ankle joint with cast or CAM boot Movement of the toes. - Active flexion and extension in the ankle joint during the change of the dressing - Movement with help of orthopedic devices (crutches, trapeze) without weightbearing. - Movements in all joints of the operated extremity
2-3	Phase I (FU 1) - Sutures out, early range of motions: - Without immobilization, ankle-foot up and down movements for 5-10 minutes 5 times a day to maintain range of motion - Compression stockings, using ice bag, elevation of leg to control swelling - Sleeping with immobilization devices	2 (14±3 days)	Phase I (FU 1) - Sutures out, progress of ankle-foot up and down movements for 5-10 minutes 5 times a day. - achievement of full range of motions in joints - putting on compression socks in the morning in a lying position, and periodically keeping the leg elevated to control swelling and pain - sleeping with immobilization devices - vibrational exercise (tapping the floor with the heel of the operated extremity in the splint).
4-6	Phase II (FU 2) - Early Range of Motion, gait training - The weightbearing is determined by specialist after X-ray control, but not earlier than 6th week (protocol - 6-8 weeks). - Progressive weight bearing using crutches/walkers, starting in shoes from 25% and increasing by 25% every 1-2 weeks. - Immobilization devices during walking. - Reaching 75% of weightbearing, allows using one crutch in the opposite hand. - Soft tissue mobilization. - Middle part of the foot mobilization. - Stationary bike.	3-6 (42±3 days) from 3d week from 5th week	Phase II (FU 2) - Gait training - Progressive weight bearing using crutches/trapeze-walkers with pain control (even in patients with type 44C2.1-2.3 fractures with proximal blocking) - weightbearing is allowed for patients with type 44C2.1-2.3 fractures without proximal blocking using crutches/trapeze-walkers - weight bearing start with 25% of the weight and an increase by 25% every 1-2 weeks. - Instead of wearing a brace or immobilization devices, patients wore shoes with insoles. - progress in flexion-extension movements of the ankle joint - Isometric exercises - weightbearing the lower extremity to full range - Proprioception exercises
6-8	Fracture healed (FU 3) - Wearing shoes with insoles. Starting the first steps in shoes at home, and later - outside. - Weightbearing the lower extremity to full range - Daily stretching activities - Isometric exercises - Proprioception exercises - Increasing range of motion in the subtalar joint	6-8 (56±3 days)	Phase III (FU 3) – Return to Function - exercises to increase the inversion-eversion movements, balance exercises, proprioception exercises - Simulators, stretching, walking on a treadmill, jogging, running, and intensification of sports activities were allowed.
8-10	Phase III (FU 3) – Return to Function (8-12 weeks) - Balance and proprioception exercises - Continue simulators exercises, stretching, progress in range of motion. - Treadmill walking program	8-10	Running and intensification of stretching and proprioception excersises - Insoles if necessary - Sports exercises
12-16	- Intensify activities with jogging and running - Insoles if necessary - Stretching and proprioception exercises - Sports exercises		

**Unified protocol based on Operative Ankle Fracture Protocol 2020 (South Bend Orthopaedics), [24], Ankle Fracture Post-op Rehabilitation Protocol (Minnesota Orthopaedic Sport Medicine Institute) [25].*

Table 2. Median values of FADI scale. Subscale of Sports Activity in 2 groups

Control examinations (days)	p between comparison groups		
	I (Main)	II (Control)	MW-U test
KO 1 (14 ±3)	6,0 [2,0-7,0]	2,0 [2,0-2,0]	[1]0,003045
KO 2 (42±3)	11,0 [8,0-13,0]	2,0 [2,0-2,0]	[2]0,0000001
KO 3 (56±3)	16,0 [14,0-17,0]	11,0 [10,0-12,0]	[3]0,000001
KO 4 (168±3)	28,0 [26,0-29,0]	26,0 [24,0-28,0]	[4]0,000133
F-ANOVA test	0,000001	0,000001	-

Notice: 1. F-ANOVA test – Friedman. 2. MW-U test - Mann-Whitney 3. Normal – 32 points

ankle joint functional recovery. Median values of the score showed that sport activity was at the level of 2 points, the same as in FU 1. In the same period, the values of the main group I already reached 11.0 points and were 5.5 times above the control group II (p2<0.001).

On the day 56±3, the main group I overreached the control group II by 1.5 (p3<0.001). Higher functional activity rate of the operated extremity was maintained in patients of the main group I during all FU and on day 168 ± 3 it was equal to 28 points (almost reaching the norm of 30 points). Positive quantitative dynamics in scores characterized patients from both groups, although none of them reached the normal (32 points) at the final term (FU 4). The observational difference (FU 4) with advantage of the main group I was 28.0 [26.0-29.0] points; patients of the control group II - 26.0 [24.0- 28.0] points, although it was insignificant (by 2 points) (p4<0.001).

Therefore, the minimally invasive HSEF of unstable ankle joint injuries in trans- and supra-syndesmotic fractures allows the early beginning of the designed rehabilitation program. The combination of intraosseous restored external column (fibula) with the intramedullary nail and elastic TightRope®, adequately stabilizes anatomical structures of ankle joint "fork" (Figure 2).

Figure 1. Positioning screw. Breakage (indicated by a blue arrow) of the positioning screw/ Topogram and transverse CT scan

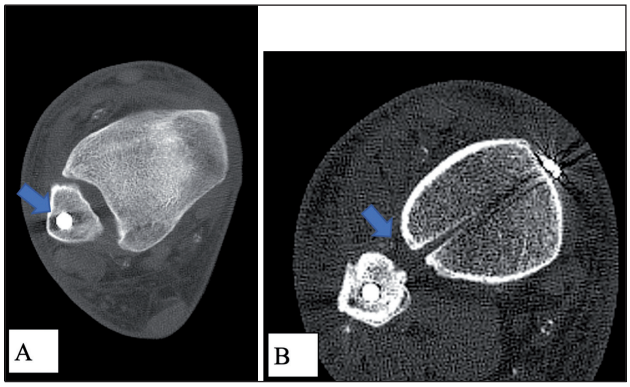

Figure 2. CT scan. Transverse scan. HSEF. A – stabilization with an intramedullary nail of the fibula. B – Elastic fixation of DTFS with a Tightrope. Self-centering effect.

DISCUSSION

Attention of researchers was directed to hybrid methods of fixation for combined injuries. Our results proved that biomechanical features of hybrid systems are close to original functionality of a distal segment of lower extremity. In the publications are described numerous variations of operative interventions with the combined use of various structures [26]. For example, Weng, Q. et al. developed new form of plate with a wing-shaped plate that preserves the direction of the positioning screw [27]. There is also "ACUMED" system for hybrid stabilization with an intramedullary nail and restoration with a positional screw [28]. In addition, among the analogues of various hybrid systems, there are applications with use of TightRope® (Arthrex) [29].

The method of fibula nail osteosynthesis and syndesmosis Tightrope fixation shows advantages during a recovery process. Elastic fixation with TightRope® is able to reproduce biomechanical features during the rehabilitation period [30]. Fracture osteosynthesis enables early rehabilitation after

the pain reduction. Studies confirm that active controlled weightbearing shows positive effect on the union of unstable fractures [31].

Rehabilitation programs enable to improve and maintain active functioning of the lower extremity over the year. According to assessment of the rehabilitation outcomes, 73% of patients with ankle injuries continue to have movement limitations (even a year after the injury), especially when they perform sport activities. Review of publications confirms that among guidelines and protocols [24, 25] there are no evidence-based studies related to rehabilitation of patients after a hybrid osteosynthesis method.

Originality of the authors' rehabilitation protocol is in the early weightbearing, starting from the 2nd or 3d week. Systematic Cochrane review [32] indicates that early dosed weightbearing of the lower extremity in the post-operative period in comparison with late weightbearing does not affect the long-term functional outcome. Our results prove that on 168th post-operative day, according to FADI scale, the main group was only 2 points above the control one. Nevertheless, the process of overcoming the pain syndrome to correct balance distribution on both feet, limits routine functional activity. The method of osteosynthesis with a proper rehabilitation significantly (in 5.5 times) improves results during the first 42 post-operative days, and up to 1-2 weeks shorten the recovery period for patients.

Consequently, the sport goals can be reached in shorter period (up to 8-10 weeks) and with better outcomes.

CONCLUSIONS

Comparative analysis of functional results according to FADI scale proves the effectiveness of the implementation of our original rehabilitation protocol. HSEF for supra- and trans-syndesmosis fractures of the fibula and damaged DTFS allows to speed up (by 1-2 weeks) post-operative recovery period due to the early activation of movements in the ankle joint and weightbearing of the lower extremity.

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Conflict of interest:
The Authors declare no conflict of interest

Received: 28.04.2022
Accepted: 22.10.2022

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Assessment of Functional Status and Rehabilitation Intervention in Patients with Coronavirus Disease (COVID-19)

Ocena stanu funkcjonalnego i interwencja rehabilitacyjna u pacjentów z zakażeniem koronawirusem (COVID-19)

DOI: 10.36740/ABAL202206106

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SUMMARY

Aim: To assess the functional status of patients and to investigate the effectiveness of rehabilitation intervention in coronavirus disease (COVID-19).

Materials and Methods: There were 21 patients with clinically-laboratory confirmed coronavirus disease (COVID-19), who participated in the study. Among the examined patients there were 16 (76.2%) women and 5 (23.8%) men. The average age of the patients was 58±5.08 years. The rehabilitation cycle included an initial and final assessment of the patients' functional status, after which a rehabilitation intervention was carried out, which consisted of breathing exercises and motor activity.

Results: The initial assessment of the patients' functional status in physical exertion during the 1st day showed that the heart rate (HR) was 127.09±0.55 bpm, the respiratory rate (RR) was 28.05±0.39/min, SpO2 was 85.95±0.38 %, systolic arterial pressure (APs) – 145.09±1.48 mmHg, diastolic arterial pressure (APd) – 84.33±0.86 mmHg. Up to the 5th day of the rehabilitation cycle, heart rate decreased at 25.9%, RR – at 16.8%, SpO2 increased at 6.8%, APs decreased by 14.3%, APd decreased at – 9.3% ($p<0.001$). The SpO2 saturation index after respiratory gymnastics increased significantly starting from the first up to the 5th day of rehabilitation from 92.29±0.44% to 97.62±0.29% ($p<0.001$). Subjective indices under the influence of rehabilitation intervention had reliable dynamics with a tendency to the decrease of manifestations of shortness of breath according to the Modified Borg scale (MBS) at 63.6% ($p<0.001$), leveling of general fatigue according to the Borg CR10 scale – at 63.4% ($p<0.001$), an increase in the patient's mobility index – at 66.4% ($p<0.001$), an increase in tolerance to the physical exertion for 6-minute walking distance 6MWD – at 93.4% ($p<0.001$).

Conclusions: Thus, rehabilitation assessment and intervention is an extremely important stage in the treatment of patients with the coronavirus disease (COVID-19), which provides an opportunity to improve the functional status of patients by physically influencing the pathogenetic mechanisms of the disease.

Key words: COVID-19, rehabilitation, diaphragmatic breathing, shortness of breath

Słowa kluczowe: COVID-19, rehabilitacja, oddychanie przeponowe, duszność

Acta Balneol, TOM LXIV, Nr 6(172);2022:529-533

INTRODUCTION

Despite the war in Ukraine and geopolitical redistribution of power around the world, the COVID-19 pandemic, caused by the SARS-CoV-2 coronavirus, still remains relevant. Due to the large scale of vaccination against COVID-19, it was possible to stop the pandemic process, but the epidemiological situation has acquired a seasonal character and does not allow itself to be forgotten in the autumn-winter period. According to statistical data, in approximately 40% of patients with COVID-19, the disease proceeds in a mild or moderate form (40.0%), but in approximately 15.0% – a severe disease requiring oxygen support develops; and in 5.0% a critical course with such complications as respiratory failure, acute respiratory distress syndrome, sepsis and septic shock, thromboembolism, multiple organ failure, including acute kidney and heart damage, is observed [1, 2].

In addition to medicinal support, patients with coronavirus disease need early rehabilitation intervention, regardless

of the disease course severity. Rehabilitation needs in severe cases of COVID-19 are related to the consequences of ventilatory support and prolonged immobilization, as well as exacerbation of the underlying health condition. Rehabilitation intervention should be carried out at all stages of resuscitation, starting with the intensive care unit (acute rehabilitation) and ending with the outpatient stage (long-term rehabilitation). Restorative influence must be directed at overcoming pulmonary dysfunction; low tolerance to physical exertion, muscle weakness [3].

A multidisciplinary and patient-centered approach makes it possible to ensure an effective rehabilitation process, in which restorative medicine specialists are involved; physical therapy; occupational therapy; speech and language therapy; clinical psychology [4, 5].

AIM

The aim of the study was to assess the functional status of patients and to investigate the effectiveness of rehabilitation intervention in coronavirus disease (COVID-19).

MATERIALS AND METHODS

There were studied 21 patients who were confirmed SARS-Cov-2 infection by polymerase chain reaction of a nasopharyngeal swab and clinical examination. There were 16 (76.2%) women and 5 (23.8%) men among the examined patients. The average age of the patients was 58±5.08 years. The rehabilitation cycle included a mobile multidisciplinary team's initial and final assessment of the patients' functional status [6]. All patients were assessed in the conditions of the intensive care ward and therapeutic departments of the Communal Non-Profit Enterprise "Central City Clinical Hospital of the Ivano-Frankivsk City Council", Ivano-Frankivsk, Ukraine, after which rehabilitation intervention was carried out.

Functional assessment of patients was carried out according to the following indices: HR, RR, SpO2 (at rest before and after respiratory gymnastics using diaphragmatic breathing), APs and APd. The control was carried out according to the parameters of the resuscitation monitor of the patient at rest and during physical exertion (it included passive movements of the upper and lower limbs, with a subsequent transition to active ones, mobility in bed using positioning, verticalization and gradual movement within the ward and beyond it). The assessment of these parameters was performed from the 1st till the 5th day of the rehabilitation cycle, comparing their reliability with the first day of the rehabilitation intervention.

The assessment took into account the biopsychosocial model based on the International Classification of Functioning, Disability and Health (ICF) [7]. According to the ICF domain b, the disorders of cardiovascular function; immune, respiratory and blood systems were assessed; according to the domain s – the damage to the structure of the cardiovascular, immune and respiratory systems; organism; according to d – the activity and participation (learning and application of knowledge, general tasks and requirements, communication, mobility, self-care, household activities, interpersonal interactions and relationships); e – environmental factors and personal factors [8].

Intensity and dynamics of shortness of breath were assessed according to the Modified Borg scale (MBS), 1982 [9], subjective tolerability of physical exertion – according to the modified Borg CR 10 scale, 1970 [10], patient mobility – according to the Rivermead Mobility Index (Rivermead Mobility Index – RMI) [11,12], tolerance to physical exertion – by the 6-minute walking distance test (6-minute walking distance – 6MWD). Assessment was performed before physical exertion during the 1st, 5th, 9th and 14th day of the rehabilitation cycle, comparing the reliability of the results with the initial assessment [13,14].

Indications for termination of examination/intervention were the so-called "Red Flags" and "Yellow Flags". "Red flags": heart rate at rest was 130 beats per minute; RR>40 per minute; oxygen saturation at rest ≤ 90% and/or during exercise/activity 38.0°; exhaustion (Borg scale score ≥5 out of 10 at rest); high blood pressure at rest (180/100 mmHg) [15]. "Yellow flags": pathological (paradoxical) breathing; history of delirium; fear of physical exertion/exercise; fear of suffocation; sleep problems; post-traumatic stress disorder; external locus of control (tendency to attribute performance results to the external factors); negative beliefs and/or preoccupation with symptoms [16, 17].

Statistical analysis was carried out depending on the distribution of the statistical sample using Student's parametric criteria. The method of descriptive statistics was used to represent the data obtained (mean, standard deviation, minimum and maximum value, range, number of valid cases for quantitative changes); number, share and distribution for qualitative parameters. The results were considered reliable at $p<0.05$.

In order to find out the correlation relationship between individual indices, Pearson's rank correlation coefficient (r) was determined. To assess the effectiveness of the rehabilitation intervention and the prognostic value of the results, the dynamics of the odds ratio (Odds ratio, (OR), 95% confidence interval CI, p) was determined.

RESULTS

The rehabilitation route began with the inpatient rehabilitation stage and was carried out during two periods – acute and post-acute ones. In particular, 9 (42.9%) patients who needed rehabilitation intervention in the acute period were in the intensive care unit, of which 3 (14.3%) patients were on CPAP-therapy for about two weeks (C – Constant, P – Positive, A – Airway, P – Pressure); 2 (9.5%) patients were on CPAP-therapy for about one week; 4 (19.05%) patients – up to one week. The rehabilitation session in such patients lasted from 15 to 30 minutes, depending on the general condition. Afterwards 12 (57.1%) patients needed acute rehabilitation; and the session of rehabilitation lasted from 25 minutes to 1 hour. For the period of rehabilitation intervention in the acute period, all the patients were referred to stationary or mobile oxygen concentrators with an oxygen delivery rate of 10 l/min – 9 (42.9%) patients and 5 l/min – 12 (57.1%) patients.

According to the clinical-instrumental examination and anamnestic data, 1 (4.8%) patient was diagnosed with

acute respiratory distress syndrome, 9 (42.9%) patients were diagnosed with a severe course of the disease with the development of severe pneumonia, and 12 (57.1%) patients were diagnosed with a moderate course disease with the development of pneumonia. According to computer tomography, all patients who participated in the examination, had signs of covid pneumonia. In particular, there were observed focal subpleural foci of "frosted glass" compaction in 15 (71.4%) patients; nodes and focal exudation were observed against the background of compaction foci in 5 (23.8%) patients; diffuse compaction and the "white lung" symptom were observed in 1 (4.8%) patient.

The initial assessment of the functional state of the patients during physical exercise during the 1st day showed that the HR was 127.09±0.55 beats/min, RR – 28.05±0.39/min, SpO2 – 85.95±0.38%, APs – 145.09±1.48 mmHg, APd – 84.33±0.86 mmHg. During the 2nd day of the examination, the indices of the functional state significantly changed compared to the 1st day, in particular the heart rate up to 121.95±1.39 bpm, which was at 4.04% lower compared to the first day of rehabilitation ($p<0.001$); RR decreased at 8.3% up to 25.71±0.77/min ($p<0.01$); SpO2 increased at 0.6% ($p>0.05$) up to 86.48±0.43; APs decreased at 3.9% up to 139.38±2.45 mmHg ($p<0.05$); APd – at 1.7% up to 82.91±0.85 mmHg ($p>0.05$). Functional indices during the 3rd day of the rehabilitation cycle, compared to the first day, underwent reliable dynamics, in particular, the heart rate decreased at 12.9% up to 110.66±3.21 bpm ($p<0.001$), RR decreased at 11.8% up to 24.76±0.81/min. ($p<0.001$), SpO2 – at 1.3% up to 87.05±0.42% ($p<0.05$), Aps up to – 134.62±2.89 mmHg, APd – 81.95±0.79 mmHg. at 7.2% and 2.8%, respectively ($p<0.01$, $p<0.05$) During the 4th day, heart rate significantly decreased at 20.0% up to 101.62±3.16 bpm., RR – at 7.1% to 24.09±0.81/min, SpO2 – at 2.4%, APs and APd – at 11.3% and 5.03%, respectively ($p<0.001$). There was observed pronounced dynamics when comparing indices at the beginning of rehabilitation and during the 5th day of the rehabilitation cycle. Thus, heart rate decreased at 25.9% to 94.19±2.33 bpm, RR – at 16.8%, SpO2 increased at 6.8%, APs decreased at 14.3%, APd decreased at 9.3% ($p<0.001$) (Table 1).

Intensity and dynamics of shortness of breath according to the modified MBS scale were as follows . At the initial assessment, the intensity of shortness of breath was significant and amounted to 8.14±0.22 points, during the 5th day of the rehabilitation cycle, the intensity of shortness of breath decreased at 33.9% up to 5.38±0.35 points ($p<0.001$), during the 9th day – at 48.5% ($p<0.001$), before the end of the rehabilitation cycle, patients experienced slight shortness of breath, the severity of which decreased at 63.6% up to 2.95±0.26 points ($p<0.001$).

The dynamics of exercise tolerance according to the modified Borg CR 10 scale under the influence of rehabilitation intervention was as follows. At the initial assessment, patients felt significant fatigue, which corresponded to 9.24±0.22 points according to CR 10. After five days, the severity of general fatigue decreased at 21.6% up to 7.24±0.28 points ($p<0.001$), and during the 9th day, the level of general fatigue was estimated as 5.29±0.49 points, which was at 42.7% less than at the initial assessment ($p<0.001$). Before the end of the rehabilitation cycle, fatigue was moderate and amounted to 3.38±0.25 with a decrease in the index at 63.4% ($p<0.001$).

The patient's mobility according to the RMI index during the day of the initial assessment was 3.19±0.17 points. During the 5th day, in addition to rotations in bed, transitioning to a sitting position and maintaining balance in it, patients could get up with minor external support estimated as 4.14±0.34

Table 1. Dynamics of functional indices of the cardiovascular and respiratory systems in patients with coronavirus disease (COVID-19) during physical exercise load M±m

Indices	Day 1 (n=21)	Day 2 (n=21)	Day 3 (n=21)	Day 4 (n=21)	Day 5 (n=21)
	1	2	3	4	5
HR, bpm p, Δ.%	127.09±0.55	121.95±1.39 p1-2<0.001. 4.04	110.66±3.21 p1-3<0.001 12.9	101.62±3.16 p1-4<0.001 20.0	94.19±2.33 p1-5<0.001 25.9
BP, min p, Δ.%	28.05±0.39	25.71±0.77 p1-2<0.01 8.3	24.76±0.81 p1-3<0.001 11.8	24.09±0.81 p1-4<0.001 14.1	22.33±0.73 p1-5<0.001 16.8
SpO2, % p, Δ.%	85.95±0.38	86.48±0.43 p1-2>0.05 0.6	87.05±0.42 p1-3<0.05 1.3	88.05±0.44 p1-4<0.001 2.4	92.09±0.75 p1-5<0.001 6.8
AP systolic p, Δ.%	145.09±1.48	139.38±2.45 p1-2<0.05 3.9	134.62±2.89 p1-3<0.01 7.2	128.76±2.83 p1-4<0.001 11.3	124.33±2.42 p1-5<0.001 14.3
AP diastolic p, Δ.%	84.33±0.86	82.91±0.85 p1-2>0.05 1.7	81.95±0.79 p1-3<0.05 2.8	80.09±0.91 p1-4<0.001 5.03	76.52±1.06 p1-5<0.001 9.3

Notes: n – number of patients; p – the reliability of the index

points and was at 29.8% higher than during the 1st day (p<0.05). After 9 days of rehabilitation intervention, patients stood and moved independently, walked with minor external support, and some patients walked independently, this was estimated as 7.19±0.56 points, which was at 55.6% higher than during the 1st day (p< 0.001). At the end of the rehabilitation cycle during the 14th day of the intervention, the patients moved independently around the ward, could overcome small obstacles and lift objects from the floor without experiencing fatigue and discomfort, which was estimated according to the RMI scale as 9.48±0.61 points (p<0.001).

The physical load tolerance according to the 6MWD test at the initial assessment was significantly reduced, so a small part of the patients covered a distance of 5.76±0.21 m. During the 5th day of rehabilitation intervention, the physical load tolerance increased at 81.9%, the patients covered a distance of 31.91±1.95 m (p<0.001). By the 9th day, patients covered a significantly greater distance at 89.05%, subdividing the distance of 52.62±5.22 m into rest breaks (p<0.001). Before the 14th day of observation, the patients independently moved around the ward, went out into the corridor, some of them went out into the street while covering a distance of up to 87.15±5.76 m (p<0.001) (Table 2).

Having assessed the functional state of the patients, we've performed a correlation analysis between the dependence of tolerance to physical exertion and the SpO2 saturation index, there was found the presence of a direct, strong relationship between these values, which in mathematical terms was r=+0.98, p<0.001 (Figure 1).

The chance of adverse consequences based on the SpO2 index was calculated and there was found a significant decrease in the chances of adverse consequences in patients with the coronavirus disease (COVID-19) under the influence of respiratory gymnastics and physical exercises. Thus, before the beginning of the rehabilitation cycle, the ratio of the chances of adverse consequences was OR=1.41 (95% CI=0.27-7.26;

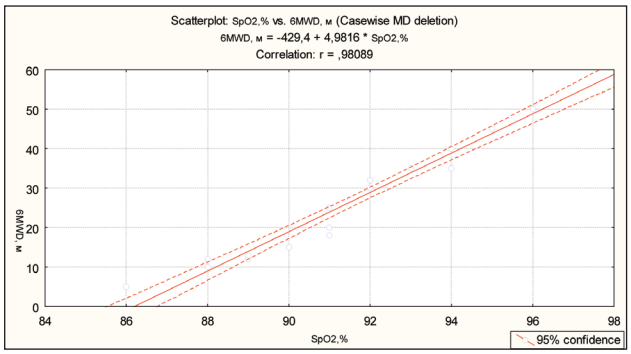

Figure 1. Correlational dependence of exercise load tolerance on SpO2% in patients with coronavirus disease (COVID)

p=0.9), after the completion of the rehabilitation cycle, the ratio was – OR=0.14 (95 % CI=0.04-0.59; p=0.012). Chances of adverse consequences according to the SpO2 index have been confirmed in practice, as evidenced by a decrease in the intensity of oxygen therapy in such patients. Under these conditions, out of 21 patients, 14 (66.7%) were observed as outpatients without oxygen therapy, without oxygen concentrator use, 7 (33.3%) patients still used oxygen therapy at the level of oxygen flow at a rate of 5 l/min with a gradual decrease up to 3 l/min, while 1 (4.8%) patient used oxygen therapy around the clock, and 6 (28.6%) patients – only a few times a day.

DISCUSSION

There were achieved scientific goals with the help of this study; they reflected the effectiveness of rehabilitation intervention in patients with coronavirus disease (COVID-19) regardless of the rehabilitation period. The prospects of this study are the investigations of functional indices at the long-term stage of rehabilitation in outpatient conditions.

CONCLUSIONS

Thus, the rehabilitation effect is an extremely important stage in the treatment of patients with the coronavirus disease

Table 2. Assessment of the subjective state of a patient with coronavirus disease (COVID-19) during a rehabilitation session. M±m

Indices	Day 1 (n=21)	Day 5 (n=21)	Day 9 (n=21)	Day 14 (n=21)
	1	2	3	4
Scale MBS, points p, Δ.%	8.14±0.22	5.38±0.35 p1-2<0.001 33.9	4.19±0.27 p1-3<0.001 48.5	2.95±0.26 p1-4<0.001 63.6
Scale Borg CR, points p, Δ.%	9.24±0.22	7.24±0.28 p1-2<0.001 21.6	5.29±0.49 p1-3<0.001 42.7	3.38±0.25 p1-4<0.001 63.4
Scale RMI, points p, Δ.%	3.19±0.17	4.14±0.34 p1-2<0.05 29.8	7.19±0.56 p1-3<0.001 55.6	9.48±0.61 p1-4<0.001 66.4
6MWD, м p, Δ.%	5.76±0.21	31.91±1.95 p1-2<0.001 81.9	52.62±5.22 p1-3<0.001 89.05	87.15±5.76 p1-4<0.001 93.4

Notes: n – number of patients; p – the reliability of the index.

(COVID-19). These study has proved the mathematical and clinical effectiveness of rehabilitation measures. Thus, with the help of rehabilitation intervention, using respiratory gymnastics and diaphragmatic breathing, it was possible to maximally increase blood oxygen saturation according to the SpO2 index ($p<0.001$), which made it possible for 66.7% of patients at rest and during physical exertion not to use an oxygen concentrator. Physical exercises in such patients increased the endurance and tolerance to physical exertion by normalizing HR and RR, which allowed them to return to normal everyday life without experiencing discomfort and the consequences of Post-COVID-19 syndrome.

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This study was carried according to the research plan of the Ivano-Frankivsk National Medical University in accordance with the theme "Changes in the internal organs in the remote period of the coronavirus disease, taking into account concomitant pathology" (state registration number 0122U002315).

Conflict of interest:
The Authors declare no conflict of interest

Received: 23.03.2022
Accepted: 15.09.2022

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Issues of Depression and Comorbidity in Rehabilitation

Problemy depresji i współchorobowości podczas rehabilitacji

DOI: 10.36740/ABAL202206107

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SUMMARY

Aim: To analyze data on the presence of comorbidity in patients with depression and to determine the strength of the relationship between the degree of depression and related diseases.

Materials and Methods: The study involved 67 women with depression. We determined the level of depression according to the Patient Health Questionnaire-9 (PHQ-9). Correlation relationship was assessed by Spearman's rank correlation coefficient (r) at significance level of $p \leq 0,01$.

Results: According to the obtained data, only 17.9% of depressive patients with depression had no concomitant diseases. The most frequent ones were: diseases of the traumatic organs (32.8%), neurological disorders (22.4%), and respiratory disorders (19.4%). Two or more comorbidities were found in 44.8% of depressed patients. The study of the interdependence between the degree of depressive disorders and related diseases revealed a positive correlation of significant strength between significant depressive disorders and respiratory diseases (r=0,59); positive correlation of significant strength to a mild degree of depression and respiratory disorders (r=0,36) as well as to significant depressive disorders and protein exchange disorders (r=-0,36).

Conclusions: Comorbidity occurs in the majority (82,1%) of depressive patients. Correlations of varying strength between the degree of depressive disorder and related diseases were found. The findings confirm the importance of taking into account the presence of concomitant pathology when planning a course of treatment and rehabilitation. Moreover, the necessity of screening for depression is confirmed when depressed patients ask for medical treatment.

Key words: physical therapy, depressive disorders, concomitant diseases

Słowa kluczowe: fizjoterapia, zaburzenia depresyjne, choroby współistniejące

Acta Balneol, TOM LXIV, Nr 6(172);2022:534-536

INTRODUCTION

Nearly 300 million [1, 2] – 350 million [3] people in the world suffer from depression, and one out of six people in the world has experienced a depressive episode at least once in their life [4]. The presence of a depressive state is indicated by certain behavioural disorders – increased sensitivity, expressiveness, and aggressiveness [5]. Individuals suffering from depression lose their jobs twice as often as other people in the general population [6].

Isolated depression is practically uncommon [7]. As a rule, it is accompanied by comorbid conditions with somatic disorders, and disorders of cardiovascular system functioning that lead to marked manifestations of depression [8].

According to the interpretation, comorbidity is the combination of two and/or more chronic diseases in one patient, which are pathogenetically related to each other, or consist over time in one patient, regardless of the activity of each of them. The term "comorbidity" (in Latin co – together, morbus – disease) was introduced by the prominent American epidemiologist Alvan R. Feinstein [9]. Hidden depression is an endogenous depressive state in which various non-specific symptoms of comorbid conditions come to the fore, and the symptomatology of depression is poorly differentiated [10], the quality of life in such patients is decreased [11].

AIM

To analyze data on the presence of comorbidity in patients with depression and to determine the strength of the relationship between the degree of depressive disorder and concomitant diseases.

MATERIALS AND METHODS

The study involved 67 female patients with recurrent depressive disorders treated at the hospital of the Volyn Regional Psychiatric Hospital in Lutsk. The study was conducted from November 2021

to June 2022. Patients' age was 45.37±12.01 (min – 23; max – 69). Patients who personally (or their parents) did not agree to participate were not included in the study. The level of depression was determined by the Patient Health Questionnaire-9 (PHQ-9). The correlation relationship was analyzed using Spearman's rank correlation coefficient (r) at a significance level of $p \leq 0.01$.

The correlation relationship was assessed as weak at r=0.1-0.29; medium strength at r=0.3-0.49; significant at r=0.5-0.69; strong at r=0.7-0.89; very strong at r=0.9-0.99. The complementary coefficient of correlation indicates the direct (positive) connection between the indices, and the significant coefficient indicates the reverse (negative) connection.

The study is authorized by the Bioethics Commission of the Lesya Ukrainka Eastern European National University (protocol No. 1 of 18.06.2020) within the scientific research topic approved by the decision of the Scientific Council of the Lesya Ukrainka Eastern European National University (Protocol No. 8 of 23.06.2020).

RESULTS

During the initial examination of patients with depression, depending on the complaints and detected health disorders, the attending physician determined the need to include in the multidisciplinary team rehabilitation specialists, physicions of narrow specialties (cardiologist, gastroenterologist, urologist, gynecologist, pulmonologist, endocrinologist, neurologist, etc.) for a targeted detailed examination to identify concomitant diseases. The obtained data from consultations of narrow specialists and data from additional examination methods make it possible to diagnose the comorbid state in patients with depression and, accordingly, adjust the rehabilitation program using physical therapy.

According to the data obtained in our study, 32.8% of patients with depression had signs of diseases of the digestive system; 22.4% – neurological disorders were recorded; 19.4% – respiratory diseases; 17.9% - metabolic disorders; 16.4% – gynecological diseases; 11.9% – cardiovascular diseases. In 17.9% of patients with depression, no concomitant pathologies were detected, and in 44.8%, the presence of two or more comorbid diseases was confirmed.

Analyzing the frequency of detection of two or more concomitant diseases in patients with depression, we found that the highest frequency of combined pathologies (8.9%) is metabolic disorders and diseases of the digestive system; 7.5% of patients with depression had a combination of Neurological Disorders and diseases of the digestive system, and 4.5% – a combination of neurological disorders with respiratory diseases. With the same frequency (3%) a combination of concomitant diseases was observed in patients with depression: respiratory diseases and digestive diseases; respiratory diseases and metabolic disorders; diseases of the respiratory system and diseases of the cardiovascular system; neurological disorders and metabolic disorders; neurological disorders and cardiovascular diseases. 1.5% of patients suffering from depression were found to have a combination of gynecological diseases with diseases of the digestive system, neurological disorders, and metabolic disorders.

To screen for depression and determine the degree of depression, we used the PHQ-9 questionnaire. According to its results, 13.4% of patients had signs of minimal depression (0-4 points); a third of patients (34.4%) had mild depressive symptoms (5-9 points); a quarter (23.9%) had moderate depressive symptoms (10-14 points); 14.9% of patients had significant depressive disorders (15-19 points); 13.4% of patients had severe depression (20-27 points). To analyze the relationship between the degree of depression and existing comorbidity, we calculated Spearman's rank Correlation Coefficient (r).

Depression with minimal symptoms was found to have a direct weak correlation with diseases of the digestive system (r=0.15) and with respiratory diseases (r=0.25); an inverse weak correlation (r=-0.25) with neurological disorders, gynecological diseases, and cardiovascular diseases.

Mild depression with respiratory diseases has a direct interdependence of moderate strength (r=0.36) and an inverse correlation of moderate strength with neurological disorders (r=-0.35); weak positive interdependence was found with diseases of the digestive system (r=0.12), metabolic disorders (r=0.28), cardiovascular diseases (r=0.18); weak negative interdependence can be traced with gynecological diseases (r=-0.27).

Moderate depression directly correlates with a weak connection with respiratory diseases (r=0.16), gynecological diseases (r=0.27), cardiovascular diseases (r=0.14); inversely correlates with metabolic disorders (r=-0.23).

Patients with significant depression have a positive correlation of significant strength with respiratory diseases (r=0.59); medium strength with metabolic disorders (r=0.36), weak strength with digestive diseases (r=0.18); negative correlation of medium strength with gynecological diseases (r=-0.39).

Severe depression is inversely correlated with the medium strength of connection with digestive diseases (r=-0.36), weak strength with neurological disorders (r=-0.24); directly interrelated with weak strength with metabolic disorders (r=0.11).

DISCUSSION

When interpreting the results obtained, we adhered to the definition that "comorbidity" is not just a combination of several diseases, but the presence of an additional clinical picture, complications and course that are not characteristic of the underlying disease, showing a significant impact on the quality and duration of life. Depression refers to diseases that often have a latent character and occur in combination with other disorders. Only 17.9% of depressive patients treated as inpatients were found to have no concomitant illnesses. Concomitant diseases of the digestive system (32.8%), neurological disorders (22.4%), and respiratory diseases (19.4%) are most often diagnosed. In 44.8% of patients with depression, two or more concomitant diseases were detected. The most common comorbidity of diseases of the digestive system is their combination with metabolic disorders (8.9%) and with neurological disorders (7.5%). The data

obtained are important to take into account when prescribing pharmacological treatment to prevent drug antagonism and the development of side effects, as well as when developing a rehabilitation plan with the selection of adequate means of physical therapy.

An important stage of an individual approach to the implementation of the rehabilitation program for patients with depression is to take into consideration the interdependence with concomitant diseases that can change the clinical picture causing polymorphism. The data obtained make it possible to state that there is a positive significant relationship between severe depressive disorders and respiratory diseases (r=0.59). A positive relationship of moderate strength can be traced between mild depression and respiratory diseases (r=0.36); between severe depressive disorders and metabolic disorders (r=-0.36). Such correlation results confirm the need for depression screening when examining somatic patients with suspected depressive disorders.

Further long-term research plans include studying the features of creating a rehabilitation plan and individual physical therapy programs for patients with depression, considering comorbidity and the interdependence of concomitant diseases.

CONCLUSIONS

The vast majority (82.1%) of depressive disorders are comorbid. Correlations of varying strength between the degree of depressive disorder and related diseases were found. The findings confirm the importance of considering the presence of concomitant pathology when planning treatment and rehabilitation, and the necessity of screening for depression for patients asking for medical help.

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The study was carried out within the framework of the scientific research topic "Physical therapy of patients with recurrent depressive disorder" approved by the decision of the Scientific Council of the Lesya Ukrainka Eastern European National University (Protocol No. 8 of 23.06.2020).

Conflict of interest:
The Authors declare no conflict of interest

Received: 30.04.2022
Accepted: 15.10.2022

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Dynamics of the Level of Functioning of Patients After Laparoscopic Cholecystectomy in the Long-term Rehabilitation Period

Dynamika poziomu funkcjonowania pacjentów po laparoskopowym usunięciu pęcherzyka żółciowego w okresie długotrwałej rehabilitacji

DOI: 10.36740/ABAL202206108

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SUMMARY

Aim: to determine the dynamics of the level of functioning of patients after laparoscopic cholecystectomy in the long-term rehabilitation period.

Materials and Methods: 79 patients after laparoscopic cholecystectomy were included, double-blind survey on the presence of impairments in functioning, activity and participation using the ICF. Statistical methods: measurement of the median value (Me), upper and lower quartiles (25%; 75%). The Mann-Whitney U-test was used to compare independent samples; the Wilcoxon T-test was used for dependent samples.

Results: under the influence of rehabilitation, positive dynamics in the state of the gastrointestinal tract and the gait activity of patients of group A were revealed after the implementation using a biomedical approach. The rehabilitation method of group B was based on the assessment of the patient's functioning using the ICF and the organization of problem-oriented and aimed at achieving long- and short-term tasks with a patient-centered approach. to achieve improved functioning of gastrointestinal functions, general endurance, aerobic capacity, muscle strength and improved activities.

Conclusions: the dynamics of the level of functioning and activity of patients after laparoscopic cholecystectomy in the long-term rehabilitation period was better in the group that used a biopsychosocial approach with the use of ICF.

Key words: cholecystectomy, rehabilitation, functioning, participation

Słowa kluczowe: cholecystektomia, rehabilitacja, funkcjonowanie, uczestnictwo

Acta Balneol, TOM LXIV, Nr 6(172);2022:537-541

INTRODUCTION

The health care system of Ukraine is at the stage of harmonizing the legislation of Ukraine with the legislation of the European Union on the path of our country to EU membership. Law of Ukraine "On rehabilitation in the field of health care", which provides for "determination of the legal, organizational and economic principles of rehabilitation of a person with limitations day-to-day functioning in the field of health care in order to achieve and maintain an optimal level of functioning in its environment"[1]. The use of a patient-centered approach in rehabilitation requires the use of the international classification of functioning, limitations of life and health (ICF) to develop individual rehabilitation programs and evaluate their effectiveness give a link to my article ICF [1, 2].

AIM

To determine the dynamics of the level of functioning of patients after laparoscopic cholecystectomy in the long-term rehabilitation period.

MATERIALS AND METHODS

The study included 79 patients after laparoscopic cholecystectomy, aged 45 to 59 years, who underwent surgery from 1 to 6 months. Exclusion criteria: patients with inflammatory processes in the stomach and duodenum; with exacerbation of the inflammatory process in the

pancreas, with chronic enteritis and colitis in the phase of severe exacerbation; with acute pyelonephritis; malignant diseases of digestive organs; with a violation of the passage of food masses through the gastrointestinal tract; with complicated urolithiasis; acutely expressed insufficiency of blood circulation, with neuropsychological pathology; refusal of patients to participate in the study, participation of the patient in another study. 79 patients underwent rehabilitation in the health-resort complex Morshinkurort rehabilitation department "Lavanda", who were divided into 2 groups by the method of randomization by simple random selection with drawing lots: group A (n=39) age 52,56±0,62 years, duration of rehabilitation intervention 19,85±0,61 days; group B (n=40) 52,80±0,64 years, duration of rehabilitation intervention 18,78±0,72 days. Group A patients received rehabilitation services according to the standard scheme of the medical institution using a biomedical approach (diet, hydrotherapy, mineral or coniferous baths and therapeutic physical education using general-developing exercises). In the group B, individual rehabilitation programs were formed on the basis of identified functional disorders with the help of ICF, using a biopsychosocial approach. The program included physical therapy, if necessary occupational therapy, diet, hydrotherapy." Methods: A parallel-group research design was used. Double blinding was carried out: patients and assessors during the survey, examination and processing of the received data. A survey was conducted regarding the presence of impairments in functioning, activity and participation using the ICF (according to the 2001 version of the World Health Organization) [1]. Methods of synthesis, analysis, randomization. Evaluation of the degree of violations according to the general classification of the ICF was evaluated Function/Structure/Activity and participation. Statistical analysis. The obtained results were processed by means of mathematical statistics using the IBM SPSS Statistics 23 program. The calculations included the measurement of the median value (Me), upper and lower quartiles (25%; 75%). The Mann-Whitney U-test was used to compare independent samples, dependent samples – Wilcoxon T-test.

The higher the percentage of violations, the higher the score received by the patients. When the violations were absent or insignificant, patients received 0 points during the assessment (0-4%); 1 point – light, minor violations (5-24%); 2 points – violations are average, significant (25-49%); 3 points – serious, significant, intense violations (50-95%); 4 points – absolute, total violations. No patients were dropped from the study.

The methods used in the research were approved by the ethics commission of the Ivano-Frankivsk Medical University (IFMU).

RESULTS

Our study concerns the assessment of the dynamics of the level of functioning of patients after laparoscopic cholecystectomy in the long-term rehabilitation period. And evaluation of the effectiveness of the application of ICF in the development of individual rehabilitation programs for such patients in comparison with the generally accepted methodology of a health-resort facility. The presence in patients of groups A and B "postcholecystectomy syndrome" [3, 4], became the reason for continuing treatment in sanatorium-resort conditions according to the clinical protocol. Groups A and B in SCC conditions received, according to the clinical protocol, an individual dietary regimen [5].

Along with diet therapy, the patients of both groups were prescribed hydrotherapy. Diluted therapeutic mineral water (DTMW) of well No. 3-k was used. with. Goryshnoe of Stryi district of Lviv region in a dilution of 3.0-3.4 g/dm3 when used internally. When diluting the brines of well "No. 3-k" with weakly mineralized water of spring "No. 4" in a ratio of 1:41.69 to 1:41.55, the chemical composition of DTMW will correspond to the following formula:

$SO_4$77-81CI 16-20
$M_{3,0\text{-}4,0}$
(NA+K) 82-85 Mg 12-16

DTMW refers to low-mineralized sulfate, chloride-sulfate-sodium. Mineral water was taken in the amount of 200-250 ml. for one dose, with a temperature of 40-42 0C, 40 minutes before eating three times a day [5, 6]. Group A patients, along with hydrotherapy and diet therapy, received coniferous or mineral baths or other passive water procedures; group daily therapeutic gymnastics lasting 30-45 minutes, which consisted of general developmental exercises, classical massage of the back and abdomen lasting 25-30 minutes, applications with ozokerite on the abdominal area in the absence of contraindications were also prescribed.

The rehabilitation method of group B was based on the evaluation of the patient's functioning using the ICF. The process was problem-oriented and aimed at achieving long- and short-term goals. We used a patient-centered approach, which involved planning and carrying out rehabilitation taking into account the needs, capabilities and wishes of the person who received rehabilitation assistance. Each person in this group was selected an individual rehabilitation plan in accordance with the change in the functional state of the person who received rehabilitation assistance. Special means of rehabilitation were selected for each detected dysfunction. The rehabilitation process was consistent, taking into account the actual changes in the functional state of the person, the reaction to the performed procedures. Physical activity increased gradually. The duration of therapeutic exercises was determined strictly individually, taking into account the condition of the patients. The entire rehabilitation process was aimed at achieving the optimal level of functioning and quality of life of a person in his environment [7]. Physical therapy included the following means: breathing exercises (diaphragmatic breathing exercises with prolonged exhalation prevailed), exercises to strengthen the muscles of the abdominal press on exhalation to avoid increase in intra-abdominal pressure, exercises for stretching the front and side areas of the abdomen. Exercises aimed at improving motor performance (strength, coordination and flexibility) were used, depending

on individual indicators. For patients with impaired endurance function and aerobic capacity, cyclic exercises in the aerobic mode, such as dosed walking, riding an exercise bike, Nordic walking, and circuit training, were also used. Massage and management of scars were also used according to the indications, with existing diastasis – kinesiotaping. When experiencing intestinal colic – applications with ozokerite. In more detail, the method of rehabilitation intervention based on ICF group B is depicted in Table 1. The results of the assessment of the level of functioning of patients by group before and after the rehabilitation intervention are presented in Table 2.

DISCUSSION

When comparing both groups before the start of the rehabilitation intervention, no statistical difference was found between the two groups in the presence of impairments in functionality and activity and participation.

Many scientific works have proven that LHC improves the quality of life and condition of patients with calculous cholecystitis [10]. Many works are also devoted to the effectiveness and improvement of surgical treatment tactics. But there are many works that indicate that there is a percentage of patients after LHC who have the so-called post-cholecystectomy syndrome and need rehabilitation intervention not only in the acute, sub acute, but also in the long-term period. Although such a percentage of complications is not large, however, taking into account the large number of cholecystectomies performed annually in Ukraine and the world, it becomes clear that this issue remains relevant for many patients. The reasons for this are quite different – from the complication of surgical intervention to the presence of concomitant pathology of the abdominal organs, or concomitant diseases. Most of the works are devoted to the effectiveness of medical treatment of post-cholecystectomy syndrome. Our study, thanks to the use of ICF, established that patients with post-cholecystectomy syndrome, in addition to the function of the biliary system [5], also have disorders of the tone of the muscles of the trunk and abdomen, a decrease in aerobic capacity, muscle strength and general endurance, some difficulties in certain activities and disorders participation [9]. Drug treatment or hydrotherapy, although effective, will not be able to solve all problems, but requires a broader view and intervention with the use of physical therapy and occupational therapy methods to restore or improve the impaired functions identified during the initial examination and restore activity and participation.After the implementation of the rehabilitation intervention, when analyzing the dynamics of the level of functioning and activity in group A, a statistically significant improvement was found in the following indicators ($p < 0,05$): b28012 Pain in the stomach or abdomen, 515 Digestive functions, namely in b5153 Tolerance of food, b5250 Removal

Table 1. Methodology of rehabilitation intervention based on the ICF of the group

Code	Methods of Rehabilitation
Body function	
b 134 Sleep functions	Positioning, sleep management
b 152 Functions of emotions	Patient education
b 28012 Stomach or abdominal pain	Use of DTMV, therapeutic exercises
b 28013 Back pain	Therapeutic exercises, massage
b 440 Respiratory functions	Breathing exercises, cyclic aerobic exercises, therapeutic exercises
b 4550 Overall physical endurance	Cyclic aerobic exercises, therapeutic exercises
b 4551 Aerobic ability	Cyclic aerobic exercises, therapeutic exercises
b 4552 Fatigue	Cyclic aerobic exercises, therapeutic exercises
b 515 Digestion functions	Use of DTMV, dietary nutrition, massage
b 5250 Removal of feces	Use of DTMV, dietary nutrition
b 5252 Frequency of defecation	Use of DTMV, diet, cyclic aerobic exercise
b 5254 Flatulence	Use of DTMV, dietary nutrition, massage
b 5350 Feeling sick	Taking DTMV, dietary nutrition, massage, breathing exercises, cyclic aerobic exercises
b 5351 Feeling bloated	Use of DTMV, dietary nutrition, massage
b 5352 Feeling of intestinal colic	DTMV consumption, dietary nutrition, cyclic aerobic exercise, positioning, preformed physical factors, ozokerite
b 7305 Torso muscle strength	Strength exercises, cyclic aerobic exercises
b 7355 Torso muscle tone	Therapeutic exercises, breathing exercises
b 7401 Endurance of muscle groups	Therapeutic exercises, breathing exercises, cyclic aerobic exercises
b 7402 Endurance of all muscles of the body	Cyclic aerobic exercises, therapeutic exercises
Activities and participation	
d 4501 Walking long distances	Ergotherapeutic exercises, aids, cyclic aerobic exercises, therapeutic exercises
d 5100 Washing body parts	Ergotherapeutic exercises, aids, therapeutic exercises
d 5204 Toenail care	Ergotherapeutic exercises, aids, therapeutic exercises
d 5402 Putting on the lower extremities	Ergotherapeutic exercises, aids, therapeutic exercises
d 5701 Adherence to diet and fitness	Special training on lifestyle modification, diet, calorie intake, physical activity

Table 2. The results of the assessment of the level of functioning of patients by group before and after the rehabilitation intervention

Code ICF	Points Me [25 %, 75 %]				p-value			
	Group A		Group B		for Wilcoxon T-test		for Mann-Whitney U-test	
	before rehabilitation	after rehabilitation	before rehabilitation	after rehabilitation	Group A before and after rehabilitation	Group B before and after rehabilitation	Groups A i B before rehabilitation	Groups A i B after rehabilitation
b 134	1 [1; 2]	1 [1; 2]	1 [1; 2]	1 [0; 1]	0,067	0,000	0,479	0,000
b 152	2 [2; 3]	2 [2; 3]	2 [2; 3]	1 [1; 2]	0,523	0,000	0,274	0,000
b 28012	2 [2; 3]	1 [1; 1]	2 [2; 3]	1 [1; 1]	0,000	0,000	0,390	0,215
b 28013	2 [1; 2]	2 [1; 2]	2 [1; 2]	1 [0; 1]	0,320	0,000	0,355	0,000
b 440	2 [1; 2]	2 [1; 2]	2 [1; 2]	1 [0; 1]	0,113	0,000	0,298	0,000
b 4550	2 [2; 3]	2 [2; 2]	2 [2; 3]	1 [1; 2]	0,186	0,000	0,336	0,000
b 4551	2 [2; 2]	2 [1; 2]	2 [2; 2]	1 [1; 2]	0,120	0,000	0,256	0,000
b 4552	2 [2; 2]	2 [2; 2]	2 [2; 3]	1 [1; 2]	0,436	0,000	0,058	0,000
b 515	2 [2; 3]	2 [1; 2]	2 [2; 2]	2 [1; 2]	0,000	0,000	0,282	0,494
b 5250	2 [2; 3]	1 [1; 2]	2 [2; 3]	1 [1; 1]	0,000	0,000	0,346	0,001
b 5252	2 [2; 3]	2 [2; 2]	2 [2; 3]	1 [1; 1]	0,000	0,000	0,377	0,000
b 5254	2 [2; 2]	2 [2; 2]	2 [2; 3]	2 [1; 2]	0,086	0,000	0,262	0,138
b 5350	1 [1; 2]	1 [1; 1]	1 [1; 2]	1 [0; 1]	0,036	0,001	0,226	0,349
b 5351	3 [3; 3]	2 [1; 2]	3 [3; 3]	1 [1; 2]	0,000	0,000	0,284	0,121
b 5352	3 [3; 3]	1 [1; 2]	3 [2; 3]	1 [1; 2]	0,000	0,000	0,186	0,180
b 7305	3 [2; 3]	3 [2; 3]	3 [2; 3]	2 [1; 2]	0,333	0,000	0,540	0,000
b 7355	2 [2; 3]	2 [2; 2]	2 [2; 3]	2 [1; 2]	0,089	0,002	0,454	0,019
b 7401	2 [2; 3]	2 [2; 2]	2 [2; 3]	2 [1; 2]	0,068	0,000	0,412	0,000
b 7402	2 [2; 2]	2 [2; 2]	2 [2; 2]	2 [1; 2]	0,301	0,000	0,305	0,017
d 4501	2 [2; 3]	2 [1; 2]	2 [2; 3]	1 [1; 2]	0,002	0,000	0,352	0,019
d 5100	1 [0; 1]	1 [0; 1]	1 [0; 1]	0 [0; 1]	0,375	0,002	0,256	0,036
d 5204	2 [1; 2]	1 [1; 2]	2 [1; 2]	1 [0; 1]	0,380	0,000	0,497	0,000
d 5402	1 [1; 2]	1 [1; 2]	1 [1; 2]	1 [1; 1]	0,306	0,002	0,300	0,004
d 5701	2 [2; 3]	2 [2; 2]	2 [2; 3]	2 [1; 2]	0,050	0,000	0,456	0,000

of feces, b5252 Frequency of defecation, b5350 Sensation of nausea, b5351 Sensation of bloating, b5352 Sensation of intestinal colic. Such results prove the effectiveness of the rehabilitation program using the standard scheme of a medical institution using a biomedical approach (diet, hydrotherapy, mineral or coniferous baths and physical therapy using general developmental exercises) on the condition of the gastrointestinal tract, normalization of sleep and emotions of patients. Also, particularly d4501 Long-distance walking, improved in this group, as the patients walked more than 5 km per day on average.

In group B, after the implementation of the rehabilitation intervention, the indicators improved statistically significantly: b 134 Sleep functions, b 152 Functions of emotions, b 28012 Stomach or abdominal pain, b 28013 Back pain, b 440 Respiratory functions, b 4550 Over all physical endurance, b 4551 Aerobic ability, b 4552 Fatigue, b 515 Digestion functions, b 5250 Removal off feces, b 5252 Frequency of defecation, b 5254 Flatulence, b 5350 A feeling of nausea, b 5351 Feeling bloated, b 5352 Feeling of intestinal colic, b 7305 Torso muscle strength, b 7355 Torso muscle tone, b 7401 Endurance of muscle groups, b 7402 Endurance of all muscles of the body, Activities and participation, d 4501 Walking long distances, d 5100 Washing body parts, d 5204 Toe nail care, d 5402 Putting on the lower extremities, d 5701 Adherence to diet and fitness.

CONCLUSIONS

Therefore, the method of rehabilitation intervention with the use of mineral water, hydrotherapy and diet therapy, coniferous or mineral baths, or other passive water procedures, group daily therapeutic gymnastics, classic massage of the back and abdomen, applications with ozokerite on the abdominal area in the absence of contraindications can reliably improve the dynamics functions that are responsible for the functions of sleep, emotions, the gastrointestinal tract and long-distance walking activity. The rehabilitation method of group A, which was based on the evaluation of the patient's functioning using the ICF and the organization of problem-oriented and aimed at achieving long- and short-term tasks with a patient-centered approach, and the combination of the use of mineral water and diet therapy can affect the achievement of improvement

not only in the optimal level of gastric functioning -intestinal functions, but also improving activity, which will help patients with post-cholecystectomy syndrome to function as actively as possible in society.

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The methods used in the research were approved by the ethics commission of the Ivano-Frankivsk Medical University (IFMU) during the planning of complex research work, approved by the decision of the Scientific Council of the IFMU protocol No. 19 dated 12.20.2018. on the topic: "Development and improvement of the organizational and methodological foundations of physical therapy for patients with diseases of the abdominal cavity and nervous system" (state registration number 0119U000448) and scientific research of IFMU in the field of health care from the specialty 227 "Physical therapy, occupational therapy" on the topic : "Theoretical and methodological foundations of physical therapy of patients after laparoscopic cholecystectomy" (state registration number 01119 U 2951).

Conflict of interest:
The Authors declare no conflict of interest

Received: 23.04.2022
Accepted: 18.09.2022

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A – Research concept and design, B – Collection and/or assembly of data, C – Data analysis and interpretation, D – Writing the article, E – Critical revision of the article, F – Final approval of article

Effectiveness of Preventive Measures in the Inactive Course of Chronic Parenchymatic Mumps in Children

Skuteczność działań profilaktycznych w nieaktywnym przebiegu przewlekłej świnki miąższowej u dzieci

DOI: 10.36740/ABAL202206109

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SUMMARY

Aim: To study the effectiveness of preventive measures in the inactive course of chronic parenchymal mumps in remission.
Materials and Methods: In the dynamics of precautionary measures, aimed at preventing of exacerbation of chronic processes in the parotid glands, were examined 29 children aged from 2 months to 16 years with inactive mumps in remission and 10 control persons aged from 7 to 15 years.
Results: According to the assessment of the cellular composition of parotid secretion before anti-relapse measures in 9 patients out of 19, it was possible to detect the presence of latent chronic inflammation in symmetrical glands in the absence of classical clinical symptoms and clear secretion. After the completion of the treatment-and-prophylactic complex, the number of inflammatory cells and the degree of its contamination with microorganisms decreased significantly.
Conclusions: The study of the composition of parotid secretion with taking into account of the results of ultrasound examination and sialography in the dynamic monitoring of chronic parenchymal mumps indicate its high diagnostic informativeness and allows a rational approach to planning preventive measures. The methodological approach, which was developed and tested by us and which was used in the active course of mumps, showed its high efficiency and inactive form of the disease, for the first year of observation the number of exacerbations decreased by 10 times, and for 5 years term- by 16 times, which allowed to prolong the remission period and improve the rheological properties of parotid secretion.

Key words: children, chronic parenchymal mumps, prevention of exacerbations

Słowa kluczowe: dzieci, przewlekła świnka miąższowa, profilaktyka zaostrzeń

Acta Balneol, TOM LXIV, Nr 6(172);2022:542-546

INTRODUCTION

Large salivary glands are secretory-excretory structures that perform important and diverse functions, affect the general condition of the body, the activity of the digestive system and endocrine status. Age-related anatomical and physiological features of the child's body determine the need to study their morphological structure, clinical manifestations in various nosological forms of the pathological process directly in the salivary glands, and reactive changes in them in various diseases of the maxillofacial area and other anatomical localization. Usually, most often it is a chronic recurrent mumps, which occupies a leading position among all chronic forms of sialadenitis in children [1-4].

The variety and polymorphism of clinical manifestations of mumps often leads to errors at all stages of diagnosis. Therefore, a clear understanding of the characteristic symptoms, features of the disease and glandular function, changes in the amount of parotid secretion, its cellular composition, physicochemical and biochemical properties, the presence of organic disorders in the structural elements of the gland becomes important for correct diagnosis. It is possible to unify the diagnostic algorithm due to the introduction into clinical practice of modern technologies and their use as special, highly informative research methods in the early stages of the survey [5-8].

Due to the controversial issue of the role of a variety of exogenous and endogenous etiological factors involved in the formation of chronic inflammation, the signs of which can be present in the initial clinical manifestations of mumps, this controversy remains far from resolved. Identification

of numerous pathogenetic mechanisms involved in the exacerbation of the pathological process and maintenance of conditions to promote long-term remission, allows to determine the scope of treatment of both symptomatic and pathogenetic direction in all periods of chronic parenchymal mumps [9-11].

Despite the encouraging results obtained recently in the study of individual components of the pathogenesis of mumps, it is not always possible to timely predict the likelihood of exacerbation of disease or determine the duration of the stable remission phase of it. Moreover, the tactical approach to address these issues largely depends on the activity of the inflammatory process in the parotid gland, which determines the severity of functional and organic disorders at both local and general levels [12-14]. Early diagnosis plays a particularly important role in the effectiveness of treatment and prevention measures, which prevents significant progression of morphological changes in the future in the structural elements of the parenchyma and duct system, which determines the relevance of our work.

AIM

To study the effectiveness of preventive measures in the inactive course of chronic parenchymal mumps in remission.

MATERIALS AND METHODS

Scientific work was performed by summarizing of the results of 5 years' experience of anti-relapse measures in 29 children with inactive chronic parenchymal mumps, who are registered in the municipal enterprise "Children's City Clinical Dental Clinic of Poltava City Council", which is also the basic medical institution for the Department of Pediatric Surgical Dentistry. The age of patients ranged from 2 months to 16 years, and the control group consisted of 10 practically healthy individuals of primary and secondary school age (7-15 years). According to the International Classification of Diseases to Dentistry and Stomatology, based on the content of ICD-10, this disease is classified as Class 11 (K11).

At the first request for medical care for the diagnosis of recurrent mumps, general methods were used: survey, anamnesis of life and disease, palpation examination. Particular attention was paid to heredity, the nature of pregnancy and child development in the postnatal period, the presence of concomitant somatic diseases and clarified the cause that could provoke clinical manifestations of chronic pathological processes in the parotid glands.

Patients were also probed with the main excretory duct, visually determining the amount and nature of parotid secretion from which smears were made for further study of their cell composition after Romanowski-Giemsa staining. In order to detect structural changes in the anatomical structures of the salivary glands, ultrasound and sialography were performed in direct and lateral projections after the introduction of 76% solution of triombrast into the duct system. The parenchyma of the gland was fine-grained and had a homogeneous structure and a capsule of normal thickness in children of the control group.

To confirm the role of some strains of microorganisms in maintaining the periodic manifestation of the inflammatory process, their species affiliation and quantitative parameters were determined in accordance with the order of the Ministry of Health of Ukraine №236 from 04.04.2012 and recommendations of the European Association for Clinical Microbiology and Infectious Diseases.

Taking into account the final effectiveness of treatment and prevention measures was carried out on the basis of comparing the results of clinical and special research methods obtained in dynamic observation. Statistical processing of digital material was carried out.

RESULTS

Previous publications have highlighted issues related to the specifics of the effectiveness of anti-relapse measures in the remission phase in the active course of chronic parenchymal mumps in children. The conducted studies clearly showed the high diagnostic informativeness of the study of the cellular composition of parotid secretion in the dynamics of observation, ultrasound diagnosis and sialography. The implementation of a prophylactic complex aimed at preventing exacerbations has significantly reduced the amount of exacerbations and the severity of inflammatory reactions in the parotid salivary gland and achieve longer remission period [14].

Encouraging results from previous studies have prompted us to continue working in this direction, but this has already applied to patients with inactive form of disease. To achieve this goal, a group of 29 patients was formed, who a month after treatment of the next exacerbation underwent an in-depth double examination – at the beginning and after the end of preventive measures. Bilateral parotid glands lesions with clinical manifestations were observed in 10 children (34.5%), and unilateral lesion were observed in 19 children (65.5%).

At the initial period, patients or their relatives had no complaints, but all patients experienced a salty taste in the mouth, especially before eating. Examination of patients did not reveal any visual changes, meanwhile, palpation revealed small foci of compaction within the anatomical location of individual lobes of the gland in 11 cases (37.9%). Enlargement of regional lymph nodes was found only in 9 children (31.0%). The oral mucosa was pale pink and well moisturized, and at the mouth of the duct of the gland there was a slight swelling and redness of the mucosa in 15 patients (51.7%) and in 11 cases (37.9%) there was a gaping duct. When massaging the parotid glands after dilatation of the duct with a salivary tube was obtained parotid secretion of sufficient quantity and normal viscosity in 7 children (21.1%), and in another 22 (75.9%) - the secretion was viscous and had single small whitish crumbs inclusion.

In the study of cell composition in cytograms of parotid secretion, which had whitish inclusions and was taken during the initial examination, in all 22 patients on a low-density protein substrate found a moderate number of scattered leukocytes, single lymphocytes, macrophages and coccal microflora (Figure 1).

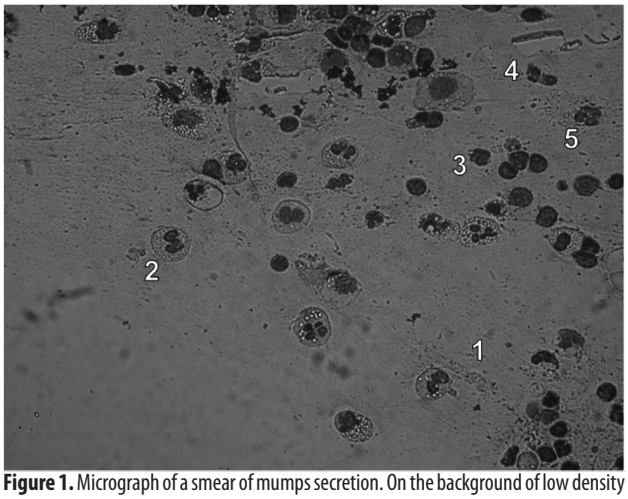

Figure 1. Micrograph of a smear of mumps secretion. On the background of low density protein substrate (1) a moderate number of destroyed forms of leukocytes (2), lymphocytes (3), single macrophages (4) and coccal microflora (5) is determined

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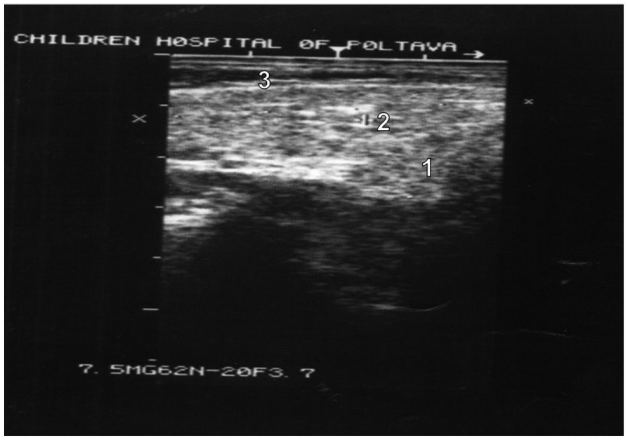

Figure 2. A small number of small, scattered dialectases (1), compaction of parenchymal tissues around them (2) and capsule compaction (3) are determined

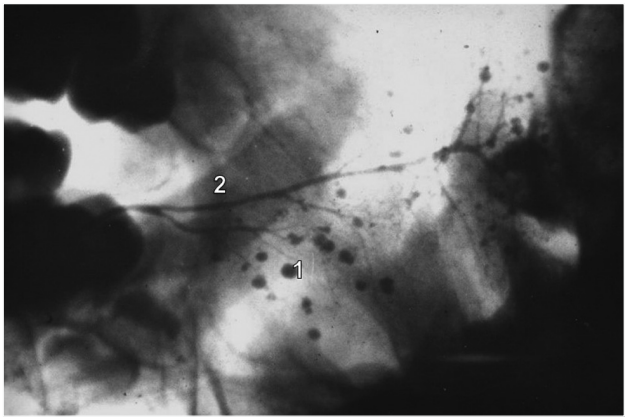

Figure 3. Sialogram of the left parotid gland in lateral projection. In some lobes of the gland, single small sialectases (1) and a slight expansion of the main excretory duct (2) are detected

During the study of the results of ultrasound diagnostics in all cases the compaction of the gland capsule was observed, and the parenchyma looked heterogeneous due to the alternation of single hypoechoic and echo-compacted areas (Figure 2). A few scattered, small sialectases were discovered on sialograms (Figure 3).

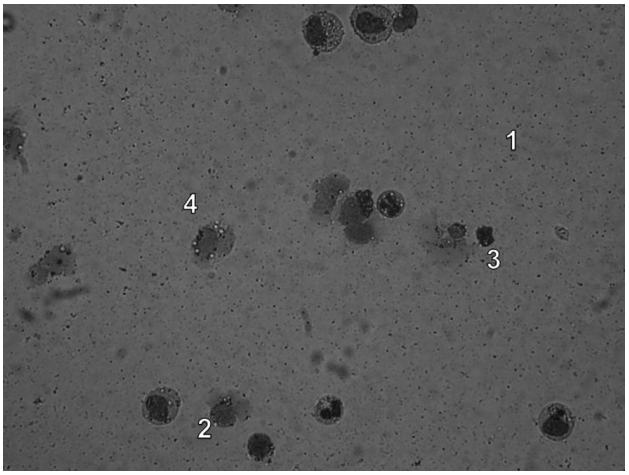

Figure 4. Micrograph of a smear of mumps secretion. On the background of mucus cells (1) a few, partially destroyed neutrophils (2), lymphocytes (3) and coccal microflora (4) is determined

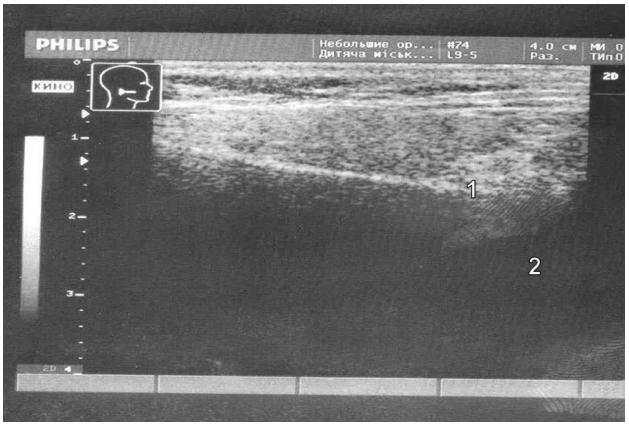

Figure 5. Ultrasound image of the right parotid gland. The image shows a single small sialectases (1) and compaction of parenchymal tissues (2)

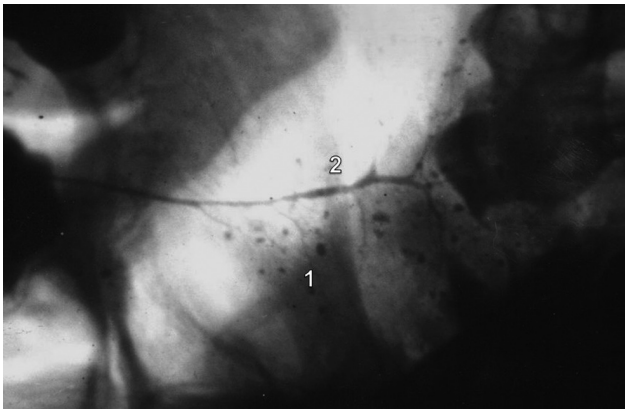

Figure 6. Sialogram of the right parotid gland in lateral projection. In the parenchyma, single small sialectases (1) and uneven contours of the main duct (2) detected

In 9 (47.3%) of 19 patients who did not have clinical manifestations of the disease in symmetrical glands, and their secretion was visually transparent, cytological examination of smears revealed the presence of a small number of inflammatory cells (Figure 4). The performed ultrasound examination revealed single, small and medium-sized sialectases in some lobes of the gland, around which the echo-dense parenchyma was visualized (Figure 5), and the presence of single small sialectases was found on sialograms (Figure 6).

Microbiological examination of 41 portions of parotid secretion, which was obtained from glands involved in chronic inflammation, revealed representatives of the coccal microflora in the amount from $5 \cdot 10^4$ to $5 \cdot 10^5$ per 1 ml of substrate. Streptococcal vegetation was determined in the analysis of secretion smears: in 8 cases (19.5%) hemolytic, and in 28 (68.3%) non-hemolytic and in 5 cases (12.2%) bacterial growth was not determined.

Given the fact that the proposed amount of treatment and prevention measures used in the treatment of active mumps showed good results, we tested its effectiveness in inactive form of disease.

At the time of completion of the prevention course, children and their relatives had no complaints. Visual examination of the face was symmetrical, and palpation revealed small single compacted areas of the parotid gland only in 3 children (10.3%). The oral mucosa was well moisturized in all children, edema around the mouth of the excretory duct was not found, and ductal yawning was observed in only 5 children (17.2%) with bilateral pathological process. After massaging of the parotid glands, in 21 children (72.4%) were received a clear secretion of normal viscosity, and only in 8 cases (27.6%) secretion had a slightly increased viscosity and included single small whitish flaky inclusions.

During the study of the cell composition of cytograms, it was found that in all patients whose secretions contained inclusions, and in 7 children (24.1%) whose secretions did not include inclusions, there was a low background field density and the presence of single, distinct destructive forms of neutrophils.

At the end of the treatment and prevention course, bacterial inclusions were isolated only from the parotid secretion of 23 glands, which is in 1.6 times less than in the first examination. Quantitative parameters of certain microorganisms in these smears has no significant differences in comparison with baseline level.

During the first year, with this approach to this category of patients, the number of exacerbations decreased by 10 times and in 5 years term – by 16 times. All children showed an improvement in the functional activity of the parotid salivary glands, and periodic exacerbations occurred with less pronounced clinical manifestations.

DISCUSSION

Chronic parenchymal mumps is a leader in all nosological forms of chronic sialadenitis, and it is characterized by a long course of the disease and frequent exacerbations, and therefore it requires significant efforts of doctors, material resources and financial costs. For the correct establishment or confirmation of the clinical diagnosis, in addition to general methods of examination, special methods are widely used, including the study of the cellular composition of glandular secretions, ultrasound, sialography, conventional radiography. These measures allow for a detailed differential diagnosis, but their informativeness in the literature is still debated, because their importance depends on degree of the activity of the disease [5, 6, 11]. In particular, the study of the cellular composition of parotid secretion, which provides comprehensive information about the severity of the inflammatory process in the dynamics of observation and allows you to monitor the results of treatment, is not often used, especially during the period of remission [14]. In our opinion, it is necessary to use this method of examination more widely in everyday clinical practice in order to make a differential diagnosis of diseases of the large salivary glands of inflammatory nature, specific and nonspecific diseases of soft tissues of the maxillofacial area located in this anatomical area. The results of our work testify of the high informativeness of cytological examination of the cellular composition of parotid secretion, ultrasound examination and X-ray with artificial contrast of the structural elements of the parotid salivary glands. Recent methods allow to obtain high-quality images of both the duct system and parenchyma and to establish the severity of their organic disorders, which may be the key to forming a more targeted pathogenetic effect on the pathological process, determining the type and scope of treatment, which we recorded [6,14].

CONCLUSIONS

Evaluation of the effectiveness of a set of treatment and prevention measures in children with chronic parenchymal mumps should be based on the generalization of dynamic changes in the cellular composition of parotid secretion and its microbiological contamination. The severity of structural disorders in the anatomical components can be successfully established on the basis of ultrasound and sialographic picture. Planning and standardization of the treatment process should be based on functional criteria and structural disorders both in the duct system of the glands and directly in the parenchyma. With this methodological approach for the first year of observation the number of exacerbations decreased by 10 times, and for 5 years term – by 16 times, which is more pronounced than in the active course of the disease. It would be important to develop indications and contraindications to the use of more modern methods of examination, such as magnetic resonance imaging, sialography and endoscopy in order to detail the severity of duct deformities of various orders.

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Conflict of interest:
The Authors declare no conflict of interest

Received: 11.05.2022
Accepted: 30.10.2022

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A – Research concept and design, B – Collection and/or assembly of data, C – Data analysis and interpretation, D – Writing the article, E – Critical revision of the article, F – Final approval of article

Predictors of Successful Smoking Cesstion in Cardiac Rehabilitation Patients with a History of Acute Coronary Syndrome

Predyktory skutecznego zaprzestania palenia wśród pacjentów rehabilitowanych kardiologicznie po przebyciu ostrego zespołu wieńcowego

DOI: 10.36740/ABAL202206110

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SUMMARY

Aim: To establish socio-psychological and clinical smoking predictors cessation at the stage of health-resort rehabilitation in patients who have recently suffered an acute coronary event.

Materials and Methods: 68 patients aged 42-68 years (average age 56.70±6.1 years) who underwent a cardiorehabilitation program in the heart rehabilitation department of the health-resort complex„Morshinkurort" after a recent ACS (no more than 28 days ago) were examined. Depending on the smoking habit, all patients were divided into two groups. The first (I) group included smoking patients who gave up smoking in the course of CR (n=38, average age 57.10±6.73 years), the second (II) group included smokers who continued smoking during the health-resort stay treatment (n=30, average age 56.58±5.74 years). Predictors of smoking cessation were determined in patients of the studied groups using the method of binary logistic regression.

Results: In the course of the study, 5 independent predictors of quitting smoking were established, which turned out to be statistically significant - smoking index, anxiety level, body mass index, comorbidity and marital status. The chances of quitting smoking were 1.79 times greater (95% CI from 1.25 to 2.56) in patients with higher BMI and 3.23 times (95% CI from 0.57 to 18.40) in those who are in family status. High comorbidity, higher SI score, and higher anxiety levels were significantly associated with a reduced likelihood of quitting smoking.

Conclusions: Cardiac rehabilitation patients with high nicotine dependence, lower body weight, loneliness, significant anxiety symptoms, and multiple comorbidities are less likely to successfully quit smoking. Established independent predictors of smoking cessation must be used when choosing strategies for the treatment of tobacco addiction at the stage of CR. Screening and treatment for anxiety disorders should be included in smoking cessation programs to improve the SI effectiveness.

Key words: cardiorehabilitation program, health-resort, nicotine dependence, multiple comorbidities

Słowa kluczowe: program rehabilitacji kardiologicznej, sanatorium, uzależnienie od nikotyny, liczne choroby współistniejące

Acta Balneol, TOM LXIV, Nr 6(172);2022:547-551

INTRODUCTION

Smoking remains one of the most aggressive risk factors for cardiovascular disease (CVD) [1-3], as smokers have been shown to have twice the risk of cardiovascular (CVD) mortality than non-smokers. Accordingly, quitting smoking in people even in the elderly is useful [4]. Data from a meta-analysis showed that the increased CV risk in patients who got rid of this habit decreased over time [4]. Another study found a directly proportional relationship between smoking and CVD: the more cigarettes smoked and the longer the history of smoking, the higher the risk of myocardial infarction (MI) [5].

The authors of a meta-analysis of 12 cohort studies suggested that smoking cessation is closely related to a reduction in overall mortality [6]. It was found that in patients who did not give up smoking after an MI, mortality increased significantly and amounted to 20%. The scientific results of another retrospective American study Partners YOUNG-MI Registry [7] showed that smoking cessation in young patients (< 50 years old) who underwent MI was reliably

associated with a decrease in total mortality and mortality from CV diseases by approximately 70-80%. And this, in turn, confisms the critical importance of smoking cessation in young patients after MI. Another convincing result was obtained in a 15-year follow-up of patients who underwent coronary bypass surgery [8]. A study found that patients who smoked within 1 year after surgery had a risk of subsequent MI and reoperation more than twice as high as patients who quit smoking after surgery [8]. Patients who continued to smoke 5 years after surgery had an even higher risk of MI and reoperation compared with patients who quit smoking after surgery and patients who had never smoked. It was also found that the risk of MI was similar among non-smokers and those who managed to quit smoking after surgery [8]. In a meta-analysis of 20 studies, it was found that the effect of smoking cessation was prognostically more favorable than lowering cholesterol, in which the latter sometimes the greatest attention is focused [9].

Despite the fact that smoking necessity cessation in the process of cardiorehabilitation (CR) has been proven, little is known among the participants of CR about the factors associated with the patients' refusal to quit smoking. That is why researchers have begun to study predictors of smoking cessation in order to improve and increase the effectiveness of cardiorehabilitation programs. The results of many studies have established variables that influence the process of quitting smoking, namely: the degree of tobacco dependence (number of cigarettes smoked per day, smoking history), number of previous attempts to quit smoking, gender, age, marital status and level of depression. However, the obtained scientific results of such studies are contradictory and require additional study to accurately determine the factors that are associated with the successful cessation of smoking by smoking patients after an acute coronary event at the stage of active completion of CR programs.

AIM

To establish socio-psychological and clinical predictors of smoking cessation at the stage of health-resort rehabilitation in patients who have recently suffered an acute coronary event.

MATERIALS AND METHODS

68 patients aged 42-68 years (average age 56.70±6.1 years) who underwent a cardiorehabilitation program in the rehabilitation department after heart diseases of the „Morshinkurort" health-resort complex after a recent heart attack (no more than 28 days ago) were examined. Depending on the smoking habit, all patients were divided into two groups. The first (I) group included smoking patients who gave up smoking during the CR process (n=38, average age 57.10±6.73 years), the second (II) group – smokers who continued to smoke during the health-resort treatment (n=30, average age 56.58±5.74 years). The measures of the rehabilitation program were carried out according to the recommendations of the ESC working group on cardiorehabilitation and physical training [10]. The CR program included dosed therapeutic walking, therapeutic gymnastics (ThG), laser therapy for the cubital vein, and optimal medical therapy (OMT). In order to quit smoking, all smoking patients were given individual counseling using the "5As" strategy, unmotivated smokers - the "5R" strategy in accordance with Order 746 dated 09/26/2012 "On the approval of Methodological recommendations for medical workers of health care institutions on providing medical and preventive care for persons who want to get rid of tobacco addiction" [11,12]. The length of stay of all cardiac rehabilitation patients in the rehabilitation department was 24 days.

All CR participants were interviewed using the Fagerstman test to assess the degree of nicotine addiction. The smoking index (SI) was calculated according to the formula: (SI)=Ch*C/20, where Ch is the number of cigarettes smoked (per day), C is the smoking experience (years). All patients were also subjected to anthropometric measurements of body weight (m) using medical scales and height (h) to calculate BMI according to the formula: BMI = m/h2, where m is body weight (kg), h is height (m). The level of depression and anxiety was assessed using the HADS scale (The Hospital Anxiety and Depression Scale) [13]. All rehabilitation patients underwent biochemical blood analysis, echocardiography and physical stress tests at the start of the cardiorehabilitation process.

We also used the primary data of rehabilitation patients to conduct the study: age, sex, presence of concomitant diseases, cardiovascular risk and marital status. In the course of the study, all of the above indicators were used to synthesize a mathematical model for predicting the outcome of smoking cessation in patients with ACS using the binary logistic regression method. The conducted analysis made it possible to establish the factors affecting the outcome of smoking cessation and to calculate the probability of this event depending on the values of independent predictors.

RESULTS

During our calculations of binary logistic regression using the Wald exclusion method, 5 key parameters were determined that were statistically significant in terms of the influence on the process of smoking cessation in rehabilitation patients. The coefficients of the selected binary logistic regression model are presented in the Table 1.

The logistic regression model we created was statistically significant ($G = 54.036$ at $p\ (\chi 2) < 0.00000$) and the obtained Hosmer-Lemeshov (HL) value, which was 9.264 at a significance level of $p>0.05$ ($p = 0.320$), indicated about the high consistency of our model. In the logistic model we created, the influence of indicators (SI, HADS-T, BMI, marital status and the presence of concomitant diseases) on smoking cessation was 58.79% (Table 2).

The effectiveness of the created model was confirmed with the help of our ROC-analysis by constructing a curve. The calculated area under the ROC curve (AUC) was 0.7877 [0.67-0.90] at p=0.0001, which corresponds to the "good" quality of the created model according to the expert AUC scale. The effectiveness of the model is represented by high threshold indicators of sensitivity (84.21%) and

Table 1. Coefficients of the binary logistic regression model calculated to predict the outcome of patients' smoking cessation

Indicators	Conventional designations	b -coeffi-cients	Standard error	Wald Criterion	r	Odds	95% confidence interval	
							Lower	Upper
IR	X1	-0,1005	0,04	5,92	0,015	0,90	0,83	0,98
HADS-T	X2	-0,2298	0,16	2,18	0,023	0,79	0,59	1,08
BMI	X3	0,5830	0,18	10,27	0,001	1,79	1,25	2,56
Concomitant diseases	X4	-0,5139	0,92	0,31	0,042	0,60	0,10	3,66
Marital status (married)	X5	1,1713	0,89	1,74	0,046	3,23	0,57	18,40
Constant	K	-10,0809	4,76	4,48	0,034	0,00		

Table 2. Characteristics of the binary logistic regression model

-2 Log Plausibility (G)	χ2	p	R2 Nigelkerka
54,036	39,288	0,00000	0,5879

Table 3. ROC analysis results

Area under the curve	Standard. error	p	95% CI	
			Lower limit	Upper limit
0,7877	0,06	0,0001	0,67	0,90

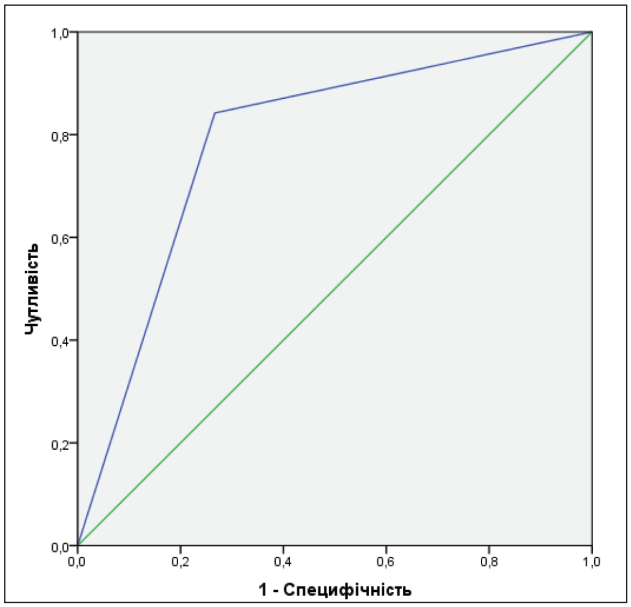

Figure 1. ROS-curve of diagnostic testing of the quality of the binary logistic model smoking cessation in patients undergoing ACS (specificity)

specificity (73.33%), which confirms its significant practical diagnostic value for use by health care institutions (Table 3, Figure 1).

Thus, in the course of our analysis, it was established that only five studied indicators, namely, the level of nicotine dependence (NI), the level of anxiety according to the HADS scale, BMI, the presence of concomitant diseases and family status, are independent predictors of quitting smoking .

In particular, the chances of quitting smoking were 1.79 times greater (95% CI from 1.25 to 2.56) in patients with higher BMI and 3.23 times (95% CI from 0.57 to 18.40) – in patients who are in family status. High comorbidity, a higher IS score, and a higher level of anxiety were significantly associated with a reduced likelihood of quitting smoking.

DISCUSSION

Our analysis revealed that rehabilitation patients with a high level of nicotine dependence, severe anxiety disorders, low BMI, multiple comorbidities, and the absence of a partner had a low probability of effective smoking cessation during the CR program. Compared with smokers who continued to smoke, patients who successfully quit smoking were less anxious, had lower nicotine dependence, fewer comorbidities, higher body weight, and more frequent marital status.

Our results are consistent with a number of other studies [14-17]. In particular, at the study of Ahmad Salmanet. al [14] also found that patients without a partner, with lower body weight, with major depressive disorders and with high comorbidity were less likely to quit smoking. However, the authors of this study also found that the younger the age of the patients and the lower the cardiovascular risk, the more likely rehabilitation patients will get rid of the bad habit. In our study, there was no significant difference in age and cardiovascular risk among the CR participants. Similar results were obtained in the study of E. Vangeliet. al [18], where age was not significantly associated with smoking cessation attempts. Marital status was

also identified as an important predictor of smoking cessation in another retrospective study [19]. The authors of the analysis observed that smokers, whose partners objected to smoking, gave up the bad habit more often.

We also did not observe statistically significant differences in the gender of rehabilitation patients. The obtained results were consistent with the conclusions of other studies, in which also no probable gender difference was found in smoking patients of the studied groups [20, 21]. On the other hand, some studies report that male gender is a strong independent predictor of smoking cessation [22], while in the study of T. Chandola et al. al identified female gender as an important predictor of smoking cessation [19]. Such conflicting conclusions indicate the need for a series of more thorough statistical analyzes to identify factors of successful smoking cessation in participants of cardiorehabilitation programs. The quality of our study consisted in the use of an observational approach using a large set of primary data of rehabilitation patients to create a statistically significant logistic regression model.

Thus, the predictors of smoking cessation obtained by us are very important characteristics that must be taken into account when counseling smoking patients at the stage of the cardiorehabilitation process. This, in turn, can help in the correct choice and rapid application of more intensive treatment strategies for smoking cessation by angry smokers already at the start of health-resort treatment. Moreover, cardiac rehabilitation programs should prioritize rehabilitation patients without partners, with high nicotine dependence, severe anxiety disorders, and multiple comorbidities to maximize the SI use of health care resources.

CONCLUSIONS

Cardiac rehabilitation patients with high nicotine dependence, lower body weight, loneliness, significant anxiety symptoms, and multiple comorbidities are less likely to successfully quit smoking. Established independent predictors of smoking cessation must be used when choosing strategies for the treatment of tobacco addiction at the stage of CR. Screening and treatment for anxiety disorders should be included in smoking cessation programs to increase the SI effectiveness.

Our scientific-research work was carried out on the basis of rehabilitation department after cardiac diseases at "Morshynkurort" health-resort complex under supervision of scientific department at Danylo Halytsky Lviv National Medical University.

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Conflict of interest:
The Authors declare no conflict of interest

Received: 02.04.2022
Accepted: 28.10.2022

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The Features of Post-infarction Period in Patients of Law Tolerance to Physical Activity and Chronic Heart Failure

Cechy okresu po niedokrwieniu wśród pacjentów z niską tolerancją wysiłku fizycznego i przewlekłą niewydolnością serca

DOI: 10.36740/ABAL202206111

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SUMMARY

Aim: To determine the features of the early post-infarction period in patients after acute coronary syndrome with concomitant arterial hypertension, depending on the response to dosed physical activity.

Materials and Methods: 120 patients with a reduced response to dosed physical activity, with Q, QS MI and concomitant hypertension, who were at the stage of rehabilitation and recovery treatment, were examined.

Results: In the course of the study, during the 6-minute walk test, a decrease in oxygen consumption was found in the group of patients of an adequate tolerance to physical activity by 18.42% compared to 15.21% in the group of patients of low tolerance to activity. During the analysis of ABPM (Ambulatory Blood Pressure Monitoring**)** indicators, it was found that in patients who made up the group of low tolerance to DPA (Dosed Physical Activity), significantly higher average values of systolic blood pressure (SBP) (159.24±3.4) mm Hg and diastolic blood pressure (DBP) (96.26±2 .49) mm Hg, as well as heart rate. During urgent coronary angiography, it was found that in patients of an adequate response to DPA, one vascular lesion was detected in most cases (73.3%), in the group of patients of low tolerance to DPA, one vascular lesion of CA was detected in (14.5%), in (55.5%) recorded two vascular lesions of the CA, and (30%) patients had three or more vascular lesions of the CA. The level of troponin I in blood serum at the time of hospitalization in the group of patients of low tolerance to DPA was 36.38±6.79 ng/ml, the level of NT-proBNP – 726.4±36.32 pg/ml, the level of endothelin-1-9,37±1.34 pmol/L.

Conclusions: During the recovery period of treatment of patients after an acute myocardial infarction with concomitant arterial hypertension, a low tolerance to dosed physical activity occurs (in 63.7% of cases), which is accompanied by the appearance of anginal pain, changes in clinical indicators in the early and late post-infarction period and prevents the conducting a full range of rehabilitation measures.

Key words: myocardial infraction, chronic heart failure, physical activity

Słowa kluczowe: niedokrwienie mięśnia sercowego, przewlekła niewydolność serca, aktywność fizyczna

Acta Balneol, TOM LXIV, Nr 6(172);2022:552-556

INTRODUCTION

The main goal of rehabilitation of patients who have suffered an acute disorder of coronary circulation is to restore the patient's life as fully as possible, including returning to work. Physical, psychological, and socioeconomic factors should be taken into account during rehabilitation. The process should begin as early as possible after admission to the hospital and continue over the following weeks and months. These rehabilitation processes cannot take place without concomitant drug therapy.

The presence of concomitant pathology complicates the postoperative period of patients of this category, and a need for a differentiated purpose of treatment and rehabilitation complexes occurs. The course of both the acute phase of a myocardial infarction and the early post-infarction period affects the effectiveness of the purpose of treatment and rehabilitation complexes.

The prognosis of patients in the distant period after a myocardial infarction (MI) is insufficiently studied and is primarily based on the risk factors and clinical and laboratory indicators in the acute period of MI [1, 4, 9]. As is known, the immediate and long-term prognosis of patients with AMI associated with the development of AHF (acute heart failure) is in most cases caused by a decrease in the contractility of the myocardium of the left ventricle. Heart failure develops in approximately 30% of patients who have undergone AMI.

Usually, the prognosis for such patients is unfavorable, and the mortality rate reaches 50% during the first year [1, 7]. It has been found that even after successful PCI (percutaneous coronary intervention), the risk of adverse events is 10% during the first year and 5% annually for four years after the intervention (D. Erlinge, M. Radu, 2015). Therefore, it remains relevant to identify factors that have an impact on the long-term prognosis in patients with an inadequate response to dosed physical activity and with Q, QS MI after PCI. However, the impact of hypertension on the course of the early post-infarction period is controversial. Several studies of the patients after MI have shown that hypertension is associated with an increased incidence of adverse outcomes such as stroke, heart failure, and cardiovascular death [6]. From the other side, some studies did not find the impact of hypertension on prognosis after MI [3, 5, 8]. In the studies of Abrignani et al. it was found that patients with hypertension and the first AMI have a more favorable outcome in the hospital than patients of the same age and sex but without hypertension, possibly due to less spread of the infarct zone or other pathophysiological mechanisms [2].

AIM

To determine the features of the early post-infarction period in patients after acute coronary syndrome with concomitant arterial hypertension, depending on the response to dosed physical activity.

MATERIALS AND METHODS

120 patients with a reduced response to dosed physical activity, with Q, QS MI and concomitant hypertension, who were at the stage of rehabilitation and recovery treatment, aged from 40 to 82 years (on average (66.22±0.53) years), were examined, of which 52 are women and 73 are men. 30 relatively healthy persons were also examined, who made up the comparison group.

At the stage of inclusion in the study, all patients underwent a six-minute walk test to determine the nature of the response to dosed physical activity, which were divided into two groups (using a simple randomization method): 1) patients of an adequate response to DPA (n=30); 2) patients of low tolerance to DPA (n=90). Complications during the test were not observed in any case.

Statistical processing of the obtained results was carried out with the help of the STATISTICA-7 computer program and the package of statistical functions of the "Microsoft-Excel" program on a personal computer using the variational statistical method of analysis. In the course of the work, the arithmetic mean M, the standard deviation δ, the average error of the arithmetic mean m, the number of variant (n), the probability of the difference between the two-arithmetic means "p", values $p<0.05$ were considered probable.

RESULTS

When comparing the obtained indicators of the conducted 6-minute walk test between the groups, it was found that the values of such indicators as the distance walked, the capacity of the performed activity, the oxygen consumption during the activity, decreased significantly ($p<0.001$) in comparison with the group of patients of low tolerance to dosed physical activity (Table 1).

Compared with the group of healthy individuals, in the group of patients of an adequate response to DPA, a decrease in oxygen consumption was noted by 18.42%, in the group of patients of low tolerance to DPA – by 15.21%, respectively. The values of the average heart rate before the test in the groups of patients did not differ significantly ($p>0.05$). When evaluating the values of such indicators as the maximum heart rate and the increase in heart rate during the test, a significant ($p<0.001$) decrease in these indicators was found in the two groups of patients, as well as in comparison with the group of healthy individuals and with each other.

The analysis of anamnesis data and medical documentation of patients who were at the stage of rehabilitation after an AMI with concomitant hypertension (Table 2) showed that in a fairly significant percentage of patients in the main group, 34.4%, destabilization of CAD (coronary artery disease) was detected during the last year, whereas in the control group destabilization due to CAD was observed only in 16.7% of individuals. In 65.6% of patients of the main group, the duration of CAD was from 1 to 5 years, 62.2% had CAD for more than 5 years. 62.2% of the examined patients from the group of low tolerance to DPA had hypertension for more than 5 years, and 37.8% of individuals noted an increase in blood pressure for 1-5 years. Concomitant hypertension also occurred in patients of an adequate response to DPA, namely, 46.7% of the examined had hypertension for more than 5 years, and 53.3% of individuals had hypertension for 1-5 years. The patients of both groups had excessive BMI (30.83±0.58) kg/m^2.

In the group of patients of low tolerance to DPA, the II degree of hypertension was diagnosed in 51 patients (56.7%), and the III degree was diagnosed in 39 patients (43.3%). In the group of patients of an adequate response to DPA, these indicators were (63.3%) and (36.7%), respectively.

28.91% of the examined patients had MI in their anamnesis. Among the risk factors, smoking is present in 14.51% with an intensity of (18.51 ± 2.23) pack/years, in 59% – overweight with an average body mass index (BMI) of (29.70±0.33) kg /m^2, 33% have hypercholesterolemia with an average value of (5.03± 0.01) mmol/l. Chronic heart failure in the vast majority of the examined (63.3%) corresponded to the II-III FC of NYHA.

It was found that most patients from the group of low tolerance to DFN complained of shortness of breath (46.7%), pain behind the breastbone (42.2%), a feeling of interruptions in the work of the heart (22.2%) and rapid fatigue (31.1%).

During the analysis of ABPM indicators, it was found that in patients who made up the group of low tolerance to DPA, significantly higher average values of SBP and DBP, as well as heart rate were observed, in particular, in patients of low tolerance to DPA, the average daily level of SBP was (159.24 ±3.4) mm Hg, which is higher in comparison with the group of an adequate response, where the similar indicator was equal to (141.2±3.1) mm Hg ($p<0.001$). During the

Table 1. Indicators of the 6-minute walk test in patients after AMI with different tolerance to DPA

Indicator	Healthy (n=30)	Patients with an adequate response to DPA (n=30)	Patients with low tolerance to DPA (n=90)
1	2	3	4
Distance walked, m	606,07±33,67	451,21±40,0 p<0,01	302,13±33,98 p<0,001 p_1<0,01
Time, min	5,99±0,30	4,54±0,22 p<0,001	3,42±0,15 p<0,001 p_1<0,001
Load capacity, W	152,79±16,78	101,22±12,22 p<0,05	70,01±8,59 p<0,001 p_1<0,001
Oxygen consumption, ml/kg/min	26,05±0,86	18,42±1,14 p<0,05	15,21±0,68 p<0,001 p_1<0,001
SBP, mm Hg	126,00±2,49	142,14±3,72 p<0,001	154,74±4,74 p<0,001 p_1<0,05
$SBP_{max.}$, mm Hg	142,00±3,69	160,47±4,21 p<0,01	176,41±5,02 p<0,001 p_1<0,05
DBP, mm Hg	70,3±2,46	86,4±3,16 p<0,01	96,46±4,13 p<0,001 p_1<0,05
$DBP_{max.}$, mm Hg	86,59±2,34	96,26±2,49 p<0,01	106,49±3,49 p<0,001 p_1<0,05
Heart rate, initial, b/min	75,68±6,48	72,30±7,02 p>0,05	78,96±7,51 p>0,05 p_1>0,05
Heart $rate_{max}$, b/min	121,01±6,90	103,15±5,01 p<0,05	100,13±6,38 p<0,05 p_1>0,05
Increase in Heart rate, min	45,32±5,01	31,24±4,16 p<0,05	22,09±1,2 p<0,001 p_1<0,05

Notes: *1.- p- the reliability of the difference in comparison with the control group (healthy); 2.- p1 – the reliability of the difference in comparison with the group of an adequate response to DPA.*

analysis of ABPM indicators, it was noted that in patients of low tolerance to DPA, there was a significant variability of systolic blood pressure, namely – (12.69±1.01) mm Hg, in the group of an adequate response it was – (10.31 ±0.85) mm Hg (p<0.05). The indicators of the variability of DBP in these groups were within the normal range.

Hypertensive disease in the examined patients was characterized by the following types of daily blood pressure profiles: in 17 people from the group of an adequate response to dosed physical activity, the "dipper" profile was found, which was 56.7%, against 44 (44.9%) patients from the group of low tolerance to DPA. The "non-dipper" profile was stated in 7 (23.3%) patients of an adequate response to DPA and in 23 (25.6%) patients of Fig. 1. Distribution of the examined patients by types of daily BP profiles.

At the time of hospitalization, the level of troponin I in blood serum in the group of patients of low tolerance to DPA was 36.38±6.79 ng/ml and was higher compared to the group of an adequate response to DPA (10.46±2.52) ng/ml (p<0.001). The level of NT-proBNP in blood serum in the main group was 726.4±36.32 pg/ml, and in the individuals from control group – 679.64±33.98 pg/ml. The level of endothelin-1 in the blood plasma of the studied patients of an adequate response to DPA was 9.37±1.34 pmol/L, while in patients of low tolerance to DPA it was significantly higher and equal to (15.17±3.49) pmol/L (p<0.05).

A reliable positive correlation was established between the level of endothelin-1 and NT-proBNP (r=0.81; p<0.001). That is, with an increase in the level of NT-proBNP, the level of endothelin increases.

Table 2. Clinical characteristics of patients of different tolerance to DPA

Features	Patients of an adequate response to DPA (n=30)	Patients of low tolerance to DPA (n=90)	All patients (n=120)
Duration of hypertension:			
- 1-5 years	16 (53,3 %)	34 (37,8 %) p>0,05	50 (41,7 %)
- more than 5 years	14 (46,7 %)	56 (62,2 %) p>0,05	70 (58,3 %)
Duration of hypertension, in years	6,46±0,35	7,54±0,42 p>0,05	
Stage of heart failure:			
- I	17 (56,7 %)	38 (42,2 %) p>0,05	55 (45,8 %)
- II A	13 (43,3 %)	52 (57,8 %) p>0,05	65 (54,2 %)
Heart failure according to FC:			
- I	11 (36,7 %)	21 (23,3 %) p>0,05	32 (26,7 %)
- II	15 (50,0 %)	54 (60,0 %) p>0,05	69 (57,5 %)
Duration of CAD:			
-1-5 years	16 (53,3%)	32 (35,6 %) p>0,05	48 (53,3 %)
-more than 5 years	14 (46,7 %)	58 (64,4 %) p>0,05	72 (80,0 %)
Destabilization of CAD during the last year	5 (16,7 %)	31 (34,4 %) p<0,05	36 (30,0 %)

Notes: 1. the percentage of the total number of individuals in the group is indicated in parentheses, 2. p - the reliability of the difference between groups.

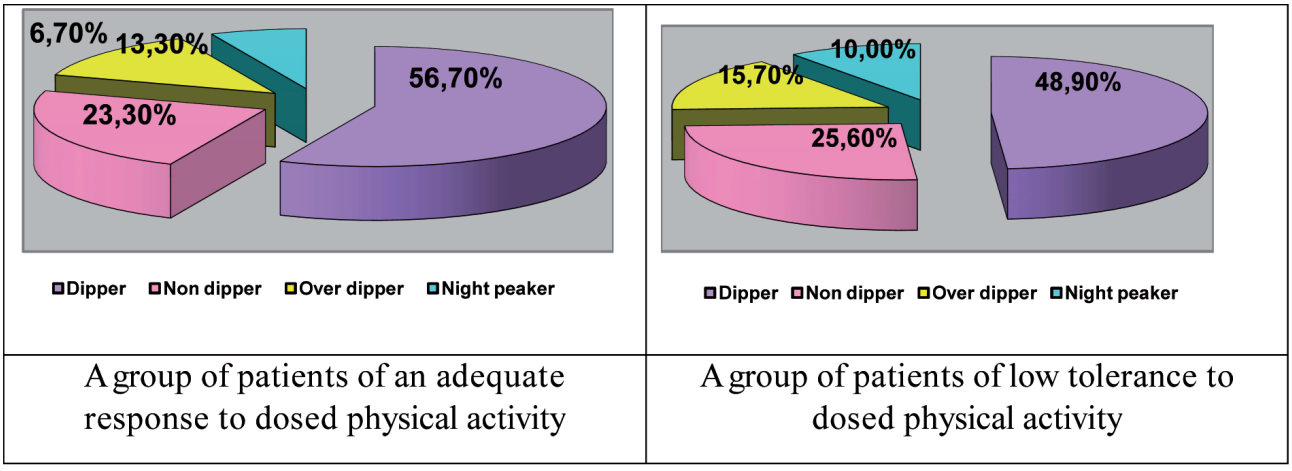

Fig. 1. Distribution of the examined patients by types of daily BP profiles.

Evaluating the structure of coronary artery lesions during urgent coronary angiography, it was found that in patients of an adequate response to DPA, one vascular lesion was detected in most cases – 22 patients (73.3%), two vascular lesions – in 8 patients (26.7%). In the group of patients of low tolerance to DPA, 13 patients (14.5%) had one vascular lesion of the CA, 50 patients had two vascular lesions of the CA (55.5%), and 27 patients had three or more vascular lesions of the CA (30 %).

DISCUSSION

In the course of study, the reasons for the occurrence of low tolerance to DPA after a myocardial infarction with concomitant hypertension were studied. Clinical-pathogenetic

predictors of the occurrence and development of low tolerance to physical activity are atherosclerotic lesions of two or more coronary arteries, myocardial infarction in the anamnesis (in 46.6% of cases), excess body weight (in 30%), a decrease in the coronary and myocardial reserves of the heart according to the data of six-minute walk test. A modern method of predicting the development of low tolerance to dosed physical activity after an MI with concomitant hypertension in the recovery period by determining the levels of NT-proBNP and endothelin in blood serum, is proposed, that makes it possible to identify a contingent of patients with a high risk of an adverse course in the post-infarction period. The number of lesioned coronary arteries, a high level of ET-1 and natriuretic peptide also affects the occurrence of low tolerance to dosed physical activity.

The aim of further research is to prescribe a comprehensive approach to the treatment of MI, taking into account both drug therapy and a complex of physical exercises and training. The main purpose will be to increase tolerance to physical activity in both studied groups. The effectiveness of physical rehabilitation is determined by the strict dosage and phasing of physical activity, its continuity and regularity, and the gradual increase in volume and intensity. As with drug treatment, the fundamental factor of cardio rehabilitation and, in particular, PR (physical rehabilitation) is the individualization of exertion.

CONCLUSIONS

In the recovery period of treatment of patients after an acute myocardial infarction with concomitant arterial hypertension, a low tolerance to dosed physical activity occurs (in 63.7% of cases), which is accompanied by the occurrence of anginal pain, changes in clinical indicators in the early and late post-infarction period and prevents the conducting a full range of rehabilitation measures.

Preconditions for the occurrence of low tolerance to physical activity are signs of multivessel damage to the coronary arteries, the presence of signs of chronic heart failure and arterial hypertension before an acute coronary event, extensive ischemic damage to the myocardium in the acute period of myocardial infarction.

After an acute coronary syndrome, it is necessary to conduct the dosed physical activity to form groups of low tolerance to physical exertion.

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Conflict of interest:
The Authors declare no conflict of interest

Received: 22.04.2022
Accepted: 02.10.2022

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Portable Device Use for Arterial Stiffness Determination as a Control Method at the Recovery Stage of Rehabilitation

Wykorzystanie przenośnych urządzeń do określania sztywności tętnic jako metoda kontrolna podczas rehabilitacji

DOI: 10.36740/ABAL202206112

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SUMMARY

Aim: To create a device for PWPV evaluation which would be cheap and could be easily used not only at the inpatient but also at the restorative outpatient and health-resort stages of rehabilitation.

Materials and Methods: The clinical examination included 90 people who were randomized into the group of observation (n=75) with patients of AH various degrees. 15 practically healthy persons were involved into the control group. PWPV was measured using a specially designed device according to the generally accepted carotid-femoral technique.

Results: Our results showed that the PWPV of healthy persons measured using original device failed to differ statistically from the literature reference values and indicated the correspondence of the measurements we obtained with the data received using traditional apparatus. Out data of original PWPV measurement obtained from examined and treated patients do not differ from the results obtained in wide range of patients aged from 40 to 70 years with the 1st -2nd stages of AH.

Conclusions: We described an efficacy of PWPV determination using an original device. The use of the proposed device does not contradict with the generally accepted method of vascular stiffness measuring and studying. The results obtained on it are comparable with the data of the most used stationary device SphygmoCor for these purposes. The prospects of the device using are without the limitations in patients with vascular diseases at the stage of rehabilitation.

Key words: vascular wall, arterial hypertension, stiffness, treatment efficacy, rehabilitation

Słowa kluczowe: ściana naczyniowa, nadciśnienie tętnicze, sztywność, skuteczność leczenia, rehabilitacja

Acta Balneol, TOM LXIV, Nr 6(172);2022:557-560

INTRODUCTION

It is well known that with age there is a change in the elastic properties of large arterial vessels. When studying blood vessels biomechanical properties one should attract special attention to pulse wave propagation velocity (PWPV) – an arterial vessels elastic-viscous state indicator. It just accurately reflects biological age and demonstrates a close relationship with chronological age in combination with other criteria reflecting a slow or accelerated type of aging of an certain individual [1, 2]. Discussing the vascular aging one should assume that especially the progressive increase in large arteries stiffness is its central marker [3, 4].

According to authors, an increase in stiffness and a decrease in elasticity of large arteries plays an important role in the pathogenesis of many cardiovascular diseases (CVD) and primarily in the arterial hypertension (AH) development [5, 6]. We know that blood pressure increase causes changes in the vascular wall together with arteriolosclerosis development which can result in arterial stiffness increase [7]. Thus, the vascular wall remodeling is associated both with age and with hereditary and other risk factors for CVD development i.e. hypertension, smoking, hypercholesterolemia, carbohydrate metabolism disturbances, etc. [8, 9]. Arterial stiffness evaluation is recommended by vascular specialists to detect the asymptomatic target organ damage as well as for CVD prevention as additional information for their development risk assessment [10, 11]. Experts also emphasize that PWPV increase is not only an independent predictor of cardiovascular complications but also their most reliable prognostic marker [12, 13].

The principle of PWPV determination is to register two pulse waves in different areas with a known distance (L) to

measure the transit time (t) from the beginning of the first wave increase in the nearest area to the initial point till the second wave initiation at the distal end of the arterial vessels and is calculated by the formula:

$$PWPV = L\ (m)/t\ (s)$$

This indicator integrates the geometry and elastic properties of the vessel that described by the Moens-Korteweg formula in accordance to which it follows that PWPV increases with increasing the vascular wall both stiffness and thickness [14]. Therefore, PWPV is significantly higher in the vessels of the muscular type at a young and mature age: for example, PWPV in the aorta (Se) equals to 4-6 m/s while in the peripheral arteries of the muscular type (Sm) it equals to 8-12 m/s.

Analyzing abovementioned it becomes clear that the level of arterial stiffness is important for potential risks evaluation in patients with CVD and especially with arterial hypertension as the most common nosological index among them. PWPV determination becomes even more important at the outpatient and recovery stages of rehabilitation as an effective method of cardiovascular risks preventing at the early stages of disease manifestation.

However it should be noted the vascular wall functional condition can now be non-invasively evaluated only using magnetic resonance, computed tomography and ultrasound methods. These methods and equipment are quite expensive, difficult to operate and many of them are not available on the Ukrainian market. There are no analogous domestic manufacturers and the available foreign devices are rare used in well-equipped private clinics and only at the stationary stage of rehabilitation.

AIM

The aim of the present work was to create a device for PWPV evaluation which would be cheap, easy to use, not bulky and finally could be used not only at the inpatient but also at the restorative outpatient and sanatorium-resort stages of rehabilitation. The additional aim of the work was to perform the comparative investigation of PWV indexes obtained using our original device with the reference literature data in healthy people and in patients with arterial hypertension determined with the help of SphygmoCor device.

MATERIALS AND METHODS

The clinical examination included 90 people. These persons were randomized into the group of observation (n=75) in which the patients with AH various degrees were involved. 15 practically healthy persons were involved into the control group for PWPV indexes verification. The examined patients were hospitalized at the cardiology clinic of the Military Medical Clinical Center of the Southern Region (Odesa).

We used the following criteria of patients' inclusion into the clinical investigation: the patient's informed agree to the study and the presence of hypertension of various degrees. Exclusion criteria were the following: the 3rd degree of hypertension, cardiac rhythm and conduction disturbances, any forms of atrial fibrillation, rheumatological diseases with vascular damage, acute coronary syndrome, type 1 or 2 diabetes mellitus, internal organs chronic diseases in the stage of subcompensation and decompensation, oncological diseases.

Table I. PWPV normal values depending on age (according to [16])

Age, years	PWPV, m/s (median (10th - 90th percentile)
Less 30	6,1 (5,3-7,1)
30-39	6,4 (5,2-8,0)
40-49	6,9 (5,9-8,6)
50-59	8,1 (6,3-10,0)
60-69	9,7 (7,9-13,1)
Above 70	10,6 (8,0-14,6)

The average age of healthy individuals was 23.40±1.96 years, among them there were 8 men and 7 women. The average age of patients with hypertension (from 28 to 59 years) was equal to 42.4±7.8 years, among them were 44 men and 31 women.

PWPV was measured using a specially designed device (Patent of Ukraine No. 145472) according to the generally accepted carotid-femoral technique [15]. These device was composed of strain gauge pulse sensors, an analog-to-digital converter and a personal computer with software. Mechanosensitive sensors were applied on the skin surface in the area of the carotid (the 1st sensor) and femoral (the 2nd sensor) arteries followed by simultaneous recording of two pulse waves, and then PWPV was calculated from the data obtained.

For PWV reference values we used the normal indexes obtained in a population study by P. Boutouyrie et al. (2010) for the European population taking into account age and blood pressure (Table 1) [16].

The results are presented as M±m, where M is the arithmetic mean, m is the error of the mean. The data obtained were calculated statistically using 'Statistica 10.0' program. The Shapiro-Wilk test was used to test the groups for the Gaussian distribution. Assuming the obtained normal distribution the further statistical calculation was performed using One Way Analysis of Variance (ANOVA-test). The minimum statistical probability was determined at $p<0.05$.

RESULTS

One of the main tasks for our original device introducing into practice was to compare the obtained PWPV values with the known referent indexes in patients of the same age and pathology – in our study, patients with the 1st degree of AH. The comparison of the obtained results was carried out with the literature data of PWPV measurement using the SphygmoCor device which is the most accurate and commonly used device at the stationary stage of rehabilitation. The results obtained are presented in Table 2.

Our results showed that the PWPV of healthy persons measured using original device were equal to 6.66±1.42 m/s that failed to differ statistically from the literature reference values [6.1 (5.3-7.1)] and indicated the correspondence of

Table 2. PWPV comparative analysis

Patients	PWPV, m/s (literature data) (M±m)	PWPV, m/s (original data) (M±m)	p
Healthy persons	6,1 (5,3-7,1)	6,66±1,42	
Patients (Chazova I.Ye.with co-authors) [17]	10,1±2,5	10,3±1,2	=0.943 >0.05
Patients (Liventseva M.M.with co-authors) [18]	10,1±0,3	10,3±1,2	=0.876 >0.05

Notes: p indicated significant differences of the investigated index compared with the same described in the literature data (criterion used – one-variant ANOVA + Krushkal-Wallis)

the measurements we obtained with the data received using SphygmoCor apparatus (p>0.05). It should be stressed that the age range of the studied group of healthy individuals corresponded to the age of the person in whom PWPV indexes were measured according to literature data – 23.4±1.96 years and "less than 30" years, respectively.

One could see that in the group of patients with the 1st stage of AH the PWPV index was 10.3±1.2 m/s exceeding the standard values (5.9-8.6 m/s) in their age group. These results coincide with the data of other authors showed that PWPV index increase in AH patients of the same age. The data obtained in the study Chazova I.Ye. co-authors (2018) revealed that PWPV index was also in the range of 10,1±2,5 m/s in patients aged from 40 to 70 years with the 1st-2nd stages of AH [17]. One could objectively see that these data do not differ from the results obtained using the original device (p=0.943 that is statistically <0.05). The correspondence of the measurements using the original device was also confirmed by the data of Livintseva et al. (2015) who showed PWPV equal to 10.1±0.3 m/s in patients with hypertension of the same age, and it should be stressed that there is no significant difference between the literature and our obtained data (10.3±1.2 m/s) (p=0.876) [18].

DISCUSSION

The investigation of blood vessels elastic properties becomes a highly informative predictor of cardiovascular accidents possible development. This dictates the need to determine the PWPV indicator as the "gold standard" for vascular stiffness studying not only at the inpatient but also at the outpatient, health-resort and recovery stages of rehabilitation.

The use of the proposed device does not contradict with the generally accepted method of vascular stiffness measuring and studying. The results obtained on it are comparable with the data of the most used stationary device SphygmoCor for these purposes.

The invention is quite convenient in operation, since the developed system is mobile which makes it possible to measure PWPV index at the patient's bedside at any time and determine risk factors with subsequent correction and treatment control. This device is also recommended for use as a screening method for population clinical examination to determine possible risk factors and prevent cardiovascular complications.

We believe that original device for arterial stiffness measuring does not have pronounced restrictions on technical application since we have indicated above its advantages and advantageous differences from similar devices and technologies currently used in the clinic. At the same time it is important to understand that relative limitations of original device and the method proposed clinical use are contraindications for certain groups of patients with vascular diseases which we indicated in chapter "Materials and Methods".

According to the prospects of the original technique with the developed device clinical use we note that these prospects are the best and most convenient and informative in patients with vascular diseases (in our case, with arterial hypertension) at the stage of rehabilitation. Using the original device we will achieve several effects: firstly, it will be easier to control the effectiveness of the therapy prescribed by doctors and, secondly, the actual data of the device can be an important factors in the vessels functional activity monitoring in certain patients at the rehabilitation stage which from a preventive point of view will allow to receive information about the possible developing pathology of the vascular wall.

CONCLUSIONS

With accordance to the aim of the present work we described an efficacy of PWPV determination using an original device.

The device constructed allowed to measure PWPV index in patients with AH throughout the whole epoch of their treatment and especially at the stage of rehabilitation which seems to be more effective and important.

The use of the proposed device does not contradict with the generally accepted method of vascular stiffness measuring and studying. The results obtained on it are comparable with the data of the most used stationary device SphygmoCor for these purposes.

The prospects of the device using are without the limitations in patients with vascular diseases (in our case, with arterial hypertension) at the stage of rehabilitation.

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The work is fragments of scientific-research investigation "Peculiarities of vascular disturbances in patients with cardio-rheumatological profile: modern methods of diagnostics and therapy", state registration No 0119U003576

Conflict of interest:
The Authors declare no conflict of interest

Received: 02.05.2022
Accepted: 18.10.2022

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Legal Characteristics of Medical and Social Rehabilitation During the Post-COVID Recovery Period

Prawna i medyczna charakterystyka resocjalizacji w okresie rekonwalescencji postcovidowej

DOI: 10.36740/ABAL202206113

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SUMMARY

Aim: The purpose of this article is a thorough review and assessment of the problematic issues of ensuring the post-covid restoration of health, work capacity, and occupational safety in current conditions. Analysis and generalization of components of individual types of rehabilitation and determination of measures to combat acute respiratory disease COVID-19.

Materials and Methods: The research is based on the analysis of international documents, strategies, recommendations, guidelines, empirical and analytical data of the World Health Organization and the International Labor Organization; scientific and analytical research. The article is grounded on dialectical, comparative-legal, cysteine-structural, formal-legal, and analytical methods. Additionally, in order to establish the facts of the provision of rehabilitation procedures, a survey of 1,063 respondents who suffered COVID-19 disease was conducted through social networks.

Conclusions: Rehabilitation is one of the main components of medical and social care. It is the rehabilitation after COVID-19 that makes it possible to eliminate the negative consequences of the suffered virus disease. Among the effective post-covid recovery rehabilitation measures special attention should be paid to innovative means that can integrate the social protection system. COVID-19 recovery should take place through the treatment provided by professional rehabilitators; an individual program should be developed for each patient who has sought help, which will depend on the patient's state of health and needs; also, modern techniques and equipment must be used.

Key words: rehabilitation, medical rehabilitation, social rehabilitation, post-COVID recovery, health care, COVID-19.

Słowa kluczowe: rehabilitacja, rehabilitacja medyczna, resocjalizacja, rekonwalescencja postcovidowa, opieka zdrowotna, COVID-19

Acta Balneol, TOM LXIV, Nr 6(172);2022:561-567

INTRODUCTION

The global epidemiological crisis caused by the rapid spread of the COVID-19 pandemic significantly affected the development of social relations and revealed a huge number of problems and gaps in health care regulation, access to adequate medical care, exercising the right to work, and occupational safety, social protection of the population, development of economic relations. But, at the same time, it became the cause of an unprecedented socio-economic crisis and had a significant impact on health care, namely the provision of fast, professional, and high-quality specialized medical care; rehabilitation, and disease prevention procedures.

Acquired clinical experience shows that disorders of the nervous system that occurred during COVID-19 can last for an indefinite period of time. Disorders of both the central and peripheral nervous and muscular systems are noted. Post-COVID-19 syndrome is characterized by the occurrence of neurocognitive disorders of varying degrees of severity lasting ≥12 weeks. Residual psychoneurological symptoms after coronavirus infection persist in 40–60% of patients [1].

The coronavirus, like any other disease, negatively impacts the human body and also affects the psychological and emotional state. In order to eliminate negative manifestations, it is necessary to undergo rehabilitation. Post-injury rehabilitation is a positive and effective method for a person to return to a normal rhythm of life.

It is worth paying attention to the fact that in the preamble of the Charter (Constitution) of the World Health Organization,

"health" means a state of complete physical, mental and social well-being, and not only the absence of diseases or physical defects [2].

A. Kemrad-Scott draws attention to the fact that the health care system should actively and effectively respond to global pandemics, and international and governmental organizations should work in concert to prevent, stop and overcome the consequences of pandemics and continuously prepare for them in order to reduce their destructive consequences for society [3].

That is why it is worth emphasizing that the World Health Organization plays a key role in the formation of the anti-crisis health care order, and pays considerable attention to the priority areas of its protection by developing standards, recommendations, guidelines, model legislation, and publishing annual reports on the situation in health care [4].

The modern approaches to understanding public health care are increasingly focused on disease prevention and rehabilitation. The coronavirus has had a negative impact on rehabilitation services, resulting in their reduction and hastening the scale of changes in health care, both from the point of view of clinical practice and the development, delivery, financing, and cooperation in the field of providing such services [5, 6].

After analyzing information from the UK biobank on 431,051 patients who suffered coronavirus infection, it became clear that the decline in cognitive functions in patients with post-covid syndrome is a statistically significant symptom. Analysis by subgroups showed that such disorders occur not only in the elderly but also in the young and middle-aged persons [1].

In addition, the researchers emphasize that all persons who have suffered the coronavirus infection, regardless of age, are at risk of cognitive impairment [1]. It is clear that in this case the rehabilitation of patients is relevant.

Rehabilitation, according to the definition of the World Health Organization, means a set of interventions aimed at optimizing the functioning and alleviating functional limitations of persons with impairments or special health conditions in their interaction with the environment. That is, it is related to the impact of a health condition on a person's life, which is most often accompanied by a disruption of the regular life activity of the body; restrictions on the implementation of various types of activities; total or temporary limitation of working capacity and participation in the social life [7].

That is, rehabilitation is aimed at eliminating limitations in the mental, physical and social functioning of a person, and directly at his life activities; optimization of functioning, and expansion of opportunities to manage one's health [8].

It is worth agreeing with the opinion of a number of scientists that rehabilitation is one of the most important components of medical measures to respond to emergency situations in health care and the outbreak of various infectious and non-infectious diseases [9].

Thus, rehabilitation services are essential: they should continue during and after the pandemic, as they are an essential component of the high-value care offered to people throughout life to optimize physical and cognitive functioning to reduce disability [10].

But it is worth noting that due to the pandemic, most countries introduced a state of emergency and tried to use all the necessary means and methods to fight the disease and overcome the consequences with the help of the health care, response, prevention, and rehabilitation system. That is why the issue of post-COVID-19 rehabilitation is gaining more and more relevance.

AIM

The purpose of this article is a thorough review and assessment of the problematic issues of ensuring the post-covid restoration of health, work capacity, and occupational safety in current conditions. Analysis and generalization of components of individual types of rehabilitation and determination of measures to combat COVID-19.

MATERIALS AND METHODS

The research is based on the analysis of international documents, strategies, recommendations, guidelines, empirical and analytical data from the World Health Organization and the International Labor Organization; scientific and analytical research on medical and social rehabilitation in the period of post-covid restoration of health and working capacity of persons who have suffered COVID-19. The basis of the research methodology and the achievement of the scientific validity of the results is a set of methods for learning an objective reality, based on dialectical, comparative-legal, cysteine-structural, formal-legal, and analytical methods. In addition, in order to establish the facts of rehabilitation procedures, a survey through social networks of 1,063 respondents who suffered COVID-19 was conducted.

REVIEW AND DISCUSSION

The field of rehabilitation services and their regulatory legal support is still very fragmented, and there is a need for more unified advocacy from rehabilitation professional groups, individual professionals, and users [11]. However, the COVID-19 pandemic has accelerated the need to develop strategies for rehabilitation services in the period of post-COVID-19 recovery and to provide detailed step-by-step recommendations related to the provision of rehabilitation services. In addition, as the population's access to health care services expands, the role of rehabilitation as a means of maximizing the efficiency and effectiveness of these services increases. But, at the same time, it is worth agreeing that in current conditions, the need for rehabilitation assistance significantly exceeds its availability [12]. Post-COVID-19 recovery of health and working capacity requires urgent response measures from the national health systems and governments worldwide. Leading scientists investigating the issue of rehabilitation determine that the types of rehabilitation should be considered in unity and interaction. The classification of rehabilitation types is quite extensive, but scientists and international organizations distinguish three main ones: medical, labor (professional), and social. That is, the process of COVID-19 recovery and rehabilitation entails, in addition to the restoration of health,

the need to restore work capacity and social status. Modern understanding of rehabilitation includes a complex of medical, psychological, economic, social, legal, professional means and methods, the main goal of which is to restore human resources for further normal existence. At the same time, in our opinion, special attention should be paid to medical and social rehabilitation and relevant recommendations of international organizations in this regard. It should be emphasized that COVID-19 and its rapid spread worldwide exposed a lot of problems in health care and set a number of tasks that are directly related to the rapid detection, treatment, and prevention of this disease, the provision of specialized professional medical assistance, before the relevant specialists. According to many scientists who studied the issue of medical rehabilitation, the latter should be carried out comprehensively by specialists in medical rehabilitation, namely: the doctor to whom the patient is assigned, a doctor of physical therapy, a physiotherapist, a methodical instructor of physical therapy [13]. To date, many countries have developed and approved national-level guidelines and methodological recommendations for assistance in post-epidemic recovery. At the same time, such recommendations are also developed by related medical professional organizations or their associations, as well as by local bodies under whose jurisdiction such healthcare institutions are acting [14]. Meanwhile, during the survey of respondents from Ukraine regarding post-COVID-19 rehabilitation, the following was established.

The question: Have you suffered a COVID-19 infection? was answered by 1061 persons:
- 47% answered positively;
- 30.2% answered negatively;
- 22.8% answered that they do not know.

The question: Have your relatives and friends been suffered a COVID infection? was answered by 1063 persons:
- 71.9% answered positively;
- 18% answered negatively;
- 10.2% answered that they do not know.

The question: What is your attitude to post-COVID-19 rehabilitation in general? was answered by 1060 persons:
- 40.2% answered that it is a guarantee of our health;
- 30.9% answered that they don't mind if they have free time;
- 28.9% answered that they do not consider it appropriate.

The question: Did you undergo post-COVID-19 rehabilitation, in case of illness? was answered by 790 persons:
- 25.5% answered positively;
- 22.8% answered that they have doubts about its expediency;
- 52.2% answered that they do not have the appropriate material resources to obtain it.

It should be noted that medical rehabilitation is included in the Program of Medical Guarantees, which is reimbursed by the National Health Service of Ukraine. However, there are some limitations. Patients can receive such services in Ukraine under three packages:

1. Medical rehabilitation for adults and children 3+ y.o. with lesions of the nervous system;
2. Rehabilitation of adults and children 3+ y.o. with lesions of the musculoskeletal system;
3. Rehabilitation of children under the age of 3 y.o. who were born prematurely or with diseases [15]. Thus, it is obvious why the majority of patients with COVID-19 infection were not able to receive rehabilitation services. Individual researchers considered the methods of providing rehabilitation services, both medical and professional and social in nature, which can be carried out according to special programs in health-resort institutions [16]. However, unfortunately, these types of rehabilitation services are provided only on a commercial basis. We consider it expedient to give examples of the organization of rehabilitation services in the provision of post-COVID-19 care in some countries. Thus, Sweden has developed a rehabilitation route for those who suffered COVID-19; Spain is constantly actively working on the development of post-COVID-19 rehabilitation services; Montenegro increases and improves rehabilitation services at the level of primary care; the United Kingdom has approved a route for providing multidisciplinary care for the post-COVID-19 syndrome. In line with the above, the World Health Organization is constantly developing guidelines and recommendations for the fastest possible overcoming of this ailment. Thus, the following had been adopted: Exemplary complexes of medical gymnastics at the stages of medical rehabilitation in case of COVID-19; Recommendations for supporting independent rehabilitation after diseases caused by COVID-19; Instructions for physical rehabilitation after a viral infection caused by COVID-19 [17]. Also, it is worth noting that the World Health Organization, in order to assist countries in improving the rehabilitation system, has developed the guideline "The Rehabilitation in health systems: guide for action", which will directly contribute to the strengthening of planning functions in the field of rehabilitation through assessment of the situation, strategic planning; improvement of information support and improvement of accountability mechanisms by enhancing the system of monitoring and evaluation of rehabilitation services. This document was adopted for the period of implementation of all its provisions until 2030 and contains the main directions of activity in the field of rehabilitation, namely:
   1. Building a strong capacity for political support at the supranational, national and global levels to improve the provision of rehabilitation services.
   2. Improvement of mechanisms for planning and provision of rehabilitation services within the framework of emergency preparedness and response.
   3. Strengthening the integration of rehabilitation services in the health care system and strengthening intersectoral relations in order to effectively and efficiently meet the needs of the population.
   4. Ensuring the possibility of general access to rehabilitation services.
   5. Determination and approval of models of comprehensive provision of rehabilitation services to gradually ensure equal access to quality services, including assistive technologies, also for people living in rural and remote areas.

6. Creation of a multidisciplinary range of specialists in the field of rehabilitation, considering the specifics of each country, as well as ensuring that training programs for all categories of health care professionals include rehabilitation assistance.
7. Improvement of mechanisms for expansion of financing of rehabilitation services.
8. Collection of information related to the provision of rehabilitation services, including general data on rehabilitation and functioning using the International Classification of Functioning.
9. Building research potential and expanding the availability of reliable data on rehabilitation. 10. Creation and consolidation of networks and partnerships for the provision of rehabilitation services, especially between low-, middle-, and high-income countries [18].

Turning to the content of the specified guide, it is worth noting that its main purpose is to provide methodical assistance to the state's authorities, especially low and medium-income ones. Such assistance is mainly aimed at strengthening the rehabilitation system, which consists of the assessment of the situation, development of a strategic plan for the development of rehabilitation; building a general system for monitoring types of rehabilitation and evaluation processes of such a review; strict implementation and approval of strategic plans [18].

It is likely that after COVID-19, people with a more complicated form of the disease will need various types of rehabilitation. But the problems of insufficiency of resources, qualified rehabilitation doctors and clinical psychologists, unplanned and chaotic organization of rehabilitation still exist. In view of the above, we suggest to once again refer to the Guidelines approved by the World Health Organization "Rehabilitation in health systems: guide for action", the content of which defines six main components of the health care system, which should be taken into account when developing strategic plans for the improvement of the healthcare by the governing bodies. These main components include:

- the rehabilitation component of leadership and strategic management, which includes: development of laws, programs, plans and strategies related to rehabilitation; identifying the structure that will regulate the mechanism and main processes of rehabilitation; improvement of processes; planning of cooperation and coordination for the purpose of rehabilitation development;
- financing, characterized by an increase in financing and payment of services in health care, which also includes rehabilitation services;
- personnel resources of health care, the main component of which is qualified medical personnel working in rehabilitation medicine, therapy and rehabilitation care;
- provision of services in health care institutions, which is determined by securing the appropriate status for medical services and organizations that provide rehabilitation services in special hospitals, centers, wards, departments whose main form of activity is the rehabilitation process itself;
- the use of therapeutic means and technologies generally used by persons who have access to rehabilitation and use special auxiliary means;
- information systems in health care, i.e. availability of data on rehabilitation in the information systems of health care institutions; the presence in these systems of research data relevant to policies and programs in the field of rehabilitation [18].

Given the above, we think it is worth agreeing with the opinion of scientist D.T. Wade, who in his work devoted to the issues of the latest approaches to rehabilitation defines and initiates changes in rehabilitation issues, which relate to the rationalization and reorganization of a large number of services into a comprehensive rehabilitation service; ensuring that every patient has the opportunity to be examined in such a rehabilitation service; provision of rehabilitation services in parallel with medical services; the opportunity to receive such rehabilitation services regardless of age, gender and health status; ensuring full integration between mental health services and rehabilitation services; solving the issue and improving the process of obtaining rehabilitation services from specialists with expert knowledge and skills [19].

These approaches should be taken into account by authorities when fighting the consequences of COVID-19 and providing rehabilitation services to those who really need it. At the same time, the World Health Organization defined concepts for the organization of rehabilitation care in the health care system by 2030. Among the main concepts proposed by the relevant international organization, the following are highlighted: specialized highly effective rehabilitation; improvement of rehabilitation services integrated into the activities of the secondary and tertiary sectors of health care; improvement and implementation of rehabilitation services integrated into the system of primary health care; restoration and improvement of mechanisms of rehabilitation services provided at the level of municipalities; self-rehabilitation and rehabilitation on an informal basis, that is, the provision of such services at home, at school, in nature, in specialized health facilities, etc. [18].

But unfortunately, in the current conditions, a serious problem for persons who need medical post-COVID-19 rehabilitation is the lack of appropriate structural units and rehabilitation centers at their place of residence. In addition to post-COVID-19 rehabilitation provided by health care institutions, the study of other types of rehabilitation, namely professional and social, is of particular importance. The essence of this type of rehabilitation consists of labor adaptation and the possibility of restoring one's labor potential and ensuring social integration of a person who has suffered COVID-19. Because the so-called "post-COVID-19 syndrome" is common among the able-bodied population, which is socially active and needs support in restoring the ability to work and returning to work where proper, safe, and healthy working conditions are ensured.

It is worth agreeing with the statement that restoring the working capacity of people who have recovered from

the coronavirus may require a long process and appropriate adaptation to working conditions [17]. Since the COVID-19 pandemic, a large number of workers employed in various fields have worked and unfortunately will continue to work in harmful and dangerous conditions, with increased workload and threats to their own life and health (for example, medical professionals). Moreover, during the performance of their professional duties employees are negatively influenced by employers, for example, in matters of forced vaccination; suspension from work; threats of dismissal. The above persons worked/are working under conditions of constant stress caused by certain factors. Such factors, in our opinion, include: changes in the of work regime; introduction of new modes of operation; the risk of disease and infection during the performance of one's professional duties, the lack or total absence of personal protective equipment, physical fatigue, and most importantly, the lack of local regulations at enterprises, institutions, organizations, which determine the step-by-step mechanism of employers' and employees' actions in the event of the disease outbreak.

The increased level of labor intensity, the introduction of new innovative technologies, and the rise of dangerous infectious diseases have become the impetus for the dynamic growth of stressful situations in the workplace, which is caused by emotional, psychological, and moral stress. It is worth noting that scientists conducted a special study and survey among health care professionals who assist patients with COVID-19 and came to the conclusion that 14.5% of respondents feel anxious during the performance of their professional duties; 8.9% suffer from depressive symptoms; 6.6% – feel an increased level of stress; 7.7% – feel clinical signs of stress [20].

At the same time, researchers on the issue of the psychological state of employees recommend testing and referral to a psychologist for consultation. And if such an employee needs psychological correction, substitute him and, after successful rehabilitation, return him to the performance of his professional duties. Further, in order to recover from an illness and a stressful state, such workers should be provided with adequate nutrition and vitamins [21].

According to the recommendations provided by the World Health Organization, the principle of saving energy in everyday life is key to returning to work after suffering from the coronavirus disease. For an effective assessment of post-COVID-19 needs, first of all, it is necessary to thoroughly analyze the nature of the employee's labor activity. WHO recommendations define that physical needs include postural hygiene and rational workload. In addition, the issue of return to work is influenced by the status of the individual, the nature of his employment contract, the structure of social protection, and national legislation in the field of labor relations [22].

According to analytical studies conducted by the WHO, the main means for restoring working capacity can be: reduction of workload; use of remote or home work; approval of work performance deadlines; activity planning, etc. [22].

It is also necessary to note the fact that the International Labor Organization has paid attention to the issue of realizing the ability to productive, free and safe work. The international labor standards developed and adopted by this organization in the context of the COVID-19 crisis determine a comprehensive approach to mitigating the socio-economic consequences of the pandemic and providing member countries with assistance in the recovery process. The policy of the International Labor Organization in this direction provides for several measures that must be adapted to the specific countries: 1) stimulation of the economy and employment; 2) support of enterprises, institutions, and organizations; preservation of jobs and incomes; 3) protection of employees at workplaces; 4) use of social dialogue to find various solutions [23].

In the course of restoring work capacity or finding suitable work during the COVID-19 crisis, attention should be paid to Recommendation No. 205 adopted by the International Labor Organization in 2017 "On employment and decent work within the framework of ensuring peace and the potential for countermeasures".

This document outlines strategic approaches to crisis response that can be used by member countries in current conditions. The main ones include:

- stabilization of state and income by immediate adoption of social protection and employment measures;
- promotion of economic recovery and socio-economic reintegration;
- promotion of stable employment, decent work, social protection, and stable development;
- carrying out an assessment of the impact of national recovery programs on employment;
- promotion of social dialogue and collective negotiations;
- creation and restoration of the labor market [23].

The International Labor Organization also drew attention to the fact that collective and coordinated measures should be created and ensured to reduce threats and protect workers from infectious diseases by ensuring infection control, safety and health at the workplace, management of labor resources and ensuring psychological health and its support [24].

Also, it should be noted that at the European Regional Technical Briefing of the World Health Organization, held by the European Regional Office of the WHO, the main ideas and necessary future actions were voiced, which should be used and implemented by all countries, on issues of rehabilitation after COVID-19:

- increasing understanding of the need for rehabilitation after infection with COVID-19;
- collection of data on the spread of post-COVID syndrome and its impact;
- construction of complex models for the provision of rehabilitation services;
- formation of strong multidisciplinary rehabilitation personnel;

– inclusion of patients with COVID-19 in the planning and organization of services;
– inclusion of available services in the structure of primary medical and social care [22].

CONCLUSIONS

Summing up the above research, it is worth noting the following. The issue of rehabilitation is quite popular today. Rehabilitation is one of the main components of medical and social care. Recovery after the coronavirus differs depending on person. The time of such recovery is determined by the severity of the disease, age and physical condition. But, at the same time, it is the rehabilitation after COVID-19 that makes it possible to eliminate negative consequences of the disease suffered. Among the effective post-covid recovery rehabilitation measures special attention should be paid to innovative means that can integrate the social protection system. COVID-19 recovery should take place through the treatment provided by professional rehabilitators; an individual program should be developed for each patient who has sought help, which will depend on the patient's state of health and needs; also, modern techniques and equipment must be used.

Also, in our opinion, a necessary step in the issue of post-COVID-19 recovery is the implementation and improvement of the norms of national legislation of countries that would correspond to the recommendations, methods, and provisions of the World Health Organization on rehabilitation issues. In this regard, it is necessary to improve the regulatory and legal frameworks that regulate the issue of undergoing various types of rehabilitation and to properly finance medical institutions in order to provide high-quality rehabilitation services and to carry out constant control of enterprises, institutions, and organizations in matters of creating and implementing the possibility of professional rehabilitation and ensuring proper conditions and labor protection. We believe that rehabilitation services should remain at the center of discussions regarding their mandatory inclusion in the system of medical guarantees for everyone without exception and any restrictions by type of disease. Also, it is necessary to eliminate barriers in the way of creating the necessary infrastructure, implementation, and financing of this type of medical services.

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Conflict of interest:
The Authors declare no conflict of interest

Received: 30.03.2022
Accepted: 25.08.2022

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Characteristics of the State of Mental Health of the Population of Ukraine as a Consequence of Prolonged Hostilities

Charakterystyka stanu zdrowia psychicznego mieszkańców Ukrainy będącego skutkiem przewlekłych działań wojennych

DOI: 10.36740/ABAL202206114

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SUMMARY

The article presents the general characteristics of the mental health of the population of Ukraine, analyzes the incidence of mental disorders in Ukraine during the period 2018-2020, identifies the level of medical staff in Ukraine compared to EU countries, and features of the microclimate on the psychophysiological state the body of patients and medical staff of psychiatric hospitals. The content analysis of scientific literature and the bibliosemantic method was used in the work. In the course of the analysis, the statistical data of the Ministry of Health of Ukraine for the period 2018-2020 were used on the incidence of mental and behavioral disorders and the provision of medical personnel, forms № 18 of the Ministry of Health of Ukraine "Report on the work on the control of environmental factors affecting the health of the population" for the period 2014-2021. It was found that men for the period 2018-2020 were more treated and treated in hospitals from 67,2% to 65,3%, respectively, and treated in day hospitals from 57,3% to 59,4%, respectively. At the same time, women were treated on an outpatient basis from 78,9% to 81,0%, respectively, with less treatment in psychiatric hospitals from 32,8% to 34,7%, respectively. The largest share of non-compliant microclimate was in 2015 – 11,3% and 2016 – 12,9%, and the lowest allowance in 2014 – 3,2%, in 2020 – 4,4%, and 2021 – 4,2%. Therefore, there is a need to create conditions for the provision of psychological and psychiatric care in mental health facilities of a new multidisciplinary type by qualified professionals.

Key words: psychological trauma, war, psychological and psychiatric care

Słowa kluczowe: uraz psychiczny, wojna, opieka psychologiczna i psychiatryczna

Acta Balneol, TOM LXIV, Nr 6(172);2022:568-573

INTRODUCTION

The modern society of Ukraine for the last ten years inhibits conditions of psychological tension and stress caused by hostile military invasion of the territory of our state. The existing catastrophic problems of the transformative Ukrainian society were connected with the preservation of territorial integrity and national unity. Over the years, the vast majority of Ukrainian families have experienced psycho-emotional stress and mental trauma due to the disability or death of a loved one as a result of a hybrid war. Remarkable deterioration in the mental health of the population is due to constantly forced displacement. Yes, before migration: for torture, violence, trauma, abduction of children, property, livelihoods, deadly violence; during migration: betrayals, "harsh" environmental conditions, separation from family members; after migration: language and communication barriers, discrimination, low income, changes in living conditions, adaptation of children to new circumstances s in the school, kindergartens, etc. [1].

All traumatic events had a considerable impact and consequences on people of different ages of varying severity to engage in daily life and perform unquestionable tasks, responsibilities, and orders. The hostilities continue, but everyday life continues and continues, which today requires maintaining the mental health and emotional state of every citizen of the state. Due to the prolonged hostilities in Ukraine (ATO/OOS) and the beginning of full-scale operations in Ukraine, the professional psychological and psychiatric assistance of qualified specialists has become significantly needed for mental health care [2, 3].

In today's Ukraine, psychiatric medical care was provided by 91 institutions under the "Inpatient psychiatric care" package and 65 medical institutions under the "Psychiatric care package provided by mobile multidisciplinary teams".

According to a WHO survey, 129 studies had conducted in 39 countries, and one in five people (22,0%) who have survived the war or other armed conflict in the last ten years suffer from depression, anxiety disorder, post-traumatic stress disorder, bipolar disorder or schizophrenia [4].

According to the Minister of Health of Ukraine, it has become known that every fifth person in Ukraine will suffer severe mental trauma due to the consequences of prolonged hostilities, and every tenth will experience anxiety, depression, psychosomatic disorders of moderate and severe severity, which can last from 7 to 10 years even though the war continues. About 15 million Ukrainians, of whom more than 7,7 million internally displaced persons need psychological counseling, and 3-4 million Ukrainians need medical treatment [5]. It is worth noting that the precedence, priority area of mental health care in Ukraine in the coming years should be aimed at maintaining mental health for the sake of a healthy Ukrainian nation. The Soviet biopsychosocial model, which focused on the psychosocial and pharmaceutical direction of the treatment of patients with mental disorders, should be replaced by a new multidisciplinary/intersectoral/interagency model, which has been operating in European countries for many years [6, 7].

The guarantees provided by the Constitution of Ukraine in Articles 3 and 49 for free quality medical care in health care facilities are declarative, with the WHO in 2013-2020 formulated directions for the provision of safe medical care in each state, regardless of the level of security of the population [8, 9].

Much work is being done in European countries on mental health in a multidisciplinary/intersectoral/interagency model to provide psychological and psychiatric care. In the EU, people with mental disorders first go to Mental Health Centers, as in Poland. They have the right to receive a free consultation without a referral and possibly without insurance. Initially, patients had contacted by center psychologists, and when there is a complex case, the patient is in crisis, he is consulted by a psychiatrist, who decides with the consent of the patient and relatives where the patient will treat, or on day departments of general hospitals, or outpatient treatment in their families doctors of the territorial community, or in a specialized psychiatric hospital.

The European Union from the European Social Fund of the EU is constantly funding many projects in the field of mental health, as in the Republic of Poland: "Return to the community", reconstruction of old mental health facilities, construction of new modern clinics, centers and other [10].

AIM

The purpose of the work is to conduct a general description of the mental health of the population of Ukraine during the long hostilities, to analyze the incidence of mental disorders in Ukraine during the period 2018-2020, to determine the level of medical staff in Ukraine compared to EU countries and features of the influence of the microclimate on the psychophysiological state of the body of patients and medical staff of mental health institutions.

MATERIALS AND METHODS

The content analysis of scientific literature and the bibliosemantic method had used in work. Statistical data had used during the analysis of the Ministry of Health of Ukraine for the period 2018-2020. on the incidence of mental and behavioral disorders and the provision of medical personnel, forms № 18 of the Ministry of Health of Ukraine "Report on the work on the control of environmental factors affecting the health of the population" for the period 2014-2021.

REVIEW AND DISCUSSION

The consequences of prolonged hostilities in Ukraine hurt the psychophysiological state of man, both civilians, and military. According to US military scientists, the number of mental disorders in the army increased by 300% compared to the First World War, and during the US military operations in Korea and Vietnam was about 24-28%. According to the latest WHO data, during armed conflicts around the world, "10,0% of people who have survived traumatic events will have serious mental health problems, and another 10,0% will develop behaviors that interfere with their ability to function effectively". The level of mental illness among refugees (internally displaced persons) reaches 40,0% compared to migrants who leave their country for economic reasons reaches only 21,0%. In the structure of emotional disorders (depression, anxiety, irritability,) the occurrence of anxious thoughts is up to 100%, in the format of some-vegetative disorders there are permanent sympathetic and tonic states (psychogenic pain) in 90,0%, and in the structure of cognitive disorders there are ideas of inferiority in 90,0%, in the construction of cognitive disorders complicate everyday actions (difficulty concentrating, memory impairment difficulties in planning and organization) in 92,0%, there are suicidal thoughts in 28,0% [11].

In Ukraine, according to the World Psychiatric Association in 2020, it was established that there was a crisis in the psychiatric care system due to insufficient funding for the mental health service, which led to a reduction in medical staff, and beds in psychiatric hospitals. However, no new mental health facilities have been built/reconstructed where patients with mental disorders can seek mental health centers, district/central general hospitals, primary care centers, and university clinics [12].

According to the analysis of statistical reports for the period 2018-2020, It had established that in Ukraine every year from 183 thousand to 170 thousand for the first time detected and entrenched cases of mental and behavioral disorders are registered, respectively. Given the duration of hostilities and the full-scale war of today in Ukraine, there

has been an increase in internally displaced persons outside the country, and those in the war zone need timely, high-quality psychological and psychiatric care. The solution to this issue in our country must be carried out at the state level and for many years [13].

According to statistics for the period 2018-2020, in Ukraine, we see an increase in the number of patients with mental disorders seeking medical care in outpatient psychiatric institutions, which had built according to the old requirements and which did not take into account the "therapeutic, healing environment": from 63,8% to 70,6% of patients and a decrease in visits to psychiatric hospitals from 32,2% to 27,0% due to "stigmatization, hospitalization" and to day hospitals from 4,0% to 2,4%, respectively (Figure 1) [14, 15].

According to the results of the analysis (Table 1) on gender specifics concerning requests for medical and psychiatric care, it had found that men for the period 2018-2020 had treated in psychiatric hospitals from 67,2% to 65,3%, respectively, were treated in day hospitals from 57,3% to 59,4%, respectively. Women for the same period (2018-2020) gave priority to the treatment of mental illness in an outpatient setting from 78,9% to 81,0%, respectively, and fewer women were treated in psychiatric hospitals from 32,8% to 34,7% in accordance. People living in rural areas sought less psychiatric care than the urban population and preferred to treat in psychiatric hospitals due to poor transport links and the lack of outpatient specialists [16].

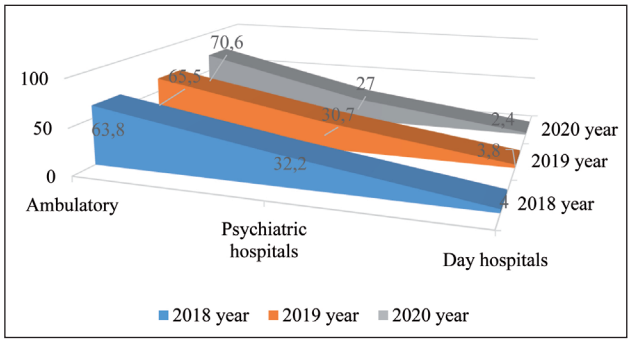

Figure 1. The share of applications for psychiatric care in Ukraine during the period 2018-2020,%

According to the statistics of the Ministry of Health of Ukraine for the period 2018-2020. Regarding the number of individuals who provide psychiatric care in various institutions, the number of psychiatrists in hospitals has slightly increased, while the number of beds has decreased (Table 2). During the period from 1990 to 2019, the number of hospital beds decreased by 61,3% (per 10 thousand population), and the number of outpatient clinics increased two times – 6,9%/13,8% (per 10 thousand population) [8, 13].

The number of psychologists in this period decreased 29 times compared to psychiatrists. We observe a similar picture concerning the number of social care nurses compared to nurses in 12,4-23,7 times less, respectively. We detect a decrease in the number of psychologists, social workers, and social care nurses in recent years of mental health reform in Ukraine compared to EU countries, and therefore qualitative changes in the health of the psychiatric service in recent years have not occurred [9].

According to the 2015 report of the International Medical Corps with the support of the World Bank Group in Ukraine "On assessment and recommendations for the

Table 1. The share of gender features of psychiatric care and hospital stays during the period 2018-2020 in Ukraine, %

	Outpatient psychiatric care			Psychiatric care in day hospitals			Inpatient psychiatric care		
	2018	2019	2020	2018	2019	2020	2018	2019	2020
Men	21,1%	20,8%	19,0%	57,3%	56,6%	59,4%	67,2%	66,6%	65,3%
Women	78,9%	79,2%	81,0%	42,7%	43,4%	40,6%	32,8%	33,4%	34,7%
The rural population	8,6%	8,7%	7,9%	10,0%	8,0%	8,2%	32,1%	32,6%	31,9%

Table 2. The share of the number of individuals in various networks of psychiatric care during the period 2018-2020 in Ukraine, %

	2018	2019	2020	2018	2019	2020	2018	2019	2020
Psychiatrist (including children)	24,7	26,5	27,1	24,7	25,5	23,6	10,8	11,0	12,5
Psychotherapist	0,9	0,9	1,9	1,0	0,63	0,79	0,19	0,2	0,18
Psychologist	0,6	1,0	0,77	2,0	2,2	1,6	0,45	0,45	0,43
Practical psychologist	3,5	2,8	3,1	2,7	3,5	5,5	2,2	2,5	2,5
Social worker (with higher education)	0,7	0,9	0,9	1,7	1,6	0	0,4	0,4	0,22
Social worker (without higher education)	0,2	0,25	0,24	0	0	0,39	0,22	0,15	0,14
Social care nurse	3,6	3,6	1,9	0	0	0	0,4	0,31	0,19
Nurse	44,7	45,6	45,0	56,3	53,8	53,9	75,3	74,9	73,1

integration of mental health into primary care", the number of psychiatrists was 11,6% per 100 thousand population, and in the EU – 7,75%, while that of practical psychologists per 100 thousand population in Ukraine – 1,3%, and in the EU was 2,7% per 100 thousand population. In the EU, the provision of specially trained psychiatric nurses was 824 (2009) per 100 thousand population, while in Ukraine 752 per 100 thousand population. Unfortunately, in Ukraine, it remains unclear about the weak relationship between psychiatrists and psychotherapists, social workers with higher education, psychologists in the treatment of patients with mental disorders, rehabilitation, and occupational therapy [6,8,9].

According to the WHO, the mental health of the population of Ukraine is insufficiently qualified psychiatric medical staff to provide psychosocial care. This had confirmed in the report of the Ministry of Health of Ukraine for 2019 on certified doctors who successfully passed the exam was 85,1% – among psychiatrists, 82,7% – neurologists, 70,0% – psychotherapists in the field of mental health. However, 87,2% of general practitioners are inexperienced in managing patients experiencing mental health crises, 80,9% of staff have not been trained to understand mental disorders, and personnel focuses on physical injuries rather than mental health disorders. It may affect the correct management of patients. Thus, 50,0% of patients with depression complained of back and abdominal pain. At the same time, in the EU countries, mental health institutions constantly conduct surveys of patients, and relatives of patients on satisfaction, living conditions, and the attitude of medical staff to patients in these institutions [12].

According to the results of the analysis of state statistical forms № 18 Vinnytsia Regional Laboratory Center of the Ministry of Health of Ukraine for the period 2014-2021 "Report on environmental factors affecting human health" according to the "Study of physical environmental factors" provided by the Main Department of the State Sanitary and Epidemiological Service in Vinnytsia region, SI "Vinnytsia Regional Laboratory Center of the State Sanitary and Epidemiological Service of Ukraine", was analyzed environmental indicators -prophylactic health care institutions of Vinnytsia region [9, 14, 16].

According to the results of laboratory measurements of lighting in the workplaces of medical workers and the wards of patients of health care facilities, it was found that natural light for the reporting period 2014-2021 met in 100% of cases the sanitary and hygienic requirements (KPO was 1,0-1,5%). Regarding the measurements of artificial lighting, the non-compliance with the regulatory requirements of DSP №173-96, DBN B.2.5.-28: 2018 "Natural and artificial lighting" the largest share was in 2017 – 11,8% and in 2019 – 10,7%, and the lowest indicators of non-compliance were observed in 2015 – 3,4% and in 2018 – 3,78%.

In connection with the Law of Ukraine "On temporary features of state supervision (control) in the field of economic activity" (Articles 2 and 3) moratorium on state supervision (control) of planned measures for state supervision (control)

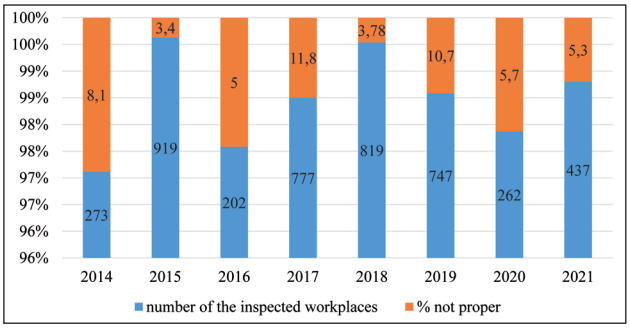

Figure 2. The number of surveyed jobs in treatment and prevention facilities of Vinnytsia region for 2014-2021 and the number of measurements of artificial lighting that did not meet regulatory requirements, (%)

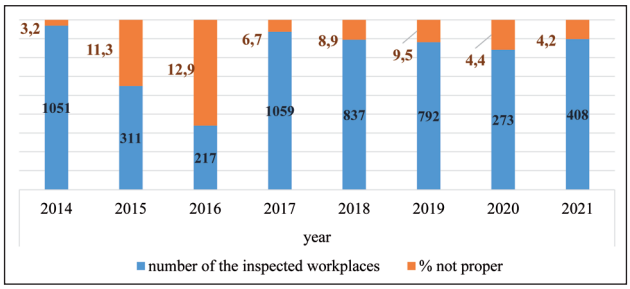

Figure 3. Indicators of the microclimate in treatment and prevention facilities of Vinnytsia region for 2014-2021, (%)

of institutions' health care in the period 2014-2021, the number of surveyed jobs decreased every year. The smallest number of surveys, not more than 300, was conducted in 2014, 2016, and 2020 (Figure 2) [9, 16].

According to laboratory measurements of the equivalent sound level in medical and preventive institutions of the Vinnytsia region, they met the requirements and did not exceed the regulatory requirements of SOS DBN B.1.1-31: 2013 "Protection of territories, buildings, and structures from noise" (Figure 3).

According to LTO 3.36.042-99 "Sanitary norms of microclimate of industrial premises" data of measurements of parameters of microclimate for 2014-2021.

According to the "Study of physical factors of the environment" provided by the Main Department of the State Sanitary and Epidemiological Service in Vinnytsia region, SI "Vinnytsia Regional Laboratory Center of the State Sanitary and Epidemiological Service of Ukraine" 9,0% and the lowest share in 2014 – 3,2%, in 2020 – 4,4% and in 2021 – 4,2%.

According to the results of the analysis of these forms № 18 Vinnytsia Regional Laboratory Center of the Ministry of Health of Ukraine for the period 2014-2021 "Report on environmental factors affecting human health", we observe violations of the in-hospital environment of treatment and prevention facilities of Vinnytsia region: insufficient level of artificial lighting, non-compliance with the requirements for the microclimate. The in-hospital habitat of treatment and prevention facilities can create a risk of exacerbation of the disease, depression, anxiety, and increased aggression,

and this is a consequence of increasing the length of stay of patients with mental disorders in an inpatient facility. At the same time, disruption of the in-hospital environment can create a risk for medical staff who spend a long time in the workplace with patients, having additional negative factors while working as an emotional, psychophysical condition that predict the development of emotional burnout.

CONCLUSIONS

Thus, in Ukraine during and after prolonged hostilities it is necessary to carry out the following preventive measures:

- information – explaining and communicating important information about mental health;
- providing psychosocial support – providing opportunities and safe conditions to share their own psychodramatic experience, gain mutual understanding and support, master the skills of emotional regulation, ways of self-help, and analysis of their psycho-emotional state;
- expansion of interpersonal sensitivity in matters of mental response in interpersonal interaction – reducing the level of stress in communication;
- identification of internal resources to overcome past events and difficulties;
- obtaining information on places of treatment of social, psycho-correctional medical care – psychoeducation, social skills training, social adaptation and assistance, counseling with adaptation and resocialization, communication in target groups.

Given the above material, further prospects should become: in Ukraine, it is necessary to create the conditions for the provision of psychological and psychiatric care in mental health facilities of a new multidisciplinary/intersectoral/interagency type by qualified professionals.

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Conflict of interest:
The Authors declare no conflict of interest

Received: 22.04.2022
Accepted: 23.10.2022

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