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MOTOR UNIT INVOLVEMENT IN SCALENE, STRENOCLEIDOMASTOID, AND RECTUS ABDOMINIS MUSCLES DURING EUPNEA, TACHYPNEA, AND BRADYPNEA OF SEDENTARY YOUNG MALE ADULTS: AN OBSERVATIONAL STUDY

Susmit Roy Chowdhury[1 B,E,F]
• ORCID: 0000-0002-3928-0850

Rajdeep Pathak[1 B,E]
• ORCID: 0000-0002-0704-4343

Priyam Chatterjee[1 B-E]
• ORCID: 0000-0002-8303-2395

Anupam Bandyopadhyay[1 A,D-F]
• ORCID: 0000-0001-7678-1913

[1] Department of Physiology, Serampore College, Serampore, Hooghly, West Bengal, India

A – study design, **B** – data collection, **C** – statistical analysis, **D** – interpretation of data, **E** – manuscript preparation, **F** – literature review, **G** – sourcing of funding

ABSTRACT

Background: It is well-established that extra-diaphragmatic muscles participate in respiration depending on the physiological situation. Even in clinical conditions where the diaphragm cannot act optimally, extra-diaphragmatic muscles can compensate for the breathing mechanics.

Aim of the study: This study aims to determine the role of motor units in various respiratory conditions by monitoring the motor unit discharge in the scalene, sternocleidomastoid, and rectus abdominis during eupnea, tachypnea, and bradypnea using surface electromyography (sEMG).

Material and methods: In this study, 28 healthy, sedentary males without a history of ailments participated. Using sEMG, the motor unit discharges from the scalene, sternocleidomastoid, and rectus abdominis were measured in three breathing patterns: normal breathing, hyperventilation, and intermittent breath retention.

Results: The motor unit discharges of the rectus abdominis during eupnea, bradypnea, and tachypnea were significantly different, indicating that only the rectus abdominis' motor units were actively involved. Rectus abdominis muscle experienced changes in motor unit discharges that were highest and lowest during tachypnea and bradypnea, respectively [$p<0.05$].

Conclusions: This study has tried to evaluate the role of the motor units of three extra-diaphragmatic muscles in healthy sedentary young male adults with different respiratory conditions. This study has revealed that the rectus abdominis actively participates in the physiological conditions in young, sedentary healthy adult males. In scalene and sternocleidomastoid, active involvement of the motor unit has not been observed.

KEYWORDS: electromyography, motor unit, rectus abdominis, respiratory muscle, respiratory rate

Background

Any deformities in the diaphragm, a muscle that is crucial for respiration, cause serious interruptions in breathing. Mechanical ventilation is routinely employed to save lives in patients with various respiratory disorders, but it weakens the muscle and induces rapid disuse atrophy and proteolysis in the fibers of the diaphragm [1,2]. Therefore, when the diaphragm muscle is not operating sufficiently, alternative use of extra-diaphragmatic muscles such as the scalene, sternocleidomastoid, and rectus abdominis muscles may be advantageous.

A motor neuron and all of the skeletal muscle fibers that the neuron's axon terminals innervate, along with the neuromuscular junctions that connect the neuron and the fibers, together form a motor unit [3]. A motor unit is the tiniest functional component of the nervous system and serves as the culmination of motor commands [4]. The precision of musculer motion depends on how many muscle fibers a motor neuron innervates. Also, if a muscle fiber has a large number of motor neurons innervating it, the muscle produces large motions [5]. The participation of motor units in those extra-diaphragmatic muscles has been the subject of relatively little research, and the majority of the studies were linked to specific clinical disorders. Even though mechanical ventilation is employed in a variety of clinical situations, additional diaphragmatic muscles are still involved in a variety of physiological situations. It is currently not understood to what extent these muscles contribute to various physiological states, such as eupnea, bradypnea, and tachypnea.

Multiarticular muscles, such as the scalene, perform equally intricate and crucial activities. They function as auxiliary breathing muscles. The spinal nerves from C3 to C8 provide the motor nerves. Along with the scalene muscles, the sternocleidomastoid muscle of the neck serves as the auxiliary muscle of inspiration [3,4]. The rectus abdominis muscle aids in expiration and assists in the flexion of the pubic symphysis and sternum, as well as the thoracic and lumbar spine. T7 to T12 spinal neurons supply the rectus abdominis [5]. The C2 and C3 anterior branches innervate the sternocleidomastoid muscle [6]. All three muscles are involved in the expansion or contraction of the chest cavity, which contributes to breathing [7].

A respiratory rate (RR) of more than 20 breaths per minute in an adult or adolescent is referred to as Tachypnea [8]. Tachypnea is a common occurrence in daily activities including strenuous physical activity and employment. Tachypnea can be produced artificially even while the patient is resting. Healthy young adults often breathe 12 to 20 times per minute, and this condition is known as eupnea. When the respiration rate is less than 12 breaths per minute, it is called bradypnea [9]. A person may experience bradypnea when awake or asleep. Bradypnea can be brought on by several things, including consuming alcohol, using certain medicines, and ion imbalances. Bradypnea can also be created in a lab setting using sporadic breath-holding procedures.

Myopathic and neurogenic muscle atrophy and weakening are distinguished by electromyography (EMG), which is frequently employed in a variety of clinical disorders. In clinically normal muscles, it can find anomalies, such as persistent denervation or fasciculations. The motor unit transmits the neural drive of the muscles and causes the innervated muscle unit to experience action potentials. Surface electromyography (sEMG) is becoming increasingly popular and straightforward because it is non-invasive and simple to insert the electrodes at the necessary muscle. The identification of motor unit action potentials from the interference EMG signals provides information about the discharge activity of specific motor neurons because of the physiological safety factor at the neuromuscular junction. The motor neuron is the only nerve cell in humans that can be non-invasively recorded based on this method. These factors have led to the development of some surface EMG techniques over the past three decades [10,11]. Applying sEMG is a clinically useful, non-invasive method for evaluating the neuromuscular activation of respiratory muscles in clinical respiratory care [12]. Although very few investigations have been conducted under physiologically normal conditions, these sEMG signals are thought to be the most valuable as electrophysiological signals in clinical physiology. The primary approach for comprehending how the human body behaves under healthy and pathological circumstances is supplied by the recording of sEMG signals.

Aim of the study

This study takes into account employing a surface EMG machine to measure motor unit discharge in the scalene, sternocleidomastoid, and rectus abdominis during induced tachypnea and bradypnea. The involvement of the three extra-diaphragmatic muscles' motor units in physiological situations is thought to make it easier to compare and understand the alterations observed in clinical settings. Additionally, it can be directed to increase the participation of those muscles with increased bodily demands.

Methods

Study design

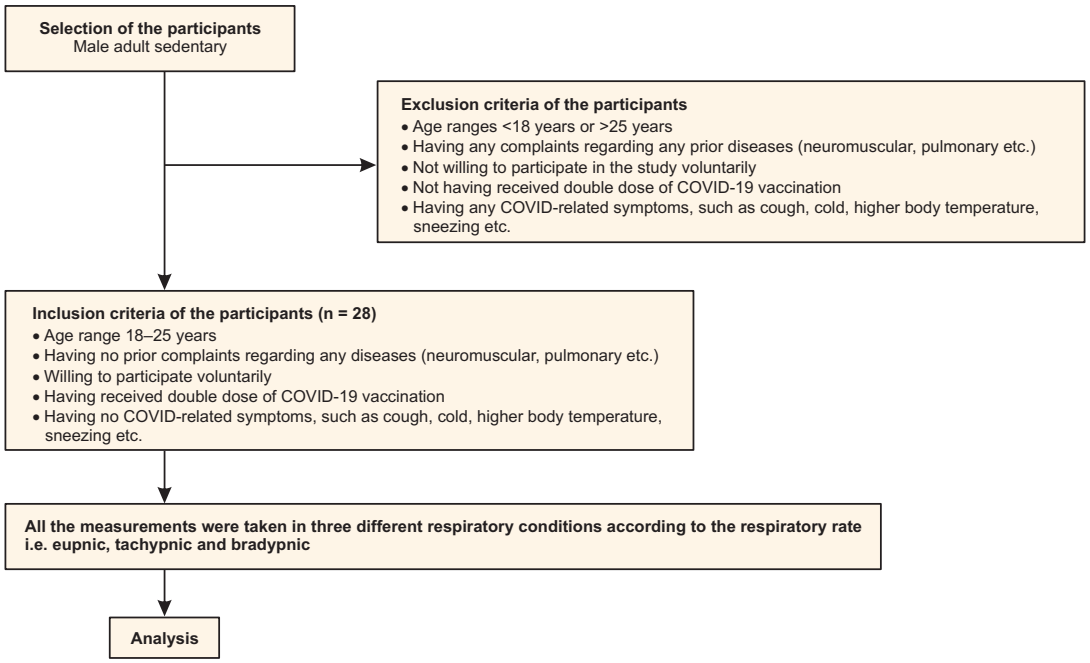
For the investigation, a cross-sectional study approach was taken.

Setting

This study was conducted at the Sports and Exercise Physiology Laboratory, Department of Physiology, Serampore College, affiliated with the University of Calcutta, Serampore, Hooghly, West Bengal, India. Participants were brought into the laboratory. They were allowed to rest for 10 minutes in the supine position in the laboratory at 25°C room temperature before participating in the study. A digital hygrometer was used to record the average relative humidity of the laboratory for the six days of the experimentation, which ranged from 60% to 68%.

Participants

This study comprised male college students who were healthy adults between the ages of 18 and 25 (average 20.14±1.671 years). 28 healthy, sedentary male college students with no history of pulmonary or neuromuscular disease actively participated. All of the volunteers had received two Coronavirus Disease (COVID) vaccinations prior to enrolment and did not exhibit any COVID symptoms, such as a high body temperature, a cold or cough, sneezing, or anything similar (please see details on the flowchart below for the inclusion and exclusion criteria).



Variables

Mainly physical and anthropometric measurements were made, including height, weight, lean body mass, fat percentage, and body mass index (BMI). After that, normal respiratory rates were assessed, and participants were advised to take a rest if they were found to be higher than the usual eupnic range. In order to evaluate the muscle activity of all three muscle groups under various respiratory conditions, electromyographic variables, primarily the root mean square and maximum voluntary contraction, were assessed.

Measurement

Physical and anthropometric variables

Stature: The SECA 213 Portable Stadiometer was used to measure stature, which is defined as the distance between the transverse planes of the vertex and the inferior aspect of the feet (range of measurement 60 cm to 220 cm). The 'Stretch Stature Method' was used to measure stature [13,14].

Weight, Body Mass Index, Lean Body Mass & Fat Percentage: Bioimpedance Analysis (BIA) was used to measure weight, lean body mass, and fat percentage. The bio-impedance analyzer calculated the body composition. By delivering low-voltage, safe electrical scales to measure the muscle and fat in addition to the total body measurement, the segmental body composition monitor Tanita BC-601 uses the BIA approach to measure body composition with scientifically validated accuracy [15]. After manually entering the subject's measured height, weight, gender, and age, the measurements were taken using the standard setting. The BMI was measured, using the conventional method and using the following equation [14,16].

$$\text{BMI} = \text{Body weight (kg)} / (\text{Height in meter})^2 = \text{kg/m}^2$$

Electromyographic variables

The iWorx EMG recording kit was set and prepared for recording. Three different accessory respiratory muscles, the scalene, sternocleidomastoid, and rectus abdominis were employed for the EMG recordings. Surface button electrodes were used to apply the gel to the skin once the muscles were isolated [17]. The areas where electrodes were positioned received the application of the ultrasonic gel. By eliminating the air pockets found in the stratum corneum of the dermis, the ultrasonic gel enhances the coupling between the electrode and the skin, increasing the conductivity of the signal. Connected to the physiologic amplifier device were the surface EMG electrodes. The participant was instructed to lie down for the recording to take place. The following combination of surface electrode pairs was used to gather surface signals from the scalene, sternocleidomastoid, and rectus abdominis muscles:

– An electrode pair was positioned on the scalene between the sternocleidomastoid muscle and the clavicle in the posterior triangle of the neck [18].

– For sternocleidomastoid, on the middle third of the sternocleidomastoid muscle, identified by palpation, on the right or left side, usually opposite to the medications for a central venous line [19].

– For rectus abdominis (abdominal muscle), electrodes were positioned 2 cm lateral from the midline of the umbilicus [20].

A minimum of 2 cm separated each pair of electrodes, and care was made to position the electrodes such that they face the same direction as the muscle fibers. According to the requirements of the experiment, the individuals were requested to display three different breathing patterns. These three artificial breathing patterns were associated with three distinct respiratory conditions: eupnea, tachypnea, and bradypnea.

The subjects participated in their regular breathing to create the eupnic condition. Adults breathe between 12 and 20 times per minute while at rest. While resting, an atypical respiration rate is less than 12 or greater than 25 breaths per minute. Subjects were instructed to breathe rapidly and shallowly at a rate of more than 20 breaths per minute to induce tachypnea. By enabling the individual to undergo shallow inspiration breathing holding, a bradypnea state was produced, Breathing for more than two minutes at a pace below 12 breaths per minute [8,9]. For all the conditions, root mean square (RMS) and maximum voluntary contraction (MVC) values of all the muscles were obtained after successful normalization.

Ethics

The Human Ethical Committee (HEC, Serampore College, affiliated with the University of Calcutta, Serampore, Hooghly, West Bengal, India, with reference number **SC/HEC/2022/P1C**) gave its approval to the study. Participants who did not fit the age range, had any respiratory illnesses, or had any muscle impairments were excluded from the study. The participants were given a full explanation of the study's objectives before the experiment. They provided informed consent before participating in the study.

Statistical methods

Statistical analysis of all data was performed by IBM Statistical Package for Social Sciences (SPSS) version 25. Data were found to not be normally distributed by the Shapiro-Wilk normality assumption. Descriptive statistics were also performed for all the variables to find out the mean and standard deviation. Kruskal-Wallis nonparametric analysis of variance (ANOVA) test was performed to determine whether the scores of different groups of the electromyographic variables differed substantially. The statistically significant variables further underwent Mann-Whitney *U* multiple comparison tests to determine the inter-group significant differences. The p-value <0.05 was considered to be a statistically significant result of all assumptions.

Results

Participants and descriptive data

The total number of participants was 28 (n=28). The general characteristics of the participants are shown in Table 1. The average age of the participants (18-25 years) is 20.14±1.671 years. The average fat percentage of young males is very high (28.757±8.593%) though the BMI (24.05±4.353 kg/m^2) indicates that they have healthy body weight. The average respiratory rate (RR) was also found to be within the normal range (17.536±2.659 breaths/minutes) though the different respiratory conditions were deployed individually.

Table 1. Mean and standard deviation values of age, height, weight, BMI, lean body mass, and normal respiratory rates of young healthy adult males (n=28)

Variables	Mean±SD
Age (years)	20.14±1.671
Height (cm)	168.471±7.722
Weight (kg)	68.092±12.182
BMI (kg/m2)	24.05±4.353
Lean Body Mass (kg)	47.671±5.768
Fat (%)	28.757±8.593
Normal Respiratory Rate (breaths/minute)	17.536±2.659

Main results

Electromyographic variables

The analysis of electromyographic variables in the three different breathing conditions is shown along with the Kruskal-Wallis nonparametric ANOVA in Table 2. Three different conditions are eupnic (RR=17.536±2.66 breaths/min), tachypnic (RR=50.679±9.43 breaths/min), and bradypnic (RR=6.429±1.87 breaths/min). Insignificant differences were found between mean values of root mean square (RMS) and maximum voluntary contraction (MVC) in scalene (Figure 1) and sternocleidomastoid (Figure 2) muscles during eupnea, bradypnea, and tachypnea. However, significant differences [p<0.05] were observed in the mean values of RMS and MVC in rectus abdominis during eupnea, bradypnea, and tachypnea.

Since the RMS and MVC values of the rectus abdominis muscles were found to be significant, Mann-Whitney *U* multiple comparison tests were performed to find out the inter-group differences. Both the RMS and MVC of the rectus abdominis muscle were found to be significantly higher in the tachypnic condition than in both the eupnic and bradypnic conditions (Figure 3), while no inter-group significant difference was found between eupnic and bradypnic conditions (Table 3).

Table 2. Kruskal-Wallis nonparametric ANOVA test values and level of significance of electromyographic variables (RMS and MVC) in eupnea, bradypnea, and tachypnea among scalene, sternocleidomastoid, and rectus abdominis muscles

Variables	Respiratory Conditions according to Respiratory Rate (RR) (Means ±SD)			Chi-square value	Level of significance (p values)
	Eupnic (n=28) (10–20 per minute) [17.536±2.66 breaths/min]	Tachypnic (n=28) (>20 per minute) [50.679±9.43 breaths/min]	Bradypnic (n=28) (<10 per minute) [6.429±1.87 breaths/min]		
Scalene RMS (mv)	0.018±0.016	0.019±0.127	0.020±0.015	0.678	0.712 (ns)
Scalene MVC(mv)	0.036±0.047	0.043±0.058	0.039±0.050	0.440	0.802 (ns)
Sternocleidomastoid RMS (mv)	0.017±0.007	0.027±0.046	0.018±0.006	0.267	0.875 (ns)
Sternocleidomastoid MVC (mv)	0.042±0.054	0.038±0.049	0.033±0.042	0.318	0.853 (ns)
Rectus Abdominis RMS (mv)	0.022±0.024	0.128±0.037	0.024±0.028	49.347	0.000*
Rectus Abdominis MVC (mv)	0.056±0.107	0.156±0.107	0.053±0.093	35.444	0.000*

n=sample size; p=probability of significance; *p<0.05, ns=not statistically significant.

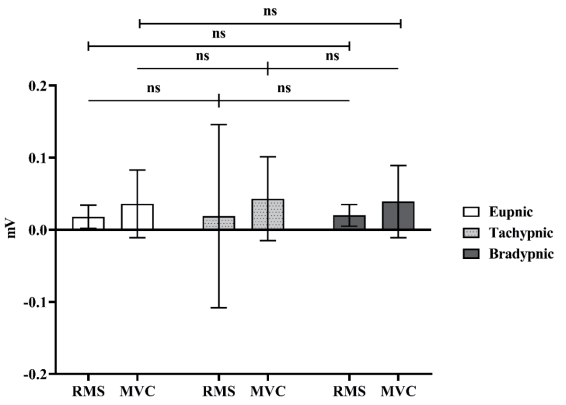


Figure 1. Graphical representations of the electromyographic variables (RMS and MVC) of the scalene muscle in different respiratory conditions i.e. eupnic, tachypnic, and bradypnic. (n=28, ns=not statistically significant, *p<0.05)

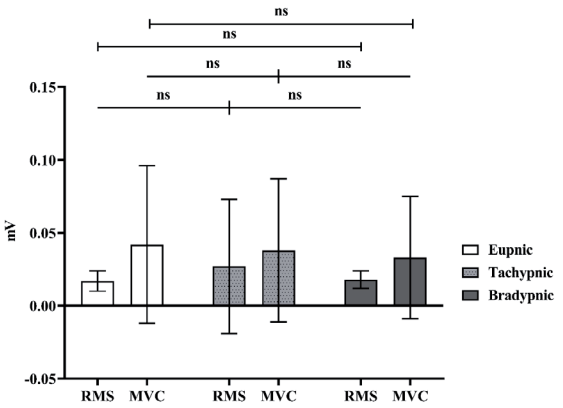


Figure 2. Graphical representations of the electromyographic variables (RMS and MVC) of the sternocleidomastoid muscle in different respiratory conditions i.e. eupnic, tachypnic, and bradypnic. (n=28, ns=not statistically significant, *p<0.05)

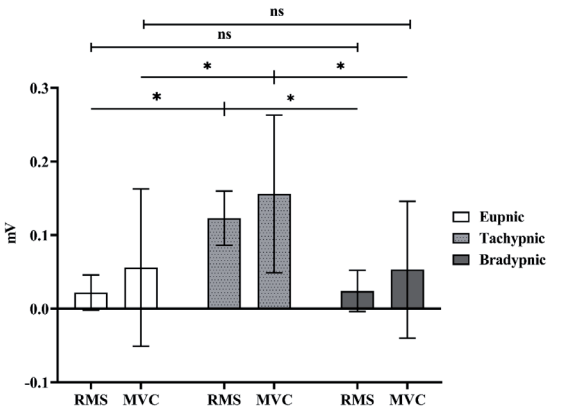


Figure 3. Graphical representations of the electromyographic variables (RMS and MVC) of the rectus abdominis muscle in different respiratory conditions i.e. eupnic, tachypnic, and bradypnic. (n=28, ns=not statistically significant, *p<0.05)

Table 3. Mann-Whitney U multiple comparison test values and level of significance of electromyographic variables (RMS and MVC) of rectus abdominis in eupnea, bradypnea, and tachypnea

Variables	Mann -Whitney U multiple comparison test (U, p values)		
	Eupnic vs Tachypnic	Tachypnic vs Bradypnic	Eupnic vs Bradypnic
Rectus Abdominis RMS (mv)	24.000, (p=0.000*)	25.000, (p=0.000*)	375.500, (p=0.782, ns)
Rectus Abdominis MVC (mv)	74.000, (p=0.000*)	88.500, (p=0.000*)	361.500, (p=0.609, ns)

p=probability of significance; *p<0.05; ns=not statistically significant.

Discussion

Key results

This approach has previously shown that high-fat content lowers the forced expiratory volume in 1 second (FEV1) and forced vital capacity (FVC) in elderly men, and the body fat percentage recorded is very high (28.757±8.593 %) [21]. The mean body weight reveals the prevalence of being overweight, using WHO's 2016 country-specific recommendations. It can be one of the causes of eupnea's faster breathing rate. When in the supine position, the increased fat content affects the thoracoabdominal kinematics, increasing the abdominal and decreasing the rib cage's contribution to ventilation.

Scalene and sternocleidomastoid did not affect inactive, young, healthy male adults in supine posture during eupnea, bradypnea, or tachypnea, according to statistically negligible differences in muscle power and motor unit discharge. In calm, hypo, and hyper breathing modes, the rectus abdominis muscle's power and motor unit discharge considerably differ, showing the distinct role of this extra-diaphragmatic muscle in the supine posture of young, healthy male adults. The rectus abdominis exerts the most force or power, and it engages more motor units, during tachypnea than during bradypnea, suggesting that it actively participates in physiologically-relevant hyperventilation.

Limitations

Due to bradypnea's slower respiratory rate than eupnea, the rectus abdominis muscle produces less force and uses less of its motor unit. However, due to its limitations, this study was unable to explain why the rectus abdominis muscle participates in bradypnea. As the respiratory rate is lower in the supine position of young male adults, it is evident that the rectus abdominis uses less muscular power and motor unit participation during silent breathing than during tachypnea. The small differences in rectus abdominis muscle force and motor unit participation between eupnea and bradypnea support the notion that the thoracic cavity undergoes little to no change and that the rectus abdominis plays no part in quiet breathing or breathing that is less than usual.

Although three extra-diaphragmatic muscles are involved in this investigation, they are ultimately not the major muscles for respiratory mechanics. Therefore, other primary muscles should be engaged and examined for a comprehensive interpretation. It will be essential for the interpretation to compare the functions of primary and auxiliary muscles. Although the participant pool of this study is small, it can nonetheless provide us with some insight into the mechanics of breathing and the supporting functions of the aforementioned muscles. Therefore, additional research on participants of diverse age, gender, etc. groups is required to support the assertions.

Generalizability

Extra-diaphragmatic muscles play a crucial role in intensive respiration as the amount of air required for intake and expiration increases. In silent breathing, the contraction and relaxation of the diaphragm and intercostal muscles are sufficient to cause the thoracic cavity's volume to change, resulting in inspiration and expiration. This study aims to determine the role of motor units in healthy young male individuals' normal ventilation, hypoventilation, and hyperventilation.

Conclusions

This study used data based on the motor unit activity of a few auxiliary muscles, also known as extra-diaphragmatic muscles of respiration, by interpreting the sEMG findings. Few electromyographic studies of these extra-diaphragmatic muscles, such as the scalene, sternocleidomastoid, and rectus abdominis muscles, have been documented, and the majority of them are linked to various clinical disorders. This study included details on how young, healthy males respond to physiological situations, including eupnea, bradypnea, and tachypnea by using their motor units. The goal is to demonstrate that, if the function of these muscles can be understood in terms of the

motor unit's involvement in physiological conditions, then the mechanism by which to extend the chest cavity must be explained in terms of respiratory mechanics.

Additionally, for the promotion of effective respiration, various clinical circumstances might be contrasted with physiological settings. In addition, a variety of breathing exercises could be used to strengthen the muscles that are directly involved in breathing. From this study, it can be inferred that while the rectus abdominis actively participates in physiological circumstances in young, healthy adult males who are inactive, scalene and sternocleidomastoid have little role.

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Correspondence address:
Dr. Anupam Bandyopadhyay, Associate Professor
Department of Physiology, Serampore College
Serampore, Hooghly, West Bengal, India
E-mail: baneranupam@gmail.com

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SETTING HEALTH TRAINING OBJECTIVES BASED ON THE ASSESSMENT OF PREFERRED AREAS OF HEALTH BEHAVIOR IN A GROUP OF ACTIVE WOMEN WITH CHRONIC BACK PAIN: A PILOT STUDY OF THE CROSS-SECTIONAL RESEARCH

Małgorzata Kałwa[1 A-F]
• ORCID: 0000-0001-6190-6015

Renata Myrna-Bekas[2 B,E-G]
• ORCID: 0000-0003-1356-9725

Urszula Dębska[3 A,D]
• ORCID: 0000-0002-0692-631X

[1] University of Health and Sport Sciences in Wrocław, Poland
[2] Witelon Collegium State University in Legnica, Poland
[3] Institute of Psychology, University of Wrocław, Poland

A – study design, **B** – data collection, **C** – statistical analysis, **D** – interpretation of data, **E** – manuscript preparation, **F** – literature review, **G** – sourcing of funding

ABSTRACT

Background: The systematicity of health training (HT) for a participant with back pain still remains a challenge, while the regularity of exercises is an important objective of HT.

Aim of the study: Getting to know the health determinants of active women with chronic back pain (ChBP), assessing the degree of variation in the hierarchy of health criteria, and their areas according to the length of HT.

Material and methods: Women (n=159; 19–76 years old) were divided into three groups according to their length of training: A – less than 2 years and/or unsystematic, B – systematic 2–4 years; C – systematic for more than 4 years. List of Health Criteria Questionnaire by Zygfryd Juczyński.

Results: Women from group A place health in the area related to the maintenance of the condition. The ladies from group B are focused on a specific health outcome. The women from group C understand that health is the need to follow a specific process and to work towards a defined goal.

Conclusions: Attendance during the entire training cycle can be used to assess a participant's understanding of HT goals. The motives for HT depend on the length of training. In the beginners' group, other educational arguments should be used to build awareness of the long-term goals of HT.

KEYWORDS: health training, health criteria, goal setting, women with ChBP

Background

As a result of many years of promoting health-enhancing activities, an increased social trend of people striving to achieve and maintain acceptable physical fitness, body shape, and general well-being can be observed [1–3]. Physical activity (PA) is supposed to be a response to occupational stress and everyday problems, and it should support intellectual activity [4–7]. As a consequence, the fitness industry is expanding its offerings by proposing a wide range of activities for the growing number of exercise enthusiasts [8]. However, from an overriding objective of training for health and strategic action in the field of public health, the essence of health training (HT) should be to maintain high weekly attendance at physical activities.

Recommendations for regular PA especially concerning people who, for various reasons, have a lower utilitarian motor potential [9–11]. This group includes people with chronic back pain (ChBP), whose condition of the passive and active locomotor apparatus depends on the ratio of appropriate to undesirable actions [11–13]. The effects of HT will depend on the quality of the therapeutic factors being implemented and on their time of emission. However, back problems do not always motivate the participant to participate in HT exercises, and systematic training becomes a challenge for him/her [9,14,15]. For people with ChBP, the priority is to reduce or eliminate pain and maintain the therapeutic effect. For this reason, before participating in HT, the patient must undergo a rehabilitation process. Only when the pain is minimal and there are no contraindications or other diseases can we talk about maintaining these benefits by participating in HT, which should focus on the individual goals of the participant. To achieve and maintain these goals, systematic training is necessary.

Therefore, under such conditions, maintaining the regularity of corrective actions is an end in itself. The question, therefore, arises as to how trainers should formulate training goals and tasks in order to maintain high attendance throughout the training cycle. Identification of preferred health behaviors and dominant lifestyle elements in everyday functioning may help to answer this question.

The aim of the study

The purpose of this study was to identify the determinants of health in women with ChBP who participate in HT and to evaluate the differences in the hierarchy of declared health criteria clustered in designated action areas according to their length of training. Identifying these factors in a group of women with back problems may be helpful to therapists and trainers in maintaining the regularity of training by skillfully raising participants' awareness of the long-term effects of training. The health determinants indicated by women may be a benchmark for the skillful definition of goals and movement tasks and the motivation of systematic PA.

Material and study methods

Participants, study design, and organization

A total of 159 women aged 19–76 were surveyed which included volunteers from Wrocław, Legnica, and other areas. Participants in the study were divided into three groups: A – training unsystematically and systematically for up to 2 years, B – women training systematically for 2 to 4 years, and C – women systematically active for more than 4 years. The study was conducted in two centers, the University of Health and Sport Sciences in Wrocław and Witelon Collegium State University in Legnica from 2018–2020 (prior to the Covid-19 pandemic). The study inclusion criterion required the participant to be currently experiencing pain. As specified in the demographics for research purposes which included preferences for PA and a self-assessment of one's physical fitness and health on a scale of 1–5, where 1 is the lowest value and 5 is the highest (Attachment 1).

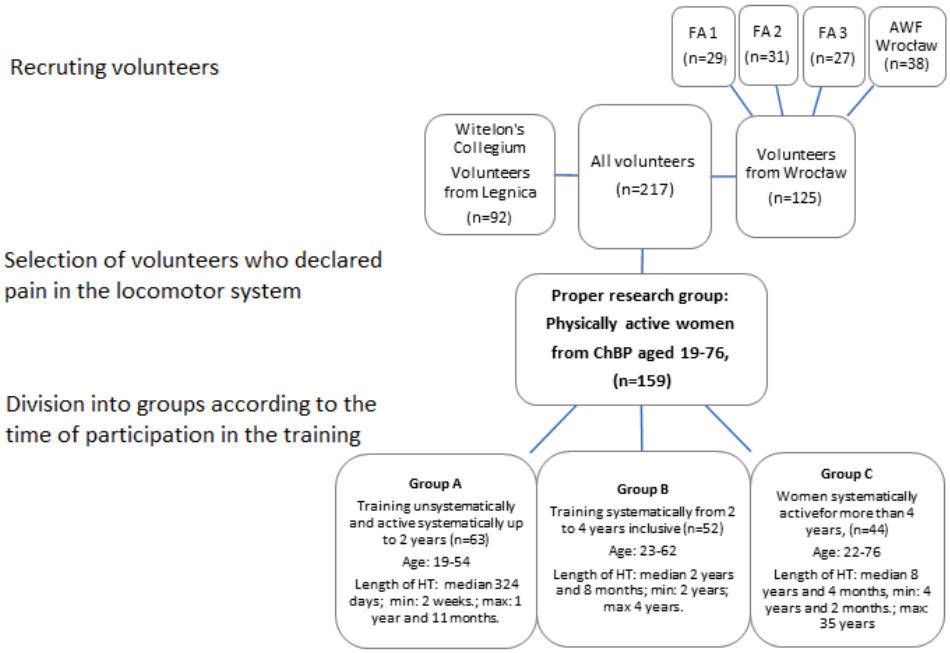

Figure 1. Criteria for selecting a research group

Research method

A diagnostic survey method using the demographics for research purposes and the List of Health Criteria (in polish Lista Kryteriów Zdrowia, LKZ] questionnaire by Zygfryd Juczyński [16] were used in the study. This method is useful for the modification of health, therapeutic, and rehabilitation behavior activities [16, p. 126]. The study was carried out anonymously in 4 Wroclaw fitness clubs located at different points in the city at least 5 km away from one another and in one club in Legnica. The LKZ contains 24 questions covering multiple areas such as physical, mental, and social components. Respondents may additionally indicate other health criteria than those given in the questionnaire if they believe they are more important for staying healthy. The objective of the survey is to answer the questions: What do respondents understand about health? What does being healthy mean to them? According to the method, health criteria are assigned to five categories:

- *Objective*: Health is a point to strive for.
- *Process:* Health is a set of specific actions to be pursued.
- *Condition:* Health is the maintenance of a particular satisfactory state of affairs (health parameters).
- *Result:* Health is a measurable value – the effect of actions taken to achieve a specific health outcome.
- *Relevance:* Health is understood as a quality that one possesses or does not possess (responsible for well-being).

The women included in this survey choose 5 statements that were most important to them and then ranked them from 1 (the least important) to 5 (the most important).

The research objective was to diagnose one's understanding of health as declared by participants of group health training and to compare the results between the designated groups.

Statistical methods

The results of the research were described quantitatively in Excel 13.1 and the Statistica 12.0 program. The Kruskal-Willis test was performed after a standardized evaluation of the data distribution using the Shapiro-Wilk test. Additionally, one-way analysis of variance (ANOVA, NIR test) was used to determine the smallest significant difference between the results in the individual health areas.

Ethics approval and consent to participate

The research was conducted with the consent of the Senate Committee of Ethics at the University of Health and Sport Sciences in Wrocław (nr 5/2013). The participants expressed their consent to participate in the study in writing.

Results

The study assessed the degree of variation in health perceptions and motivations for taking corrective action based on the length of participation in PA.

The study group consisted of women aged 19–76 (n=159), whose average body weight was 65.2±10.3 kg. The majority of them assessed their physical fitness as very good to good (75%), similar to their level of health (73.5%, Figure 2).

The interview was supplemented by questions regarding medication use, chronic illnesses, and

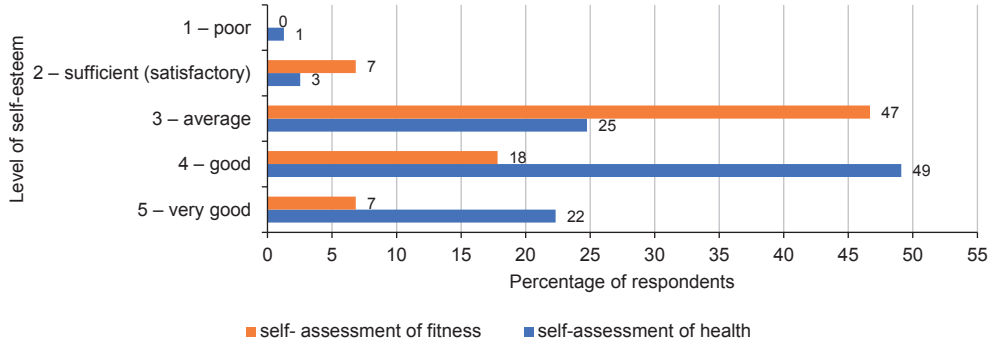

Figure 2. Percentage of individual health and fitness assessments as perceived by female respondents

manifestations of pain. It may be noted that pain was reported to a greater extent in persons with lower PA levels (Figure 3). About 50% of female respondents with ChBP declared that they feel pain in at least two areas of the body. The biggest number of these respondents pointed to spinal pain in the lumbar region and sacrum. Due to incomplete data, no information was provided on the degree of pain intensity, comorbidities, and medications used by the subjects.

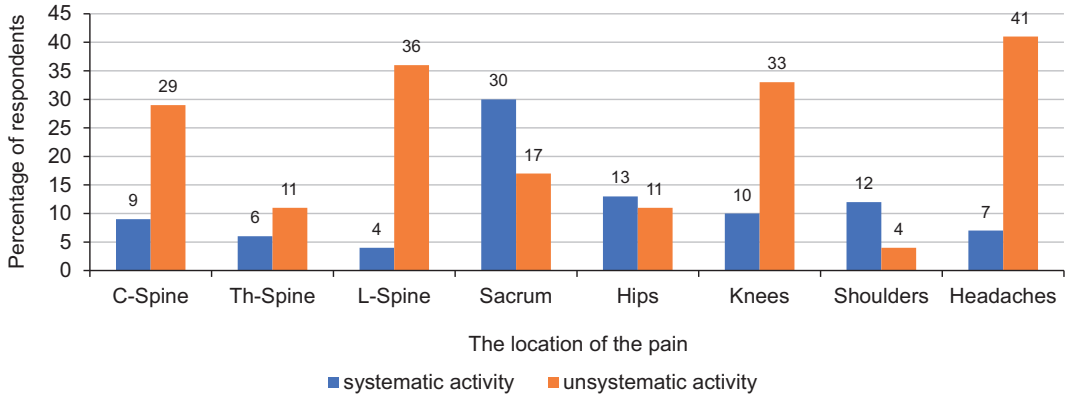

Figure 3. Frequency of pain in the women surveyed versus the declared physical activity (including co-occurring pain)

The regularity of training in the study group was specified based on a participant's responses. The majority of participants in the study engaged in PA one to three times a week. The training lasted on average 51 minutes (±22.6 minutes). Over 40% of participants in the study preferred training on Tuesdays, Wednesdays, and Saturdays (Figure 4).

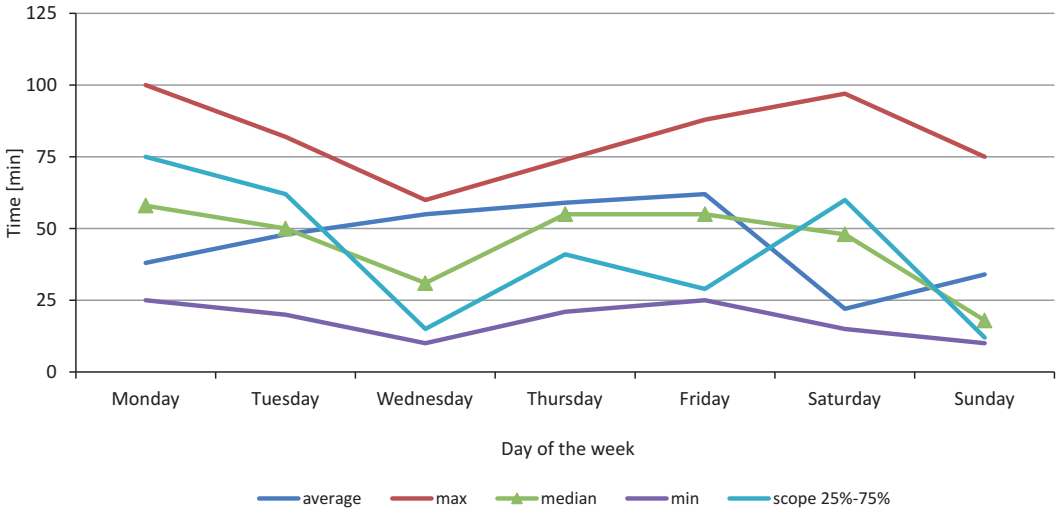

Figure 4. The volume of physical activity during the week. Grey color is used to indicate more frequently selected days of the week (40% of participants)

Analysis of the results obtained by the LKZ questionnaire is presented in Figure 5 (the dependent variable is the health criteria category) and Figure 6 (the length of training is the grouping variable).

Comparing the indicated health criteria in groups of women with ChBP and different lengths of HT, a certain regularity is noted. Persons training the shortest (group A), identify the activities aimed at maintaining a particular condition and achieving a particular result to be most important. This was based on the frequency of selecting statements focused on the areas that mainly concerned the need to accept one's appearance and be attractive to others. The most often selected expressions in this group were "*to have a suitable body weight*", "*to have healthy eyes, hair, and complexion*", "*to have no physical discomfort*", and in the open-ended question (supplementary answers appeared in this group only) answers reflected '*weight loss' and 'displaying a satisfactory figure'*. Interestingly, the beginner female group with ChBP participated in physical training not because of their medical condition but for aesthetic reasons. A similar pattern of health determinants was found among women in group B – training for up to 4 years. These women strived for a better, more comfortable well-being by keeping up with the training group. In addition to the activities aimed to improve their figure and fitness, training improved their comfort of acceptance and social belonging. Frequently mentioned statements, such as "*I want to accept myself, know my possibilities, and deficiencies*" and "*to be able to get along well with other people*" suggest a desire to identify with the training group and to open up to new acquaintances and friendships. It is interesting that both groups of women, those exercising on an ad hoc or short-term basis and those exercising for 4 years had the least

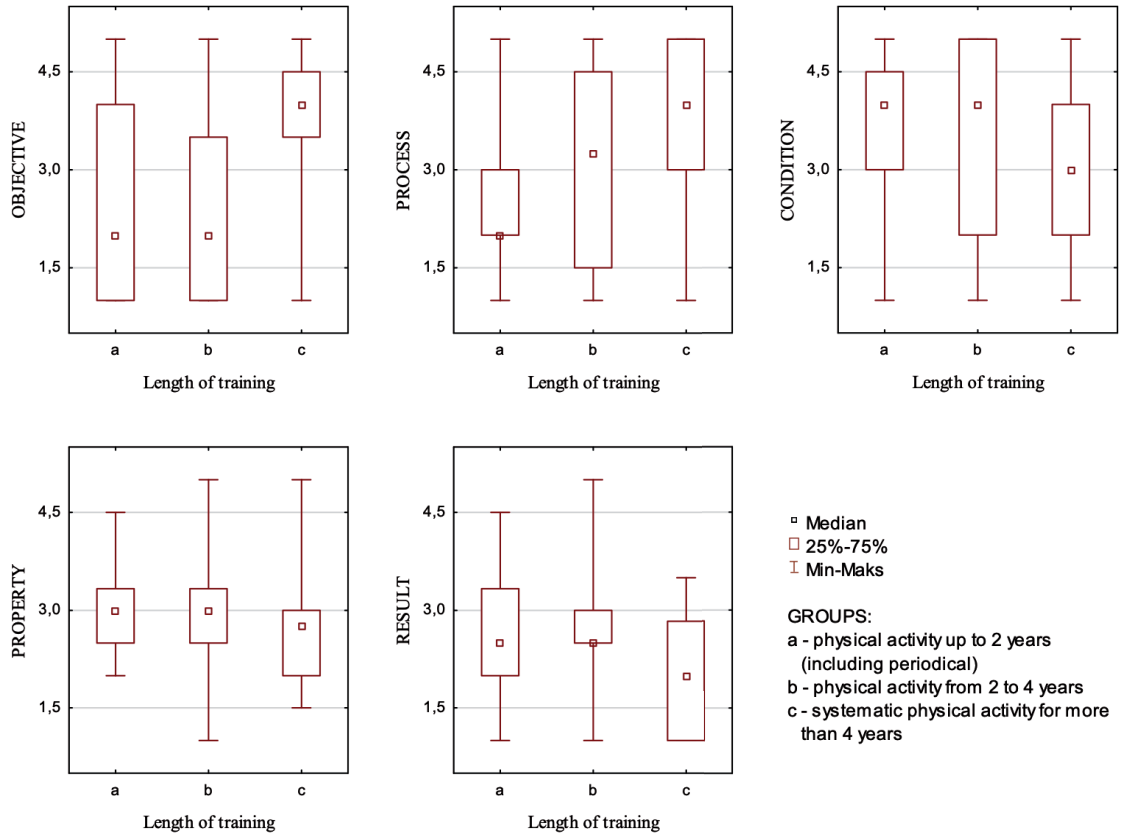

Figure 5. Preferred health areas in relation to the length of training in women based on the Health Criteria List. Median, minimum, and maximum

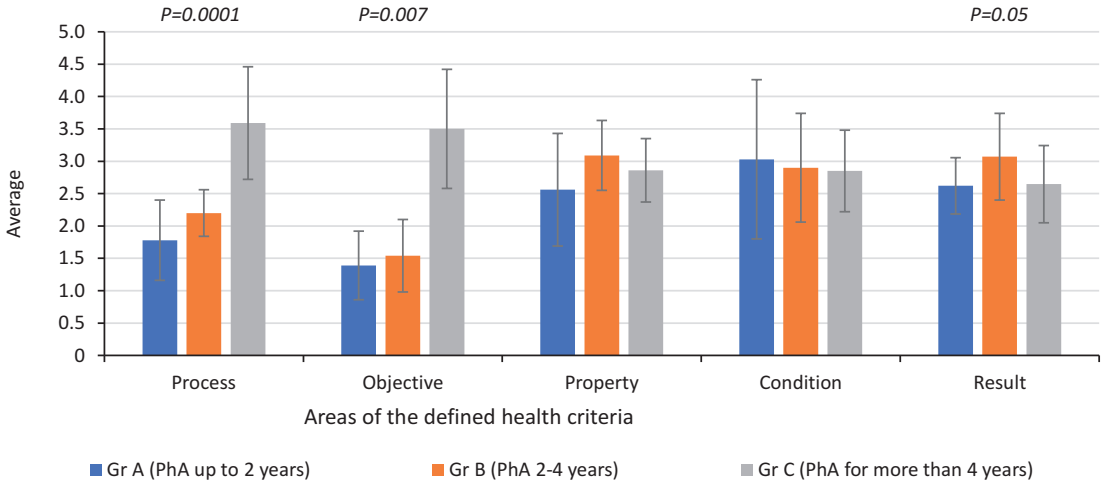

Figure 6. Assessment of the smallest significant differences between the average results for individual health areas in groups A, B, and C (ANOVA, univariate, NIR test). Group A – Physical activity for less than 2 years, Group B – Physical activity from 2 to 4 years, and Group C – Physical activity for more than 4 years

focused attention on the objectives of their training activity. Both groups are rather geared towards a specific, relatively quick effect, where improving figure and fitness was the most often mentioned.

In group C – training the longest – a reversal in the importance of criteria and a focus on personal commitment, responsibility, and long-term action, which is the process of taking care of one's own health, can be observed. The criteria selected by women from group C indicated a deeper psychological condition for undertaking a specific training activity. The following terms were often used *"to eat a proper diet", "to be able to work without tension and stress"*, and *"hardly ever to have to go to the doctor"*. Women in this group

had a personal, long-term commitment to becoming healthier was present. They perceived health as a process in which they themselves became the organizers, have a greater sense of personal influence and control over the process of becoming healthier, and practice self-control.

Table 1 presents the results of the statistical analysis using the Kruskal-Willis test. Results indicating statistically significant variation in health indicators among the women studied are highlighted. It may be noted that, in general, there were no differences between the health indicators of respondents who have been training for up to 2 years or 2–4 years. The participants that have been training for more than 4 years changed their system of valuing health criteria. The results of this research show that long-term training activity of the participants with ChBP before it becomes a conscious process needs to be supported by appropriate educational and performance incentives.

Table 1. Differences in dominant health criteria from different categories between training groups A (below 2 years), B (2–4 years), and C (over 4 years). Statistically significant values are highlighted. Kruskal-Willis Test.

Comparison of groups	Process		Goal		Property		Condition		Result	
	Z	p	Z	p	Z	p	Z	p	Z	p
A-B	1.53	0.3774	0.97	0.9936	1.55	0.3605	1.55	1.000	0.85	1.000
A-C	3.45	0.0017	2.23	0.0769	1.61	0.3174	1.62	1.1962	1.91	0.1689
B-C	1.66	0.2889	3.18	0.0045	2.8	0.0147	1.81	0.1422	2.13	0.0147

Discussion

The contemporary training process for health requires a multidirectional approach including directing the HT participant's attention to the benefits of exercise in psychosocial and educational areas. This is especially true for people with multiple dysfunctions. Hegberg and Tone have demonstrated that persons with high levels of fear obtain significantly more benefits from PA in the areas of psychological and physiological functions than less anxious people [6 p.4]. The above-mentioned authors have also shown that the positive impact of PA to improve one's resistance to stress depends on the individual levels of fear and the dose of PA. In the case of therapeutic interventions in persons with various pain conditions, the volume of the workloads (understood as the frequency and duration of a single training session) is more favorable when systematic physical work is performed at least twice a week with a moderately high duration of intermittent exercise and medium intensity (understood as external resistance, body resistance, isometric tension, or core stability training). [10, 11 p. 9]. Bloxham et al. [14] and Le Corre [17 p.125] indicate that each training session ought to be supplemented with therapeutic exercises based on improving sequential and global mobility. The training can be supplemented with manual mobilization techniques, which are highly effective in eliminating pain in the lumbar spine during movements in all planes and increasing its mobility, especially in extension as confirmed by Wyszyński et al. [18 p. 19]. Evaluating the achievement of the objectives of such a training cycle (otherwise effective training) ought to be made at the mesocycle level, i.e., the midpoint of the training time plan (lasting from a few to several weeks) [19]. In this case, long-term and intermediate objectives ought to be set that would make it possible to study lasting effects at the level of motor and physiological changes [17 p. 188, 19 p. 9-11, 20]. Therefore, monitored attendance which is often a measure of participant satisfaction with training may be used to observe changes in a participant's attitude towards PA and their objectives [21–23]. The knowledge of tools used to motivate employees by management, for example, those listed in a book edited by Frey and Osterloh [24] or the work of Romanowska-Tołłoczko et al. [25], may be helpful in motivating participants to adhere to PA regimens and improve their psychosocial competences. However, proper individual and group initiatives are needed to properly motivate. Kleinert et al. showed that the motivational profile of people with back pain is significantly different from that of non-patients and depends on the age and severity of the pain [26]. Therefore, the most often declared motive concerning weight reduction by the respondents may be explained by a more or less conscious effort to alleviate pain symptoms. Kołpa et al. point out that pain in the lumbar region leads to disturbances in everyday functioning, and reducing one's weight by 5 kg over a 6-month period significantly contributes to a lower perception of pain and improves physical fitness in LBP patients [27 p. 175]. Thus, the weight loss goal, in this case, is justified and does not have to be related to a desire to look good. However, while this goal will be effective in group training for a short period, women with a long training experience require goals in areas that work towards aims, and process realization should be sought.

The essence of this paper was to specify the LKZ characteristics for HT participants with ChBP participating in different lengths of training using

assessments of statements identified with health seeking in various areas as described by Juczyński [16 p. 125]: result, objective, property, process, and condition. This paper supplements knowledge on the perceptions of health and understanding of the desire to maintain health among physically active women with ChBP. It was hypothesized that there were no differences between the preferred areas of health actions in women with different lengths of training. This study verifies this thesis and proves that systematic participation for many years in the physical culture determines the valuation of health determinants. This is confirmed by reports on the mentioned health criteria, individually different motives for health actions, expectations of activity outcomes, and different personal commitments to health activity [28–31]. The above factors are elements of motivation to participate in PA and have been the subject of much research, both in the context of strengthening motivation and weakening it [21–23, 28]. However, most authors confirm the significant contribution of PA in the unconditional acceptance of one's self and physicality, despite having some deficiencies [4, 10–15]. Among them, the following is seen next to pain: lack of satisfaction with one's body and appearance in both men and women. It turns out that this factor often becomes the leading motivation for justifying training activity. The results of this study also indicate that among women with ChBP, in whom the occurrence of pain is a motivation for improvement through exercise and self-education in kinesiotherapy, the same motivation – weight reduction – is the strongest endogenous variable motivating one to exercise. This is particularly true for women engaging in occasional or systematic short-term activity (here about one year). Once a satisfactory state of affairs has been achieved (weight loss, reduction, or elimination of pain), the activity is interrupted and possibly resumed when the appearance of further somatic symptoms or lack of self-satisfaction occurs. It follows from the research that associating systematic PA with being healthy or improving health only occurs in the group of women participating in longer durations of PA (at least 4 years) when systematically training twice a week. Personal engagement in the HT process and the priorities involving the implementation of the whole exercise routine are exposed through multidimensional intensification of their own activity. The perception of health determinants is concentrated on the factors of personal responsibility, self-control in the area of nutrition, non-use of stimulants, control of emotional behavior, and maintaining good interpersonal relations. These factors fall within the broad field of interactions focused on the psychological sphere which is dependent on the individual's level of personal awareness and responsible health activity. Due to the data from the interview, it was not possible to carry out a correlation between the weekly number of workouts and preferred health behaviors. It seems that this factor, like the trainer and the quality of the training session, may be an important predictor of these choices. These predictions, however, would have to be confirmed by separate studies.

In health activity, the implementation of a training process is recognized as an end in itself, which also triggers other actions for well-being. Consequently, the sum of these actions leads to self-acceptance and recognition of one's limitations [12–15]. Hence, the main factor for improving and maintaining one's health is by raising awareness of the need for a long-term (multi-year) process and systemic change that can be initiated by PA at any age [31]. The motivating factors in this process may be of internal and/or external origin and should become the main driver for building this awareness [9, 20, 25, 29–31].

From the point of view of health policy and public health objectives, the best way to develop the participant's focus on their health is through multidirectional, parallel actions and the commitment of coaches and sports instructors. Monitoring health needs can be useful in achieving this goal. The tool proposed by Juczyński is easy to use and can also be used by health educators as well as by psychologists.

Limitations

The limitations related to our research pertain to the number of surveyed women and the unequal number of people in subgroups A, B, and C as broken down by long-term training. Moreover, it was assumed that volunteers with ChBP from towns of varying population levels would join the research. This point of the project has not been achieved. The study was discontinued due to Covid 19, and only the data from two research centers were taken into account. For the same reason, we decided not to compare the results in relation to age, pain location, and causes of pain. Only the declaration of pain in the spine and the self-assessment of health and fitness were adopted as criteria for participation in the study. At this point, we should ask ourselves how to find this information. For this reason, this article can be seen as a pilot study. To improve the quality of this research and to deduce wider conclusions, it would be necessary to extend the research to a wider group of women and to cooperate with smaller centers to improve an accurate cross-section of the population for the research. A separate topic that inspires further research is the surprisingly high percentage of young women complaining of back problems, which we found in our group of volunteers.

Conclusions

The LKZ is useful for setting goals in HT, especially for beginners and intermediate women (with up to 4 years of training). All health promoters (especially person coaches and physiotherapists) can benefit from the potential of the LKZ, thanks to a more accurate diagnosis of the patient's expectations.

Due to the fact that health perception depends on training experience, knowing the attitudes towards PA enables you to more accurately determine the time structure of the training in order to achieve the set goals and makes it easier to modify the main goals.

To maintain a high attendance, the trainer can more precisely determine training goals, define motor tasks, and indicate their health impact. They can increase their control over training effects (at current and cumulative levels) and apply periodical or selective weight loss and body-improvement training methodologies regardless of the participant's needs.

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Attachment 1. Demographics for research purposes

1. Pseudonym: ..... **Age:** ..... **Body weight:** .....

2. Sex: Woman Man

3. Place of residence: City over 100 thousand City below 100 thousand Village

4. Education: higher secondary vocational basic

5. Do you generally feel healthy? Yes No

6. Do you suffer from chronic illness? Yes No

7. Do you take any medication? Yes No

8. Are you currently experiencing pain of the following section of the spine:

cervical	Yes	No	shoulder pain	Yes	No
thoracic	Yes	No	knee pain	Yes	No
lumbar	Yes	No	headache	Yes	No
sacral	Yes	No	hip pain	Yes	No

9. How do you assess your health condition? (5 – very good, 4 – good, 3 – average, 2 – sufficient (satisfactory), 1 – poor)

1 2 3 4 5

10. How do you assess your physical fitness? (5 – very good, 4 – good, 3 – average, 2 – sufficient (satisfactory), 1 – poor)

1 2 3 4 5

Did you play any sports in the past? (training with a view to participation in competitions)

Yes No

If yes, what sport?..... **How long?** 0–2 years 3–4 years 5–6 years >7 years

11. Are you physically active? / does not apply to housework /

Systematically		Periodically	
YES	NO	YES	NO

If yes, please give the type of activity: .....

12. Days of the week and the amount of time spent on the activity:

Mon ..... min; **Tue** ..... min; **Wed** ..... min; **Thur** ..... min; **Fri ....**.. min; **Sat** ..... min; **Sun** ..... Min

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Correspondence author:
Małgorzata Kałwa
E-mail: malgorzata.kalwa@awf.wroc.pl

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PSYCHO-SOCIAL WORKING CONDITIONS OF NURSING, MEDICAL AND PARAMEDIC STAFF IN A HOSPITAL EMERGENCY DEPARTMENT

Ada Lisowska[1 A-G]
• ORCID 0000-0002-1891-0788

Katarzyna Szwamel[2 C-G]
• ORCID 0000-0001-8186-9979

Arkadiusz Wilczek[1 E-G]
• ORCID 0000-0002-3229-1741

Grzegorz Wolf[1 E-G]
• ORCID 0000-0001-6926-8986

Krzysztof Tomsza[1 E-G]
• ORCID 0000-0002-3974-1151

[1] Emergency Department, Opole University Hospital, Poland

[2] Institute of Health Sciences, University of Opole, Poland

A – study design, **B** – data collection, **C** – statistical analysis, **D** – interpretation of data, **E** – manuscript preparation, **F** – literature review, **G** – sourcing of funding

ABSTRACT

Background: A hospital Emergency Department (ED) is a place in which numerous working conditions evoke various organizational and operational stressors that affect the medical staff employed there.

Aim of the study: Analyze the psycho-social working environment of nursing, paramedic, and medical staff, in a specific hospital ED. In particular, examine 1) work requirements 2) levels of control 3) psycho-physical wellbeing, and 4) changes expected by the staff.

Material and methods: The research was conducted among 69 employees of the ED (nursing, paramedic, and medical staff) of the University Clinical Hospital in Opole. A standardized Psychosocial Working Conditions Questionnaire (PWCQ) was applied.

Results: Mean scores were as follows: 94.99 points on the demands scale, 59.26 points on the control scale, 48.94 points on the social support scale, and 75.32 points on the desirable changes scale. Length of service in the job correlated negatively with workplace support received ($r=-0.308$, $p=0.01$). Meanwhile, the necessity for changes in the workplace was stronger in the residents of villages and towns below 100,000 residents ($p=0.007$). Material status of the respondents correlated significantly ($p<0.05$) with the answers collected in each PWCQ questionnaire subscale. Support received in the workplace was significantly higher in the paramedics (51.11±8.48), and doctors (52.95±13.66), than it was in nurses (44.39±10.26) ($p=0.005$).

Conclusions: Due to numerous stressors present in the ED, and the psycho-social working conditions, employers ought to make some effort to modify them.

KEYWORDS: hospital emergency service, work, nursing, allied health personnel

Background

A hospital Emergency Department (ED) is a place in which numerous working conditions evoke various organizational and operational stressors that affect the medical staff employed there [1]. They are especially exposed to stress resulting from the nature of work, fatigue, and sleeping disorders [2]. A large amount of stress is also generated by the culture of the organization, the type and quality of external support, and

the working environment [3,4]. However, the primary source of stress comes from the fear of committing medical malpractice and its legal consequences [5], overcrowding, time pressures, the unpredictability of events, patient aggression, dealing with deaths, family violence, and child sexual abuse [6-8].

Stress related to performing professional duties affects work satisfaction [9]. It might be enhanced by proper remuneration, good work organization, clear work and responsibility allocation, supervisor support, good communication, work autonomy, and support from co-workers' [10-13]. On the other hand, low job satisfaction may stem from staff and equipment shortages, lack of career development opportunities, low earnings, work overload, poor worker-supervisor relations [10, 14], and workplace violence [15], which is very common in EDs [6, 16-17].

Workplace tensions might derive from three basic aspects, namely, demands, control, and social support [18]. This knowledge led to the establishment of three models describing employee-organization interactions, and fluctuations in these aspects affect every single employee in an organization.

The first model is demand-control-support [19]. Demand refers to the quantity and quality of work, while control is considered as the opportunity to have some influence over the work performed, for example, the choice of methods used. The last aspect is related to the support received from supervisors and co-workers in areas such as emotional (showing positive emotions), instrumental (helping solve a specific problem), informational (supplying relevant information to deal with specific situations), and evaluation (expressing opinions) [20].

The second model refers to the balance between effort and reward. When an individual puts a lot of effort into their work they have an expectation of compensation for their effort that can fulfill their needs. However, when there is no balance in this aspect employee stress is enhanced [21-22].

The third model is job demand-recourses (JD-R), which refers to an employee's engagement with the efforts of the organization to improve the workplace. This can be achieved through resources such as support, creating educational opportunities, prizes, and feedback connected with the effectiveness of work.

The most negative workplace outcomes occur when there is a combination of high demand, low control, and a low level of social support [18, 23-24]. Such a situation might result in inadequate employee time management, a decline in productivity and quality of work, absence due to illnesses, fluctuations, resistance to change, and a higher risk of work-related accidents [25]. According to Karaska, there are four models relating to the aspects discussed above, and four different consequences that they may produce. The first consequence is stress, which is created by huge demands and a low range of control. Activity describes a situation in which there are both high demands and control, passiveness occurs with low levels of demand and control, while low demands and a very high range of control results in a relaxed response [19]. Cox et al. also described psycho-social working conditions that result from particular aspects such as organizational culture, roles fulfilled in the organization, the scope of decision-making, sense of control, development and promotion opportunities, relations with co-workers, work content, workplace equipment, workload, and pace of work [26].

Research carried out in Finland demonstrated that dedicated and satisfied staff have a huge impact on patient satisfaction with medical services [27]. These conclusions correlate with the findings of Alghamdi et al., who studied paramedics and reported that job satisfaction affected dedication and commitment to their organization and that this was directly reflected in a higher quality of service and patient satisfaction [28]. Similar conclusions were also found by research conducted within the framework of the Nurse Forecasting: Human Resources Planning in Nursing (RN4CAST) project. This work showed that the reality experienced by nurses in their workplace was not in line with their expectations and this decreased their job satisfaction [29]. Therefore, job satisfaction among nurses, paramedics, and doctors, is essential for maintaining a work-life balance. Indeed, it can reduce personal costs connected with job performance [30], stimulate greater organizational commitment [28], as well as lowering the risk of work-related stress and professional burnout, which affect approximately 65-70% of ED staff [31, 32]. Avoiding such consequences is very important as it can lead to higher absenteeism, intentions to quit work, a lower quality of services provided, a lower level of job satisfaction [33], psychoactive substance abuse, the development of depression and anxiety disorders, insomnia, problems with interpersonal relations, and even health disorders such as headaches, chronic fatigue, gastric disorders, hypertension, sleeping disorders, and immunosuppression [34, 35]. Thus, stress and burnout prevention is essential for the employee as an individual and the organization as a whole.

Working in an ED is a highly demanding job, as nurses, paramedics, and doctors, constantly interact with patients [36]. Therefore, understanding the dependencies between psycho-social work requirements and psycho-physical well-being, as well as changes desired by medical staff, is essential.

Aim of the study

The study aimed to analyze the psycho-social working environment of nurses, paramedics, and doctors,

in a specific hospital ED and, in particular, to examine 1) work requirements, 2) levels of control, 3) psychophysical well-being, and 4) changes expected by the staff. It also focused on determining the occurrence and intensity of these aspects in each profession.

Material and methods

Study design and setting

This observational study was carried out between 13th-30th August 2022 after receiving the approval of the Bio-Ethics Committee (no 41/2022) and Hospital Management (no DO-75-12/2022) on 11th July 2022. It was conducted according to the regulations of the Declaration of Helsinki (1975), as amended in 2000, and Good Clinical Practice.

Participants

Participants were recruited from ED employees of the University Clinical Hospital in Opole. The respondents were nurses, paramedics, and doctors. Criteria for inclusion in the study were: being employed in their current position for a minimum of six months, and agreeing to participate in the study. The study did not include Managerial staff. Of the 80 surveys that were sent out to participants, 69 of them were completed, which represents a completion rate of 86.25%.

Data sources/measurement

The examination was based on the diagnostic survey method, with the use of a questionnaire. A standardized Psychosocial Working Conditions Questionnaire (PWCQ Cieślak, Widerszal-Bazyl, 2000), which examines three variables (demands, control, social support) derived from the stress concept developed from the research of Robert Karaska was used. The questionnaire consists of five theoretical scales, including the demands scale (DS), control scale (CS), social support scale (SSS), wellbeing scale (WS), and desirable changes scale (DCS). Reliability of the scales, as measured with the α-Cronbach coefficient, ranges between 0.82-0.94 [37]. Each subscale of the questionnaire consists of a different number of questions, therefore, each subscale has a different range value. However, all subscales share one common characteristic; the greater the number of points, the higher the intensity of the phenomenon. The average number of points for each question was calculated for each separate scale and interpreted according to a key for every single question: 1 – the phenomenon does not occur, 2 – it rather does not occur, 3 – neutral state, 4 – it rather occurs, 5 – it definitely occurs.

Statistical analysis

Analysis of quantitative variables was carried out by calculating the mean, standard deviation, median, and quartiles. Meanwhile, qualitative variables were assessed by calculating the percentage of every value. Comparison of two qualitative variables in two groups was conducted with the use of the Mann-Whitney U test, and comparison of quantitative variables in three or more groups used the Kruskal-Wallis H test. After statistically significant differences were found, post-hoc analysis was performed with the use of Dunn's test to identify statistically different groups. Correlations between quantitative variables were analyzed with Spearman's rank-order correlation coefficient. The level of significance was set at 0.05. All analysis was performed with the use of the R program, version 4.1.1 [38].

Results

Participants

Research was conducted among 69 employees, consisting of 29 nursing staff who were mainly female (82%), with a mean age of 47 years, 23.26 years of work experience, and of whom 10% had a university education. Paramedic staff amounted to 18 individuals, 35% of whom were female, with a mean age of 36, a mean length of service of 10 years, and 11% of them having achieved university degrees. Medical staff comprised 22 doctors, three of whom were employed at the hospital ED and 19 within other wards of the hospital, but were consulting ED patients. Of the 19 working within other wards, five worked in the Cardiological Department, two within the Paediatric Ward, one in the Urological Ward, two in Paediatric Surgery, two in General and Vascular Surgery, two in the Internal Medicine Ward, and one in the Nephrological Ward. Fifty percent of medical staff were female, their mean age was 34, and the mean length of service was 7.5 years. Sociodemographic characteristics of all the respondents are presented in Table 1.

Main results

Mean scores for the Psychosocial Working Conditions Questionnaire scales

The mean score for the DS was 94.99 points, which equates to 3.8 points per question and indicates that

Table 1. Sociodemographic characteristics of the research group

Parameter		Total	Parameter		Total
Age [years]	M±SD	39.99±10.15	Education	Medical secondary school	11 (15.94%)
	Median	38		Medical College	12 (17.39%)
	Q1-Q3	32–47		Undergraduate studies	14 (20.29%)
Work experience [years]	M±SD	16.04±11.57		Master studies	10 (14.49%)
	Median	15		Medical studies	20 (28.99%)
	Q1-Q3	7–24		Doctoral studies	2 (2.90%)
Gender	Female	39 (56.52%)	Material status	Very good	13 (18.84%)
	Male	30 (43.48%)		Rather good	39 (56.52%)
Marital status	In a relationship	57 (82.61%)		Average	16 (23.19%)
	Single	12 (17.39%)		Rather bad	1 (1.45%)
Place of residence	Village	9 (13.04%)	Position	Nurse	29 (42.03%)
	City under 20 thousand inhabitants	8 (11.59%)		Paramedic	18 (26.09%)
	City of 20-100 thousand inhabitants	9 (13.04%)		Doctor	22 (31.88%)
	City of 100-500 thousand inhabitants	41 (59.42%)	M – mean; SD – standard deviation; Q1 – first quartile; Q3 – third quartile.		
	City of more than 500 thousand inhabitants	2 (2.90%)			

the respondents identified the phenomenon as existent within their workplace. The mean score for the CS was 59.26 points, which attributes 2.96 points to each subscale question and leads to the conclusion that the respondents assessed the phenomenon to be neither existent nor non-existent. On the SSS, a mean score of 48.94 points translated to 3.06 points per question. This means that the respondents claimed that the phenomenon was neither existent nor non-existent. Meanwhile, the WS returned a mean score of 75.49 points, which corresponds to 3.43 points per question and means that the respondents decided that the phenomenon was neither existent nor non-existent. Finally, the mean score for the DCS was 75.32 points, giving each question a mean score of 3.77 points. Such a score indicates that the respondents confirmed the occurrence of this phenomenon in their workplace (Table 2).

Table 2. Scales of the Psychosocial Working Conditions questionnaire

PWCQ	Value range	Mean	SD	Mean per question	Me	Min	Max	Q1	Q3
Demands Scale (DS)	25–125	94.99	7.39	3.80	95	71	111	91.00	100.00
Control Scale (CS)	20–100	59.26	9.20	2.96	58	34	95	54.00	64.00
Social Support Scale (SSS)	16–80	48.94	11.60	3.06	50	16	73	44.50	57.00
Wellbeing Scale (WS)	22–110	75.49	14.39	3.43	76	34	109	69.00	84.25
Desirable Changes Scale (DCS)	20–100	75.32	11.31	3.77	76	44	96	69.75	82.50

SD – standard deviation; Q1 – first quartile; Q3 – third quartile; min – minimum; max – maximum; PWCQ – Psychosocial Working Conditions Questionnaire.

Correlations between sociodemographic data and the Psychosocial Working Conditions Questionnaire scales

Correlations between the PWCQ scales and variables including gender, age, and marital status, proved to be statistically insignificant (all scales <0.05) (Table 3, Table 4). Length of service correlated negatively with workplace support received, with the degree of perceived support lowering as length of service increased (r=–0.308, p=0.01) (Table 3).

Table 3. Age of emergency department employees vs Psychosocial Working Conditions Questionnaire scales

PWCQ	Age	Work experience
	Spearman's rank-order correlation	
Demands Scale (DS)	r=0.07, p=0.572	r=0.148, p=0.229
Control Scale (CS)	r=0.056, p=0.649	r=0.082, p=0.507
Social Support Scale (SSS)	r=–0.228, p=0.061	r=–0.308, p=0.01*
Wellbeing Scale (WS)	r=0.072, p=0.56	r=0.012, p=0.926
Desirable Changes Scale (DCS)	r=0.073, p=0.557	r=0.117, p=0.341

* Statistically significant relationship (p<0.05).

Table 4. Correlations between PWCQ Questionnaire scales and gender, marital status, place of residence, and material status of the respondents

PWCQ		Gender		p	Marital status		p	Place of residence		p	Material status			p
		Women (N=39)	Men (N=29)		In a relationship (N=56)	Single (N=12)		Village or city up to 100,000 residents (N=26)	City of more than 100 thousand inhabitants (N=42)		Very good – A (N=12)	Rather good – B (N=39)	Average, rather bad – C (N=17)	
Demands Scale (DS)	M±SD	95.54±7.16	94.24±7.75	p=0.449	95.2±7.68	94±6.05	p=0.623	95.92±6.93	94.4±7.68	p=0.258	97.92±7.61	94.31±7.86	94.47±5.85	p=0.333
	edian	96	94		94.5	95.5		96.5	94		97.5	94	94	
	Q1-Q3	90.5–101	91–98		91–101	90.25–7.25		92.5–100.25	90.25–99.5		93.5–103	89.5–99	93–98	
Control Scale (CS)	M±SD	58.51±10.2	60.28±7.71	p=0.236	59.77±9.58	56.92±6.97	p=0.284	57.96±10.49	60.07±8.33	p=0.452	63.92±9.85	59.87±9.16	54.59±6.91	p=0.012 *
	median	58	59		58.5	55		56.5	58.5		64.5	59	53	
	Q1-Q3	53–63	55–66		54–65	52.25–63.25		50.75–65.75	55–63.75		56.25–67.5	55–63.5	50–59	A, B>C
Social Support Scale (SSS)	M±SD	47.64±12.55	50.69±10.12	p=0.286	50.45±10.63	41.92±13.73	p=0.05	47.08±12.49	50.1±11	p=0.223	57.08±11.29	48.87±10.34	43.35±11.77	p=0.004 *
	median	48	52		51	45		46.5	51		58.5	50	45	
	Q1-Q3	41.5–56	47–57		46–57	33–50.5		40.5–56.75	46.25–56.75		52–64.5	45.5–56	38–50	A>B, C
Wellbeing Scale (WS)	M±SD	73.03±14.58	78.79±13.68	p=0.108	77.46±13.42	66.25±15.76	p=0.051	77.04±17.55	74.52±12.18	p=0.35	81.83±12.44	77.77±12.79	65.76±15.13	p=0.004 *
	median	73	80		76	71.5		76	75.5		83	76	68	
	Q1-Q3	69–83	70–86		70–86	53.25–78		71–86	67.5–83		74.75–89.25	71.5–83.5	55–73	A, B>C
Desirable Changes Scale (DCS)	M±SD	76.05±11.62	74.34±11	p=0.453	74.7±11.33	78.25±11.19	p=0.303	79.54±9.96	72.71±11.41	p=0.007*	73.08±12.57	74.23±11.49	79.41±9.43	p=0.221
	median	77	74		76	81		81	74		76	76	81	
	Q1-Q3	72–82	69–84		69.75–81.25	72–86		76–85	66.25–80.75		59.75–84.25	69.5–81	74–89	

M – mean; SD – standard deviation ; Q1 – first quartile; Q3 – third quartile; PWCQ – Psychosocial Working Conditions Questionnaire; * statistically significant relationship (p<0.05).

Statistically significant correlations were reported in terms of place of residence, with the necessity for changes in the workplace found to be stronger in the residents of villages and towns below a population of 100,000 (p=0.007). Furthermore, the material status of respondents correlated significantly (p<0.05) with the answers collected for each PWCQ questionnaire subscale. In this regard, respondents' influence on their functioning in the workplace (p=0.012) and well-being (p=0.004), was significantly stronger in the groups with a very good or good material status compared to those with an average or a rather bad status. Moreover, social support in the workplace was significantly stronger for those with a very good material status in comparison to individuals with a rather good, average, or rather bad, status (p=0.004) (Table 4).

Support received in the workplace was significantly higher in the paramedics (51.11±8.48) and doctors (52.95±13.66), than it was in nurses (44.39±10.26) (p=0.005) (Table 5).

Table 5. Correlation between position in the workplace and the PWCQ Questionnaire scales

PWCQ		Position			p
		Nurse – A (N=28)	Paramedic – B (N=18)	Doctor – C (N=22)	
Demands Scale (DS)	M±SD	96.11±6.99	94±7.96	94.36±7.56	p=0.476
	median	96	94	93	
	Q1–Q3	93–100	92.25–96.75	88.25–100.25	
Control Scale (CS)	M±SD	58.54±9.58	56.72±8.29	62.27±8.97	p=0.123
	median	56.5	57	62.5	
	Q1–Q3	53–63.25	53.25–61.25	55.5–66	
Social Support Scale (SSS)	M±SD	44.39±10.26	51.11±8.48	52.95±13.66	p=0.005 *
	median	46	53.5	55.5	
	Q1–Q3	38–50.25	47–57	47.75–61.75	C, B>A
Wellbeing Scale (WS)	M±SD	73.18±15.1	74.56±15.81	79.18±11.97	p=0.406
	median	73.5	76.5	80	
	Q1–Q3	69–83	66.25–84.5	71.5–84.75	
Desirable Changes Scale (DCS)	M±SD	76.43±9.93	77.33±11.49	72.27±12.62	p=0.242
	median	78	76.5	72	
	Q1–Q3	73.75–82	70.25–85.75	61.5–79.5	

M – mean; SD – standard deviation; Q1 – first quartile; Q3 – third quartile; p – Kruskal-Wallis test + analysis post-hoc (Dunn's test); PWCQ – Psychosocial Working Conditions Questionnaire; * statistically significant relationship (p<0.05).

Detailed analysis of selected questionnaire questions relevant to emergency department staff

As the PWCQ Questionnaire does not include norms designed for paramedics and doctors, it was decided to further analyze the questions that were significant from the perspective of ED staff and present the frequency of the answers in all three researched groups.

Requirements at work

For the question of whether their work requires a lot of concentration, 57.97% (40) of the respondents answered 'to a large extent'. This general tendency was reflected in the group of nurses (18; 62.06%), paramedics (12; 66.86%), and doctors (10; 45.45%).

When questioned on whether they had enough time to perform their duties, none of the nurses answered 'definitely yes' (0; 0.00%). A great deal of the respondents in this group answered 'rather yes' (15; 21.73%), and one of them answered 'rather no' (1.44%). In the group of paramedics, the most common answers were 'rather yes' and 'to some extent' (5; 27.77%). No paramedics answered 'definitely no' (0; 0.00%). The medical staff most commonly chose the 'rather yes' answer (8; 36.36%) and, similar to the paramedics, no one declared 'definitely no' (0; 0.00%).

On the question of whether their work requires solving complicated problems, 22 answers were received for both 'to a large extent' and 'to a very large extent' (31.88%). No respondents chose the answer 'to a small extent' (0; 0.00%). The most common answer was 'to a very large extent' among both the nurses and paramedics (12; 41.37% vs. 6; 33.33% respectively). In response to the same question, most doctors answered 'to a large extent' (9; 40.90%), and none of them answered 'to a negligible extent' (0; 0.00%).

Constant learning takes place 'almost permanently' for 57% of the respondents, and only 4% of them considered it 'not necessary at all'. Fifteen nurs-

es (51.72%) decided that they needed to learn new things at work 'almost permanently', and none of them chose the 'to a small extent' answer (0; 0.00%). Paramedics and doctors also chose the 'almost permanently' option most frequently (7; 38.88% vs. 7; 31.81% respectively).

When asked if their workplace is a place of a great deal of interpersonal conflicts, 37% responded 'to an average degree', 27% 'to a large degree', and only 4% 'to a small degree'.

The opportunity to control and influence their work

On the question of whether they are able to decide individually when to perform a given task, 43% responded 'to a small extent' and 2% of all respondents chose 'always' as their answer.

When asked how much of an influence they had on their work, 39% of the respondents described it as 'large', while 35% responded with 'moderate', and only 2% reported 'no influence at all'. 'Large' and 'moderate' influence was found in nurses (8; 27.58%), and none of them chose the 'no influence at all' answer (0; 0.00%). Similarly, the group of paramedics declared 'large influence' (6; 33.33%). None of the doctors chose the 'almost full influence' option (0; 0.00%), but both the 'moderate' and 'large influence' answers were chosen by six respondents each (27.27%).

The question concerning opportunities of receiving feedback on whether they perform their duties well was most commonly answered as 'generally yes' (13; 18.84%) and 'occasionally yes' (12; 17.39%). When asked whether they are informed about the most important events concerning the institution, 35% of the respondents chose 'I'm not frequently informed' and only 4% answered 'I'm informed about everything'. However, 69% declared a complete lack of opportunity to participate in making decisions related to the institution they worked for, and only 23% chose 'a small share' in this respect. Among nurses, nobody declared 'full share' in the decisions, and the largest number of examinees chose 'no share at all' (18; 62.06%). For the paramedic group, 38.88% (7) chose the same option, and it was also the most common answer among doctors (10; 45.45%). Lack of staff consultation before introducing changes in the organization was reported by 51% of the respondents. No consultation at all was notified by doctors (8; 36.36%), and very little consultation by nurses and paramedics (8; 27.58% vs. 7; 44.44%). The opportunity to participate in making decisions related to the organization was 'full' or 'large' in 2% and 4% of the respondents, respectively, and 69% of them had no impact in this aspect at all. Access to information indispensable to everyday work was determined as 'moderate' by 39.13% (27), and 'quite good' by 24.63% (17) of the respondents.

Social support

The question concerning the extent of social support the respondents might expect from their supervisors received an answer of 'very small' from 11.59% of participants, while 39% responded 'average'. Nurses and doctors most commonly declared receiving an 'average extent' of support (10; 34.48% vs. 6; 27.27%), and the paramedic staff 'small' (5; 27.77%). Support from co-workers was reported by 2% as being 'to a small extent' and 'to a large extent' by 55% of the respondents, whereas, the most common answer in nurses, paramedics, and doctors was 'to a large extent' (12; 41.37% vs 8; 44.44% vs 8; 57%).

The question referring to the extent to which the respondents may expect their abilities to be appreciated by their supervisors received no 'to a very large extent' answers, whilst 34.78% (24) answered 'to an average extent', and 15.94% (11) answered 'to a small extent'. All three professions most commonly chose being appreciated 'to an average' extent, and the data were 34.48% for nurses, 44.44% for paramedics, and 27.27% for doctors. Appreciation by co-workers was marked at the average level (51%), and this was the most commonly declared answer in all three groups. The examinees reported that they may rely on their supervisors for necessary information 'to an average extent' (27; 39.13%), but on their co-workers 'to a large extent' (25, 36.23%). Understanding and consolation in difficult situations were provided by the supervisors 'to an average extent' (23; 33.33%) and by co-workers 'to a large extent' (29; 42%). Respondents decided that both supervisors and co-workers make them feel as though they are somebody important 'to an average extent' (20; 28.98% vs 29; 42%).

Wellbeing

The occurrence of stress symptoms was declared by 31.88% (22) of the respondents as 'quite frequent', while 26% (18) reported them as 'sometimes' occurring. In regards to job satisfaction, 57% were 'rather satisfied' with their work, only 2% were 'very dissatisfied', and 23% of the staff were neither satisfied nor dissatisfied.

In terms of exhaustion in the workplace, 41% of the respondents were 'rather more frequently' exhausted recently than they had been before. Tightness in the chest was experienced 'quite rarely' by 27% of examinees, and 'quite frequently' by only 4% of them, while no paramedics or doctors experienced the condition 'quite frequently' or 'very frequently'.

Gastric disorders were found to occur 'quite rarely' in 22% of the respondents and 'quite frequently' in 16% of them, while the most common response was 'almost never' (37%). When asked about their ease of falling asleep, the greatest number of respondents replied 'rather easily' (27%). However, a very similar number of respondents chose 'rather hard' (25%). Finally, 35% of the staff examined for the study declared waking up once at night, 20% woke up 2-3 times, and 14% woke up 4-5 times.

Desirable changes

According to 63% of the respondents, the institution 'definitely' requires some organizational changes. Furthermore, 27% claimed changes were 'rather necessary' and none thought they were "rather not' or 'not necessary at all'. This was reflected in the answers of all three professional groups, with the most common answer being 'definitely necessary' (65% of nurses, 64% of paramedics, and 57% of doctors). None of the participants chose the answer excluding the necessity for changes. The need for a temporary substitution at work was reported as 'barely necessary' by 29% of staff, and 10% of respondents did not see any need in the matter at all.

Regarding organizational change, 51% of respondents would 'rather be' provided with more detailed information, and 37% would 'definitely' like to get information, while no respondents answered 'there is no need' for such information. The necessity for more employee-supervisor consultations was reported as 'definitely necessary' by 57% of the examinees. Within the subgroups, 57% of doctors and nurses thought consultations were 'definitely necessary', while 50% of paramedics shared this opinion. In terms of career development, 47% of the respondents opted for career development opportunities as 'definitely necessary' and only 2% decided they were 'rather unnecessary'.

Discussion

Key results

Employees have a huge impact on the functioning of the whole organization. Their ability to meet the requirements of a particular job, with minimal probability of mistakes, in determined conditions and time, depends on working conditions that avoid quantitative and qualitative overload [39]. Professional work ought to fulfill the workers' following needs: physiological, safety, social recognition, respect, and self-realization [40], and therefore, the psycho-social environment of the workplace is of great importance.

Work requirements, control, and social support

Research conducted in Belgium by Karaska with the PWCQ questionnaire demonstrated that high requirements and low levels of control in the workplace predicted employee absences due to depressive disorders [41]. Plaister et al. [42] also showed that psychological work requirements increased the risk of anxiety and depressive disorders in employees, whereby, women declared low levels of control and men had high psychological demands. The authors also found social support promoted good mental health, which was similar to some Dutch research that discovered a link between social support and the prevention of anxiety disorders [43]. Moreover, a study by Ylipaavalniemi et al. conducted among Finnish hospital staff investigated correlations between the occurrence of depression and working conditions, including psychological requirements, control, organizational climate, and unfair treatment on the part of supervisors. They showed that there was a positive correlation between improper social climate or unfair treatment, and the occurrence of depression [44]. Vu-Eickmann et al. noted that dealing with many patients, working under time pressure, staff shortages, low sense of control connected with multitasking, and interruptions, were found as essential stressors among German doctors. It was found that their work-related stress mostly resulted from their lack of sense of control in the workplace, which was reported by 85.1% of the respondents studied [45]. Basu et al. also reported that ED staff experienced low levels of opportunity to self-control their work, high work requirements, and low autonomy arising from, among others, a lack of opportunity in making decisions, such as when to take a break or how to take care of patients. These were, together with low supervisor support and insufficient staff engagement in organizational changes, the main stressors [48]. Kowalczuk, while examining nurses' psychosocial working conditions, showed that staff characterized by long work experience and older age evaluated social support and the opportunity of control to be much worse, but appreciated work requirements much higher. Furthermore, the assessment of social support and the opportunity for control was determined by the level of education, with a more positive opinion given by those who had a higher level of education [49]. Additionally, this self-reported research showed that respondents claimed that their work environment sets high demands but that their opportunity for control over what happens at work was neither existent nor non-existent. Results for the social support aspect were similar, and assessment was lower as work experience increased. However, the support experienced at work was significantly higher in employees with very good material status and was

much higher in doctors and paramedics than it was for nurses. Finally, the group declared the necessity for changes in the workplace.

Representatives of the nursing staff examined by Misztal named the following psycho-social factors as affecting their job involvement and motivation: stability of employment (92%), supervisor appreciation of their engagement at work (81%), modern equipment in their hospital units (71%), supervisor interest in their career development (69%), good atmosphere among employees in the ward (65%), supervisor interest in the problems and needs of nursing staff (61%), clear job responsibilities (58%), and supervisor interest in creating a good atmosphere in the ward (30% of the respondents) [50]. In addition, Pawlik underlined that the nurses she studied pointed at the form of employment, nice workplace atmosphere, good supervisor-employee relations, clear working time schedules, as well as praise and supervisor recognition, as having an important impact on their work [51]. Factors that caused demotivation were related to excessive duties, lack of time to perform assigned duties, and excessive work connected with documentation [52].

Kondracka et al. studied conflicts arising in hospitals and found that manager-employee information flow was most frequently 'neither good nor bad' (78%). Examination of the information flow between supervisors and their workers was most often considered as 'rather good' (91%) [53]. This self-reported study presented that 69% of respondents declared no opportunity for participation in decision-making in their institution, and a third were not frequently informed about important events in their organization. Also, working with patients was strongly linked with the necessity of dealing with their, and other staff's, emotions, a finding that was also confirmed by the Central Institute of Work Prevention. Their research demonstrated that the healthcare sector is the work environment in which workers have to participate in emotional discomfort-creating situations most commonly [54]. Specifically, stress was caused mainly by a chronic state of tension connected with the responsibility for patients' lives and health. Furthermore, EDs are a stressful work environment [55] due to overcrowding and multitasking [56, 57]. These phenomena are related to the necessity to select which patient has to be attended to first and the awareness/fear that a patient, who might be in a health or life-threatening condition, would have to be left to wait for treatment [58].

Research among paramedics by Wnukowski et al. showed that working shifts caused tiredness and disturbances in family life and, most of all, contributed to malpractices being committed. Also, duties performed by paramedics are connected with exposure to harmful biological and chemical agents [59]. Moreover, working in an ED is connected with experiencing verbal and physical aggression from both patients and staff members in the forms of screaming (54-96%), vulgarism (92%), insults (70%), threats (68%), undermining competence (40%), pushing (64%), spitting (62%), and even hitting (18%). As many as 43% to 62% of ED employees experienced such behaviors at least a few times per week [60-64]. Also, dealing with traumas such as death, pain, or child abuse, may have a lot of psychological consequences, including burnout or post-traumatic stress disorder (PTSD) [17, 65-67].

Social support received from supervisors and co-workers constitutes an essential factor that affects the level of stress experienced at work [54]. Research conducted among German doctors and nurses showed that nurses declared more social support compared to doctors [68]. Similarly, low levels of external support among Australian paramedics predisposed them to experience fear, depression, or PTSD [2].

Wellbeing

The psycho-social hazards mentioned in the content of this study (work overload, work timeline) and included in its context (position in the organization, interpersonal relations) may evoke work-related stress [69] and, consequently, physiological reactions such as increased levels of hormones, hypertension, headaches, gastric disorders, sleeping issues [70], peptic ulcer disease, coronary artery disease, L-S spine aches, or musculoskeletal system disorders [54]. Additionally, they may invoke psychological reactions such as sadness, depression, irritation, tension, the feeling of energy deficiency, improper ability to perform at work, a lower level of job satisfaction [70-72], lowered concentration, memory problems, decision-making issues [25], making mistakes, and conflicts [73]. There is also a possibility that somatization could occur as a defense mechanism, where somatic symptoms may arise which cannot be assigned to any organic cause (MUS – medically unexplained symptoms) [74-76].

Kivimaeki et al. demonstrated that a huge discrepancy between effort and reward, unfair treatment by supervisors, inconsistent decisions, and unequal participation of co-workers in their work, may cause general health deterioration and predispose them to depression [77]. This self-reported study discovered that a good state of mind at work was neither existent nor non-existent.

According to data collected by the General Statistics Office, negative factors influencing employee well-being might be physical (such as temperature, light, or noise) or psychological (huge time pressure, work overload, abuse or endangerment of abuse, threats,

insufficient communication in the organization, difficult customers/patients, lack of influence on the work performed). As many as 38.4 % of Polish workers experienced work-related health issues, and these manifested most often as headaches (11.2% of women vs 7.6% of men), neck or shoulder aches (14.7% of women vs 13.1% of men), and backache (20.1% of women vs. 22.4% of men) [78]. According to the General Statistics Office, 7.3 million working people in Poland declared that there were factors that badly affected their mental well-being in their workplace during the second quarter of 2020. For 24.2% of them, it was time pressure and work overload, and for 20.9% it was dealing with a difficult customer/patient. In the healthcare sector, the aspects mentioned above affected 60% of employees. In 2019, research conducted in European countries reported that healthcare workers were subjected to mental risk factors in the workplace, with 45% of them working under time pressure, 21% working long hours, and 51% having experienced patient aggression [79]. This self-reported study informed that almost half of the respondents declared experiencing fatigue more often than before in recent times, while a third of them reported sleeping disorders and waking up several times at night. However, they reported almost no gastric issues and chest tightness occurred rather rarely.

Need for change

Research by Kowalczuk conducted among nursing staff showed that workers with longer work experience and older age highlighted the necessity for changes in their organizations more frequently [49]. This self-reported study found that 63% of respondents claimed that organizational changes were necessary and more than half would like to receive more detailed information about changes.

Limitations

Limitations of the research include the small number of respondents and the fact that it was restricted to only one ED.

Interpretation

Due to numerous stressors present in EDs and the psycho-social working conditions, employers ought to make some effort to modify them to take care of their staff, as the ability of staff to carry out their roles affects the functioning of the whole organization.

Conclusions

The level of social support given by supervisors to their employees ought to be enhanced. Furthermore, the information flow between supervisors and employees needs to be improved.

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Correspondence address:
Ada Lisowska
Uniwersytecki Szpital Kliniczny w Opolu
al. Wincentego Witosa 26
45-401 Opole, Poland
E-mail: ada.lisowska@o2.pl

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STATIONARY REHABILITATION ROBOT AND FUNCTIONAL ELECTROSTIMULATION FOR THE TREATMENT OF PATIENTS IN THE INITIAL SIX MONTHS AFTER STROKE: A RANDOMIZED CONTROLLED TRIAL

Kamila Niewolak[1 A,B,D,F,G]
• ORCID: 0000-0001-9473-1813

Paula Pecyna[1 B]
• ORCID: 0000-0002-0452-7120

Jolanta Piaskowska[1 B]
• ORCID: 0000-0003-4060-0361

Laura Piejko[2 A,D-F]
• ORCID: 0000-0002-5338-1842

Wojciech Marszałek[3 C,D]
• ORCID: 0000-0003-3780-1090

Mariusz Baumgart[4 D]
• ORCID: 0000-0002-5736-5348

Aleksandra Bula[2 E,F]
• ORCID: 0000-0002-7457-1506

Anna Polak[2 A,D-F]
• ORCID: 0000-0001-6932-5047

[1] Medical and Rehabilitation Center Solanki, Inowroclaw, Poland

[2] Institute of Physiotherapy and Health Sciences, Academy of Physical Education, Katowice, Poland

[3] Institute of Sport Sciences, Academy of Physical Education, Katowice, Poland

[4] Department of Normal Anatomy, The Ludwik Rydygier Collegium Medicum in Bydgoszcz, The Nicolaus Copernicus University in Torun, Poland

A – study design, **B** – data collection, **C** – statistical analysis, **D** – interpretation of data, **E** – manuscript preparation, **F** – literature review, **G** – sourcing of funding

ABSTRACT

Background: Results from studies investigating the effects of rehabilitation robots, including those using robots combined with functional electrostimulation (FES), on gait quality and postural control post-stroke are conflicting. Therefore, the evidence supporting the use of this approach to rehabilitation remains inconclusive and further research is required into how robotic therapy and FES can improve gait function and postural control at different times after stroke.

Aim of the study: To gain knowledge on the effectiveness of stationary robotic exercises, and robotic exercises combined with FES of the lower extremity muscles, on activities of daily living, gait quality, postural control, and quality of life, in people who were between one and six months post-stroke.

Material and methods: A randomized controlled clinical pilot study was conducted. Forty-three post-stroke patients hospitalized at a rehabilitation center were randomly assigned to the following three groups: the GEO Group, for whom stationary robotic exercises were provided, the GEO+FES Group, for whom stationary robotic exercises were provided in combination with FES, and the Control Group, for whom conventional overground gait training was provided. Exercises were undertaken by all groups for 20 minutes a day, six days a week, for three weeks. In addition, all patients were provided with basic post-stroke therapy based on the principles of best clinical practice. All patients were assessed for stroke symptoms before and after therapy using the National Institutes of Health Stroke Scale (NIHSS), for independence in activities of daily living using the Barthel Index, and for quality of life using the Stroke Impact Scale Questionnaire. Static and dynamic postural control and gait performance were assessed using the Berg Balance Scale, the Timed Up and Go Test,

the Functional Reach Test, and the 10 Meter Walk Test. Static postural control and gait quality were also assessed using a treadmill with a stabilometric platform.

Results: Exercising on a stationary robot, both with and without FES of the lower extremity muscles, contributed to a statistically significant reduction in stroke symptoms (NIHSS, $p<0.05$). Additionally, exercising on a stationary robot without FES application significantly improved patient quality of life ($p<0.05$). However, these effects were not significantly different between the experimental and control groups.

Conclusions: Stationary robotic exercise, either with or without FES, can be used as a substitute for traditional overground gait training to reduce stroke symptoms and improve quality of life in the first six months post-stroke. They can also be used as exercises to augment standard post-stroke therapy.

KEYWORDS: robotic rehabilitation, functional electrical stimulation, gait, postural control, stroke

Background

Stroke is a serious medical and social problem and, according to the World Health Organization, it is the second most common cause of death and the third most common cause of disability worldwide [1]. Post-stroke rehabilitation is multidirectional and long-lasting and is conducted in line with the principles of best clinical practice. Different types of therapies are implemented in stroke patients to enable neuromuscular re-education and restore functions that were lost or impaired as a result of stroke [2, 3].

New therapeutic methods are still being sought for post-stroke rehabilitation that aim to expand on the methods available and to be motivating and attractive to patients. Modern devices such as rehabilitation robots, which are used for gait re-education and postural control, are currently being introduced. Attempts are also being made to combine robotic exercises with functional electrical stimulation (FES) of the lower limb muscles. From this, it is thought that robots could provide a complete and reproducible gait pattern, which is difficult to achieve using conventional overground gait training [4].

Both stationary and mobile robots are used in post-stroke rehabilitation. Stationary robots are mainly used to exercise patients with severe functional impairments of the lower limbs and spine. In contrast, people with paresis of the lower limbs can exercise on mobile robots, but they require the ability to at least partially stabilize their spine. Although robots have been used in rehabilitation for several years, there is still insufficient science-based knowledge regarding their effectiveness and application in post-stroke rehabilitation.

Stationary robots have been evaluated in eleven randomized clinical trials [5-15] for their suitability to re-educate and improve postural control [6-8, 10] and gait [5-15] in stroke patients. The majority of these studies involved people who were between one and three months post-stroke [5, 7, 9-14], with only three studies focusing on the chronic (>6 months) post-stroke period [6, 8, 15].

In all of the cited studies, conventional therapy was used in both the experimental and control groups. Stationary robotic exercises were used in the experimental groups, and results were compared to those obtained for the control groups. The studies employed several different strategies for their control groups, including standard rehabilitation therapy that was not specifically directed at improving gait and postural control [8, 9, 13], traditional overground gait training [6, 7, 10-12, 14], and exercises on a treadmill [5, 15].

In three of the trials, additional experimental groups were formed in which exercise on a stationary robot was combined with FES of the lower limb muscles. Results from therapy in these groups were compared with the results of robotic therapy without FES and with the results of overground gait training [6, 7, 10]. Two of these studies were conducted in people who were up to three months post-stroke [7, 10], and one study involved individuals in the chronic post-stroke period [6].

In all studies that followed patients for up to three months after stroke, stationary robot therapy significantly improved functional gait quality, which was assessed using the Functional Ambulation Categories (FAC) scale [5, 7, 9-14]. Four studies also reported significant improvements in walking during the 6-minute Walk Test (6MWT) [6, 11], and in the 10-Metre Walk Test (10MWT) [7, 10, 11], after exercise on a stationary robot. However, these effects were not found in two separate studies [5, 14]. Different results were also found when the effects of stationary robot exercise on static and dynamic body balance in patients three months post-stroke were assessed using the Berg Balance Scale (BBS) [7, 10]. Tong et al. [7] reported an improvement in body balance after exercise on the stationary robot, whereas Ng et al. [10] did not show this effect.

For chronic post-stroke patients, only one study has reported an improvement in gait parameters, including speed, cadence, and stride length, assessed on a treadmill [15], and in body balance assessed by the BBS [15], after stationary robot therapy. In the

other two studies, exercise on a stationary robot did not have a significant effect on gait quality [6, 8] or body balance [6, 8] in chronic post-stroke patients.

In those who were within six weeks of their stroke, significantly better gait quality was reported after stationary robotic exercises combined with FES of the lower limb muscles when compared to traditional overground gait training [7,8]. In addition, improvements in body balance were found when robotic exercise was combined with FES [7], though such an effect was not shown in other research [14]. In the only study to be conducted in chronic post-stroke patients, FES combined with stationary robotic exercise did not affect gait quality or body balance [6].

Due to conflicting results from studies carried out to date, evidence of the effect of rehabilitation robots, including robots combined with FES, on gait quality and postural control after stroke remains inconclusive. Therefore, further research is required to clarify how robotic therapy and FES can be applied to improve gait function and postural control in different post-stroke periods.

Aim of the study

The goal was to gain knowledge on the effectiveness of stationary robotic exercise and stationary robotic exercise combined with FES of the lower limb muscles on activities of daily living, gait quality, postural control, and quality of life, in patients who were between one and six months post-stroke.

Material and methods

Study design

A randomized controlled clinical trial was designed to compare the effectiveness of three weeks of post-stroke rehabilitation treatment between three parallel groups of patients. Participants in the study undertook either, exercises on a stationary rehabilitation robot, exercises on a stationary rehabilitation robot plus FES, or overground gait training. The study was approved by the Bioethics Committee for Scientific Research at The Jerzy Kukuczka Academy of Physical Education in Katowice (No. 5/2020 of 09 July 2020).

Inclusion and exclusion criteria

The following inclusion criteria were adopted: men and women over 18 years of age who had a first ischemic or hemorrhagic stroke between one and six months prior to entering the study, who had attended a 3-week rehabilitation course as an inpatient, had given consent to participate in the study, who understood and could follow the physiotherapists' instructions, and who were able to walk a distance of 10 meters independently. Those with subarachnoid hemorrhage were excluded from the study, as were individuals with conditions other than stroke that impaired body balance or gait quality. Individuals who had contraindications to FES and the exercises used in the study, in particular, body weight above 95 kg, body height below 150 cm or above 199 cm, >1.5 cm length difference between lower limbs, spasticity above grade 3 on the Ashworth scale, or wounds at the body attachment points on the robot, were also excluded from participating.

Information on patient demographics and health status was obtained from medical history, medical records, and from medical and physiotherapeutic examinations.

Location and funding of the study

The study was conducted at the Solanki Inowrocław Health Resort and was co-financed by the European Development Fund for the Kujawsko-Pomorskie Voivodeship (No. RPKK.01.02.01-04-0016/18; Solanki Inowroclaw Sp. z o.o., 77 Solankowa Street, 88-100 Inowroclaw).

Patient information and randomization

Patients were referred to the study by their physicians. Before entering the study, all patients were informed in writing about the purpose and conduct of the study. They were also informed of the possibility of resigning from the study, at any stage, without giving a reason. Withdrawal from the study did not affect the future treatment of the patient.

After consenting to participate in the study, patients were randomly assigned to one of three groups. The first experimental group underwent stationary robotic exercise therapy (GEO Group), the second experimental group underwent stationary robotic exercises with FES of the lower limb muscles (GEO+FES Group), and the third group (Control Group) had conventional overground gait training.

Patients, the physicians qualifying patients for the examination, and the medical personnel involved in the therapy and diagnostics of patients, were not aware of which group participants would be assigned to as a result of randomization. Randomization was carried out by the main study investigator, who had no direct contact with the patients included in the study prior to randomization.

Prior to the start of the study, the study leader prepared 45 opaque envelopes and 45 cards with the letters A (15 cards), B (15 cards), or C (15 cards) on them. Letter A represented the Control group, letter B the GEO Group, and letter C represented the GEO+FES Group. The envelopes and cards were given to a person not involved in the study, who placed one card into each envelope, sealed the envelopes, and then numbered them randomly from 1 to 45 and returned them to the main study investigator. Once a patient was qualified to participate in the study, the main study investigator opened an envelope, in sequential order, and the patient was directed to a group based on the symbol on the card inside the envelope.

Blinding

The person who assessed the clinical progress of the therapy and the person who performed the statistical analysis of results were blinded to the study groups.

Therapeutic interventions

In both experimental groups, exercise on the stationary robot G-EOSYSTEM™ (RehaTechnology, Germany) was undertaken once a day for 20 minutes, six days a week (Monday to Saturday), for three weeks. If the patient could not withstand the entire training routine at once, a break of 5 minutes was taken in the middle of the exercise or the session was stopped completely. The actual exercise duration was recorded for each session. The only form of therapy provided to the GEO Group was the stationary robot (Figure 1). Meanwhile, training on the robot was combined with simultaneous FES of the lower limb muscles (extensors and flexors of the hip, knee, and ankle) in the GEO+FES Group (Figure 2). Electrodes were attached along the course of the muscle fibers, at the beginning and end of the muscle bellies. An example of electrode placement during FES is shown in Figure 3.

Electrostimulation was carried out using several electrical circuits, which allowed simultaneous stimulation of the thigh and calf muscles of both lower limbs. The flow of current in the individual electrical circuits was activated automatically, depending on the phase of gait, to allow sequential and alternating work of the extensors and flexors of the lower limbs. An alternating rectangular current with a pulse duration of 400 μs and a frequency of 40 Hz was used. The current intensity was dosed individually for each patient to obtain non-painful but visible muscle contractions. Amplitude was modulated to allow con-

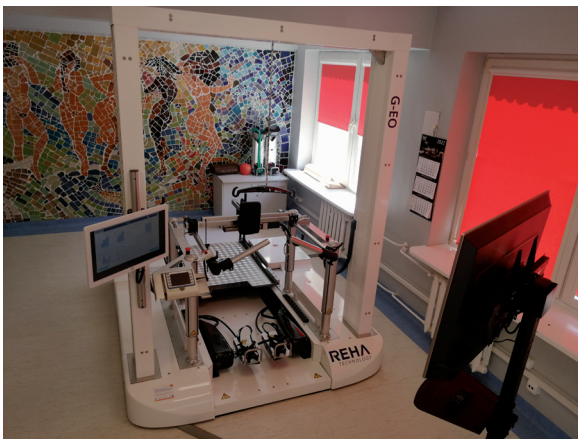

Figure 1. GEO stationary robot

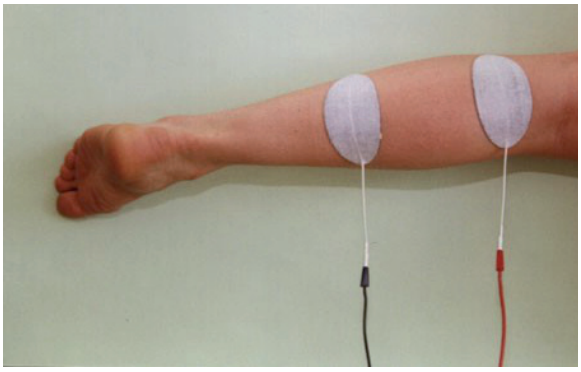

Figure 3. FES electrode placement

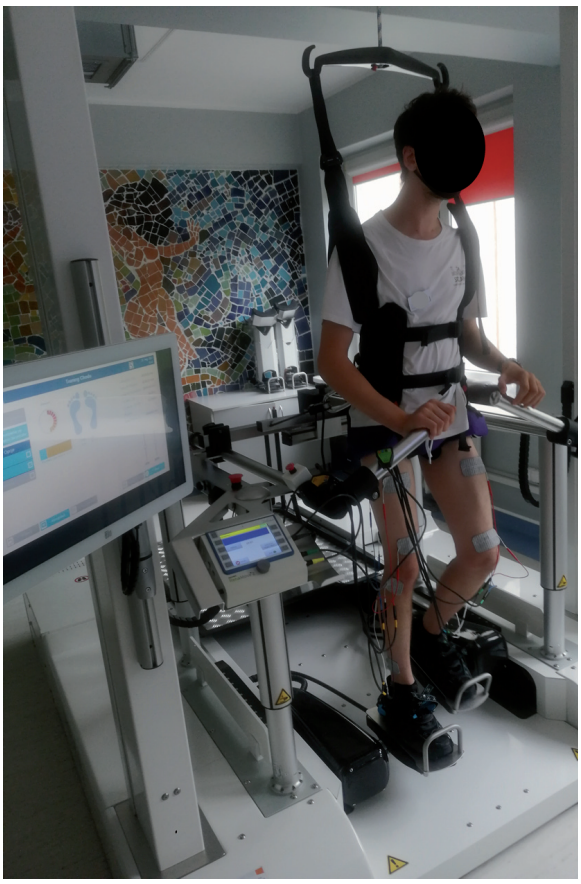

Figure 2. GEO training with FES

traction and relaxation of individual muscle groups depending on the gait phase.

If necessary, partial support of patient body weight was provided for both groups during the robotic exercises, the value of which was individually adjusted so that the patient's knee joints were straightened. Walking speed (0.7-2.5 km/h) and stride length (34-48 cm) were individually selected for each patient. The gait cycle ratio phases were 60% and 40% between the stance and swing phases, respectively.

In the Control group, overground gait training was undertaken once a day for 20 minutes, six days a week (Monday to Saturday), for three weeks. All exercises were carried out under the direct supervision of a physiotherapist. When additional patient assistance was required, the exercises were supported by two physiotherapists.

In addition to the experimental rehabilitation, basic post-stroke therapy based on the principles of best clinical practice was provided to all three groups, six days a week, for three weeks. Therapy included exercises focused on re-education and improvement of movement patterns.

Measures

Immediately before and after therapy, all patients were assessed for stroke symptoms using the National Institutes of Health Stroke Scale (NIHSS). Assessments were also carried out for activities of daily living with the 100-degree Barthel Index (BI), of motor function using the Brunnström Scale, of muscle spasticity using the Ashworth Scale, and quality of life using the Stroke Impact Scale Questionnaire (SIS 59). Postural control and gait quality were also assessed in all patients before and after therapy using functional clinical tests, including the BBS, Timed Up and Go Test (TUG), and 10MWT.

Static body balance and gait quality were assessed on a treadmill equipped with a stabilometric platform (Zebris FDM-T; Rehawalk, MaxxusDaum h/p Cosmos Force, Germany). Static balance was tested with eyes open for 60 seconds. During the test, the patient stood still on the platform in a relaxed upright posture (with arms lowered alongside the body and feet comfortably apart). The gait quality test lasted for 30 seconds, with treadmill speed selected individually for each patient to allow them to walk freely forward at their maximum comfortable pace.

Outcomes

Treatment effects in individual groups were used as primary study outcomes. In all three groups, the results after treatment were compared to baseline results, taking into account the severity of stroke symptoms (NIHSS), activities of daily living (BI), quality of life (SIS – 59), functional quality of gait and dynamic balance (TUG), static and dynamic body balance (BBS), walking speed (10MWT), static body balance assessed on a stabilometric platform, and gait quality assessed on a treadmill.

Secondary study outcomes compared the effects of therapy between the groups concerning the severity of stroke symptoms (NIHSS), activities of daily living, (BI), quality of life (SIS – 59), functional quality of gait, and dynamic balance (TUG), static and dynamic body balance (BBS), walking speed (110MWT), static body balance assessed on a stabilometric platform, and gait quality assessed on a treadmill.

To compare treatment effects between groups, percentage change rates in diagnostic variables obtained in each group were calculated and compared. Percentage change rates were calculated using the following formula: $\%WZ=[(Z1 - Z0) / Z0] \times 100\%$; where %WZ=percentage change rate, Z0=value of the variable before therapy, and Z1=value of the variable after therapy.

Statistical analysis

Statistica 12 software (StatSoft, Poland) was used for all statistical analyses, with statistical significance set at $p \leq 0.05$ for all tests. The distribution of variables characterizing the patients was examined using the Shapiro-Wilk test, whilst homogeneity of variance was examined using Levene's test. Due to the non-normality of distribution and the lack of homogeneity of variance between groups, non-parametric tests were then used for statistical analysis. Also, as the skewness and kurtosis were <2.5 and the distributions of variables were unimodal, in addition to median and quartiles, means and standard deviations were given as measures of location and dispersion, respectively.

Variables characterizing patients in both groups before treatment were compared using the Chi-square test of highest reliability, the Kruskal-Wallis rank-sum analysis of variance (ANOVA) test, and the Kruskal-Wallis post hoc test. Pre-therapy and post-therapy scores between groups were compared using the Wilcoxon signed-rank test. Percentage changes in post-therapy versus pre-treatment scores were compared between groups using the Kruskal-Wallis rank-sum ANOVA test and the Kruskal-Wallis post hoc test.

Results

Between 10th October 2021 and 30th June 2022, 48 people were enrolled in the study. Three subjects did not meet the inclusion criteria, and the remaining 45

were included and randomized into three groups of 15, including the GEO, GEO+FES, and Control Groups. Two subjects (4.44%) did not complete the study due to health deterioration unrelated to study procedures (one subject in the GEO Group and one subject in the GEO+FES Group). Therefore, statistical analysis was performed on the treatment results obtained for 43 subjects, including 14 in the GEO Group, 14 in the GEO+FES Group, and 15 in the Control Group. The course of the study is shown in Figure 4.

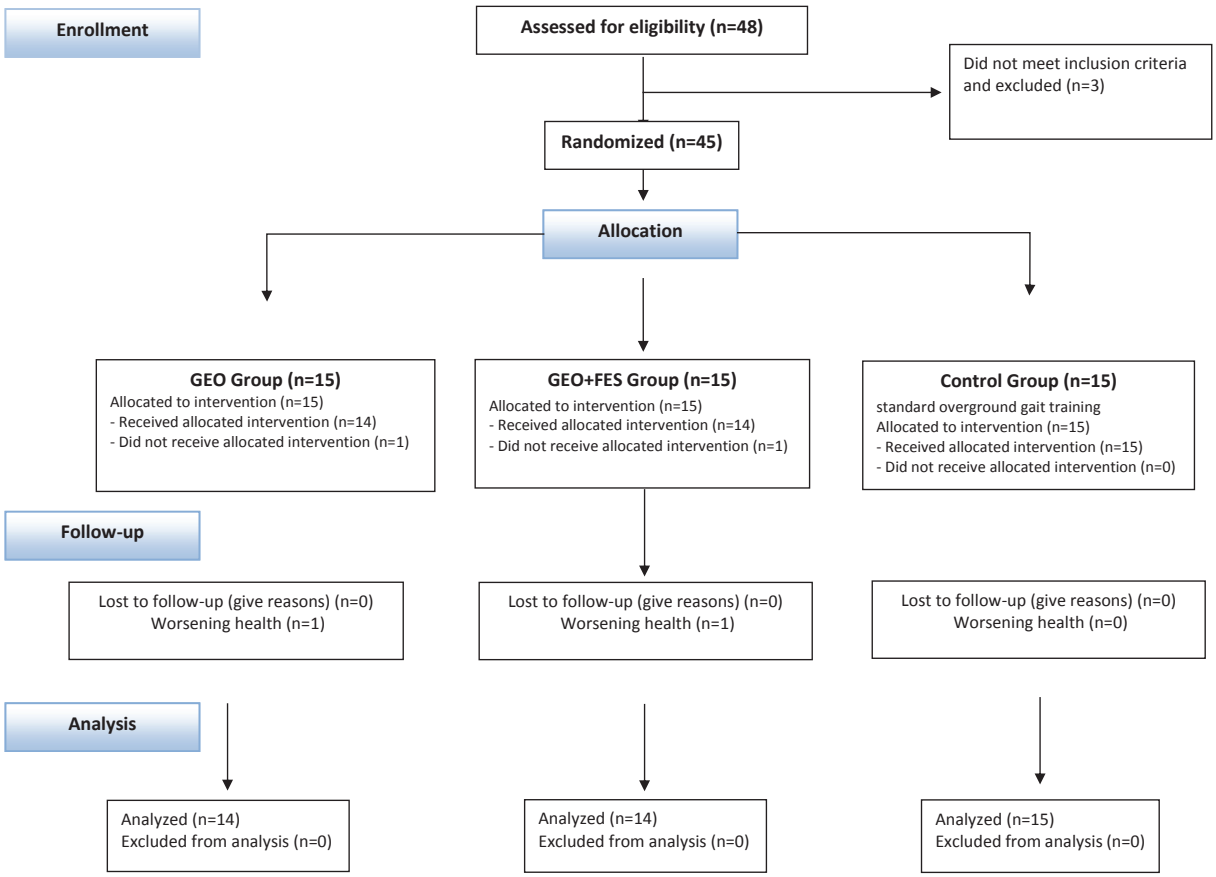

Figure 4. Flow diagram of the study (FES=functional electrical stimulation; GEO=stationary robot rehabilitation exercises)

There were no significant differences in patient characteristics between groups before therapy ($p>0.05$). Detailed data are presented in Tables 1 and 2.

Primary study outcomes for individual groups

Experimental groups

In both experimental groups, there was a significant reduction in stroke symptoms after treatment compared to before treatment (GEO, $p=0.012$ and GEO+FES, $p=0.002$). Patient quality of life improved significantly in the GEO Group ($p=0.011$), but not in the GEO+FES group ($p=0.402$). Functional Reach Test (FRT) range increased significantly in both experimental groups (GEO, $p=0.008$ and GEO+FES, $p=0.005$). Results are shown in Table 3.

None of the experimental groups experienced a significant change to independence in activities of daily living after treatment compared to before treatment (GEO, $p=0.260$ and GEO+FES, $p=0.063$), to static and dynamic balance (GEO, $p=0.154$ and GEO+FES, $p=0.075$), to dynamic balance and locomotion (GEO, $p=0.093$ and GEO+FES, $p=0.155$) or to time obtained in the 10MWT (GEO, $p=0.285$ and GEO+FES, $p=0.066$). Detailed results are shown in Table 3.

In stabilometric tests, there were no significant changes in the center of pressure (COP) path length (GEO, $p=0.551$ and GEO+FES, $p=0.510$) or COP surface area ($p=0.507$ and GEO+FES, $p=0.845$) after treatment compared to before treatment. However, there was a decrease in the length of maximum COP swings in the GEO+FES Group ($p=0.009$), which was not observed in the GEO Group ($p=0.510$). Results are shown in Table 4.

There were no changes to gait parameters in the experimental groups after therapy compared to before treatment. In all cases, the p-value was >0.05. Results are shown in Table 4.

Table 1. Characteristics of the groups before treatment (n=43)

Variables	Group		
	GEO (n=14)	GEO+FES (n=14)	Control (n=15)
*Gender: Female / Male [number of patients]	5 / 9	3 / 11	7 / 8
**Age: mean (SD) [years]	68.28 (9.38)	66.357 (9.920)	70.867 (10.357)
**BMI: mean (SD) [kg/m^2]	25.40 (4.15)	26.804 (4.925)	28.633 (5.676)
*Ischemic/hemorrhagic stroke [number of patients]	12 / 2	14 / 0	14 / 1
*Dominant limb: right/left [number of patients]	8 / 6	13 / 1	14 / 1
*Side affected: right/left [number of patients]	12 / 2	13 / 1	14 / 1
Brunnström Recovery Scale: III / IV / V / VI [number of patients]	1 / 3 / 6 / 4	1 / 3 / 5 / 5	0 / 1 / 8 / 6
Modified Ashworth Spasticity Scale: 0 / I / II / III [number of patients]	9 / 4 / 1 / 0	12 / 2 / 0 / 0	14 / 1 / 0 / 0
Questionnaires and functional tests			
**Stroke symptoms: mean (SD) [points][1]	4.36 (3.249)	3.71 (2.94)	3.26 (2.57)
**Independence in daily activities: mean (SD) [points][2]	87.14 (16.257)	91.42 (11.83)	94.33 (7.52)
**Quality of life: mean (SD) [points][3]	160.28 (45.69)	177.64 (46.28)	165.13 (45.16)
**Static and dynamic balance: mean (SD) [points][4]	41.64 (12.73)	45.85 (8.90)	45.13 (7.66)
**Dynamic balance and gait efficiency: mean (SD) [s][5]	17.35 (10.08)	13.21 (6.87)	15.33 (7.15)
**Functional reach test range: mean (SD) [cm][6]	26.71 (10.26)	28.85 (8.85)	29.73 (9.40)
**10 Meter Walk Test time: mean (SD) [s][7]	14.71 (9.80)	12.28 (6.19)	13.00 (5.94)
Stabilometric assessment			
**COP path length: mean (SD) [mm]	885.57 (485.03)	761.28 (404.01)	715.13 (482.93)
**COP surface area: mean (SD) [mm^2]	14.78 (7.92)	12.64 (6.82)	12.26 (7.93)
**Length of maximum COP swing: mean (SD) [mm]	33.58 (22.37)	44.84 (42.92)	38.93 (26.37)

GEO – experimental group in which stationary robotic exercise was conducted; GEO+FES – experimental group in which stationary robotic exercise combined with functional electrostimulation of lower limb muscles was conducted; Control – control group in which standard, overground gait training was conducted; [1] National Institutes of Health Stroke Scale; [2] Barthel Index; [3] Stroke Impact Scale; [4] Berg Balance Scale; [5] Timed Up and Go Test; [6] Functional Reach Test; [7] 10 Meter Walk Test; SD – standard deviation; COP – center of foot pressure; n – number of subjects. **In all cases, differences between groups were statistically insignificant (p>0.05); * Chi-square test of highest reliability; ** Kruskal-Wallis rank-sum ANOVA test.**

Table 2. Characteristics of groups before treatment cont. (n=43)

Variables	Group		
	GEO (n=14)	GEO+FES (n=14)	Control (n=15)
Gait parameters			
Step length on left leg: mean (SD) [cm]	20.28 (13.28)	29.92 (11.63)	26.66 (11.21)
Step length on right leg: mean (SD) [cm]	21.50 (12.05)	29.35 (11.00)	24.10 (15.60)
Double step length: mean (SD) [cm]	41.50 (24.66)	58.80 (20.01)	56.66 (38.58)
Step width: mean (SD) [cm]	13.21 (4.45)	17.27 (15.21)	13.80 (3.57)
Single support phase on left leg: mean (SD) [%]	70.35 (6.48)	69.23 (4.27)	66.46 (13.14)
Single support phase on right leg: mean (SD) [%]	68.11 (3.81)	68.05 (18.13)	69.06 (9.49)
Left leg swing phase: mean (SD) [%]	29.15 (6.77)	31.17 (4.15)	29.26 (7.59)
Right leg swing phase: mean (SD) [%]	31.92 (3.72)	27.67 (4.76)	31.51 (11.29)
Gait speed: mean (SD) [km/h]	1.04 (0.70)	0.62 (1.86)	1.09 (0.52)
Cadence: mean (SD) [number of steps per minute]	80.64 (23.99)	75.55 (29.39)	76.93 (17.77)

GEO – experimental group in which stationary robotic exercise was conducted; GEO+FES – experimental group in which stationary robotic exercise combined with functional electrostimulation of lower limb muscles was conducted; Control – control group in which standard, overground gait training was conducted; SD – standard deviation; n – number of subjects. **In all cases, differences between groups were statistically insignificant (p>0.05); Kruskal-Wallis rank-sum ANOVA test.**

Table 3. Treatment outcomes in the experimental groups (n = 28)

Variables	Mean (SD); Median (lower quartile – upper quartile)		p-value*	Mean (SD); Median (lower quartile – upper quartile)		p-value*
	Before therapy	After therapy		Before therapy	After therapy	
	GEO (n=14)			GEO+FES (n=14)		
Stroke symptoms [points][1]	4.35 (3.24); 4.00 (2.00-7.00)	2.78 (2.77); 2.50 (0.00-4.00)	0.012	3.71 (2.94); 3.00 (2.00-4.00)	1.15 (1.86); 0.00 (0.00-1.00)	0.002
Independence in daily activities [points][2]	87.14 (16.25); 95.00 (80.00-100.00)	90.71 (13.42); 97.50 (85.00-100.00)	0.260	91.42 (11.83); 95.00 (85.00-100.00)	97.30 (4.83); 100.00 (95.00-100.00)	0.063
Quality of life [points][3]	160.28 (45.69); 172.00 (118.00-195.00)	185.21 (44.49); 182.00 (165.00-227.00)	0.011	177.64 (46.28); 178.00 (144.00-207.00)	186.53 (44.40); 213.00 (162.00-222.00)	0.402
Static and dynamic balance [points][4]	41.64 (12.73); 43.00 (30.00-54.00)	45.50 (11.51); 49.50 (38.00-56.00)	0.154	45.85 (8.90); 46.50 (42.00-52.00)	50.07 (7.81); 55.00 (43.00-56.00)	0.075
Dynamic balance and gait efficiency [s][5]	17.35 (10.08); 16.50 (8.00-21.00)	15.00 (8.31); 13.000 (9.00-20.00)	0.093	13.21 (6.87); 10.00 (8.00-17.00)	10.61 (3.79); 9.00 (8.00-11.00)	0.155
Functional reach test range [cm][6]	26.71 (10.26); 24.00 (20.00-32.00)	37.21 (15.03); 34.00 (28.00-48.00)	0.008	28.85 (8.85); 30.00 (23.00-37.00)	39.15 (8.37); 41.00 (37.00-45.00)	0.005
10 Meter Walk Test time [s][7]	14.71 (9.80); 12.50 (7.00-19.00)	23.28 (39.58); 10.00 (8.00-20.00)	0.285	12.28 (6.19); 10.50 (8.00-13.00)	10.07 (4.38); 9.00 (8.00-11.00)	0.066

GEO – experimental group in which stationary robotic exercise was conducted; GEO+FES – experimental group in which stationary robotic exercise combined with functional electrostimulation of lower limb muscles was conducted; Control – control group in which standard, overground gait training was conducted; [1] National Institutes of Health Stroke Scale; [2] Barthel Scale; [3] Stroke Impact Scale; [4] Berg Balance Scale; [5] Timed Up and Go Test; [6] Functional Reach Test; [7] 10 Meter Walk Test; SD – standard deviation; n – number of subjects. *Wilcoxon signed-ranks test.

Table 4. Results of the stabilometric and gait quality assessments in the experimental groups (n=28)

Variables	Mean (SD); Median (lower quartile – upper quartile)		p value*	Mean (SD); Median (lower quartile – upper quartile)		p value*
	Before therapy	After therapy		Before therapy	After therapy	
	GEO (n=14)			GEO+FES (n=14)		
Stabilometric assessment						
COP path length [mm]	885.57 (485.03); 903.50 (462.00-1196.00)	784.28 (606.04); 587.50 (277.00-1273.00)	0.551	761.28 (404.01); 692.00 (566.00-933.00)	616.50 (401.33); 653.00 (226.00-770.00)	0.510
COP surface area [mm^2]	14.78 (7.92); 15.00 (8.00-20.00)	13.00 (10.06); 10.00 (5.00-21.00)	0.507	12.64 (6.82); 11.50 (9.00-16.00)	11.71 (6.60); 11.50 (6.00-16.00)	0.845
Length of maximum COP swings [mm]	33.58 (22.37); 23.75 (20.40-34.10)	26.00 (13.77); 28.35 (13.70-37.20)	0.510	44.84 (42.92); 29.55 (24.30-52.70)	23.55 (8.14); 22.55 (19.50-32.60)	0.009
Gait quality assessment						
Step length on left leg: mean (SD) [cm]	20.28 (13.28); 18.00 (10.00-31.00)	20.85 (15.76); 15.00 (9.00- 36.00)	0.706	29.92 (11.63); 32.00 (18.00-36.00)	30.78 (11.74); 31.000 (23.00-43.00)	0.576
Step length on right leg: mean (SD) [cm]	21.50 (12.05); 21.50 (12.00- 29.00)	22.00 (13.43); 17.50 (10.00-35.00)	0.660	29.35 (11.00); 29.50 (20.00-38.00)	29.92 (13.52); 30.00 (15.00-44.00)	0.807
Double step length: mean (SD) [cm]	41.50 (24.66); 43.00 (16.00- 60.00)	43.00 (27.99); 29.50 (19.00-72.00)	0.530	58.80 (20.01); 60.00 (41.00-72.00)	60.92 (24.41); 60.00 (45.00-90.00)	0.505
Step width: mean (SD) [cm]	13.21 (4.45); 13.50 (8.00- 16.00)	12.71 (5.18); 12.00 (8.00-17.00)	0.552	17.27 (15.21); 14.50 (9.00-17.00)	12.57 (4.84); 12.00 (10.00-15.00)	0.530
Single support phase on left leg: mean (SD) [%]	70.35 (6.48); 70.80 (65.10-75.10)	73.12 (6.71); 71.75 (69.00-78.00)	0.064	69.23 (4.27); 67.85 (67.10-72.80)	69.10 (5.51); 68.00 (65.40-70.80)	0.600
Single support phase on right leg: mean (SD) [%]	68.11 (3.81); 67.90 (65.70-70.40)	69.20 (5.63); 69.15 (67.10-73.20)	0.807	68.05 (18.13); 72.10 (67.90-75.20)	72.41 (5.22); 70.85 (69.40-75.20)	0.754
Left leg swing phase: mean (SD) [%]	29.15 (6.77); 28.90 (23.80- 34.90)	26.87 (6.70); 28.25 (22.00-31.00)	0.124	31.17 (4.15); 32.25 (29.80-32.90)	30.87 (5.50); 32.00 (29.20-34.40)	0.807
Right leg swing phase: mean (SD) [%]	31.92 (3.72); 32.10 (29.60- 34.30)	30.79 (5.63); 30.85 (26.80-32.90)	0.814	27.67 (4.76); 27.90 (24.80-32.10)	27.58 (5.22); 29.15 (24.80-30.60)	0.754
Gait speed: mean (SD) [km/h]	1.04 (0.70); 1.00 (0.40-1.50)	1.05 (0.89); 0.50 (0.50-1.800)	0.610	0.62 (1.86); 0.12 (0.11-0.15)	1.30 (0.44); 1.45 (1.10-1.60)	0.674
Cadence: mean (SD) [number of steps per minute]	80.64 (23.99); 84.50 (64.00- 97.00)	78.21 (19.67); 78.00 (66.00-91.00)	0.814	75.55 (29.39); 71.00 (62.00-102.00)	74.57 (17.82); 74.00 (65.00-85.00)	0.845

GEO – experimental group in which stationary robotic exercise was conducted; GEO+FES – experimental group in which stationary robotic exercise combined with functional electrostimulation of lower limb muscles was conducted; SD – standard deviation; COP – center of foot pressure; n – number of subjects; * Wilcoxon signed-ranks test.

Control group

In the Control Group, a significant reduction in stroke symptoms (p=0.016) and improvement in patient quality of life (p=0.001) were noted after therapy compared to baseline. There was also a significant increase in static and dynamic balance (p=0.029) and FRT (p=0.044). After therapy, the time to walk a distance of 10 meters was faster when compared to before therapy (p=0.026). Detailed results are shown in Table 5.

No significant change was found for independence in activities of daily living (p=0.374), and there was no change in dynamic balance and movement (p=0.279) after treatment compared to before treatment. Results are presented in Table 5.

In the stabilometric tests, the Control Group did not improve post-treatment. There were no changes recorded in COP path length (p=0.802), COP surface area (p=0.722), or the length of maximum COP swings (p=0.594). Results are shown in Table 6.

Gait analysis, assessed on a treadmill, demonstrated a significant increase in gait speed (p=0.041) and cadence (p=0.013) after therapy compared to before treatment. Values of the other gait parameters after therapy were no different from the pre-treatment values (p>0.05 in all cases). Detailed results are shown in Table 6.

Secondary study outcomes (comparison of results between groups)

There were no significant differences between the groups in stroke symptom severity, independence in daily activities, or quality of life. There were also no differences between the groups for changes in locomotion, static and dynamic balance, or FRT range. Furthermore, no differences were recorded between the groups for postural control parameters or gait quality indices. Details of data are shown in Table 7 and Table 8.

Discussion

Exercise on a stationary robot, either with or without FES of the lower limb muscles, contributed to a significant reduction of stroke symptoms according to the NIHSS (p<0.05). Furthermore, stationary robot exercise without the addition of FES significantly improved patient quality of life (p<0.05). However, these effects were not significantly different from the results found for the Control Group, in which conventional overground gait training was used. This allows us to conclude that for patients in the first six months post-stroke, stationary robotic exercises, with or without FES supplementation, can be used as a substitute for overground gait training to reduce stroke symptoms and improve patient quality of life. Also, stationary robotic exercises, with or without FES, can be used as an extension to standard post-stroke therapy.

Three weeks of stationary robotic exercise, both with and without the use of FES, did not affect the patient's functional performance in activities of daily living (p>0.05). Ng et al. [16] also included patients in the subacute period after stroke in their study and reported no improvement of functional performance in activities of daily living after four weeks of stationary robot exercises either with or without the use of FES. However, in three other studies [7, 9, 12]

Table 5. Results of therapy in the control group (n=15)

Variables	Mean (SD); Median (lower quartile – upper quartile)		p-value*
	Before therapy	After therapy	
Stroke symptoms [points][1]	3.26 (2.57); 2.00 (1.00-6.00)	1.53 (1.80); 1.00 (0.00-2.00)	0.016
Independence in daily activities [points][2]	94.33 (7.52); 95.00 (95.00-100.00)	96.00 (7.12); 100.00 (95.00-100.00)	0.374
Quality of life [points][3]	165.13 (45.16); 185.00 (125.00-205.00)	196.60 (42.53); 214.00 (147.00-228.00)	0.001
Static and dynamic balance [points][4]	45.13 (7.66); 45.00 (38.00-52.00)	49.60 (6.58); 53.00 (43.00-56.00)	0.029
Dynamic balance and gait efficiency [s][5]	15.33 (7.15); 13.00 (11.00-21.00)	14.20 (8.17); 12.00 (8.00-18.00)	0.279
Functional reach test range [cm][6]	29.73 (9.40); 28.00 (21.00-35.00)	34.73 (5.40); 35.00 (33.00-39.00)	0.044
10 Meter Walk Test time [s][7]	13.00 (5.94); 11.00 (9.00-18.00)	10.86 (5.06); 10.00 (7.00-14.00)	0.026

Control – control group in which standard, overground gait training was conducted; [1] National Institutes of Health Stroke Scale; [2] Barthel Scale; [3] Stroke Impact Scale; [4] Berg Balance Scale; [5] Timed Up and Go Test; [6] Functional Reach Test; [7] 10 Meter Walk Test; SD – standard deviation; n – number of subjects; * Wilcoxon signed-ranks test.

Table 6. Results of stabilometric assessment and gait quality in the control group (n=15)

Variables	Mean (SD); Median (lower quartile – upper quartile)		p-value*
	Before therapy	After therapy	
	Control (n=15)		
Stabilometric assessment			
COP path length [mm]	715.13 (482.93); 560.00 (355.00-964.00)	721.53 (511.16); 545.00 (443.00-836.00)	0.802
COP surface area [mm^2]	12.26 (7.93); 13.00 (6.00-16.00)	11.93 (8.43); 9.00 (7.00-14.00)	0.722
Length of maximum COP swings [mm]	38.93 (26.37); 29.20 (16.80-47.70)	32.74 (29.97); 28.50 (18.60-31.90)	0.594
Gait quality assessment			
Step length on left leg: mean (SD) [cm]	26.66 (11.21); 26.00 (19.00-34.00)	25.86 (9.44); 27.00 (18.00-34.00)	0.594
Step length on right leg: mean (SD) [cm]	24.10 (15.60); 21.00 (15.50-32.00)	24.86 (11.98); 26.00 (21.00-36.00)	0.695
Double step length: mean (SD) [cm]	56.66 (38.58); 46.00 (31.00-70.00)	51.00 (20.65); 52.00 (36.00-70.00)	0.600
Step width: mean (SD) [cm]	13.80 (3.57); 14.00 (10.00-16.00)	13.60 (4.22); 14.00 (10.00-16.00)	0.851
Single support phase on left leg: mean (SD) [%]	66.46 (13.14); 69.40 (62.80-73.80)	68.36 (6.91); 69.80 (64.10-76.30)	0.638
Single support phase on right leg: mean (SD) [%]	69.06 (9.49); 67.50 (65.40-73.70)	66.23 (15.28); 66.00 (63.60-74.60)	0.363
Left leg swing phase: mean (SD) [%]	29.26 (7.59); 30.00 (25.40-37.10)	30.38 (5.48); 29.90 (23.70-35.60)	0.826
Right leg swing phase: mean (SD) [%]	31.51 (11.29); 32.50 (26.30-34.60)	29.93 (6.43); 30.10 (25.40-35.00)	0.551
Gait speed: mean (SD) [km/h]	1.09 (0.52); 1.00 (0.90-1.20)	1.26 (0.61); 1.20 (0.80-1.50)	0.041
Cadence: mean (SD) [number of steps per minute]	76.93 (17.77); 75.00 (63.00-87.00)	82.93 (18.37); 83.00 (66.00-94.00)	0.013

Control – control group in which standard, overground gait training was conducted; SD – standard deviation; COP – center of foot pressure; n – number of subjects;* Wilcoxon signed-ranks test.

Table 7. Comparison of percentage rates of change in diagnostic results between groups (n=43)

Variables	Percentage rates of change after therapy compared to before treatment [%] Mean (SD); Median (lower quartile – upper quartile)			Statistical significance
	GEO (n=14)	GEO+FES (n=14)	Control (n=15)	p*
Stroke symptoms [points][1]	–1.57 (2.02); –1.00 (–2.00-0.00)	–2.64 (1.55); –2.50 (–4.00 – -2.00)	–1.73 (2.25); –1.00 (–4.00-0.00)	0.171
Independence in daily activities [points][2]	3.57 (11.67); 2.50 (0.00-5.00)	–1.07 (19.72); 0.00 (0.00-5.00)	1.66 (8.59); 0.00 (0.00-5.00)	0.909
Quality of life [points][3]	24.92 (29.33); 21.50 (0.00-50.00)	–4.42 (70.14); 15.50 (–34.00-26.00)	31.46 (32.29); 22.00 (16.00-41.00)	0.370
Static and dynamic balance [points][4]	3.85 (11.96); 2.00 (0.00-11.00)	0.64 (8.36); 1.50 (–1.00-5.00)	4.46 (7.37); 3.00 (0.00 10.00)	0.650-
Dynamic balance and gait efficiency [s][5]	–2.35 (5.48); –2.500 (–5.00- –1.00)	–3.35 (7.91); –1.00 (–3.00-0.00)	–1.13 (4.83); –1.00 (–4.00-1.00)	0.693
Functional reach test range [cm][6]	10.50 (13.08); 5.50 (3.00-22.00)	7.50 (14.12); 9.00 (3.00-12.00)	5.00 (8.36); 5.00 (2.00-14.00)	0.675
10 Meter Walk Test time [s][7]	8.57 (30.18); 0.000 (–1.00-5.00)	–2.92 (6.68); –1.00 (–3.00-0.00)	–2.13 (3.09); –2.00 (–5.00-1.00)	0.073

GEO – experimental group in which stationary robotic exercise was conducted; GEO+FES – experimental group in which stationary robotic exercise combined with functional electrostimulation of lower limb muscles was conducted; Control – control group in which standard, overground gait training was conducted; [1] National Institutes of Health Stroke Scale; [2] Barthel Scale; [3] Stroke Impact Scale; [4] Berg Balance Scale; [5] Timed Up And Go Test; [6] Functional Reach Test; [7] 10 Meter Walk Test, SD – standard deviation; n – number of subjects; * Kruskal-Wallis rank-sum ANOVA test.

Table 8. Comparison of percentage rates of change in diagnostic results between groups (n = 43)

Variables	Percentage rates of change after therapy compared to before treatment [%] Mean (SD); Median (lower quartile - upper quartile)			Statistical significance
	GEO (n=14)	GEO+FES (n=14)	Control (n=15)	p*
Stabilometric assessment				
COP path length [mm]	–101.28 (562.99); –43.00 (–466.00-293.00)	–144.78 (529.05); –18.00 (–707.00-125.00)	6.40 (351.00); 9.00 (–294.00-213.00)	0.636
COP surface area [mm^2]	–1.78 (9.22); –1.00 (–8.00-5.00)	–0.92 (8.38); 0.50 (–7.00-3.00)	–0.33 (5.39); 0.00 (–5.00-3.00)	0.867
Length of maximum COP swings [mm]	–7.57 (26.90); –1.90 (–28.70-10.200)	–21.29 (42.96); –6.35 (–32.80- –0.50)	–6.19 (30.88); 0.00 (–10.90-8.00)	0.360
Gait quality assessment				
Step length on left leg: mean (SD) [cm]	0.57 (7.90); 0.00 (–2.00-7.00)	0.85 (6.70); 1.00 (–3.00-7.00)	–0.80 (7.48); –1.00 (–6.00-4.00)	0.731
Step length on right leg: mean (SD) [cm]	0.50 (7.28); 1.00 (–3.00-5.00)	0.57 (6.27); 0.50 (–5.00-7.00)	0.76 (14.90); 0.00 (–4.00-10.00)	0.975
Double step length: mean (SD) [cm]	1.50 (14.08); 4.00 (–6.00-10.00)	2.12 (10.01); 0.50 (–4.00-6.00)	–5.66 (29.54); –3.00 (–8.00-6.00)	0.590
Step width: mean (SD) [cm]	–0.50 (3.79); –1.00 (–4.00-2.00)	–4.70 (15.38); 0.00 (–3.00-1.00)	–0.20 (4.42); –1.00 (–5.00-2.00)	0.974
Single support phase on left leg: mean (SD) [%]	2.77 (4.18); 0.90 (–0.20-6.80)	–0.12 (2.37); –0.20 (–1.80-0.70)	1.89 (13.71); 0.40 (–1.20-2.10)	0.155
Single support phase on right leg: mean (SD) [%]	1.09 (5.92); 0.35 (–2.50-2.20)	4.36 (17.28); –0.60 (–1.20-1.00)	–2.833 (16.994); –1.10 (–2.60-1.30)	0.732
Left leg swing phase: mean (SD) [%]	–2.27 (4.06); –0.65 (–5.60-0.20)	–0.12 (2.37); –0.2 (–1.80-0.70)	1.89 (13.71); 0.40 (–1.20-2.10)	0.345
Right leg swing phase: mean (SD) [%]	–1.13 (5.91); –0.35 (–2.20-2.50)	–0.29 (2.33); 0.10 (–1.00-1.10)	1.11 (5.06); –0.10 (–1.80-1.90)	0.874
Gait speed: mean (SD) [km/h]	0.01 (0.46); 0.10 (–0.10-0.20)	–0.09 (2.33); 0.60 (–1.00-1.20)	–1.58 (9.78); 0.20 (–1.30-2.30)	0.374
Cadence: mean (SD) [number of steps per minute]	–2.42 (20.36); 0.00 (–10.00-16.00)	–0.97 (27.25); –0.50 (–12.00-6.00)	6.00 (7.37); 6.00 (–1.00-11.00)	0.306

GEO – experimental group in which stationary robotic exercise was conducted; GEO+FES – experimental group in which stationary robotic exercise combined with functional electrostimulation of lower limb muscles was conducted; Control – control group in which standard, overground gait training was conducted; SD – standard deviation; COP – center of foot pressure; n – number of subjects; * Kruskal-Wallis rank-sum ANOVA test.

conducted in subacute post-acute patients, 4-week therapy conducted on a stationary robot (including robot therapy in combination with FES [7]) resulted in a significant improvement in the performance of daily living activities compared to overground gait training [7, 12] and conventional therapy not specifically aimed at gait training ($p>0.05$) [9]. Ng et al. [10] and others [7, 9, 12] used the same methods as the present study, the BI, to assess functional performance in activities of daily living.

In functional tests, there was a significant increase in the FRT after exercise on the stationary robot, both with and without the use of FES. This may be related to improvements in body balance, as well as improved mobility of the spine, hip girdle, and lower limbs. The improvement was at a similar level to the change found in the Control Group who had undergone traditional overground gait training. It can therefore be concluded that stationary robotic exercises, including robotic exercises combined with FES of the lower limb muscles, can be used to improve functional reaching range as a substitute for overground gait training in patients in the subacute post-stroke period.

Results of the other functional tests did not indicate any improvement in gait performance or body balance (TUG, 10MWT, and BBS) (all $p>0.05$). Also, the treadmill test did not show an improvement in gait quality after exercises on the stationary robot, either with or without FES. These results differ from those obtained in other studies of patients in the subacute post-stroke period, who demonstrated improvements in mobility (Rivermead Motor Assessment) [5, 11-13], functional independence (Functional Independence Measure) [7], gait [5, 7, 9-14], walking speed time in the 10MWT [5, 7, 10, 11], and static and dynamic balance (BBS) [7], after rehabilitation exercises on a stationary robot. Nonetheless, Ng et al. [10] and Ochi et al. [14], also found no improvements in body balance [10], walking speed in the 10MWT, or functional independence [10, 14], after exercises on a stationary robot.

In studies in which FES was applied to the lower limb muscles during stationary robot exercises [7, 10], the results of the therapy did not differ from those obtained in the groups in which only the robot exercises were conducted without FES application. However, it is worth noting that the GEO+FES Group in the current study demonstrated a significant decrease in the range of COP swings. This may be due to an increase in lower limb muscle strength under the influence of FES, and thus represent an increase in body stabilization. Further clinical studies should be conducted to test this hypothesis further.

It is currently difficult to unequivocally explain the discrepancies between the results of our study and those found by others. However, it should be noted that the robotic treatment methodology used in the current study differed to some extent from that used in previous studies. In both experimental groups, the robotic exercises were conducted for three weeks, which was determined by the 3-week stay of the patients at the resort treatment facility. Exercises lasted 20 minutes per day and were conducted six days per week (18 exercises in total). In the first experimental group, only robotic exercises were conducted and in the second experimental group, FES of the lower limb muscles was applied during the robotic exercises. In most other previous studies, robotic exercises were conducted for 20 minutes per day [5, 7, 9-11, 14], five days per week [5, 7, 9-14], and over four weeks [7, 9, 10, 12-14]. This amounts to a total of 20 treatments for each patient. Fewer studies provided therapy for three [11] or six weeks [5], and 30 [13] or 40 minutes per day [12].

In the current study, simultaneous FES of the thigh and shin muscles of both lower limbs was performed during robotic training. A similar FES methodology was used by Ng [10] and Tong [7]. In these studies, FES was also performed with an alternating rectangular current with a pulse duration of 400 μs. Meanwhile, simultaneous electrical stimulation of the quadriceps and the fibular nerve of the paretic side was also performed. The current intensity was dosed individually for each patient to obtain non-painful muscle contractions, the amplitude of the current was modulated to allow contraction and relaxation of individual muscle groups depending on the gait phase, and the current intensity was modulated to allow >20° of knee joint extension during gait.

During robotic exercises, partial support of body weight was used as necessary, the value of which was individually adjusted so that the patient's knee joints became extended. In other studies, partial support of body weight was also applied, but the degree of support was different or not within the stated range [11, 13]. The value of patient weight support ranged from 10% to 20% of body weight [9], from 10% to 50% of body weight [12], or the value was adjusted to achieve knee joint extension [5, 7, 10, 14].

Robotic walking speed and stride length were individually selected for each patient in this study, ranging from 0.7-2.5 km/h for gait speed, and 34 - 48 cm for stride length. The stance and swing phases were 60% and 40% of the total gait cycle time, respectively. In other studies, values were also selected individually for each patient. Indeed, Wener et al. [5] varied the gait speed from 0.90-1.44 km/h, and stance and swing phases were 60% and 40% of the duration of the entire gait cycle, respectively. In a study by Pohl [9], gait speed was 1.4-1.8 km/h, and stride length was 48 cm. In another study by Peurala et al. [6], gait speed was up to 2 km/h, though step length was not mentioned. Monroe et al. [12] used a step length of 38-44 cm, and gait speed of 1.4-1.6 km/h, whilst Hesse et al. [13] did not report these gait parameters, and only stated that patients practiced 5 to 15 minutes of walking and 5 to 10 minutes of ascending (minimum 300 steps) and descending steps (minimum 50 steps) in each session. In the Ochi et al. [14] study, gait speed was 0.76 km/h, step length was 64 cm and cadence was 0.33 steps/sec. Parameters selected in the study by Tong [7] were 34-48 cm for step length, 0.72-2.16 km/h for gait speed, and stance and swing phases were 60% and 40% of the total gait cycle time, respectively. In the Ng et al. [10] study, no step length was mentioned, the gait speed was 0.72-2.16 km/h, and stance and swing phases were 60% and 40% of the duration of the entire gait cycle, respectively.

In the current study, basic post-stroke therapy based on best clinical practice principles was provided to all groups for three weeks, six days a week. The therapy included exercises focused on re-education and improvement of movement patterns. Similar to our study, other studies [5, 7, 9-14] also conducted basic post-stroke therapy based on principles of best clinical practice in all groups during the intervention, except that it was conducted once a day, five days a week.

Gait and postural control training is a therapeutic procedure that is recommended in standard rehabilitation of patients at various times after stroke, and its effectiveness has been confirmed by many clinical studies. However, given that the rehabilitation of post-stroke patients is generally long-lasting (often many years), new methods of post-stroke therapy are still being sought. These new methods should be effective and attractive to patients and should contribute to reducing the time of rehabilitation therapy. Modern technologies in rehabilitation can help, but they should be implemented according to the principles of evidence-based medicine and physical therapy. One of the modern therapies that could be implemented

into general clinical practice in post-stroke rehabilitation is the use of stationary rehabilitation robots, which can be combined with FES. However, evidence-based knowledge of their impact on the treatment of post-stroke patients is still insufficient and exercise methodologies are inconsistent. Further research in this area is therefore needed.

Results of the study indicate that post-stroke rehabilitation enriched with exercises on a stationary rehabilitation robot, together with FES, may be as effective as conventional gait training in subacute post-stroke patients. Therefore, this approach can be recommended as an alternative to conventional post-stroke therapy. However, it should be highlighted that this was a pilot study (preliminary study with single-group) with a small sample size, and the results should be verified in a high-quality randomized controlled trial in the future.

Limitations

limitations of the current study include the lack of blinding of patients and medical personnel and the lack of a placebo. The introduction of placebo and blinding was not possible due to the study topic. Also, relatively few patients (n=15) were treated in each group and there was no long-term follow-up on the effects of therapy after the completion of the robot exercises. Follow-up was not possible as the patients traveled to the therapy location, Solanki Inowrocław Health Resort, from all over Poland. After completing their therapy, the patients returned to their homes, which are generally located at a great distance from the place of the study. Statistical analysis was based on the «p» value as a measure of statistical significance, but no analysis of the effect size was performed [16]. The «intention-to-treat» analysis was not included in the statistical analysis [17].

Conclusions

Inclusion of stationary robotic exercises, including robotic exercises in combination with FES of the lower limb muscles, in standard post-stroke therapy for patients between one and six months after stroke reduced stroke symptoms and improved quality of life. Exercises on a stationary robot, both with and without FES application, also contributed to an increase in functional reaching range. Furthermore, the effectiveness of robotic exercises alone and in combination with FES was similar to that of traditional overground gait training. Therefore, stationary robotic exercises could be used independently or in combination with FES including as a substitute for overground gait rehabilitation exercises to reduce stroke symptoms, increase functional reaching range, and improve quality of life.

FES of lower limb muscles applied during exercises on a stationary rehabilitation robot may reduce the amount of patient postural COP sway and improve postural stability, but this observation needs to be confirmed in further clinical studies.

Three weeks of stationary robotic exercises, with or without concurrent FES of the lower limb muscles, applied for 20 minutes a day, six days a week, did not improve gait quality or body balance in patients between one and six months after stroke.

Application conclusion: to reduce stroke symptoms, increase functional reaching range, and improve patient quality of life, exercise on a stationary robot is recommended to be carried out for 20 minutes a day, six days a week, for three weeks.

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Correspondence author:
dr Laura Piejko
E-mail: l.piejko@awf.katowice.pl

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VAGINAL HAEMATOMA AS A POSTPARTUM COMPLICATION: A CASE REPORT

Katarzyna Janisiewicz[1 A,B,D-F]
• ORCID: 0000-0002-5681-368X

Barbara Mazurkiewicz[1 A,D-F]
• ORCID: 0000-0002-8469-805X

Małgorzata Stefaniak[1 A,D,F]
• ORCID: 0000-0002-0319-6067

[1] Department of Obstetrics and Gynecology Didactics, Faculty of Health Sciences, Medical University of Warsaw, Poland

A – study design, **B** – data collection, **C** – statistical analysis, **D** – interpretation of data, **E** – manuscript preparation, **F** – literature review, **G** – sourcing of funding

ABSTRACT

Background: Postpartum hematoma is a complication of the early postpartum period connected with natural childbirth. It can occur as a result of episiotomy or perineal tearing during labor and may require transvaginal hematoma evacuation surgery. Early recognition, diagnosis, and treatment have an impact on the condition of the patient and determine how long they need to stay in the hospital.

Aim of the study: To investigate the specificity of the diagnostic and treatment procedures, and understand the role of the midwife in patient care, following transvaginal hematoma evacuation surgery.

Case report: Data for the case study of a 30-year-old female was obtained by analyzing medical documentation collected during hospitalization and by interviewing and observing the patient. The patient had a perineal incision during labor, and two hours later was diagnosed with a 10 cm vaginal hematoma over the sutured incision site. The patient was then qualified for transvaginal hematoma evacuation surgery.

Conclusions: Management of vaginal hematoma treatment has not changed significantly, however, improved diagnostic methods have been identified. The role of the medical staff, particularly the midwife, is crucial. Indeed, midwives caring for patients should recognize the symptoms of hematoma as early as possible to allow for rapid intervention and prevent serious complications.

KEYWORDS: hematoma, puerperium, postpartum complications, obstetric care

Background

Hematoma is defined as a local build-up of blood that has leaked from damaged blood vessels into subcutaneous or intra-tissue reservoirs. This leads to the compression of blood vessels within tissue structures, extensive hemorrhage into the tissue, and damage to the vasculature [1]. Postpartum hematoma (PPH) is a complication found in obstetrics that develops as a consequence of birth canal injuries [2-6] and has potentially serious consequences for women during or after childbirth. These hematomas are typically found either above or below the levator ani muscle of the lower pelvis [10] and occur at a frequency of 1 in 762 births [7]. Estimates of the occurrence of PPHs based on size have reported small hematomas in 1 in 700 births and large hematomas in 1 in 4,000 [8].

Risk factors for PPH include vaginal delivery, perineal incision, being nulliparous, vulvar blockage, hypertension during pregnancy, fetal macrosomia, prolongation of the second stage of labor, vulvovaginal varicose veins, and coagulation disorders. Trauma during labor is also a major risk factor for the development of PPH, which can develop due to a lack of homeostasis during perineal treatment. Nonetheless, studies have shown that most hematomas result from normal, natural labor, rather than complicated labor or during the postpartum period [7-8]. Fortunately, early recognition and diagnosis of vaginal

Table 1. Details of articles included

Author	Publication year	Type of Study	Number of patients	Woman's age	Which delivery	Risk factors	Time of detection of hematoma / symptoms	Type of hematoma	Diagnostic process	Treatment
Rani et al. [3]	2017	A case-control study	39	26±4.07	Primigravida (29)	Primigravida, hypertensive disease of pregnancy, coagulopathy, and episiotomy.	The median time to detect hematoma was 6 hours / Perineal pain, tachycardia, and bleeding.	Vulvovaginal (35/39) was the most common type of hematoma.	Vaginal examination.	Drainage and occlusion of the dead space with vaginal packing for 24 hours was sufficient management for 38 hematomas. One case had arterial embolization
Youssef et al. [1]	2019	Case report	1	33	Nulliparous	Epidural analgesia, Episiotomy, and Instrumental delivery.	Two hours after labor/ asthenia and throbbing rectal pain.	Hematomas formed above the levator ani muscle.	Vaginal examination and Ultrasonography.	Drained the hematoma. Hemostatic sutures. Embolized afferent vaginal branches to the hematoma using gelatin sponge particles.
Baruch et al. [9]	2015	Case report	1	32	Primigravida	Thrombocytopenia and episiotomy.	Three hours after labor.	A right vaginal sidewall hematoma extending 8 cm in the cranial-caudal axis.	Examination under anesthesia/ ultrasonography	Embolized the distal branches of the right internal iliac artery with gelatin foam from a left femoral approach.
Tilahun et al. [11]	2022	Case report	1	28	Nulliparous	The total duration of labor was 6 hours.	Gradual swelling of the right vulva that was associated with vulvar pain. Significant swelling of the vulva, and vulvar pain. Difficulty with micturition. She also complained of palpitations, easy fatigability, vertigo, and headache.	Vulvar hematoma 12 × 20 cm right-sided vulvar mass extending to the mons pubis and posteriorly to the right buttock.	Genital examination.	Under spinal analgesia, about 700 ml of clotted blood was evacuated from the vulvar hematoma. The actively bleeding vessels were identified and ligated. Then, the wound was sutured in three layers.
Elghanmi A. and Seffar H. [12]	2015	Case report	1	28	Primigravida	Vacuum extraction and episiotomy.	Two hours later, she developed signs of shock.	Right vulvovaginal hematoma of approximately 10 cm in diameter.	On physical exam, the abdomen was tender, and the uterus was tonic. Perineal exam.	In the operating theater and under general anesthesia, the puerperal hematoma was drained. The origin of the bleeding was located in the right vaginal wall and the ischio-rectal fossa. It consisted of venous and arterial rupture of branches of the vaginal and internal pudendal arteries. Hemostatic sutures were applied and different vaginal fascia and perineal tissues were closed. Packing was left in the vagina with compressive wound dressing. Six hours later, the packing was removed with no signs of active bleeding.

Table 1 contd.

Author	Publication year	Type of Study	Number of patients	Woman's age	Which delivery	Risk factors	Time of detection of hematoma / symptoms	Type of hematoma	Diagnostic process	Treatment
Maroyi et al. [13]	2021	Case report	1	37	Primigravida	Eight prior vaginal deliveries.	The patient had visited a private clinic on days 3 and 7 postpartum; however, signs and symptoms of retroperitoneal hematoma went unrecognized. On day 14 after delivery, abdominal pain that had begun immediately after delivery and progressed throughout the postpartum period. The patient had anemia, hypotension, tachycardia, and a left costo-lumbar arch distorting the body shape on a soft and depressed abdomen.	Extensive hematoma in the retroperitoneal space from the left iliac fossa to the left flank.	Abdominal ultrasound.	A laparotomy was performed to evacuate the hematoma.
Redondo Villatoro et al. [14]	2020	Case reports	3	35-years-old, 28-years-old, and 29-years-old	35-year old – was Primigravida	Induced labor due to premature rupture of membranes, and vacuum extraction.	Anemia.	Hematoma on the right posterolateral wall of the vagina, measuring 10×7 cm, without identifying the origin of the bleeding.	Genital examination. Transvaginal and abdominal ultrasounds. Computed tomography angiography.	A conservative approach was decided upon, and the patient was transfused three units of packed red blood cells. An augmentin prescription (875 mg/125 mg, 1 tablet every 8 h as prophylaxis).
					28-year old – Primigravida	An instrumental delivery (vacuum-assisted owing to protracted labor)	In the immediate postpartum period, the patient had buttock pain and severe anemia, which persisted after the administration of 2 units of packed red blood cells.	Retroperitoneal hematoma located in the lesser pelvis, occupying the left lateral face of the vagina (collapsing the sigmoid colon and shifting the bladder) to the anterior wall of the abdomen and measuring 16×10×19 cm.	Ultrasonography, angiography CT	A conservative approach. Antibiotic therapy with augmentin (1 g/8 h) and metronidazole (500 mg/8 h) and underwent antithrombotic prophylaxis with heparin (20 mg/24 h).
					29-year old - Primigravida	Induced labor owing to premature rupture of membranes. Vacuum extraction.	In the immediate postpartum period, the patient had hypogastric pain, active vaginal bleeding, and anemia in the transfusion range.	4-cm laceration in the right lateral face of the vagina, as well as a bleeding vessel. A CT was performed, revealing a retroperitoneal hematoma measuring 6.4×10×10.5 cm	An examination under anesthesia, CT	Selective embolization of vessels was performed, accessed by the left radial artery, with 2 vials of 250-micron microparticles. The patient was prescribed antibiotic therapy with intravenous augmentin (1 g/8 h) and antithrombotic prophylaxis with clexane (40 IU/24 h).

hematoma, along with rapid intervention, can have a positive impact on a patient's condition [1,9].

Risk factors for PPH, as well as the diagnostic and therapeutic processes, were investigated by searching the relevant literature using the Medline repository via PubMed. A combination of the keywords "Vaginal hematoma" and "vaginal hematoma postpartum complication" was used in the search. Additional literature searches were carried out based on the literature cited in selected studies, with preference given to case studies (Table 1).

Aim of the study

The study aimed to understand the specificity of the diagnostic and treatment procedures, as well as the role of the midwife, in the care of patients after transvaginal hematoma evacuation surgery.

Material and methods

Study design and setting

A case study was conducted in February 2020 at The Holy Family Hospital in Warsaw. Data was obtained by analyzing medical documentation, as well as through interviewing and observing the patient during their stay at the hospital. The patient was informed of the intention of the study and provided written informed consent.

Participant

A 30-year-old patient who was 40 weeks and 5 days pregnant was admitted to the hospital on 25 February 2020. The patient was admitted at 07:30 due to three hours of strong contractile activity of the uterine muscle. This indicated that she was in the first stage of labor, and she was admitted to the labor ward.

Data sources/measurements

Examination on admission provided general observations of blood pressure (130 / 90 mmHg), heart rate (HR) (79 beats per minute [bpm]), temperature (36.8 °C), height (178 cm), and weight (56 kg). Patient weight represented a weight gain of 23 kg during pregnancy, and they were generally healthy and did not report any comorbidities during or before pregnancy. No drug allergies were reported.

Gynecological interview indicated that first menstruation occurred at the age of 15, and that menstrual cycles occurred regularly every 28 days. Periods were moderate and painless and lasted 6-7 days.

Physical examination indicated that the patient was pregnant and in generally good condition. Movements of the fetus were felt, the structure of the pelvic bone was normal, the height of the pelvic floor corresponded to the week of pregnancy, and the abdomen was soft and pain-free.

The midwife on duty assessed the obstetric situation by means of an internal examination. Per vaginum examination revealed destruction of the vaginal part of the cervix, 2 cm dilatation, preserved fetal bladder, and fetal head positioned to the left and pressed to the inlet.

After internal examination, a cardiotocographic (CTG) record was made to assess the well-being of the fetus. Fetal heart rate (FHR) was 140 bpm with undulating oscillations and a reactive recording pattern. Spontaneous contractions occurred every 5-7 minutes and basal uterine tone was normal. Estimated Fetal Weight (EFW) was approximately 3563 g on 20 February 2020.

Laboratory tests were undertaken and the results are presented in Table 2.

Table 2. Patient's laboratory tests

Laboratory tests	Wassermann reaction	Hepatitis B antigens	Group B Streptococcus	Erythrocyte antibodies	Toxoplasmosis IgG and IgM	Human immunodeficiency virus	Cytology	Other
Date	2020-01-02	2020-01-02	2020-01-17	2019-05-29	2019-09-30	2020-01-02	2019-04-03	2019-12-30
Result	negative	negative	negative	not tested	negative	negative	Grade 2	Hepatitis C negative

Results

Maternity care in the delivery room

During labor, the patient complained of pain when the uterine muscles contracted. To alleviate the pain, it was decided, inter alia, to adjust the position of the patient, and to use water immersion, breathing techniques, massage by her partner, and nitrous oxide. Despite the methods used by the midwife to alleviate pain, the patient felt that the pain was not relieved sufficiently. The patient was, therefore, qualified for

epidural anesthesia (EPI). After giving the patient 1000 ml of multiple electrolytes as an intravenous infusion, the anesthetic team was asked to administer hormone therapy. During the procedure, fetal cardiac bradycardia of 80 bpm occurred that lasted for three minutes. The doctor on duty was called and an amniotomy was performed in his presence which normalized basal FHR to 135 bpm. Per vaginum examination revealed a 7 cm opening of the external cervix. The head of the fetus was pushed strongly against the inlet and the patient could feel pressure from this. Within an hour, the second stage of labor had begun and FHR remained normal. The patient experienced several partial contractions and their position was changed to the left lateral and then to the right. At 15:24, following a lateral-right perineal incision, LJD was born by natural means and received an Apgar score of 10 points. The placenta was then delivered by Schultze's mechanism.

A continuous suture was applied to the perineal incision in a conventional manner, and sutures were also applied to the ruptured vaginal mucosa (hymen hyphae) at the entrance to the vagina on the left side. For the internal dissection of the mucous membranes of the labia minora, in the area of the clitoris, single sutures were applied.

Blood loss during childbirth was 350 ml. The uterine muscles contracted normally, and the feces from the genital tract were normal. The newborn baby was then attached to the breast and after 2 hours of skin-to-skin contact, the newborn was examined. At this time the patient reported severe pain in the perineum that was penetrating the right buttock. Examination per vaginum revealed hard swelling of the posterior vaginal wall, and the patient reported that the pain worsened on palpation. The doctor asked for an urgent consultation and per vaginum and rectal examination revealed a vaginal hematoma above the sutured incision that was approximately 10 cm in diameter. The patient was qualified for transvaginal hematoma evacuation surgery and was urgently transferred to the operating theatre, but was in generally good condition. Peripheral blood tests (morphology, coagulation system) were taken at the doctor's request.

At 17:50 in the operating room, the PPH was evacuated under general endotracheal anesthesia. The course of the procedure was described in the patient's medical history as follows: "After decontamination of the perineum under general intravenous anesthesia, the patient was catheterized. A speculum was placed in the vagina and a hematoma filling the entire vagina, approximately 10 cm long, and penetrating towards the right vaginal vault without contact with the perineal incision sutures, was observed. The hematoma was incised, and approximately 500 ml of clots were evacuated. Bleeding spots were stabbed and a thin spongostan hemostatic sponge was left in place of the hematoma. Z-sutures were applied in the usual manner to the vaginal mucosa. The patient's condition was checked and no bleeding was observed, there was no damage to the cervix, and vault control was unchanged. The uterus was shrunken and per rectum examination revealed no changes. Total blood loss was approximately 800 ml. A seton was left in place to be removed the following morning. The general condition of the patient after the procedure was good and the course of anesthesia was uneventful".

At 18:40 the patient was awake and her cardiovascular and respiratory condition was stable. She was transferred to the postoperative supervision room, however, the patient again reported severe pain around the perineum at around 20:20, despite receiving painkillers. Examination of her condition provided general observations of oxygen saturation (97%), blood pressure (150/95 mmHg), and HR (140 bpm).

At 20:30 the patient was in moderate general condition but reported increasing pain in the anus and right buttock. General observations were recorded to include blood pressure (100/60 mmHg) and HR (120 bpm). A physical examination was performed and a hematoma approximately 8 cm in diameter was detected during a rectal examination. Morphology was ordered and the patient was qualified for re-operation of the hematoma. Due to severe pain, it was decided to perform an ultrasound examination in the operating room, and the head of the department was called. The patient was informed about the risk of extending the operation to laparotomy and ligation of the iliac arteries, and the possibility of the uterus being removed. Oral consent for the procedure was obtained and surgery commenced at 21:05.

At 22:10 the patient was re-admitted to the recovery room, where two units of red blood cells (RBCs), two units of plasma, and six units of intravenous cryoprecipitate were transfused. Painkillers were administered intravenously (Ketonal 100 mg, Morphine 20 mg in 20 ml 0.9% NaCl 1.5-2 ml/h) along with an antibiotic (Metronidazole 3×500 mg). After repeated transvaginal hematoma evacuation, the patient's general condition and circulatory and respiratory efficiency were recorded. This included oxygen saturation (98%), HR (90 bpm), and blood pressure (124/62 mmHg).

Two hours after the operation, general observations were again recorded, including blood pressure (120/60 mmHg), and HR (90 bpm). The patient did not report any complaints, the abdomen was soft and painless, and the uterus was shrunken. A drain installed during surgery had collected 100 ml of bloody discharge.

At 04:00 a doctor was called because the drain had fallen out. The patient's general condition was good,

with blood pressure (130/78 mmHg), and HR (80 bpm) measured. Per vaginum and rectum examination revealed no hematoma. The drain was re-inserted and the patient remained at in-patient observation.

At around 07:00 the patient was in good general condition, and circulation and respiration were efficient. The abdomen was soft and painless, though there was slight tenderness on the right side near the iliac plate. Diuresis amounted to 1500 ml and a small amount of serous fluid was observed in the drain. The seton was removed and there were no signs of intense hyperemia.

An ultrasound examination was performed, which showed a free diaphragm dome, kidneys without stagnation in the cup-pelvic systems, no abnormal features in the retroperitoneal space, and a normal transperineal image. Tests were ordered and the patient was transferred to the maternity ward.

Obstetric care after the evacuation of vaginal hematoma, planning of care, and implementation of activities.

1. Reduction or minimization of pain through the administration of analgesics following the doctor's instructions:
   - Implement the analgesic procedure following the medical order card.
2. Postoperative wound infection prevention:
   - Supply antibiotics according to the doctor's instructions.
   - Visually evaluate the postoperative wound and observe the seton.
   - Observe the amount and nature of the contents of the drain.
   - Assess and analyze parameters of general condition that may indicate a developing infection.
3. Caring for the proper nutrition and hydration of the patient:
   - Provide an intravenous fluid supply.
4. Maintaining fluid balance:
   - Observe the quantity and quality of urine excreted.
   - Record fluid intake.
5. Pharmacological management of thromboprophylaxis:
   - Administer anticoagulants following the doctor's prescription.
6. Observation of the general condition of the patient:
   - Assess general condition using measurable parameters.
7. Observation of the patient's obstetric condition:
   - Assess obstetric condition to include the height of the fundus, contraction, and puerperal excrements.
   - Visual perineal assessment.
8. Obstetric control by the obstetrician:
   - Observe the quantity and quality of urine excreted.
   - Control of bowel movements and history gathering.
9. Providing a proper diet for the patient:
   - Provide an easily digestible diet and present principles of nutrition to the patient in puerperium and during breastfeeding.
10. Supervision over the course of lactation:
    - Assess the course of breastfeeding.
    - Observe the lactation process.
    - Assess mother-child contact.
11. Control of the patient's emotional state:
    - Assess the patients' behavior and conduct an interview regarding well-being.
12. Activities to improve the patient's well-being:
    - Strengthen the sense of competence as a mother.
    - Reassure the patient that she has a right to feel different because of a big change in her life.
    - Calm the patient by providing accurate information about her condition.
13. Observation of the discharge in the Redon bottle.
    - Visually assess the quantity and quality of the discharge in the Redon bottle.
14. Assessment and reduction of the risk of anemia.
    - Assess morphology and iron supply according to the doctor's instructions.

The obstetric treatment and care provided led to significant improvements. On the 6th day post-surgery, the patient and the newborn left the hospital in good general condition.

During vaginal delivery, perineal tears often occur due to the excessive pressure on the frontal part of the soft tissues of the birth canal; therefore, an important issue is the professional preparation of the therapeutic staff to care for a woman with a perineal injury.

Discussion

Key results

Hematoma diagnosis can be difficult because symptoms are often nonspecific and the therapeutic procedure of choice is most often surgical treatment. Developing a standard protocol for diagnosis, treatment, and care, is an important element in increasing the level of care provided.

Interpretation

Vaginal injuries, including vaginal hematomas, account for 20% of postpartum hemorrhages [15].

Vaginal hematoma is a difficult condition, not only because it is unpredictable and symptoms are often nonspecific, but also due to the potential complications it entails for the patient. The most common methods of diagnosis are imaging modalities, such as computed tomography, magnetic resonance imaging, and ultrasound [16]. The therapeutic procedure of choice is most often transvaginal hematoma evacuation surgery [15].

Before surgical treatment is undertaken the patient must provide written informed consent. This is important as the procedure has the potential for many additional interventions, including the transfusion of blood and blood products and the possibility of extending the operation to laparotomy and ligation of the iliac arteries. Furthermore, it may be necessary in some cases to remove the uterus if an unmanageable hemorrhage threatens the life or health of the patient [17]. Due to the rapid escalation of events that lead to transvaginal hematoma evacuation surgery, it is often impossible to mentally prepare a patient. Therefore, the attending midwife should take care to reduce the patient's anxiety. In the present case study, the close cooperation of midwives with the medical team meant that medical intervention was quickly initiated. As a result, the surgical procedure significantly reduced the symptoms of the growing hematoma.

Although a re-operation was necessary and caused the patient additional stress, there was no requirement to embolize the iliac arteries. Postpartum vaginal hematoma was included in the International Statistical Classification of Diseases and Related Health Problems (ICD)-10, so it can be concluded that it is an important and well-known issue. However, there is no single, strictly adopted, protocol set out to manage the issue. According to the literature, the most frequently used and most effective method of treatment is hematoma resorption to prevent further blood loss and reduce pain [5,18,19]. Indeed, a study by Shikha Rani et al. demonstrated that single resorption was insufficient in only 1 in 39 cases [3].

In the current study, re-operation was required. Morgans et al. [19], described five cases of women in whom the insertion of a drain, pressure dressing, blood transfusion, and antibiotic therapy after the evacuation of the hematoma, was successful. Similar to the current study, this study included a 26-year-old patient with recurrent vaginal hematoma after natural childbirth. Indeed, primary evacuation of the hematoma and layered suturing turned out to be insufficient and the hematoma reappeared within a few hours. Therefore, re-operation was required, and, after removing the clot, a drain was inserted and covered with a pressure dressing in the form of swabs, although the current case study differed in that a seton was used rather than swabs. The patient also had a successful blood transfusion and received antibiotic therapy [19]. However, in a retrospective study conducted between 2013-2017, the medical records of 40 patients with PPH were assessed, including patients with vaginal hematoma. Analysis of the records showed that severe hemorrhage occurred and had to be controlled by embolization of the iliac arteries [20].

The optimal treatment for a hemorrhage depends on its cause. Ultrasound is the most useful tool for the rapid diagnosis and evaluation of PPH build-up [21]. In the current study, ultrasound was only used for assessment of the hematoma when it began to grow again. However, if ultrasound was used to monitor the patient after the evacuation of the hematoma, it could have contributed to earlier detection of its growth and would have allowed for adequate measures to be applied to prevent its re-emergence.

The role of the nurse and midwife is to perform all medical procedures ordered by the duty doctor with due diligence, as well as to mentally and physically prepare the patient for surgery [22]. Immediately after the operation, the midwife has to constantly supervise the patient and take measures to prevent possible complications. In the following days, the midwife's tasks should focus on preparing the patient for childcare and self-observation. Indeed, after a complicated childbirth, patients can experience trauma and depressed mood/anxiety. Therefore, they need the support of medical personnel in addition to the support they receive from family.

Generalizability

An appropriate response to complaints reported by patients allows for quick diagnosis and identification of underlying causes, as well as for the implementation of optimal treatment and care procedures. The midwife has the closest contact with the patient while providing care during the puerperium, at which time they carry out medical orders and monitor the patient's general and obstetric condition. This allows them to quickly verify the condition of the patient and provide qualified assistance should any irregularities occur.

Study limitations

The study was limited by only having one patient. This should be expanded in the future to include additional case studies to allow for a comparison of diagnostic and therapeutic management processes.

Recommendations

In order to increase the level of care provided it is important to develop a standard protocol for the diagnosis, treatment, and care provided following transvaginal hematoma evacuation surgery.

Conclusions

Vaginal hematomas are often difficult to predict, therefore close cooperation between midwives and the medical team is important. Furthermore, procedures and care provided by the staff should give the patient a sense of security, as they may significantly affect their decisions on future reproduction.

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Correspondence address:
Stefaniak Małgorzata
Medical University of Warsaw
Faculty of Health Sciences
Department of Obstetrics and Gynecology Didactics
Litewska St. 14/16
00-575 Warsaw, Poland
E-mail: malgorzata.stefaniak@wum.edu.pl

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DIABETES DISTRESS IN ADULT PATIENTS WITH TYPE 1 AND TYPE 2 DIABETES

Dominika Kurza[1 A-F]
• ORCID: 0000-0001-6503-4605

Ewa Kobos[1 A,C-F]
• ORCID: 0000-0001-7231-8411

[1] Department of Development of Nursing, Social and Medical Sciences, Faculty of Health Sciences, Medical University of Warsaw, Poland

A – study design, **B** – data collection, **C** – statistical analysis, **D** – interpretation of data, **E** – manuscript preparation, **F** – literature review, **G** – sourcing of funding

ABSTRACT

Background: Diabetes is a chronic and demanding condition, exposing patients to complex physical and mental challenges, and making them particularly vulnerable to distress. Diabetes distress related to disease in diabetic patients is a term encompassing challenges associated with the psychosocial adaptation required of these individuals.

Aim of the study: To assess distress in patients with diabetes mellitus.

Material and methods: This study was conducted among 107 patients with type 1 and 2 diabetes mellitus reporting for follow-up at a diabetes clinic. The Diabetes Distress Scale (DDS) was used for data collection.

Results: Moderate and severe diabetes distress was found in 36.4% and 15% of respondents in the study group, respectively. The total mean score for the DDS was 2.19. The largest percentages of respondents with high levels of distress were observed in patients with a financial situation rated lower than good (30.6%), those having less than secondary education (28.0%), and those under 30 years of age (27.8%). Patients with type 1 diabetes (26.9%), a disease duration >30 years (30.8%), those using insulin pump therapy (30%) or CGM (Continuous Glucose Monitoring) and FGM (Flash Glucose Monitoring) systems (50%), and those showing ≥3 chronic diabetic complications (37.5%) experienced severe distress.

Conclusions: Overall, diabetic patients showed a moderate level of distress. The greatest inconveniences caused by the disorder were associated with regimen-related distress and emotional burden. Rural patients with a lower level of education and a lower financial status showed higher levels of distress. Patients experiencing chronic complications from diabetes and those with higher levels of glycated hemoglobin also presented with more severe distress.

KEYWORDS: type 1 diabetes, type 2 diabetes, diabetes distress, adults

Background

Diabetes mellitus (DM) is currently one of the most serious and rapidly developing non-transmissible diseases in the world. According to the International Diabetes Federation, there are approximately 61 million people diagnosed with diabetes in Europe, and this number is projected to increase by 6 million by 2030 [1]. According to the National Health Fund, there were 2.9 million people with diabetes in Poland in 2018, accounting for 9.1% of the adult population [2].

Disease distress occurring in patients with diabetes is a concept encompassing the psychosocial adjustment challenges faced by people with this disease [3]. It refers specifically to the negative emotional experiences resulting from the challenges of living with diabetes, regardless of its type [4]. The stress associated with this disease is a distinct emotional construct associated with the worries, fears, and anxieties of those struggling with a chronic condition. Diabetes distress is related to the emotional reactions associated with diagnosis, the risk of chronic complications, self-control demands, the quality of interpersonal relationships, and contacts with healthcare providers [5]. It is not a mental disorder, but if left unaddressed without any intervention, the persist-

ent and pervasive nature of distress in everyday life can lead to more serious problems [6,7].

Diabetes distress is manifested by feelings of helplessness and hopelessness, fears of hypoglycemic episodes or the development of complications, high levels of anxiety about endless self-control tasks, and frustration with medical personnel (often leading to mistrust, hostility, and missed appointments) [7]. The demands placed on diabetic patients in the daily self-control of their disease increase anxiety, frustration, and concern about inadequate adherence (i.e., maintaining a proper diet, undertaking regular physical activity, measuring blood glucose, and taking daily medications). Inadequate monitoring of blood glucose levels, as well as a failure to control diet, undertake physical exercise, or follow medical recommendations, increase distress in patients with diabetes. Anxiety about the risk of hypoglycemia is a major constant source of uncertainty, as patients worry they will be unable to recognize the symptoms of hypoglycemia and respond to them quickly enough to avoid embarrassment and danger, especially while sleeping or driving [8]. Other areas of social anxiety for patients include concerns about the reaction of others to their illness, the feeling that society will perceive and treat them negatively, and that they will no longer be attractive to employers. Another source of emotional distress relates to the need for family and friends to be involved in managing diabetes and the worry that this involvement will be either insufficient or excessive. Patients may also express anxiety about not receiving adequate help, support, and understanding from members of the therapeutic team [9].

A meta-analysis focusing on the prevalence of diabetes distress in patients with type 2 diabetes (T2DM) found that approximately 36% of patients experience significant distress [10]. It is also estimated that increased or significant diabetes distress affects approximately 20–40% of patients with type 1 diabetes (T1DM) [11,12]. Overall, it affects 18–53% of patients with both types of diabetes [13,14].

This study will update the few studies in this research area that have been conducted in Poland.

Aim of the study

To assess the prevalence of disease distress in diabetic patients.

Material and methods

Study design

This was a cross-sectional study.

Participants

Patients with DM of at least 1-year duration, aged ≥18 years, and who gave informed and voluntary consent to participate in the study were included.

Setting

The study was conducted among patients attending follow-up visits at a diabetes clinic between January and March 2022.

Measurement

A self-designed questionnaire was used to collect the patients' sociodemographic and clinical data, and the standardized Diabetes Distress Scale (DDS) [15] was used to measure the level of distress.

The DDS is a tool for assessing distress associated with diabetes. It includes four different dimensions of diabetes-related distress: emotional burden – 5 statements (maximum score 30), physician-related distress – 4 statements (maximum score 24), regimen-related distress – 5 statements (maximum score 30), and interpersonal distress – 3 statements (maximum score 18). Responses to the individual scale statements are measured on a 6-point Likert scale, where 1 means 'not a problem' and 6 means 'a very serious problem'. The mean score for each subscale is obtained by dividing the sum of scores from all responses by the number of statements that make up a given subscale. The minimum and the maximum possible scores for the total scale are 17 and 102, respectively. The mean score for the entire scale is obtained by dividing the sum of the scores from all responses by 17. The total DDS score and the mean score on each subscale were classified as no distress (mean <2), moderate distress (mean 2 to 2.9), or high distress (mean ≥3).

Ethical considerations

This study was approved by the Bioethics Committee at the Medical University of Warsaw (AKBE/217/2021).

Statistical analyses

An analysis using Pearson's non-parametric chi-squared test was conducted to determine whether there were statistically significant relationships for qualitative variables. The distribution of the quantitative data was examined using the Shapiro–Wilk test. If the distribution was determined to be non-normal-

ly distributed, the Mann–Whitney U test (U, z) was used to compare two groups, and the Kruskal–Wallis test (H) was used for three or more groups. Spearman's correlations (r) were also used. The significance level was set at $p<0.05$. The analysis was performed using the StatSoft Statistica 13.1 PL statistical package and Microsoft Office.

RESULTS

Characteristics of the study group

A total of 107 diabetic patients participated in the study, 48.6% of whom were women. The mean age of study participants was 53.5 years. The majority of patients resided in urban areas (81.3%), 58.9% of patients were in a relationship, and 39.3% had secondary education. Professionally active respondents accounted for 46.7% of the study group. A very good and good financial status was reported by 21.5% and 44.9% of respondents, respectively.

T1DM and T2DM affected 24.3% and 75.7% of respondents, respectively, with a mean disease duration of 16.0 years. Half of the patients used only oral hypoglycemics as part of their diabetes treatment. Glucose monitoring with a glucometer was performed by 94.4% of patients. Glycated hemoglobin (≤6.5%) was reported by 41.1% of participants, with a mean glycated hemoglobin of 7.36%.

Main results

The mean DDS score in the study group was 2.19 (Table 1). The highest scores in the analyzed dimensions of distress were observed for regimen-related distress (a score of 2.71).

Moderate and high distress was found in 36.4% and 15% of the respondents, respectively (Figure 1).

Table 1. Diabetes distress experienced by study patients – descriptive analysis

DDS scale	Descriptive analysis				
	M	SD	Me	Min	Max
Diabetes Distress	2.19	0.85	2.00	1.00	5.41
Regimen Related Distress	2.71	1.12	2.60	1.00	5.40
Physician Related Distress	1.39	0.90	1.00	1.00	5.75
Emotional Burden	2.56	1.09	2.40	1.00	5.60
Interpersonal Distress	1.77	1.06	1.33	1.00	5.33

Explanations: M – mean, SD – standard deviation, Me – median, Min-Max – minimum-maximum.

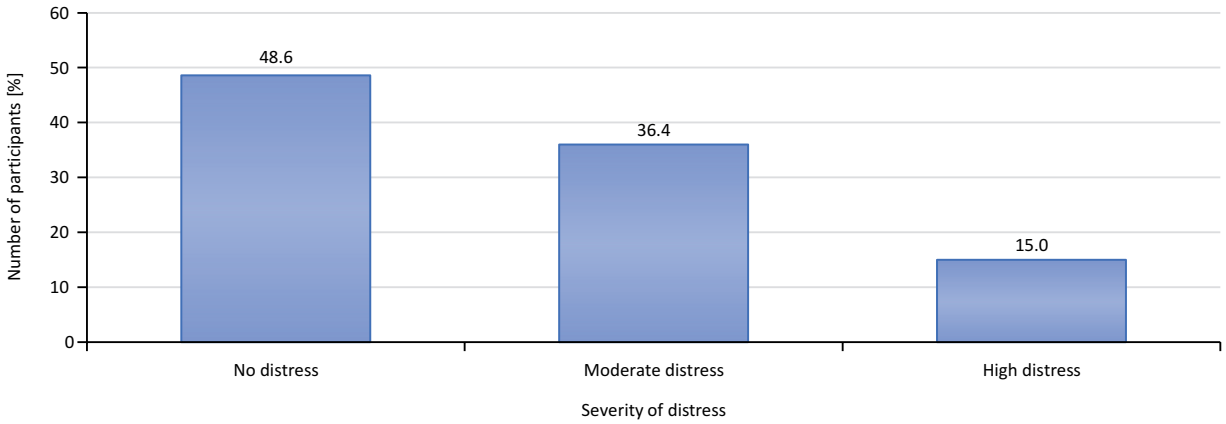

Figure 1. The severity of diabetes distress experienced by study participants

There was no statistically significant relationship between the prevalence of diabetes distress and gender ($z=0.01$; $p=0.993$) or age ($r=0.12$; $p=0.230$). Patients living in rural areas rated the overall inconvenience caused by diabetes at a statistically significantly higher level ($H=3.50$; $p=0.034$), and reported a significantly higher regimen-related distress ($H=5.42$; $p=0.006$) and emotional burden ($H=3.84$; $p=0.025$; Table 2).

Significantly higher values for interpersonal distress were observed in divorced and single respondents than in those who were in a relationship or widowed ($H=2.80$; $p=0.044$). The lower the level of education, the statistically significantly higher the overall diabetes distress ($r=-0.30$; $p=0.002$; Table 3).

There were no statistically significant differences in diabetes distress across occupational activities

Table 2. Diabetes distress and place of residence

DDS	Place of residence	Descriptive analysis						Statistics	
		n	M	SD	Me	Min	Max	H (KW)	p
Daibetes Distress	village	15	2.55	0.81	2.41	1.47	3.88	3.50	0.034
	city/town	87	2.17	0.85	2.00	1.00	5.41		
	outskirts of a big city	5	1.44	0.50	1.18	1.00	2.06		
Regimen Related Distress	village	15	3.28	1.10	3.40	1.60	4.80	5.42	0.006
	city/town	87	2.68	1.09	2.40	1.00	5.40		
	outskirts of a big city	5	1.48	0.41	1.40	1.00	2.00		
Physician Related Distress	village	15	1.35	0.67	1.00	1.00	3.50	0.42	0.657
	city/town	87	1.42	0.96	1.00	1.00	5.75		
	outskirts of a big city	5	1.05	0.11	1.00	1.00	1.25		
Emotional Burden	village	15	3.17	1.23	3.20	1.40	5.00	3.84	0.025
	city/town	87	2.50	1.02	2.20	1.00	5.60		
	outskirts of a big city	5	1.84	1.07	1.20	1.00	3.20		
Interpersonal Distress	village	15	1.91	0.70	2.00	1.00	3.00	0.85	0.431
	city/town	87	1.78	1.13	1.00	1.00	5.33		
	outskirts of a big city	5	1.20	0.45	1.00	1.00	2.00		

Explanations: M – mean, SD – standard deviation, Me – median, Min-Max – minimum-maximum, H – H value for the Kruskal–Wallis test, p – statistical significance.

Table 3. Diabetes distress and educational status

DDS	Education	Descriptive analysis						Statistics	
		n	M	SD	Me	Min	Max	Rho	p
Diabetes Distress	below secondary	25	2.72	0.86	2.53	1.65	5.41	–0.30	0.002
	secondary	42	1.97	0.64	1.82	1.00	3.59		
	high school	40	2.08	0.92	1.82	1.00	4.18		
Regimen Related Distress	below secondary	25	3.55	0.98	3.60	1.80	5.40	–0.34	0.000
	secondary	42	2.44	1.01	2.20	1.00	5.40		
	high school	40	2.46	1.07	2.20	1.00	5.40		
Physician Related Distress	below secondary	25	1.47	1.02	1.00	1.00	5.25	–0.01	0.943
	secondary	42	1.27	0.58	1.00	1.00	3.25		
	high school	40	1.48	1.09	1.00	1.00	5.75		
Emotional Burden	below secondary	25	3.33	1.17	3.20	1.00	5.60	–0.30	0.002
	secondary	42	2.33	0.96	2.20	1.00	4.40		
	high school	40	2.32	0.95	2.00	1.00	5.20		
Interpersonal Distress	below secondary	25	2.01	1.12	1.67	1.00	5.33	–0.04	0.689
	secondary	42	1.52	0.83	1.00	1.00	4.00		
	high school	40	1.88	1.21	1.33	1.00	5.33		

Explanations: M – mean, SD – standard deviation, Me – median, Min-Max – minimum-maximum, Rho – Spearman's correlation coefficient, p – statistical significance.

(H=0.02; p=0.985). However, a worse financial status was associated with a greater distress caused by diabetes (r=0.36; p=0.000; Table 4).

Patients with T1DM were found to rate the severity of interpersonal distress as higher (z=–1.99; p=0.046; Table 5).

Table 4. Diabetes distress and financial status

DDS	Financial status	Descriptive analysis						Statistics	
		n	M	SD	Me	Min	Max	Rho	p
Diabetes Distress	very good	23	1.89	0.75	1.53	1.06	4.00	0.36	0.000
	good	48	2.05	0.76	1.85	1.00	5.41		
	below good	36	2.57	0.91	2.44	1.00	4.18		
Regimen Related Distress	very good	23	2.30	0.94	2.00	1.20	4.80	0.33	0.001
	good	48	2.48	0.92	2.40	1.00	5.40		
	below good	36	3.26	1.27	3.30	1.00	5.40		
Physician Related Distress	very good	23	1.24	0.56	1.00	1.00	3.00	0.13	0.171
	good	48	1.40	0.97	1.00	1.00	5.25		
	below good	36	1.49	0.98	1.00	1.00	5.75		
Emotional Burden	very good	23	2.14	0.87	2.00	1.00	4.20	0.32	0.001
	good	48	2.38	0.93	2.20	1.00	5.60		
	below good	36	3.07	1.23	3.20	1.00	5.20		
Interpersonal Distress	very good	23	1.64	1.23	1.00	1.00	5.33	0.21	0.029
	good	48	1.65	0.96	1.17	1.00	5.33		
	below good	36	2.02	1.07	2.00	1.00	4.67		

Explanations: M – mean, SD – standard deviation, Me – median, Min-Max – minimum-maximum, Rho – Spearman's correlation coefficient, p – statistical significance.

Table 5. Diabetes distress and type of diabetes

DDS	Type of diabetes	Descriptive analysis						Statistics	
		n	M	SD	Me	Min	Maks	Z (UMW)	p
Diabetes Distress	Type 1	26	2.38	1.16	1.85	1.24	5.41	–0.05	0.957
	Type 2	81	2.13	0.73	2.06	1.00	4.18		
Regimen Related Distress	Type 1	26	2.72	1.28	2.20	1.20	5.40	0.45	0.650
	Type 2	81	2.70	1.07	2.60	1.00	5.40		
Physician Related Distress	Type 1	26	1.80	1.43	1.13	1.00	5.75	–1.95	0.052
	Type 2	81	1.27	0.60	1.00	1.00	3.75		
Emotional Burden	Type 1	26	2.58	1.14	2.20	1.20	5.60	0.17	0.862
	Type 2	81	2.55	1.07	2.40	1.00	5.20		
Interpersonal Distress	Type 1	26	2.23	1.40	2.00	1.00	5.33	–1.99	0.046
	Type 2	81	1.62	0.89	1.00	1.00	4.67		

Explanations: M – mean, SD – standard deviation, Me – median, Min-Max – minimum-maximum, Z – Z value for the Mann–Whitney test, p – statistical significance.

The longer the duration of the disease, the statistically significantly greater regimen-related distress (r=0.22; p=0.022; Table 6).

It was found that insulin pump users reported significantly higher (H=4.48; p=0.005) interpersonal distress than patients treated with other regimens. There was no statistically significant correlation between the type of glucose monitoring used and the severity of diabetes distress (z =-0.71; p=0.452).

The more complications reported by participants, the higher the severity of distress they showed in the following dimensions: regimen-related distress (r=0.34; p=0.000), emotional burden (r=0.30; p=0.002), and interpersonal distress (r=0.26; p=0.007; Table 7).

Patients with elevated levels in their last glycated hemoglobin measurement rated their overall distress as higher (z=4.79; p=0.000). They also showed great-

Table 6. Diabetes distress and disease duration

DDS	Diabetes duration (years)	Descriptive analysis						Statistics	
		n	M	SD	Me	Min	Max	Rho	p
Diabetes Distress	≤5	17	1.91	0.57	1.88	1.00	2.82	0.17	0.084
	6–10	23	2.34	1.13	1.82	1.41	5.41		
	11–20	36	2.05	0.72	1.82	1.00	4.00		
	21–30	18	2.27	0.86	2.06	1.00	4.06		
	>30	13	2.54	0.86	2.18	1.18	4.18		
Regimen Related Distress	≤5	17	2.33	0.84	2.40	1.00	3.80	0.22	0.022
	6–10	23	2.70	1.30	2.20	1.20	5.40		
	11–20	36	2.56	0.99	2.30	1.00	4.40		
	21–30	18	2.81	1.14	2.90	1.00	4.80		
	>30	13	3.48	1.19	3.40	1.40	5.40		
Physician Related Distress	≤5	17	1.13	0.27	1.00	1.00	1.75	0.04	0.712
	6–10	23	1.60	1,14	1.00	1,00	5.25		
	11–20	36	1.24	0,50	1.00	1,00	3.25		
	21–30	18	1.69	1.14	1.00	1,00	5.00		
	>30	13	1.38	1.31	1.00	1,00	5.75		
Emotional Burden	≤5	17	2.41	0.97	2.40	1,00	4.00	0.11	0.275
	6–10	23	2.62	1.25	2.20	1,00	5,60		
	11–20	36	2.43	1.03	2.00	1.00	4,80		
	21–30	18	2.54	1.13	2.50	1.00	5,00		
	>30	13	3.03	1.03	2.80	1.20	4.60		
Interpersonal Distress	≤5	17	1.43	0.65	1.00	1.00	3.33	0.02	0.877
	6–10	23	2.26	1.54	1.33	1.00	5.33		
	11–20	36	1.67	0.95	1.00	1.00	4.67		
	21–30	18	1.70	0.92	1.33	1.00	4.33		
	>30	13	1.72	0.79	1.67	1.00	3.00		

Explanations: M – mean, SD – standard deviation, Me – median, Min-Max – minimum-maximum, Rho – Spearman's correlation coefficient, p – statistical significance.

Table 7. Diabetes distress and the presence of diabetes complications

DDS	Number of complications	Descriptive analysis						Statistics	
		n	M	SD	Me	Min	Max	Rho	p
Diabetes Distress	No complications	52	1.97	0.86	1.74	1.00	5.41	0.37	0.000
	1 complication	32	2.28	0.73	2.18	1.00	3.76		
	2 complications	15	2.44	0.78	2.47	1.00	4.18		
	3 or more complications	8	2.79	1.05	2.65	1.18	4.18		
Regimen Related Distress	No complications	52	2.36	0.99	2.20	1.00	5.40	0.34	0.000
	1 complication	32	2.89	1.14	2.80	1.00	5.40		
	2 complications	15	3.16	1.20	3.00	1.00	5.40		
	3 or more complications	8	3.38	1.08	3.50	1.40	5.00		
Physician Related Distress	No complications	52	1.40	0.94	1.00	1.00	5.25	0.04	0.670
	1 complication	32	1.32	0.65	1.00	1.00	3.75		
	2 complications	15	1.15	0.40	1.00	1.00	2.50		
	3 or more complications	8	2.13	1.72	1.13	1.00	5.75		

Table 7 contd.

DDS	Number of complications	Descriptive analysis						Statistics	
		n	M	SD	Me	Min	Max	Rho	p
Emotional Burden	No complications	52	2.25	0.91	2.00	1.00	5.60	0.30	0.002
	1 complication	32	2.74	1.15	2.70	1.00	5.00		
	2 complications	15	2.99	1.22	3.20	1.00	5.20		
	3 or more complications	8	3.08	1.20	3.00	1.20	4.80		
Interpersonal Distress	No complications	52	1.61	1.13	1.00	1.00	5.33	0.26	0.007
	1 complication	32	1.78	0.88	1.67	1.00	4.00		
	2 complications	15	2.07	1.00	2.00	1.00	4.67		
	3 or more complications	8	2.21	1.34	2.00	1.00	4.67		

Explanations: M – mean, SD – standard deviation, Me – median, Min-Max – minimum-maximum, Rho – Spearman's correlation coefficient, p – statistical significance.

er scores on the dimensions of regimen-related distress (z=4.91; p=0.000), emotional burden (z=4.29; p=0.000), and interpersonal distress (z=2.14; p=0.032; Table 8).

Table 8. Diabetes distress and the last measured glycated haemoglobin level

DDS scale	Haemoglobin A1c (%)	Descriptive analysis						Statistics	
		n	M	SD	Me	Min	Max	Z (UMW)	p
Diabetes distress	≤6.5	63	1.75	0.49	1.65	1.00	4.00	4.79	0.000
	>6.5	44	2.50	0.92	2.41	1.00	5.41		
Regimen Related Distress	≤6.5	63	2.07	0.64	2.00	1.00	3.80	4.91	0.000
	>6.5	44	3.15	1.17	3.00	1.00	5.40		
Physician Related Distress	≤6.5	63	1.22	0.58	1.00	1.00	3.75	1.60	0.111
	>6.5	44	1.52	1.06	1.00	1.00	5.75		
Emotional Burden	≤6.5	63	2.02	0.72	2.00	1.00	4.80	4.29	0.000
	>6.5	44	2.94	1.14	2.80	1.00	5.60		
Interpersonal Distress	≤6.5	63	1.47	0.77	1.00	1.00	4.67	2.14	0.032
	>6.5	44	1.98	1.19	1.67	1.00	5.33		

Explanations: M – mean, SD – standard deviation, Me – median, Min-Max – minimum-maximum, Z – Z value for the Mann–Whitney test, p – statistical significance.

Discussion

The study showed that the overall prevalence of high levels of diabetes distress was 15%. This is lower compared to studies conducted only in T1DM or T2DM patients, and lower than that reported in a study including patients with both types of diabetes [15-19,20]. Overall, a mean DDS score of 2.19 was obtained in this study, which is higher than the score obtained by Joensen et al. (1.9) in a group of adults with T1DM, and comparable (2.17) with the findings presented by Islam et al. for a group of patients with T2DM [18,21].

This study found the highest scores for regimen-related distress (2.71) and emotional burden (2.56). One study measuring diabetes distress found that emotional burden was the most important domain [18]. This may be due to the difficulties in self-control of the disease, adherence to dietary and physical activity recommendations, and the psychological aspects of coping that occur in patients with chronic diseases, including diabetes [22]. As in this study, Joensen et al. confirmed that patients experienced a greater emotional burden (2.3), and lower levels of physician-related (1.9) and interpersonal distress (1.7). However, different results on the regimen-related distress dimension (1.5) were obtained compared to our study (2.71) [21]. This difference may be related to differences in the type of diabetes. Patients with T2DM predominated in our study, while Joensen et al. included only T1DM patients [21]. T1DM is characterized by a high degree of blood glu-

cose fluctuation, which can cause more difficulty in controlling glycemia.

A previous study reported no correlations between sociodemographic data and diabetes distress [16]. The current study did not confirm a correlation between age and distress, in contrast to the results of other authors [17,18]. This may be due to cultural differences in the countries where the studies were conducted. The present study also did not confirm a relationship between distress and gender, despite the fact that some previous studies have found a relationship between female gender and diabetes distress, as well as with depression and anxiety, with a higher risk in women compared to men [23]. A literature review found that T2DM-related distress was significantly higher in groups with more women (45%) as compared to male-dominated samples (32%; meta-regression, p=0.011) [10].

This study found higher overall levels of diabetes distress and a higher emotional burden and regimen-related distress in rural patients. In a study by Islam et al., the prevalence of moderate diabetes distress was higher in patients with T2DM living in the suburbs of large metropolitan areas [18]. In this study, the group of patients living near large urban areas showed the lowest diabetes distress in each dimension. It should be mentioned, however, that, in our study, analyses of this variable were not performed in relation to distress levels, but according to the scores achieved on the scale.

In this study, divorced and single patients experienced greater interpersonal distress than those who were in a relationship. This may be due to the lack of a partner to support and help the diabetic person faced with the difficulties of the disease and the responsibilities of daily life. Studies by other authors have also confirmed a correlation between single status and diabetes distress [17,24].

In our study, we found that the lower the level of education, the higher the diabetes distress overall, and the greater the regimen-related distress and emotional burden. This is consistent with the findings presented by other authors [17,18,22]. A lower level of education may be associated with less health-related knowledge, and an insufficient understanding of the nature of the disease and its complications, which may increase the likelihood of poor dietary habits, a poor adherence to medical recommendations, and less frequent attendance at check-ups. Individuals with lower education may also have a poorer occupational and financial situation, which may make it more difficult for them to purchase medicines, necessary equipment, or care products, and to attend specialist appointments.

Our analysis has shown that the worse the financial situation of the patients, the higher the severity of diabetes distress in general and in the dimensions of regimen-related distress, emotional burden, and interpersonal distress. As adequate and regular control of diabetes is often associated with high costs, patients with lower incomes have difficulty in providing themselves with the optimal conditions to control the disease. Those with lower incomes may struggle to purchase all their medications, access new non-reimbursed medicines, purchase devices for continuous blood glucose monitoring, and use private care when faced with limited access to specialists under health insurance. These findings are consistent with the data obtained by Aljuaid et al. on the interpersonal distress dimension. The authors of this latter study also found that high-income individuals had a greater emotional burden [17].

The present study found that T1DM patients had significantly higher levels of interpersonal distress compared to those with T2DM. A literature review shows that only a few studies have assessed this relationship. Schmitt et al. found that diabetes distress was significantly more common among T2DM patients and was related to physician-related distress and emotional burden [19]. Aljuaid et al. found that moderate to high distress was present in 25% of T2DM patients, while Parsa et al. reported high distress in 63.7% of T2DM patients [16,17]. Clinically significant diabetes distress was present in 32.6% of overall diabetic patients and 28.2% of T1DM patients, and was significantly more common (41.3%) in T2DM patients. These differences were associated with greater interpersonal and physician-related distress [19].

This study showed that the longer the duration of the disease, the higher the regimen-related distress. In a study by Aljuaid et al., this relationship was also confirmed for physician-related distress. In a study by Islam, the correlation between diabetes distress and disease duration was very strong [17,18]. Parsa et al. showed that the highest overall diabetes distress was observed in patients with a disease duration of more than 15 years [16]. The daily self-control of diabetes and the treatment-related burden that patients experience over many years can lead to therapeutic burnout, a sense of chronic fatigue, and significantly contribute to distress [25,26].

The present study found that insulin pump users experienced higher interpersonal distress compared to other treatments. Interpersonal distress refers to feelings of a lack of perceived support in treatment efforts and perceived emotional support from family and friends, as well as a lack of understanding that living with diabetes can be difficult. In the study by Parsa et al., patients treated with insulin had higher distress than those on oral medications alone. However, no significant differences were observed between the group of patients treated with insulin only and those treated with insulin and oral medications [16]. The

onset of insulin therapy in T2DM and the increased complexity of the treatment regimen may increase diabetes distress [27]. Insulin administration may be a source of additional anxiety related to injections and an increased risk of low blood glucose [28].

In this study, patients failing to achieve recommended total glycated hemoglobin levels showed higher diabetes distress in general and in the dimensions of regimen-related distress, emotional burden, and interpersonal distress. Correlations between distress in diabetic patients and higher HbA1c values have been confirmed in several studies [16-18]. A positive correlation between distress and HbA1c values has been reported in the literature, and a reduction in diabetes distress is accompanied by a significant improvement in HbA1c values [29]. Furthermore, Aljuaid et al. found that higher HbA1c values were significantly more common in patients with high levels of distress and an emotional burden than in those with moderate levels of diabetes distress [17].

Our study showed that the more diabetes complications patients had, the higher regimen-related distress, emotional burden, and interpersonal distress they experienced. These results are consistent with the studies of Aljuaid et al. and Islam, which reported significant relationships between diabetes complications and a higher emotional burden and regimen-related distress [17,18]. The presence of diabetes complications significantly worsens the health status and quality of life of patients [30].

Given the results of this study and the data from the literature indicating the diversity of study participants and analyses performed in this research area (e.g., T1DM versus T2DM, patients with different levels of blood glucose control, patients with different treatment regimens, patients with or without diabetes complications, etc.), it is suggested that there is a need for a regular assessment of diabetes distress [7].

Limitations of the study

This study was conducted at a single institution and in a small group of patients. The study used convenience sampling, which limits the possibility of generalizing the results obtained to the entire population of diabetic patients and does not ensure the representativeness of the study sample. This was a cross-sectional study and therefore does not account for variability over time. At some points in the discussion, the results of this study were compared to studies conducted in countries with different cultures and health systems.

Conclusions

Overall, patients with diabetes show moderate levels of diabetes distress. The greatest distress caused by diabetes is associated with the treatment regimen and the emotional burden. Diabetic patients living in rural areas, with lower levels of education, and a lower financial status show higher distress. Diabetic patients who have developed chronic complications from the disease and show higher glycated hemoglobin levels also report higher distress.

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Correspondence author:
Ewa Kobos
E-mail: ekobos@wum.edu.pl

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PULMONARY FUNCTION TEST RESULTS AND RADIOLOGICAL FINDINGS 90-120 DAYS AFTER COVID-19 PNEUMONIA: A SINGLE-CENTER RETROSPECTIVE STUDY

Hülya Dirol[1 A-G]
• ORCID: 0000-0002-7712-6467

Gamze Nur Ozbey[1 A,B,D,E,G]
• ORCID: 0000-0001-5616-5021

Omer Ozbudak[1 A,E-G]
• ORCID: 0000-0001-9516-8129

Ahmet Gokhan Arslan[2 A,E-G]
• ORCID: 0000-0002-0858-3840

[1] Chest Department, Akdeniz University Hospital, Antalya,Turkey

[2] Radiology Department, Akdeniz University Hospita, Antalya, Turkey

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ABSTRACT

Background: Survivors of Coronavirus Disease 2019 (COVID-19) pneumonia may have permanent loss of lung function and radiological sequelae. There is a need for markers that predict patients for whom follow-up is required.

Aim of the study: To identify the risk factors associated with post-COVID-19 radiological and functional findings.

Material and methods: This is a single-center retrospective study performed in a university hospital. We obtained the data from all hospitalized patients with COVID-19 pneumonia. We included those who underwent pulmonary function tests (PFT) and chest computerized tomography (CT) 90-120 days later. We analyzed initial and peak laboratory results (C-reactive protein (CRP), d-dimer, ferritin, and fibrinogen), and the length of hospital and intensive care unit (ICU) stay. We examined the relationship between baseline data and radiological findings and PFT.

Results: Fifty-six patients were included in this study. Of these, 31 (55.4%) were women. The mean age of the patients was 55.05±13.29 years. The mean peak ferritin, fibrinogen, d-dimer, and CRP values recorded during hospitalization follow-up were 285.56±339.82, 518.59±186.93, 1.99±5.69, and 98.94±80.77, respectively. The mean length of hospital and ICU stay were 10.21±8.01 and 8.38±8.90 days, respectively. In 18 (32.1%) patients, we observed a restrictive pattern on PFT, and 22 (39.3%) patients had an abnormal diffusion test. In 21 (37.5%) patients we observed ground glass opacities and in 4 (7.1%) patients reticulation was seen on their chest CT. A multivariate logistic regression analysis revealed that the first visit and peak fibrinogen values were significantly associated with abnormal PFT ($p=0.049$, $R2=0.272$), while ferritin and CRP levels at the first visit and peak levels were significantly associated with an abnormality on chest CT ($p<0.001$, $p=0.05$, respectively).

Conclusions: High initial and peak ferritin, fibrinogen, and CRP levels were associated with persistent radiological findings on chest CT and abnormal PFT at 90–120 days follow-up after COVID-19 pneumonia.

KEYWORDS: COVID-19, pneumonia, pulmonary function test, chest computerized tomography

Background

There is a growing number of patients surviving Coronavirus Disease 2019 (COVID-19) who continue to struggle with symptoms of the disease long after clinically testing negative for the disease. On the other side, there are some patients with no symptoms but that have permanent radiological findings and lung function loss. All these were evaluated under the umbrella called a post-viral syndrome. Our previous experience with acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS) suggest that the effects of coronavirus infections can last for many years. We hypothesize that similar changes in radiological findings and pulmonary function tests (PFT) may occur in patients with COVID-19. As expected, the early analysis showed a high rate of abnormal lung function and fibrotic remodeling on computerized tomography (CT), particularly in survivors of severe SARS-CoV-2-associated pneumonia. We also observed some patients with post-COVID-19 syndrome despite having non-severe COVID-19 pneumonia.

Many studies have revealed that the overall quality of life is reduced and functional losses can occur in some patients while other studies showed conflicting results on medium-term recovery [1,2]. The optimal time for obtaining a baseline radiologic test is not clear either. The British Thoracic Society (BTS) guidelines recommend a baseline chest X-ray 3 months after discharge in patients with COVID-19 pneumonia [3]. However, routine follow-up may not be necessary for all survivors of COVID-19 pneumonia. Moreover, evaluation of the radiological and functional status of all patients is not possible. So we need data to provide an accurate estimation of whom, when, and which evaluations should be performed on survivors of COVID-19. We suppose that the detection of markers that predict patients requiring advanced radiological exams and PFT will save time and money.

Aim of the study

This study aims to investigate the risk factors associated with the persistence of abnormalities on chest CT and PFT.

Material and methods

Sample

This is a single-center, retrospective study conducted at a university hospital. Among patients of our outpatient clinic, we investigated the patients who underwent a thoracic CT and PFT between 90 and 120 days after a COVID-19 PCR-positive result (Figure 1). Patients under 18 years of age or who were treated as an outpatient were excluded from the study. Patients without COVID-19 pneumonia were excluded. Patients with respiratory distress, a respiratory rate ≥30 breaths/minute, an oxygen saturation of less than 93% at rest, an arterial partial pressure of oxygen (PaO_2)/fraction of inspired oxygenation (FiO_2) ≤300mmHg, or a lesion progression of >50% within 24 to 48 hours on pulmonary imaging were interpreted as patients with severe pneumonia. The patient's age, gender, comorbidities, symptoms, laboratory tests (lactate dehydrogenase (LDH), C-reactive protein (CRP), d-dimer, ferritin, and fibrinogen) at the time of admission and their peak values during follow-up, medications, intensive care unit (ICU) need, oxygen support, noninvasive ventilation (NIV) support, mechanical ventilation (MV) support, and the length of hospital stay was examined.

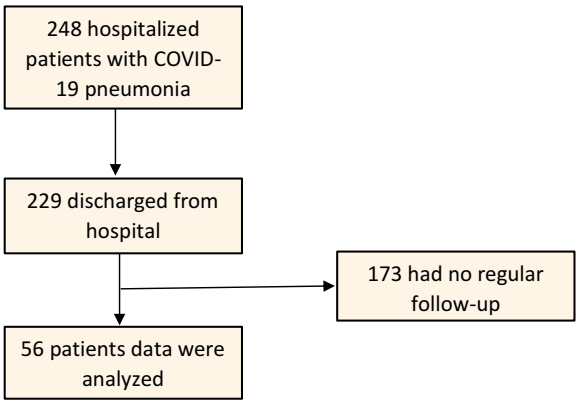

Figure 1. Flowchart of the participants

Pulmonary function tests

All PFT were performed according to the American Thoracic Society (ATS) – European Respiratory Society guidelines [4]. We obtained values for the predicted percent of forced expiratory volume in 1 second (FEV_1), forced vital capacity (FVC), forced mid-expiratory flow (FEF 25–75%), peak expiratory flow (PEF), and maximal mid-expiratory flow (MMEF). Those below 80% were considered abnormal. Those with a FEV_1/FVC<70% were classified as having an obstructive pattern, while those with a FVC below 80% and a FEV_1/FVC>70% were classified as having a restrictive pattern. Expected values of total lung capacity (TLC), diffusing capacity for carbon monoxide (DLCO), alveolar volume (VA), and DLCO/VA of those who underwent a helium diffusion test were examined. Additionally, desaturation with exertion during a 6-minute walking test was recorded. According to resting fingertip oxygen saturation, a 4%

decrease in SpO_2 during effort or a SpO_2<90 during exertion were interpreted as a desaturation.

Radiological evaluation

The thorax CT scans of the patients included in the study, which were taken simultaneously with PFT, were evaluated by one experienced radiologist. A radiologist evaluated the images for the presence of ground glass opacifications, consolidations, and reticular patterns. CT imaging features were reviewed for the following aspects: presence or absence of lesions, extent, location, distribution of lesions, and the number of involved segments.

Each of the five lung lobes was visually scored (using a semi-quantitative scoring system) based on the involved area from 0 to 4 with a 0 indicating no involvement, a 1 showing<25% involvement, 2 showing 25–49% involvement, 3 showing 50–75% involvement, and 4 having>75% involvement (Literature No). The sum of the individual lobar scores was the total CT scores with a possible range of 0 (minimum) to 25 (maximum). The relationship between radiological findings and PFT was examined.

Ethics

Approval for the study was granted by the Clinical Research Ethics Committee of Akdeniz University Faculty of Medicine (decision no: KAEK-484, dated: 08.07.2020). We also received approval from the Turkish Ministry of Health for the study.

Statistical Analysis

Statistical analyzes were performed using the SPSS (SPSS v.23, IBM, Somers, NY) program and p-values of less than 0.05 were considered statistically significant. The normality of data was determined using Shapiro-Wilk and Kolmogorov-Smirnov tests. For differences and dependencies, categorical data were analyzed using Fisher's Exact Chi-Squared and Yates' Chi-Squared tests while numerical data were analyzed using Independent Samples T-tests. The effects of the parameters on the CT score were analyzed using Univariate or Multivariate Binary Logistic Regression Tests.

Results

Descriptive data

In this study, the radiological and functional results of a total of 56 patients were examined. Of these, 31 (55.4%) were women. The mean age was 55.05±13.29 years, and 17 (34.0%) used to smoke or were still smoking. The mean smoking amount was 19.73±17.65 pack years. The most common comorbidities were diabetes (16 people, 28.6%) and hypertension (16 people, 28.6%). The most common symptom at the time of diagnosis was a cough. The mean peak ferritin, fibrinogen, d-dimer, and CRP values recorded during hospitalization follow-up were 285.56±339.82, 518.59±186.93, 1.99±5.69, and 98.94±80.77, respectively. Twenty (35.7%) patients had severe pneumonia while 36 (64.3%) patients had non-severe pneumonia. In 14 patients (25.0%), steroid treatment was used during the hospitalization. The mean hospitalization length was 10.21±8.01 days. Eight (14.3%) patients needed ICU. The mean length of stay in the ICU was 8.38±8.90 days (Table 1).

Table 1. Patient characteristics

Gender		**n**	**%**
Female		31	55.4
Male		25	44.6
Total		56	
Age (years)			
Mean/Std.Dev.		55.05±13.29	
Smoking		**n**	**%**
Never smoked		33	66.0
Smoking		7	14.0
Ex-smoker		10	20.0
(Packet x Year)			
Mean/Std.Dev.		19.73±17.65	
Comorbidity		**n**	**%**
No comorbidity		28	50.0
Comorbidity		28	50.0
	Diabetes	16	28.6
	Hypertension	16	28.6
Laboratory		**Mean/Std.Dev.**	
Ferritin peak		285.56±339.82	
Fibrinogen peak		518.59±186.93	
D-dimer peak		1.99±5.69	
CRP peak		98.94±80.77	
Clinical		**n**	**%**
Severe pneumonia		20	35.7
Non-severe pneumonia		36	64.3
Hospitalization	Length (Day-Mean/Std.Dev.)	10.21±8.01	
ICU		8	14.3
	Length (Day-Mean/Std.Dev.)	8.38±8.90	
Steroid treatment		14	25.0
	Length (Day-Mean/Std.Dev.)	9.07±5.03	

Values are given in mean and standard deviation or patient count and percentage.

Symptoms, pulmonary function tests, laboratory data, and radiological findings 90 to 120 days after COVID-19 positivity

There were no new symptoms during the 3-month period. The symptoms that were present at the beginning, disappeared in 18 (32.1%) of the patients while symptoms continued in 36 (64.3%) patients. The most common persistent symptoms were dyspnea (19 people, 33.9%) and fatigue (15 people, 26.8%).

Table 2. Clinical, laboratory, pulmonary function test and CT evaluations of the patients

Variations	At beginning	90–120th days
Clinical	**n (%)**	
Symptomatic	**54 (96.4%)**	**36 (64.3%)**
Dyspnea	25 (44.6%)	19 (33.9%)
Cough	37 (66.1%)	7 (12.5%)
Fatigue	27 (48.2%)	15 (26.8%)
Headache	18 (32.1%)	7 (12.5%)
Asymptomatic	2 (3.6%)	20 (37.7%)
Laboratory		
Ferritin ng/ml (Mean/Std.Dev.)	**244.54±304.80**	**70.43±100.86**
150< (n, %)	23 (50.0%)	5 (9.8%)
D-dimer mg/l (Mean/Std.Dev.)	**1.16±3.19**	**0.53±0.46**
0.55< (n, %)	24 (49.0%)	18 (34.0%)
CRP mg/l (Mean/Std.Dev.)	**4.82±5.72**	**0.51±0.84**
0.5< (n, %)	44 (83.0%)	15 (27.8%)
Pulmonary Function Tests	**Mean/Standard Deviation**	
Vital capacity %	**81.65±15.56**	
FEV1 %	**91.92±16.69**	
FVC %	**84.00±15.77**	
FEV1/FVC	**89.59±5.62**	
Obstructive (n, %)	0, %0	
Restrictive (n, %)	18, %32.1	
DLCO %	**78,92±14,65**	
<80% (n, %)	22, %39.3	
CT	**Right Lung**	**Left Lung**
Upper Lobe		
Ground-Glass (n, %)	19 (%48.7)	19 (%48.7)
Reticulation (n, %)	3 (%7.7)	3 (%7.7)
Middle Lob		
Ground-Glass (n, %)	16 (%41.0)	
Reticulation (n, %)	1 (%2.6)	
Lower Lobe		
Ground-Glass (n, %)	21 (%53.8)	20 (%51.3)
Reticulation (n, %)	4 (%10.3)	3 (%7.7)
Total		
Ground-Glass (n, %)	21 (%53.8)	20 (%51.3)
Reticulation (n, %)	4 (%10.3)	3 (%7.7)

Values are given in mean and standard deviation or patient count and percentage.

Ferritin, d-dimer, and CRP values performed at the 3-month follow-up were 70.43±100.86, 0.53±0.46, and 0.51±0.84, respectively. The number of patients who still had higher values was 5 (9.8%), 18 (34.0%), and 15 (27.8%), respectively.

In PFT performed at the 3 months, the mean total vital capacity, FEV_1, FVC, FEV_1/FVC, and DLCO values were 81.65%, 91.92%, 84.00%, 89.59, and 78.92%, respectively. While none of the patients displayed an obstructive pattern of PFT, 18 (32.1%) had a restrictive pattern. Diffusion tests in 22 (39.3%) patients remained low.

The most common pathological finding was ground glass opacities on thorax CT and high-resolution CT (HRCT) images taken at 90-120 days. There were 21 (37.5%) patients with ground glass opacities and 4 (7.1%) with reticulations. The most common radiological abnormalities were in the right lung (52.1%) and lower lobe (35.7%, Table 2).

Univariate/multivariate analysis for abnormal pulmonary function test between 90 and 120 days

The mean FEV_1, FVC, and FEV_1/FVC were 91.92%±16.69, 84.00%±15.77, and 89.59±5.62, respectively. The number of patients with a VC of<80% was 19 (33.9%), with a FEV_1 of<80% was 7 (12.5%), with a FVC of<80% was 18 (32.1%), and with a DLCO of<60% was 3 (5.4%).

A univariate logistic regression analysis revealed that first-visit fibrinogen values had an effect on some of the PFT (VC<80%, FVC<80%, and FEV_1/FVC<80%, p=0.035, R2=0.351). And that aging has an inversely related effect on diffusion capacity (DLCO<60%, p=0.042, R2=0.561).

A multivariate logistic regression analysis revealed that both the first visit and peak fibrinogen values were significantly associated with abnormal PFT (VC<80%, FVC<80%, FEV_1/FVC<80%, p=0.049, R2=0.272).

Univariate/multivariate analysis for CT scores between 90 and 120 days

The mean CT score was 5.11±7.31. While there were no significant differences in patient characteristics and initial symptoms in patients with a CT score equal to or greater than 1 and those with a value of 0. There was a significant difference in BUN, ferritin, fibrinogen, and CRP values at the time of diagnosis. In addition, there was a significant difference in ferritin, fibrinogen, CRP, and LDH peak values, as well as vital capacity, FEV_1, and FVC between patients with a CT score equal to or greater than 1 compared to those

with a 0. While there were no significant differences in hospitalized or ICU-admitted patients with CT scores equal to or greater than 1 and those with a 0. There was a significant difference in steroid treatment (Table 3).

A univariate logistic regression analysis revealed that age (p=0.009, odds ratio 1.101), BUN (p=0.049, odds ratio 1.223), and fibrinogen (p=0.045, odds ratio 1.005) levels during the first visit and ferritin (p=0.026, odds ratio 1.006), D-Dimer (p=0.036, odds ratio 13.310), CRP (p= 0.035, odds ratio 1.011), and LDH (p=0.021, odds ratio 1.016) peak levels were associated with post-COVID-19 radiological finding on chest tomography. A multivariate logistic regression analysis revealed that ferritin and CRP levels at the

Table 3. Patients' clinical, laboratory, pulmonary function test against CT scores

Variations	CT Score		p
	0	1+	
Gender			1.000[a]
Female (n, %)	8 (20.5%)	17 (43.6%)	
Male (n, %)	5 (12.8%)	9 (23.1%)	
Smoking			0.619[a]
Never Smoked (n, %)	9 (23.7%)	17 (44.7%)	
Smoking/Ex-smoker (n, %)	4 (10.5%)	18 (21.1%)	
1st Symptoms			
Pneumonia			0.151[a]
Non-severe (n, %)	11 (28.2%)	15 (38.5%)	
Severe (n, %)	2 (5.1%)	11 (28.2%)	
Dyspnea (n, %)	7 (18.4%)	11 (28.9%)	0.815[b]
Cough (n, %)	10 (26.3%)	15 (39.5%)	0.250[a]
Fatigue (n, %)	7 (18.4%)	13 (34.2%)	1.000[b]
Headache (n, %)	6 (15.8%)	8 (21.1%)	0.305[a]
Laboratory			
BUN 1st Visit (Mean/Std.Dev.)	11.38±3.33	16.25±7.07	**0.007**[c]
Ferritin (Mean/Std.Dev.)			
1st Visit	133.08±95.04	239.23±192.79	**0.037**[c]
Peak	123.49±104.59	324.70±264.32	**0.002**[c]
Fibrinogen (Mean/Std.Dev.)			
1st Visit	299.67±143.07	596.77±174.21	**0.002**[c]
Peak	398.71±98.82	565.81±170.80	**0.026**[c]
d-dimer (Mean/Std.Dev.)			
1st Visit	0.46±0.29	1.82±4.89	0.285[c]
Peak	0.50±0.26	3.60±8.14	0.069[c]
CRP (Mean/Std.Dev.)			
1st Visit	1.95±2.02	6.49±6.97	**0.006**[c]
Peak	60.17±65.85	125.25±87.64	**0.024**[c]
LDH Pik (Mean/Std.Dev.)	243.77±52.16	383.84±147.40	**<0.001**[c]
Pulmonary Function Tests			
Vital capacity% (Mean/Std.Dev.)	88.2±14.13	76.42±16.47	**0.035**[c]
MMEF% (Mean/Std.Dev.)	109.43±28.62	91.81±29.14	0.084[c]
FEV1% (Mean/Std.Dev.)	98.56±14.35	85.87±16.98	**0.033**[c]
FVC% (Mean/Std.Dev.)	90.99±14.18	78.56±16.50	**0.027**[c]
FEV1/FVC (Mean/Std.Dev.)	90.57±3.92	88.71±6.22	0.351[c]
DLCO% (Mean/Std.Dev.)	84.62±16.27	75.67±14.28	0.115[c]
ICU (n, %)	1 (2.6%)	7 (15.8%)	0.221[a]
Steroid Treatment (n, %)	1 (2.6%)	13 (26.3%)	**0.039**[a]

Values are given in mean and standard deviation or patient count and percentage. Statistically significant values marked bold. [a] Fisher's Exact Chi-Squared test; [b] Yates's Chi-Squared test; [c] Independent Samples T-test.

first visit and 3-month follow-up, as well as peak levels, were significantly associated with post-COVID-19 radiological findings on HRCT ($p<0.001$ and $p=0.05$, respectively). Steroid therapy had an inversely proportional and statistically significant relationship to the patient's CT scores (Table 4).

Table 4. Effects of patients' characteristics on CT score

Variations	p	Odds Ratio (%95 C.I.)	R^2
Age	**0.009**[a]	1.101 (1.024–1.184)	0.298
Smoking	0.938[a]	1.059 (0.249–4.500)	0.000
Laboratory			
BUN 1st Visit	**0.050**[a]	1.223 (1.000–1.496)	0.222
Ferritin	<**0.001**[b]		0.450
1st Visit	0.108[a]	1.005 (0.999–1.010)	0.125
Peak	**0.026**[a]	1.006 (1.001–1.011)	0.264
Fibrinogen	0.055[b]		0.230
1st Visit	**0.045**[a]	1.005 (1.000–1.030)	0.635
Peak	0.053[a]	1.010 (1.000–1.020)	0.340
d-dimer	0.339[b]		0.014
1st Visit	0.078[a]	6.875 (0.806–58.658)	0.222
Peak	**0.036**[a]	13.310 (1.179–150.318)	0.375
CRP	**0.050**[b]		0.136
1st Visit	0.071[a]	1.357 (0.974–1.891)	0.248
Peak	0.035[a]	1.011 (1.001–1.021)	0.189
LDH Peak	**0.021**[a]	1.016 (1.002–1.030)	0.394
Steroid treatment	**p**	**Unstd. Reg. Coefficient**	**R^2**
Dose (mg/day) 49.24±25.01	0.006[c]	–0.297±0.80	0.644

[a] Results of Univariate Binary Logistic Regression analysis are given in p, odds ratio (%95 C.I.), Nagelkerke's R2; [b] Results of Multivariate Binary Logistic Regression analysis are given in p, odds ratio (%95 C.I.), Adjusted R2; [c] Results of Linear Regression analysis are given in p, unstandardized regression coefficient and standart error, Adjusted R2. Statistically significant values marked bold.

Discussion

In this study, we found that 64.5% of patients had persistent COVID-19-associated symptoms at 90–120 days. Moreover, 43 (76.8%) patients had persistent radiological findings while 18 (32.1%) had abnormalities in their PFT. Some patients had persistent post-COVID-19 radiological findings or abnormal PFT but no respiratory symptoms. This suggests that the absence of respiratory symptoms cannot predict the resolution of radiological findings or abnormalities on PFT. The high levels of ferritin and CRP at diagnosis, high peak ferritin and CRP levels during the hospitalization, and high levels of ferritin and CRP at 90–120 days were significantly associated with persistent post-COVID-19 radiological findings. Moreover, the values of both the first visit fibrinogen and peak fibrinogen levels were significantly associated with abnormal pulmonary function. So, we suggest performing PFT in patients with elevated ferritin, fibrinogen, and CRP levels at diagnosis, patients with elevated peak levels of ferritin, fibrinogen and CRP during the hospitalization, or high levels of ferritin and CRP at 90–120 days whether they have persistent post-COVID-19 radiological findings on chest CT or any abnormality in PFT. The findings of our study may be a guide to predict which patients will have persistent radiological findings and losses of lung function at 90–120 days after COVID-19 pneumonia.

The loss of lung function may occur following viral pneumonia. Ventilation and blood gas diffusion abnormalities were detected in some patients after viral pneumonia [5]. During the COVID-19 pandemic, some patients had persistent symptoms, radiological findings, and lung function losses after several months [6]. We do not know whose radiological findings will not completely disappear after COVID-19 pneumonia, and who will not fully recover their respiratory functions. It is not known how long it takes for radiological or functional recovery. Moreover, even if some radiological findings persist, we do not know how they will affect the long-term health of patients. Long-term follow-up of these patients is required to understand the long-term clinical effects of the radiological and functional changes associated with COVID-19 that persist after the acute phase of the disease. However, it is not possible to follow up with every patient during the pandemic period. Therefore, it is necessary to identify patients who need long-term follow-up after COVID-19 pneumonia. This can save healthcare providers energy and labor. We think that this study will contribute to the literature regarding these issues.

Post-COVID-19 symptoms may be present weeks or even months later in some patients. It was previously reported that at least one symptom persisted in 84% of patients 60 days after the onset of COVID-19 [7]. Carvalho-Schneider et al. reported a dyspnea frequency of 30.0%, based on self-report at 2 months after noncritical COVID-19 [8]. In another study, dyspnea frequency was 29.0% based on a modified Medical Research Council Dyspnea Scale score of 2 or higher [9]. Post-COVID-19 symptoms can continue for a long time. In this study, we found that some symptoms persisted in 64.3% of patients 90–120 days after COVID-19. Our study showed that the symptoms were not associated with loss of lung function or persistent radiological findings. We have seen that patients without symptoms may also have a loss of lung function or persistent radiological findings. According to our findings, it is not appropriate to consider patients without symptoms during follow-up have no need for further radiological and functional evaluations.

When the radiological course of the disease is monitored during the acute period of COVID-19 pneumonia, the most common tomographic findings are bilateral subpleural ground-glass opacities and consolidation in the lower zones. Focal edema, organizing pneumonia, and diffuse alveolar damage are the underlying causes of these radiological findings [10,11]. Approximately 4–14 days after the onset of symptoms, the tomographic findings may appear as ground glass opacities which later may turn into consolidation by day 9 or begin to gradually disappear by day 14. However, in some patients, ground glass opacities and reticulations can be seen even in early-control tomography scans [12–14]. There are some reports suggesting that the extent of radiological findings and the severity of the disease rather than the pattern on chest CT is more important for radiological sequela [15,16]. It is important to establish a follow-up strategy to determine whether lung fibrosis is developing in patients with COVID-19 pneumonia and to initiate early and appropriate treatments to prevent lung fibrosis in high-risk patients.

Currently, there is no consensus on the frequency and methods of monitoring pulmonary complications that may occur in patients with COVID-19 pneumonia. Most of the patients have radiological improvement during the early period. Complete radiological recovery is expected within 6 months in patients with mild pneumonia without the need for hospitalization, and within 12 months in moderately severe patients who are hospitalized but do not require the ICU. Restrictive lung disease, decreased diffusion capacity, and fibrosis on tomography may develop in patients with severe disease requiring mechanical ventilation. It is recommended to perform a chest CT at 6 and 12 months after discharge to determine whether fibrotic lesions in the lungs have disappeared, partially resolved, remained unchanged, or advanced. It was recommended to perform the chest CT at 24 and 36 months to evaluate the long-term progression in patients with persistent lesions [17].

In our study, we could not perform the initial radiological evaluation of some patients because they had only received chest X-rays or had suboptimal chest CT scans from different healthcare centers. However, in our study, we found that there was a correlation between the levels of CRP, ferritin, and fibrinogen, which were associated with the severity of the disease, persistent radiological findings, and loss of lung function at approximately 3–4 months. There was also an association between steroid use and the persistence of radiological abnormalities. The use of steroids in severe COVID-19 improved clinical outcomes and it was hypothesized that steroids would improve the radiological findings [18]. Our study's results were not as expected in terms of this issue. We assume that the persistence of radiological findings was not secondary to the use of steroids.

Limitations

This study has some limitations. First of all, it is a retrospective study with a small sample size. Secondly, we could not evaluate a baseline chest CT for patients prior to their COVID-19 pneumonia or the findings during the acute phase of COVID-19 pneumonia. So, it is not certain that all the findings on the chest CT were secondary to COVID-19.

Conclusions

In conclusion, we found that symptoms persisted for approximately 3 to 4 months after COVID-19 pneumonia. Some patients had deficits in lung function tests. There were ground glass opacities and reticulations to varying extents in some patients but these findings were resolved. In particular, we found that the loss of lung function and radiological abnormalities were associated with initial high ferritin, fibrinogen, and CRP values. Therefore, we recommend that patients with high ferritin, fibrinogen, and CRP levels during COVID-19 pneumonia, should be followed up regarding lung function and radiological improvement.

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Correspondence address:
Hülya Dirol
Dumlupınar Boulevard Akdeniz University Hospital
07059, Campus, Antalya, Turkey
E-mail: hulyadirol@akdeniz.edu.tr

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APPLICATION OF A SERIES OF TRICHLOROACETIC ACID TREATMENTS AND ITS EFFECT ON SEBUM LEVELS AND ACNE SCARS: A CASE REPORT

Ewa Adamczyk[1 A,B,D,E]
• ORCID: 0000-0003-1367-6379

Karolina Chilicka[1 A,B,D,E]
• ORCID: 0000-0002-6435-0179

Monika Rusztowicz[1 A,B,D,E]
• ORCID: 0000-0001-6467-7633

[1] Institute of Health Sciences, Department of Health Sciences, University of Opole, Poland

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ABSTRACT

Background: Acne vulgaris is a condition that most often appears during adolescence and can last from a few to over a dozen years. Unpleasant remnants of acne include post-inflammatory hyperpigmentation and acne scars, which often result in a reduced quality of life and can interfere with sufferers' ability to function in society.

Aim of the study: Assess the effectiveness of trichloroacetic acid (TCA) in reducing skin sebum levels (oiling) and smoothing acne scars.

Case report: A 35-year-old female reported excessive oiliness of the skin and acne scars on both cheeks. Before and after TCA treatment, sebum levels were measured on the surface of the skin using a Sebumeter®. In addition, the cheek scars were graded using the Goodman and Baron scale.

Conclusions: After a series of five treatments with TCA, there was a large reduction in sebum on the epidermal surface, and acne scars were reduced on both cheeks.

KEYWORDS: acne vulgaris, TCA, Goodman and Baron scale, acne scars

Background

Acne vulgaris is a dermatosis that most commonly occurs in adolescence and is a problem that affects the majority of young people. However, late forms of this particular disease are starting to be seen more frequently and it occurs in 12 to 51% of adults (acne tarda). It is a chronic skin disease in which the overreactivity of the sebaceous glands, hormonal problems, genetics, inadequate skin care, and the bacteria *Cutibacterium acnes* play an important role. The consequence of the disease is post-inflammatory hyperpigmentation, as well as scars, which affect up to 95 % of acne patients. An additional problem is a reduction in the quality of life, which is associated with a reluctance to live or interact with peers. It can also lead to the development of depressive states, as well as suicidal thoughts [1-7].

Scars of varying depths are formed depending on the type of acne and the wound healing processes. Destruction of collagen in the skin occurs in about 80-90% of cases, which often leads to atrophic scars. Less frequently, there is an overproduction of collagen, which leads to adhesion scars. However, both atrophic and hypertrophic scars can occur in the same patient [8-10]. A scar is a lesion formed on the skin as a result of wound healing processes and can be caused by various types of trauma, such as chemical, thermal, or mechanical. However, in the case of acne, the most common scars are those that occur after the healing of inflammation [11,12]. Various scars, hyperpigmentation, and skin discoloration oc-

cur as a result of long-lasting ill-adapted treatment, improper care, or scratching of pimple lesions. Scarring is most common in juvenile acne, phlegmonous acne, acne conglobata, keloid acne, acne fulminans, and necrotic acne (acne rodens) [13].

Depending on their appearance, scars are classified as decolorized, atrophic, or hypertrophic. Meanwhile, atrophic scars are further divided into ice-pick, boxcar-shaped, rolling, and shallow [14]. Ice-pick scars are deep but narrow, with sharp edges and a narrowing that goes deep into the skin, and have a V-shaped cross-section. The skin looks as if it has been pierced with a skewer or some sharp instrument. Boxcar scars are round and oval in shape. They are also wide and flat, have outlined edges, and a sharply demarcated rim, and are not usually close together. They are most common on the jaw and cheeks and have a square or U-shaped cross-section. Rolling scars are shallow and wide, with a soft edge and gently defined margins. They can merge with other rolling scars and most often form clusters. The cross-section of this kind of scar is similar to the letter M. Shallow-atrophic scars have outlined borders and are most commonly found on the cheeks. Discolored scars are very difficult to remove and they are hyperpigmented, with little or no melanin. They appear as white discoloration of the skin [11-13,15].

Trichloroacetic acid (TCA) is one of the strongest and most effective acids used in cosmetology. Depending on the concentration, it can be used for superficial, medium, or deep peels. The beneficial effects of the acid include improving the appearance and condition of the skin, reducing the intensity of discolorations, and eliminating signs of skin aging. It is also applied as an anti-acne treatment [16].

Scientific research conducted over the years in the areas of acne and scar reduction has demonstrated a need for further investigation of treatment options. In this regard, TCA has been shown to have a positive effect by improving the appearance of the skin (Table 1). It also seems reasonable to use specialized research tools to measure selected skin parameters, such as those applied in the current study.

Abdel et al. compared the effectiveness of 25% TCA and 30% salicylic acid in reducing acne vulgaris and showed that TCA was more effective in the treatment of patients [17].

Argawal et al. used the chemical reconstruction of skin scars (CROSS) technique, applying 100% TCA in the treatment of atrophic scars. Sixteen patients were enrolled at the beginning of the study, but only thirteen of them completed the study. The 100% TCA solution was applied using a toothpick over four sittings at two-week intervals. The results were assessed at a 3-month follow-up visit, and more than 69% of patients responded that the technique was excellent, while 31% reported good improvement [18].

Puri et al. compared 20% TCA and Jessner's solution with 20% TCA alone, for the treatment of acne scars. The study enrolled fifty patients, who were divided into two groups. Group I was treated with Jessner's solution containing 20% TCA, and group II was treated with a 20% TCA peel. Although both groups showed a reduction in scarring, there was no statistically significant difference between the two [19].

Table 1. Details of articles investigating trichloroacetic acid for the treatment of acne

Author	Publication year	Type of study	Number of patients	Treatment	Study limitations
Alba et al. [17]	2015	Single-center, double-blind, split-face RCT.	20	Compared the therapeutic efficacy of 25% TCA peels with 30% salicylic acid peels in patients with acne vulgaris. In all patients, 25% TCA was applied to the right half of the face and 30% salicylic acid to the left half at 2-week intervals for 2 months	Possible occurrence of skin discoloration in people with a dark complexion.
Agarwal et al. [18]	2013	Open-label pilot study	16	The study assessed the efficiency of a technique using 100% TCA in the treatment of post-acne atrophic facial scars. Treatment was over a total of four sittings at 2-week intervals and the results were evaluated at a 3-month follow-up	Lack of a control group and small sample size.
Puri et al. [19]	2015	RCT.	50	Group I had chemical peeling with Jessner's solution followed by 20% TCA. In Group II, chemical peel with 20% TCA alone	Lack of control group.
Kaur et al. [20]	2014	Pilot study	10	Subcision followed by 50% TCA CROSS for three sessions at 4-week intervals. Patients were followed-up monthly for six months	Lack of a control group and small sample size.
El-Domyati et al. [21]	2018	Split-face RCT.	24	Twenty-four volunteers with post-acne atrophic scars were randomly divided into three equal groups. Procedures on each side of the face included microneedling by dermaroller alone or combined with platelet-rich plasma or a 15% TCA peel. Six bi-weekly sessions.	Lack of a control group.

Kaur et al. conducted an important pilot study that included 10 female patients. The study used subcision and 50% TCA CROSS to treat acne scars. Participants were treated three times, with a four-week interval between treatments, and were followed up monthly for six months. Scar grading improved from grade 4 to grade 2 (Goodman and Baron scale) in all the patients, and acne scars were reduced [20].

El-Domyati et al. enrolled twenty-four patients in their study and randomly divided them into three groups (8 persons per group). Procedures were performed on each side of the face, which included microneedling by dermaroller alone or in combination with platelet-rich plasma (PRP) or a 15% TCA peel. Participants received six bi-weekly sessions of treatment. The combination of dermaroller and 15% TCA was found to be more effective in the treatment of post-acne atrophic scars than the use of dermaroller and PRP or dermaroller alone [21].

Aim of the study

The study aimed to assess the effects of TCA on the secretion of sebum on the epidermal surface and the smoothing of acne scars.

Material and methods

The study was carried out between February 2021 and May 2021 at Opole University in Poland. The participant was informed of the purpose of the study and that she could abandon the study at any time, after which she provided written consent to participate. This study was approved by the Human Research Ethics Committee of the Opole Medical School (KB/57/NOZ/2019) and was conducted according to the principles of the Declaration of Helsinki.

Case report

Patient information

The participant was a 35-year-old female, who struggled with excessive facial skin oiliness, and acne scars located on both cheeks. She had been struggling with acne since the age of 15, and at the age of 29 developed severe acne lesions, including papules, nodules, pustules, and cysts with fistulas. As a result of such severe acne symptoms, scarring remained on the woman's cheeks. The patient was treated with isotretinoin for one year.

Inclusion criteria for this study were as follows: no dermatological treatment within 12 months, no current hormonal contraception, age 20-40, and the presence of acne scars.

The study had several contraindications: oral isotretinoin within the last year, other medications that could exaggerate the inflammatory reaction of the disease (corticosteroids, anabolic steroids, and contraceptive pills), sun exposure after the procedure, skin cancers, pregnancy, breastfeeding, viral, bacterial or fungal skin diseases (hepatitis, herpes simplex, warts or molluscum contagiosum), hypersensitivity to acids, skin irritation, active inflammation, psoriasis, atopic dermatitis, damage to the skin, allergy to preparations used in the treatment, surgical treatments of the face or neck, previous radiotherapy or chemotherapy, heart, kidney or liver diseases, tendency to develop keloids, dark brown skin type, outdoor working, bleeding tendency, photosensitivity, immunosuppression, melasma, unable to care for their wounds, and unavailable for follow-up.

Therapeutic interventions

TCA (15%) was used in the study, which included five treatments at 14-day intervals. First, the patient's facial makeup was removed, the treatment area was degreased, and then sensitive areas of the face such as the eye area, the area around the nostrils, the lips, and pigmented moles raised above the skin surface, were protected with Vaseline. Following this, TCA was applied to the entire facial area three times. Once the frost effect (coagulation of proteins) was achieved, the area was washed with cold water. At the end of the treatment, sunscreen with a sun protection factor (SPF) of 50+ was applied to the face. The selected skin parameter measured was sebum on the epidermal surface, which was achieved using the Derma Unit SCC3 (Courage + Khazaka electronic GmbH, Koln, Germany). Among other things, the unit has a Sebumeter®, which measures sebum levels. Measurements were taken before the treatment series and one month after the last treatment. The patient was informed that makeup should be removed from the face, neck, and neckline, and a skincare cream should be applied if necessary, on the evening prior to treatment. On the day of the measurements, washing the face and applying any preparations to the area where the Sebumeter® was to be used was prohibited. The conditions in the measurement room were constant, with a temperature of 22 C° and humidity of 40-50%. The patient was allowed 20-30 minutes to acclimatize to the conditions of the room. Sebum was then measured between the eyebrows, on the chin, on the right nostril, on the left nostril, on the right cheek, and on the left cheek.

For home care, a gentle micellar lotion, a regenerating cream, and an SPF 50+ sunscreen were recom-

mended. The patient was informed that in the first week after the acid treatment, it was necessary to wash her face every 2-3 hours and apply a regenerating cream. Applying foundation to the face was not recommended for the first 7-10 days, as the epidermis peeled very heavily and came off in patches of skin.

The participant was asked not to use new cosmetics or have other cosmetic or dermatological treatments during the study and for 30 days after its completion. Additionally, she was advised to not use a solarium, sauna, or swimming pool, or to take any dietary supplements that might affect the test results.

In addition to measuring sebum levels, the Goodman and Baron scale (Table 2), which utilizes a four-point rating system, was used before and after the treatment series. The patient was classified in the third grade on the scale before the study.

Table 2. The Goodman and Baron scale

Severity of acne scars	Type of acne scars	Number of skin lesions from 1 to 10	Number of skin lesions from 11 to 20	Number of skin lesions over 20
1	Mild atrophic acne or existing skin erythema and skin hyperpigmentation at the site of injury	1 point	2 points	3 points
2	Shallow and extensive atrophic scars up to 5 mm deep	2 points	4 points	6 points
3	Deep, extensive atrophic scars	3 points	6 points	9 points
4	Hypertrophic scars and keloids	6 points	12 points	18 points

Follow-up and outcomes

After applying a series of five cosmetic treatments using TCA (15%), the skin parameters improved very well (Table 3) and the Goodman and Baron scale improved from 3 to 2. There was also a reduction in the amount of sebum on the surface of the epidermis: between the eyebrows from 160 to 111 (μg/cm^2), on the chin from 198 to 139 (μg/cm^2), on the right nostril from 187 to 123 (μg/cm^2), on the left nostril from 192 to 130 (μg/cm^2), on the right cheek from 205 to 132 (μg/cm^2), and the left cheek from 201 to 139 (μg/cm^2).

Table 3. Sebum levels before and after the treatment

Area of measurement	Sebum level before the treatment [μg/cm^2]	Sebum level 30 days after the end of the treatment (μg/cm^2)
Between the eyebrows	160	111
On the chin	198	139
On the right nostril	187	123
On the left nostril	192	130
On the right cheek	205	132
On the left cheek	201	139

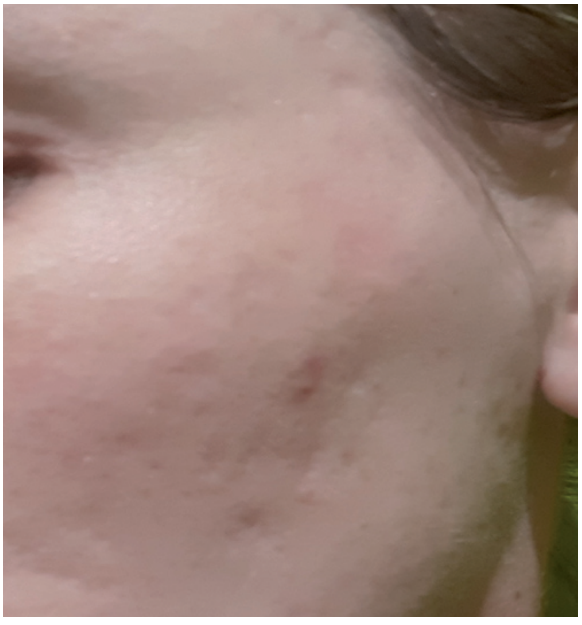

Figure 1. The patient's face before starting trichloroacetic acid treatment

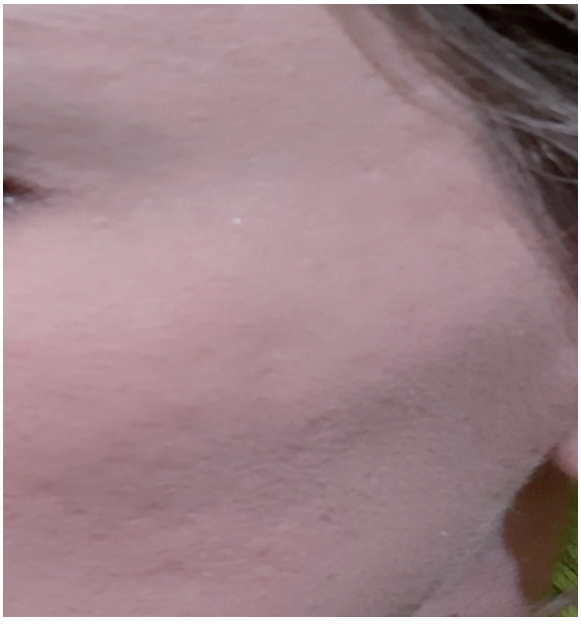

Figure 2. The patient's face after trichloroacetic acid treatment

Discussion

TCA is the strongest organic acid used to exfoliate the epidermis and reduce acne scars. It exfoliates deeply after several layers of it have been applied, and then penetration into the papillary layer of the dermis occurs. Coagulation of the epidermal proteins then occurs, resulting in a visible whitening of the surface of the skin, the so-called frost. The skin is erythematous for a few days and may also be swollen, and there is strong exfoliation (flakiness) of the epidermis. In addition to acne scar reduction, TCA is used to improve the quality of mature skin, smoothing out fine wrinkles, and reducing discoloration. Kubiak et al. compared the effects of glycolic acid (GA) and 35% TCA in a study conducted on 40 women. They found that TCA was more effective in reducing wrinkles and improving the quality of mature skin [22]. Garg et al. compared the effectiveness of different acid peel combinations in reducing melasma. They divided 30 patients into group A, who were treated with a 35% GA full-face peel, and groups B and C, who were treated with a 35% GA full-face peel followed by a 10% or 20% TCA spot peel, respectively, once every 15 days. At the end of the study, they found no difference between any of the groups, although the acids had a positive effect on reducing melasma in the test subjects [23].

Many researchers have used combined methods, such as microneedling and the application of cosmetic acids. Kontochristopoulos et al. used microneedling and 10% TCA on infraorbital dark circles, in 13 female patients. They were treated with a handheld automatic microneedle therapy system along with the topical application of a 10% TCA solution to each infraorbital area for five minutes. The study showed very promising results and very few side effects were recorded [24]. Al-Hamamy et al. used a 25% TCA superficial peel and dermasanding on thirteen patients (nine females and four males) with acne scars, and the treatments provided good results [25]. Bhardwaj et al. used 100% TCA on twelve patients with predominant atrophic ice pick post-acne scars. Eight out of ten patients were evaluated and the results were positive, with a 50 – 70% improvement and no significant side effects observed [26]. Garg et al. used microneedling and 15% TCA on 50 patients with atrophic acne scars, which are particularly difficult to treat. The treatments were performed over six sessions with a 2-week interval and the results were very good. Of 16 patients with Grade 4 scars, 10 (62.5%) improved to Grade 2, and 6 (37.5%) improved to Grade 3 [27]. Mumtaz et al. compared intra-dermal PRP (group A = 46 persons) with 50% TCA (group B = 46 persons) using the CROSS technique on atrophic acne scars. The study showed that the PRP was better than 50% TCA in reducing atrophic acne scars [28].

Limitations

The study was limited to a single female, which should be extended in the future to include more participants and genders, as well as a placebo group. Also, the study included only one concentration of TCA. Future studies should encompass a range of TCA concentrations, and use acid treatment in combination with other treatments such as radiofrequency microneedling, hydrogen purification, and microdermabrasion. This would allow for the assessment of a combination of two treatments and would help to determine if such an approach would improve acne scar reduction.

Conclusions

Treatment with TCA had a positive effect on reducing and smoothing out acne scars. There was also a reduction in sebum on the epidermal surface of the patient's skin. Nonetheless, it should be highlighted that cosmetic treatments cannot replace dermatological treatment under any circumstances.

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Correspondence address:
Karolina Chilicka, PhD
Institute of Health Sciences
University of Opole
ul. Katowicka 68
45-060 Opole, Poland
E-mail: karolina.chilicka@poczta.onet.pl

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