

Analysis of the conditions of quality of life in patients with intermittent chromia undergoing supervised treadmill training

(Analiza uwarunkowań jakości życia u chorych z chromaniem przestankowym poddawanych nadzorowanemu treningowi na bieżni)

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Abstract – Introduction: Cardiovascular system disorders have recently become more popular for people explore the quality of life of patients. Holistic assessment of their condition is not only to the biological sphere, but also focuses on the patient's well-being and functional abilities.

Aim of the study. The subject of the study was an analysis of predictors of life's quality for patients with intermittent claudication undergoing supervised treadmill training. The research described the relationship between the training change in the distance of claudication and the patient's current well-being.

Material and methods. The study included 19 people with intermittent claudication treated at the Angiologist Clinic of the University Hospital in Krakow. The research was last from 03.2017 to 04.2018. The inclusion criterion was the confirmed diagnosis of PAD in the Rutherford 2 and 3 scale. The patients have undergone supervised treadmill training for 3 months (3 trainings a week, total 36). The patient continued his effort on the treadmill until a medium intensity pain appeared, then he rested until the pain subsided completely. In order to assess the current well-being of the patients, an original quality of life questionnaire was made before the training, after 18th and 36th training.

Results. There was a significant difference in the assessment of life satisfaction between the first and third measurement ($p = 0.048$), the average difference was about 10 pts to 175. There was a positive relationship between the distance change and the quality of life ($p = 0.02$). The linear equation regression was determined, which allowed to determine the influence of such variables as: age, sex, smoking status, BMI, duration of the disease on improving the quality of life of patients with intermittent claudication undergoing supervised treadmill training.

Conclusions. The post-training improvement of claudication distance improves the quality of life in patients with atherosclerosis of the lower limbs. It is a strong argument that supervised treadmill training should be a one of the important components of the conservative treatment of people with peripheral artery disease.

Key words - atherosclerosis, intermittent claudication, supervised walking training, quality of life.

Streszczenie – Wstęp. Zaburzenia układu sercowo-naczyniowego w ostatnim czasie stały się obszarem zainteresowań osób skupiających się na ocenie jakości życia pacjentów. Holistyczna ocena stanu pacjenta sprowadza się nie tylko do sfery biologicznej, ale także skupia się nad samopoczuciem i możliwościami funkcjonalnymi chorego.

Cel pracy. Celem pracy była analiza predyktorów jakości życia u pacjentów z chromaniem przestankowym poddawanych nadzorowanemu treningowi na bieżni. Badania miały opisać związek pomiędzy treningową zmianą dystansu chromania, a aktualnym samopoczuciem chorego.

Materiał i metody. Do badań włączono 19 kolejnych osób z chromaniem przestankowym, leczonych w Poradni Angiologicznej Szpitala Uniwersyteckiego w Krakowie. Badania prowadzono w okresie od 03.2017 do 04.2018. Kryterium włączenia do badań stanowiło potwierdzone rozpoznanie PAD w skali Rutherforda 2 i 3. Pacjenci zostali poddani nadzorowanemu treningowi na bieżni przez okres 3 miesięcy (3 treningi tygodniowo; łącznie 36). Chory kontynuował wysiłek na bieżni do pojawienia się bólu o średnim natężeniu, następnie odpoczywał do całkowitego ustąpienia dolegliwości bólowych. W celu oceny aktualnego samopoczucia chorych, przeprowadzono autorski kwestionariusz jakości życia przed rozpoczęciem treningu, po 18 i 36 treningu.

Wyniki. Stwierdzono występowanie istotnej różnicy w ocenie satysfakcji życiowej między pierwszym i trzecim pomiarem ($p=0,048$), przeciętna różnica wyniosła ok. 10pkt na 175. Wykazano występowanie dodatniej zależności między wielkością zmiany dystansu, a poprawą jakości życia chorego ($p= 0,02$). Wyznaczono równanieregresji liniowej, które pozwoliło określić wpływ takich zmiennych jak: wiek, płeć, status palenia, BMI, czas trwania choroby na poprawę jakości życia pacjentów z chromaniem przestankowym poddawanych nadzorowanemu treningowi na bieżni.

Wnioski . Potreningowa poprawa dystansu chromania wpływa na poprawę jakości życia u pacjentów z miażdżycą kończyn dolnych. Wzmacnia to argument o zasadności rozpowszechnienia nadzorowanego treningu na bieżni, jako jednej z ważnych składowych leczenia zachowawczego osób z miażdżycą zarostową kończyn dolnych.

Słowa kluczowe – miażdżycza zarostowa, chromanie przestankowe, nadzorowany trening marszowy, jakość życia.

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- A. The idea and the planning of the study
- B. Gathering and listing data
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I. INTRODUCTION

Atherosclerosis

Atherosclerosis of the arteries of the lower limbs occurs in 20% of Europeans and North Americans in the group over age 55 . year of life. The incidence of this disease increases with age. Above 70 years of age, affects up to 60% of the general population [1] Atherosclerosis of the arteries of the lower limbs contributes to the gradual narrowing, and consequently to the complete closure of the main vessels of the lower limbs . Atherosclerosis is a multifactorial and long-lasting process, during which chronic inflammation occurs at each stage [1 , 2]. The individual course and the extent of the disease are influenced by co-existing individual components and environmental [2 , 3]. The main factor increasing risk of atherosclerosis of the lower limbs, even 7 times, there is smoking tobacco. Risk depends from amounts smoked cigarettes within day and increases along with

the number Package in relation to years [4]. Of course, all classic factors that cause atherosclerosis are important: age, male gender, black race, obesity, sedentary lifestyle, chronic stress, hypertension, hyperglycemia, hyperlipidemia , prothrombogenic disorders [1] .

Crunching punches

One of the main symptoms of lower limb ischemia are caused by atherosclerosis, intermittent claudication is manifested SIU muscle pain and discomfort [3]. The degree of atherosclerosis can be determined using the Fontaine or Rutherford classification [3] . The pain is the result of an imbalance between muscle demand for oxygen and nutrients , and the possibility of supply . Narrowed vessels prevent proper blood flow, necessary for muscle work, for example during walking. Other causes of the occurrence of intermittent claudication include: inflammation, vascular dysfunction, decreased microvascular flow, impaired angiogenesis and altered skeletal muscle function [5] . The ischemic muscle causes pain that forces the patient to stop. Ailments usually appear in the region of the lower leg, less often thighs, buttocks or the entire lower limb, depending on the place of narrowing. During rest, tissues are re-infused (reperfusion) , which translates into relief of symptoms and enables the continuation of the physical activity undertaken [3,5] .

The contemporary principles of diagnosis and treatment of ischemia of lower limbs on the atherosclerotic background are based mainly on *Trans Atlantic Inter- Society Consensus* (TASCII) [3]. This document includes the selected clinical character of atherosclerosis of the lower limbs (including, severe and critical lower limb ischaemia) [3].

Atherosclerosis of the lower limbs can lead to limb loss and, on the other hand, contribute to the occurrence of cardiovascular events. The modification of risk factors for the development or severity of atherosclerosis is a starting point. This includes smoking cessation [4] and reduction of excess adipose tissue [3]. Important elements of the therapy are: control of blood pressure [6] and blood glucose [7]. Comprehensive treatment should include: taking antiplatelet drugs [8] , the use of angiotensin- converting enzyme inhibitors [6,9] and preparations lowering level lipids in the blood [10]. Another element of treatment of changes resulting from ischemia on the background of atheroma is physical activity [11,12].

Training on the treadmill

According to TASC II recommendations, based on EBM, Class 1A, the patient should undergo supervised training for a period of 12 weeks, 3 times a week for about 30-60 minutes. The training intensity occur in the umbilical cord of the patient feeling pain moderate in severity (4 in 5 level scale according to American College Sport Medicine) [3, 12]. Such pain results in a break in walking and a rest phase before co- incidental activity . And not supervised training, as a treatment of intermittent claudication is in recommendations of Class II B. Regular walking training on the treadmill increases the distance of claudication, but also contributes to the creation of collateral circulation at the stenosis site [3,11-14]. The above-mentioned treatment methods can be included in conservative methods. Invasive treatment endovascular, should be used in patients in whom conservative treatment is not effective [15] . An indication that is synonymous with endovascular procedures is critical limb ischemia. When choosing a method of surgical treatment of patients with intermittent claudication, the principle of a good clinical effect should be followed, with a relatively low risk of complications [3].

Quality of life in intermittent chromanium

Disorders of the cardiovascular system have become an area of interest researchers focusing on the quality of life of patients. The overall assessment of the patient's condition is not limited to the somatic sphere , but also focuses on the self- assessment and functional possibilities of the patient. The study of the quality of life in an interdisciplinary approach has gained in importance over the last decade and has contributed that the patient may feel an active participant in the treatment process [16]. The progress of medicine has increased the average life expectancy . Longer life of patients, however, cannot be considered the only element to evaluate the effectiveness of the treatment. Thus, another challenge appeared - improving the quality of life as an important determinant of the effectiveness of treatment.16]

The quality of life is the perception of the individual's own life situation in the context of cultural conditions and the system of values in which he lives and in connection with its goals, expectations, standards and interests [17]. It can be concluded that this concept refers to the whole of human life in all its dimensions. This assessment of existence often depends on experience and expectations of the patient [1, 8, 19, 20]. It was also shown that assessment of the severity of disease symptoms is important to deter-

mine life satisfaction [20]. There are different methods and techniques used for assessing the quality of that life. One of them is the study of these questionnaires[18]. Patients with atherosclerosis of the lower limbs, as by disease, they assume social consequences: impossibility of fulfilling the existing social roles, resignation or conversion of work, or limiting contacts with family and friends [23].

When choosing a treatment method, attention is paid not only to the efficacy, but also to its reception by the patient [21]. In the treatment of patients with atherosclerosis of the lower limbs there is no one effective standard of treatment for all patients [3] . In numerous studies have shown the effectiveness of walking training in the extension of the painless distance , in patients with intermittent claudication [3,11,12,13].

In the own study an analysis of the quality of life conditions in patients with intermittent claudication, subjected to supervised treadmill training. The study focuses on the assessment of quality of life factors such as gender, age, time of disease, smoking status or elongation of claudication distance under the influence of training. In the study describe the relationship between no change in the training of claudication, and the current well-being of the patient.

II. MATERIAL AND METHODS

The material for the study was 24 consecutive people with intermittent claudication, patients of the Angiological Clinic at 8 Skawińska Street in Krakow. Patients were referred to march training by an angiologist . The study covered the period from March 2017. April 2018. The inclusion criterion for the study was the incidence of arteriosclerosis obliterans of lower limbs on a scale Rutherford 2 and 3. Disabled persons in whom diagnosis of atherosclerosis extent covered by Rutherford 4-6. The study also did not qualify people who were scheduled for revascularization treatment of lower limb arteries in the next 3 months, patients currently being treated with cilostazol . The following factors of exemption were: diseases of the musculoskeletal system which significantly impair walking training; acute coronary syndrome in the last 6 months; pulmonary embolism in the last 6 months; stroke in the last 6 months; current use of oral adrenal steroids; use of oral adrenal steroids in the last 6 weeks [3,11,12]

In the patient, qualified for supervised walking training, an interview was conducted based on Patient's card with intermittent claudication (this card contained questions about basic personal data, comorbidities, but above all fo-

cused on determining the time of onset and localization of symptoms of claudication. An important element was the definition of possible contraindications to the effort) and the author's quality of life questionnaire. This questionnaire, prepared by specialists in the clinic NZOZ Angiomed in Krakow, contained 25 questions about the occurrence of characteristic symptoms of claudication and the patient's frame of mind in the last two weeks. Each question contained seven possible responses scored in scale from 1-7. The higher the sum of points, the better the quality of life of the patients. The maximum number of points was 175.

After the analysis of the interview, exclusion of contraindications to the effort and the measurement of arterial pressure and saturation, the first march test was performed to determine the distance of claudication using the Gardner protocol. This test was treated as familiarizing the patient with the principles of moving on the treadmill (the stage of familiarization), the result was not taken into account in the subsequent analysis of the data. The patient started at an angle of 0% at a constant speed of 3.2 km / h. After every 2 minutes the angle of inclination increased by 2%. At the time of appearance of complaints described in "2" according to ACSM, the patient informed about it. The march was continued until the symptoms described by ASCM appeared as a very severe pain. After the test was stopped, blood pressure and saturation were again checked. The patient rested in a sitting position to reduce pain.

The next meeting took place after 2 days. The course of the test looked exactly like during the first attempt. After two meetings, the participants were transferred to the proper part of the supervised training on the treadmill, which was based on 36 training sessions. The patient held them regularly in the form of three meetings a week (Monday, Wednesday, Friday). Everyone began and ended with the measurement of arterial pressure and saturation. During the session lasting an average of 40-60 minutes, the patient made further marching attempts at the speed of 3.2 km / h and the individually applied angle of the treadmill (with the assumption that 1% is an additional 0.01 m in the distance covered, compared to the distance traveled at 0%). He covered the distance to the occurrence of pain with medium intensity (4 according to ACSM). Then he went to the rest phase. Each subject rested according to individual needs. After eliminating claudication, the patient made another attempt to walk. On average, the patient underwent 5 marching trials during one meeting.

During training 18 and 36, the quality of life questionnaire was again carried out.

After 36 meetings, control of the chroma distance was made using the Gardner protocol mentioned above.

There were 24 people in total, 5 people for reasons of: disease progression (n = 1), family (n = 2), unknown (n = 2), resigned from participation in the study. Finally, 13 (68%) men and 6 (32%) women were assessed. The average age of the respondents was 69.8 years ($OS = 7.6$), while in the group of women it was 66 years and in the group of men 71.5 years. There was no significant difference in the age distribution in depending on the sex of the subjects ($p = 0.15$). The mean time from the first symptoms of claudication was 4.3 years ($OS = 4.4$). The shortest time of occurrence of symptoms was declared as 0.5 years, while the longest was as 17 years. 3 people have never smoked, 11 people are exponents, 5 people are active smokers. In terms of BMI, the group can be characterized as follows: 9 are people in the norm by weight, 8 are overweight and 2 are obese.

III. RESULTS

The Statistica program was used to develop the following results

On the basis of statistical analysis, there was no significant difference in the assessment of patients' quality of life between the first and the second measurement ($p = 0.16$) and the second one, and third ($p = 0.29$). Accordingly, the increase in the first case was 5.4 points, in the second 4.4 points. There was a significant difference in the assessment of life satisfaction between the first and third measurement ($p = 0.048$). There was a significant improvement in quality of life for patients with intermittent claudication. The average difference was 9.8 points to 175. It was examined whether the effect of improving the quality of life, understood as the point difference between the first and the third measurement, is different in the group of men and women. After the student *t* test for dependent tests, no significant difference was found in the improvement of the quality of life of patients with intermittent claudication in the group of men and women ($p > 0.05$). Using the one-way analysis of variance, it was checked whether the effect of improving the quality of life is dependent on the BMI category. After the analysis, no significant difference was found ($p > 0.05$). In the group of people with a weight in the standard there was an increase in the quality of life by 6.7 points, overweight people participating in walking training assessed this improvement at 12.5 points, while patients obese at 13 points. It was examined whether the duration of the disease differentiates the quality of life of patients before starting super-

vised walking training. There was no significant relationship ($p > 0.05$) between the duration of the disease, and self-assessment of the quality of life of the subjects before rehabilitation. It was also not shown that the duration of the disease differentiates the magnitude of improvement on the quality of life scale ($p > 0.05$). In order to get an answer to the question whether the status of smoking determines the initial quality of life of patients and whether it translates into its improvement, a one-way analysis of variance was used. In both cases, no significant dependencies were found.

The status of smoking does not affect self-assessment of quality of life before marching training ($p > 0.05$) and does not differentiate the magnitude of life satisfaction improvement in the context of intermittent claudication ($p > 0.05$). The distance of claudication was then evaluated. The question was asked whether sex is a factor differentiating this distance. The student's t test did not show a significant difference ($p > 0.05$) in the distance that the patient can travel painlessly in the group of men and women. Another factor taken into account in the context of the distance of claudication was the duration of the disease. It was assumed that this is the period from the onset of its first symptoms. Initially, it was checked whether this period is different for men and women. On the basis of the t -Student test, no significant difference in the duration of claudication was found in the examined women and men ($p > 0.05$). The Pearson's linear correlation did not show a significant relationship between the distance of claudication and the duration of the disease ($p > 0.05$). It was also tested whether the smoking status affects the length of the claudication distance. Analysis of variance did not show a significant difference ($p > 0.05$) in distances, depending on whether the patient was a current smoker, stopped smoking or never smoked. The above predictors were also referred to the amount of elongation of the claudication distance in respondents. It was tested whether sex differentiates this improvement. Using the Student's t -test, the following data were obtained: the distance extension in the group of men was 0.03 m and the group of women 0.09 m. The difference was not statistically significant ($p > 0.05$). The influence of the duration of the disease and the status of smoking on increasing the distance that the patient can overcome the symptoms of claudication were also evaluated. Due to the fact that they are a different type of data, the Pearson correlation coefficient was used in the first situation, and the analysis of variance was carried out in the second case. In both situations, no significant differences were found in relation to the improvement in the distance of claudication ($p > 0.05$). Thus, the duration of the disease and the status of smoking do not affect the

magnitude of the change in lengths done patients with obliterative atherosclerosis of the lower limbs. The next step was to examine whether the duration of the disease and the status of smoking modify the relationship between the initial distance of claudication and the assessment of the quality of life of patients before starting walking training. When analyzing the multiple correlation coefficient, no relationship was found between the variables tested; that is, the duration of the disease is not a factor modifying the relationship between the distance of claudication and the quality of life ($p > 0.05$). Pearson's linear correlation checked the effect of smoking status on the relationship between the length of the patient's initial transition to the occurrence of claudication and the self-assessment of the quality of life. There was no significant relationship between the abovementioned variables in the tobacco smoking groups ($p > 0.05$). The last aspect subject to statistical analysis was the relationship between the size of the elongation of the claudication distance and the improvement of the value on the quality of life scale. There was a significant relationship between the size of the distance change and the improvement of the patient's quality of life. A positive correlation value indicates that with the increase of the length traveled, the improvement of the quality of life ($p = 0.02$) increases.

The linear regression equation was determined. The description of the dependent variable was analyzed, which was the quality of life, by independent variables such as: sex, duration of the disease, smoking status and BMI value. There was no significant influence of the abovementioned independent variables on the improvement of the quality of life ($p > 0.05$).

$$\text{IMPROVING QUALITY OF LIFE [point]} = -21.9 + 13.6 * \text{sex} - 0.7 * \text{duration of illness [years]} + 2.2 * \text{smoking status} + 4.4 * \text{BMI}$$

IV. DISCUSSION

Atherosclerosis of the lower limbs leads to chronic limb ischemia in as many as 98% of cases. Epidemiological data show that it most often affects people over 60 years of age. The disease is chronic, which I associate with the need for long-term treatment. One of the most characteristic symptoms is intermittent claudication, resting pain or the occurrence of ulcers and tissue necrosis. Due to the persistence of complaints, it causes a deterioration in the quality of life of patients [21-24].

In this context, numerous studies were conducted in patients with atherosclerosis of the lower limbs [24-28]. They observed a decrease in the level of life satisfaction in compared to healthy people of a similar age. Already in 1997 Chetter *et al.* in their studies, on a group of 235 patients, they showed a decrease in the quality of life in all aspects. The severity of the decline in life satisfaction was dependent on the degree of underdevelopment [24]. Also Seabrook *et al.* confirmed that after surgical treatment of critical limb ischemia, the poor assess the possibilities of independent self-care and mobility, compared to the control group, which were healthy people. [25] Quality of life was also evaluated in the multicamene , multicentre BASIL trials . Using the SF-36 and EuroQoL questionnaire , patients with lower limb ischemia were examined, both surgically treated and endovascular were examined. In the period of 5.5 years, 452 people with ischemia in the arterial femoral and popliteal area evaluated the quality of life before and after treatment. In both groups, the initial life satisfaction was assessed as low. After treatment, the result improved in two groups [26,27]. On the other hand, Cnotliwy *et al.* . carry out a study on a group of people who have been subjected to multiple corrective surgery due to illness. The results were obtained saying that the quality of life of the patients decreases with the increase in the number of patients [28]. The examples mentioned above referred to the surgical treatment of patients with atherosclerosis of the lower limbs.

Kowalik's research from 2004 compared the quality of life between people with peripheral atherosclerosis, treated surgically and conservatively. Patients undergoing conservative therapy assessed life satisfaction better than patients after surgery [29].

For many years there has been a discussion about the selection of the most effective form of conservative treatment of patients with intermittent claudication. There is no single protocol with clearly defined rules on: intensity of effort, frequency, speed and duration of physical training. Most of the tests refer to the effort on the treadmill, but despite the doctors' recommendations, the availability of this type of equipment is lower than that used for bicycle ergonomics used for cardiological information [1].

Tuner *et al.* Studies in their own compared the effectiveness of a workout on a movable treadmill ergonomic bike in patients with intermittent claudication. They showed that this form of training can be an alternative for people who have treadmill training, e.g. due to the disturbances in the walking pattern, it is impossible. They also stated that this form of exercise increases the metabolic response , as well as the cardiovascular system response, what is more, it is better tolerated by the patients [30].

In his doctoral thesis, Kowalski compared the effect of training on the treadmill and the cycloergometer . Both forms of training proved to be equally effective in increasing the distance of claudication in patients with atherosclerosis of the lower limbs [31].

Our own research, conducted on a group of 19 patients with peripheral atherosclerosis, concerned the assessment of quality of life predicates in patients with intermittent claudication subjected to supervised treadmill training. The influence of sex, age, duration of the disease as well as smoking status on the initial quality of life and the distance of claudication were assessed . They also studied how 12-week supervised treadmill training (taking into account these factors) affects the improvement of the quality of life and lengthening the painless march. It has been shown that training on the treadmill contributes to the improvement of quality , understood as the difference in the assessment of life satisfaction before and after rehabilitation. Improvement is positively correlated with distance elongation. Together with painless extension of claudication distance increases the improvement in the assessment of a broad sense of life satisfaction.

The aforementioned studies conducted by Kowalski also analyzed the aspect of improving the quality of life in patients with intermittent claudication, under the influence of physical training, as a form of conservative treatment. Both people training on the treadmill and cycloergometer has improved in well-being. People training on a stationary bicycle had greater improvement in the possibility of overcoming longer distances without the need to stop [30].

On the basis of the above examples, it can be concluded that the topic concerning patients with obliterative atherosclerosis is the subject of interest of many researchers. Although the research answers many questions, there are still many unknowns. Therefore, this topic is open and creates opportunities to search for new aspects, both research and clinical (application).

Own tests, due to the duration of supervised treadmill training, included a small sample, which is why some of the observations are statistically insignificant. Due to the emerging trends, research is continued and expanded with new aspects, including for assessing the improvement of the ability to perform work in mechanical terms by a patient with intermittent claudication.

V. CONCLUSIONS

- Atherosclerosis of the lower limbs, as a chronic disease, affects the quality of life of patients. In planning the treatment of these people should take into account not only the effectiveness, but also the issue of receiving therapy by the patient.
- Training on the treadmill translates to lengthening the painless walking distance. These results encourage the introduction of walking training as a basic form of treatment for patients with intermittent claudication.
- Post - workout improvement of claudication distance improves the quality of life in patients with atherosclerosis of the lower limbs. This strengthens the argument about the legitimacy of the prevalence of supervised treadmill training as one of the important components of the conservative treatment of people with obliterative atrophy of the lower limbs.

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