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ASSESSMENT OF THE QUALITY OF LIFE OF PATIENTS WITH ISCHEMIC DIABETIC FOOT SYNDROME AFTER ENDOVASCULAR TREATMENT

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The clinical course of diabetic foot syndrome negatively affects the quality of life of patients. Assessment of quality of life will help ensure better care and treatment of patients with this pathology and reduce the likelihood of severe complications of diabetes mellitus. The purpose of the study was to evaluate the quality of life of patients with the ischemic form of diabetic foot syndrome after endovascular treatment by various methods. Patients with the ischemic form of diabetic foot syndrome, depending on the method of balloon angioplasty of occlusive-stenotic lesions of the popliteal and tibial arteries, were divided into two study groups. Patient's quality of life was assessed using the SF-36 questionnaire before, 7–10 days, and 6 months after surgery. 38 (65.5 %) patients of the first and 34 (63.0 %) patients of the second group, who were included in this study, passed all stages of the survey within 6 months of observation. The obtained data make it possible to state that balloon angioplasty of the popliteal and tibial arteries in patients with the ischemic form of diabetic foot syndrome positively affects the patients' subjective assessment of their physical and mental health state both immediately after such operations and 6 months after their implementation.

Key words: assessment of quality of life, physical and mental state, balloon angioplasty, ischemic form of diabetic foot syndrome.

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ОЦІНКА ЯКОСТІ ЖИТТЯ ПАЦІЄНТІВ З ІШЕМІЧНОЮ ФОРМОЮ СИНДРОМУ ДІАБЕТИЧНОЇ СТОПИ ПІСЛЯ ПРОВЕДЕННЯ ЕНДОВАСКУЛЯРНОГО ЛІКУВАННЯ

Клінічний перебіг синдрому діабетичної стопи негативно впливає на якість життя пацієнтів. Оцінка якості життя допоможе забезпечити кращий догляд та лікування хворих з такою патологією та зменшить вірогідність виникнення важких ускладнень цукрового діабету. Метою даного дослідження було оцінити якість життя пацієнтів з ішемічною формою синдрому діабетичної стопи після проведення ендоваскулярного лікування різними методами. Пацієнти з ішемічною формою синдрому діабетичної стопи у залежності від методу проведення балонної ангіопластики оклюзійно-стенотичних уражень підколінних і гомілкових артерій були розподілені на дві групи дослідження. Оцінку якості життя хворих проводили за допомогою опитувальника SF-36 перед операцією, через 7-10 діб та 6 місяців після неї. Всі етапи опитування протягом 6 місяців спостереження пройшли 38 (65.5 %) пацієнтів першої і 34 (63.0 %) хворих другої груп, які були включеними у дане дослідження. Отримані дані, дають змогу стверджувати, що проведення балонної ангіопластики підколінних і гомілкових артерій у хворих з ішемічною формою синдрому діабетичної стопи позитивно впливає на суб'єктивну оцінку пацієнтами свого фізичного та психічного стану, як безпосередньо після проведення таких операцій, так і через 6 місяців після їх виконання.

Ключові слова: оцінка якості життя, фізичний і психічний стан, балонна ангіопластика, ішемічна форма синдрому діабетичної стопи.

The study is a fragment of the research project "Development of modern scientifically based principles of stratification, monitoring and forecasting of the course of surgical diseases and injuries", state registration No. 0120U101176.

Diabetes mellitus is one of the critical problems of modern medicine and all humanity. The International Diabetes Federation (IDF), in its 2021 report, reports that in 2021 the prevalence of diabetes among the adult population in the world was about 10.5 % (536.6 million people). By 2045, this number will increase to 12.2 % (783.2 million people). The detection of diabetes mellitus is almost the same among both men and women and is most common at 75–79 years. Let's compare the prevalence of diabetes in 2021 among the urban and rural populations. First, it should be noted that it was higher in cities and amounted to 12.1 %, in rural areas – 8.3 %, and in high-income countries (11.1 %) compared to low-income countries (5.5 %). Although between 2021 and 2045, the most significant increase in diabetes prevalence is expected to occur in middle-income countries (21.1 %) compared to high-income (12.2 %) and low-income (11.9 %) countries. The economic component of this problem is also quite important. Thus, in 2021, the economic costs of health care in the world, which are related to diabetes, were estimated at 966 billion US dollars. By 2045, according to expert forecasts, they will reach 1054 billion US dollars [8].

Diabetes mellitus is dangerous for the development of complications. One of the familiar and formidable complications of this disease is the development of diabetic foot syndrome, mainly caused by peripheral neuropathy and occlusive-stenotic lesions of the arteries of the lower extremities. Such pathological injuries cause the appearance of trophic ulcers, necrosis, and gangrene of the foot, which, if the infection spreads, can even lead to limb amputation. 30–80 % of patients with diabetes develop diabetic foot syndrome during their lifetime, a prevalent cause of long-term hospitalisation and even death of patients [2, 3]. Furthermore, in 85 % of cases, purulent-ulcerative foot defects lead to amputations of the lower extremities [12]. Performing high amputations significantly increases the risk of death and the

material costs of treatment. Thus, the five-year death rate of patients with foot ulcers for the first time is 40 %, and they are 2.5 times more likely to die than patients with diabetes without foot lesions [9]. The large number of lower limb amputations performed during the first year in patients with purulent-necrotic complications of the ischemic form of diabetic foot syndrome indicates the importance of following revascularisation earlier to reduce the risk of amputation in the long term [4, 6].

As can be seen from the above, diabetic foot syndrome has a rather negative effect on patients' quality of life, which is closely related to their health. Studies aimed at studying the impact of this syndrome, which was complicated by purulent-necrotic lesions, on patients' quality of life, showed its pronounced negative implications [7]. However, despite the high mortality rate, patients diagnosed with diabetic foot syndrome fear major amputation of the lower limb more than death [10]. Unfortunately, there is insufficient scientific data on the impact of foot ulcers and necroses on the quality of life of patients with diabetes. Therefore, a better understanding of how the course of diabetic foot syndrome affects the quality of life will help to provide better care and treatment for patients with this pathology. Also, assessment of the quality of life can identify gaps in the treatment of such patients, which will help improve its outcomes and ensure a reduction in severe complications of diabetes.

The purpose of the study was to evaluate the quality of life of patients with the ischemic form of diabetic foot syndrome after endovascular treatment by various methods.

Material and methods. An analysis of diagnosis and treatment during 2017–2021 was carried out in the Department of Vascular Surgery of the KP Poltava Regional Clinical Hospital of the Poltava Regional Council. 112 patients with an ischemic form of diabetic foot syndrome in the stage of threatening ischemia were examined. These patients' diagnoses were confirmed by preoperative colour ultrasound angioscanning of the lower extremities and pelvis. We detected occlusions and hemodynamically significant stenoses of the popliteal and tibial arteries, followed by lower extremities and pelvis percutaneous subtraction arteriography. All patients were examined clinically, laboratory and instrumentally. As a result of the examinations, type 2 diabetes mellitus in the stage of compensation and subcompensation was found. These patients included 75 (70.0 %) men and 37 (30.0 %) women, with a mean age of 62.4±2.15 years. Chronic ischemia of the lower extremities of the IV stage, according to the classification of Fontaine-Pokrovsky, was observed in 32 (55.2 %) patients of the first and 30 (55.6 %) of the second research groups. Stage III was observed in 20 (34.5 %) patients of the first and 19 (35.2 %) – of the second group, and II-B stage – in 6 (10.3 %) of the first group and 5 (9.2 %) of the second research group. Balloon angioplasty of the popliteal and tibial arteries was performed in all patients to improve peripheral blood flow in the lower extremities and preserve them. Depending on the method of its implementation, all patients were divided into two study groups. The first group included 58 (51.8 %) patients. Of them, 39 (67.2 %) men and 19 (32.8 %) women underwent balloon angioplasty of popliteal and tibial arteries according to generally accepted standardised methods. The second group of the study included 54 (48.2 %) patients (36 (66.7 %) men and 18 (33.3 %) women) who underwent step-by-step dosed balloon angioplasty of the same arteries according to our proposed method. The essence of this method is that when performing arterioplasty, the pressure in the balloon catheter was gradually increased, followed by a gradual increase in pressure by 1 atm in 1 minute and an exposure of 5 minutes when the required diameter was reached, which should correspond to the internal diameter of the artery under study [1]. In the postoperative period, all patients of both groups received disaggregants, hypoglycemic drugs, antibiotics with consideration of sensitivity, painkillers in the presence of purulent-necrotic complications, and peripheral vasodilators. The effectiveness of surgical treatment was monitored by clinical changes and performed in the early postoperative period on the 2nd and 7th-day ultrasound colour scanning of the arteries of the lower extremities with the determination of the humeral index.

The patient's quality of life was assessed using the SF-36 questionnaire before the start of therapeutic endovascular treatment, before discharge from the hospital on the 7–10th day of the early postoperative period, and six months after this surgical intervention. This questionnaire is widely used as a general indicator of the quality of life in various diseases, including diabetic foot syndrome. It consists of 36 questions, which are grouped into eight scales. After receiving the patient's answers, two parameters can be formed: physical and mental components of health [11]. All stages of the survey were completed during 6 months of follow-up in 38 (65.5 %) patients (22 (57.9 %) men and 16 (42.1 %) women) of the first and 34 (63.0 %) patients (21 (61.8 %) men and 13 (38.2 %) women) of the second groups, which we included in this study. We did not include patients of both groups who, within 180 days after the endovascular intervention, suffered a COVID infection with complications in this study, as some of them developed thrombotic complications. The obtained digital survey results were subjected to statistical research methods.

Results of the study and their discussion. Both research groups obtained patient questionnaire data were analyzed for each parameter. The physical and mental health indicators in the first and second groups of patients were considered separately.

Thus, in the first group of patients, a 2.8-fold increase in the average index of physical functioning after balloon angioplasty was recorded. Namely, from 23.09±1.10 points before surgical intervention to

63.82±3.44 points (p<0.001) after its implementation. 6 months after surgery, this indicator almost did not change and became equal to 61.32±4.26 points on average.

The indicator of role-physical functioning in patients of the first group before endovascular treatment was low and averaged 13.97±2.63 points. After surgery, there was an increase in this indicator by 5.6 times to 77.94±3.46 points (p<0.001). It remained at the same level after 6 months, with an average score of 77.21±4.27 points.

The index of pain intensity in patients of the first group averaged 25.74±1.30 points. However, after the surgical endovascular treatment, it improved 3 times, averaging 78.75±3.05 points (p<0.001). Such an effect of this indicator in persons of this group was maintained for 6 months and was equal to 80.15±3.38 points on average, which was almost 3.1 times higher than the initial value.

General health – the average value of this indicator before treatment was 37.35±1.78 points in patients of the first group and increased by 1.74 times at the time of discharge from the hospital and averaged 64.82±2.07 points (p<0.001), remaining at the same level for 6 months of follow-up almost unchanged and averaged 63.88±2.22 points.

The vital activity index of the patients of the first group before the start of treatment averaged 24.41±1.33 points. However, after performing standard angioplasty, the tibial and popliteal arteries increased 2.45 times and averaged 59.85±2.78 points (p<0.001). After 6 months, this average index reached 61.76±3.03 points, which is 2.53 times higher than the level observed before the start of the surgical endovascular intervention (p<0.001).

In the patients of the first group, before the start of therapeutic endovascular intervention, the social functioning index was equal to 21.69±1.52 points on average and increased by 3.44 times after its implementation and averaged 74.63±3.52 points (p<0.001), but after 6 months of follow-up, this indicator decreased within the statistical error to 71.59±4.12 points.

The level of role functioning in patients of the first group was also low in the preoperative period and averaged 22.55±4.16 points. However, immediately after surgery, it increased 3.43 times, averaging 77.45±3.65 points (p<0.001). Six months after the intervention, a tendency to its decrease was observed, and the average value of this indicator in the patients of the first group was 74.51±5.28 points.

The mental health index in patients of the first group before starting treatment was very low and was at the level of 13.41±1.16 points. After endovascular intervention, it increased 2.54 times and averaged 34.0±1.31 points (p<0.001). The average score in patients in the first group remained almost unchanged 6 months after the intervention, averaging 33.65±1.64 points.

In patients of the second group, who underwent prolonged dosed balloon angioplasty of the popliteal and tibial arteries, the average value of the physical functioning index in the preoperative period was 24.87±2.02 points. After the therapeutic endovascular operation, it increased 2.4 times to 60.04±3.13 points (p<0.001). During the next 6 months of follow-up of these patients, the indicator of physical functioning increased, reaching an average of 75.13±2.73 points (p<0.001). Compared to the initial one, it increased by 3 times.

The index of role-physical functioning in the patients of the second group before the start of surgical treatment was very low – at 13.16±3.23 points. However, after the surgical intervention, it increased by 5.2 times to an average of 68.42±3.85 points (p<0.001). The increase continued further. During the 6 months of observation in the patients of the second group, it reached 6.45 times higher than the initial level and became equal to 84.87±3.72 points on average (p<0.001).

The average pain intensity in patients of the second group before surgical endovascular intervention averaged 26.12±2.67 points. However, after the operation, it changed for the better. It significantly increased before discharge from the hospital. It was equal to 72.89±3.65 points on average (p<0.001) and continued to improve during 6 months of follow-up to an average of 88.88±2.97 points (p<0.001) while increasing 3.4 times compared to the initial value (p<0.001).

The indicator of general health status in patients of the second group increased from an average of 37.58±1.44 before performing surgical interventions to 55.82±2.19 points (p<0.001) at the end of hospitalization. After 6 months, the average value of this indicator increased to 63.21±2.11 points (p<0.001) and became 1.68 times higher compared to its initial value.

In the group of patients who underwent dosed balloon angioplasty, the vital activity index before treatment averaged 28.68±1.91 points. This indicator increased by 2.02 times in the early postoperative period and averaged 58.55±2.69 points (p<0.001). After 6 months of follow-up, the average value of the vital activity index increased by another 10 %, reaching an average of 64.34±2.81 points (p<0.05 compared to the average immediately after treatment).

The indicator of social functioning in patients of the second group after endovascular treatment increased in the early postoperative period compared to the same indicator, but before starting treatment by 3.06 times – from 23.36±2.63 points to 71.38±3.43 points (p<0.001). But instead of the tendency to decrease this indicator after 6 months of follow-up, as we observed in patients of the first group, in patients

of the second group, the average value of this indicator for 180 days continued to increase by another 16.5 % compared to the indicator immediately after treatment ($p<0.05$).

The level of the indicator of role functioning in persons of the second group before surgery averaged 20.18±3.21 points. After carrying out restorative endovascular operations in the early postoperative period, an increase of 3.56 times was noted ($p<0.001$). In contrast to patients of the first group, the upward trend continued in the future – up to 6 months of follow-up, averaging 85.96±4.47 points, corresponding to an increase of 19.5 % compared to the average immediately after treatment ($p<0.01$).

The average value of the mental health indicator in patients of the second group also increased immediately after surgery by 2.67 times – from 11.47±1.66 points before the operation up to 30.63±1.69 points ($p<0.001$). It continued to increase to 33.79±1.48 points after 180 days of follow-up, thus achieving an increase of another 10.3 % ($p<0.05$ compared to the indicator immediately after treatment).

The ischemic form of diabetic foot syndrome negatively affects patients' quality of life, which is confirmed by this study [6]. However, to improve treatment results and reduce the risk of lower limb amputations in the long term, patients with the ischemic form of diabetic foot syndrome require therapeutic endovascular surgical interventions earlier, which is consistent with the opinion of other authors [4, 5]. The results of the SF-36 questionnaire conducted in patients with diabetes mellitus and occlusive stenotic lesions of the popliteal and tibial arteries of both groups indicate a significant improvement in the quality of life after performing revascularisation using balloon angioplasty, both after such operations and 6 months after their implementation, which does not contradict the data of other scientists [10]. These changes are especially pronounced in patients of the second group. A comparison of the changes in the physical and mental health indicators of the patients of both groups showed that they were all almost identical before the treatment and testified to their significant limitations in physical activity and psycho-emotional state.

So, the SF-36 questionnaire is a reliable scale for assessing the quality of life of patients with ischemic diabetic foot syndrome both in the preoperative period and after reconstructive operations aimed at restoring patency of the arteries of the lower extremities, including monitoring them in the long term. We support the opinion of Ma Lin et al. [5] that this questionnaire can be used much more widely in the future and with its help it is necessary to develop various types of surgical interventions that will be aimed at improving the quality of life of patients with diabetic foot syndrome.

Conclusions

1. The data obtained with the help of the SF-36 questionnaire make it possible to assert that the implementation of restorative endovascular interventions in the form of balloon angioplasty of the popliteal and tibial arteries in patients with ischemic diabetic foot syndrome positively affects the subjective assessment of patient's physical and mental state, both immediately after such operations and 6 months after their implementation.

2. The positive effect of treatment in patients of the first group remained at the achieved level after 6 months of observation of such indicators of physical health as physical and role-physical functioning and assessment of the general condition and mental health, such as social and role functioning.

3. Patients of the second group noted not only the preservation of positive changes during the 6-month follow-up period. Still, according to most of the indicators, they stated an improvement in their physical and mental health.

The prospects of further research are assessing the quality of life of patients with the ischemic form of diabetic foot syndrome after performing endovascular restorative surgical interventions in the longer term of the study, for example, after 12–24 months with the subsequent analysis of the obtained results.

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THE ROLE OF GROWTH FACTORS IN THE DEVELOPMENT OF LEFT VENTRICULAR DIASTOLIC DYSFUNCTION IN PATIENTS WITH ARTERIAL HYPERTENSION AND TYPE 2 DIABETES MELLITUS

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The role of insulin-like growth factor-1 and transforming growth factor-β1 in the pathogenetic mechanisms of the formation of diastolic dysfunction of the left ventricle of the heart in patients with arterial hypertension and with type 2 diabetes mellitus were studied. 67 patients with type 2 diabetes mellitus and 46 with arterial hypertension and without diabetes mellitus patients were examined. Patients with arterial hypertension with concomitant diabetes mellitus were more marked than the diastolic function of the left ventricle. The relationship between the level of the transforming growth factor-β1 and the diastolic function of the left ventricle is established. In the presence of signs of diastolic dysfunction, the level of this growth factor was significantly higher in both groups of patients. The relationship between the level of insulin-like growth factor-1 and the indicators of diastolic function of the heart has not been established.

Key words: arterial hypertension, diabetes mellitus type 2, diastolic function of the left ventricle, insulin-like growth factor-1, transforming growth factor-β1.

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РОЛЬ ФАКТОРІВ РОСТУ В РОЗВИТКУ ДІАСТОЛІЧНОЇ ДИСФУНКЦІЇ ЛІВОГО ШЛУНОЧКА У ХВОРИХ НА АРТЕРІАЛЬНУ ГІПЕРТЕНЗІЮ З ЦУКРОВИМ ДІАБЕТОМ 2 ТИПУ

Вивчали роль інсуліноподібного фактора росту-1 та трансформуючого фактора росту-β1 в патогенетичних механізмах формування діастолічної дисфункції лівого шлуночка серця у хворих на гіпертонічну хворобу з цукровим діабетом 2 типу. Обстежено 67 хворих на гіпертонічну хворобу з цукровим діабетом 2 типу і 46 хворих на гіпертонічну хворобу без цукрового діабету. Хворі на гіпертонічну хворобу з супутнім цукровим діабетом 2 типу відрізнялись більш вираженими порушеннями діастолічної функції лівого шлуночка. Встановлено взаємозв'язок між рівнем трансформуючого фактора росту-β1 і показниками діастолічної функції лівого шлуночка. При наявності ознак діастолічної дисфункції лівого шлуночка рівень даного ростового фактора був достовірно вище в обох групах хворих. Взаємозв'язок між рівнем інсуліноподібного фактора росту-1 з показниками діастолічної функції серця не встановлений.

Ключові слова: артеріальна гіпертензія, цукровий діабет 2 типу, діастолічна функція лівого шлуночка, інсуліноподібний фактор росту-1, трансформуючий фактор росту-β1.

The study is a fragment of the research project "To develop methods for improving the treatment of arterial hypertension in patients with obesity based on the study of humoral and epigenetic factors and intestinal microbiota parameters", state registration No. 0120U000070.

Arterial hypertension (AH) is one of the most common cardiovascular diseases and significantly influences the disease's forecast and mortality rate. The heart and blood vessels suffer most frequently due to it. Identifying left ventricle hypertrophy in these patients and assessing its influence on disease development remains an important scientific and clinical problem. It is known that the patients with AH, especially when combined with type 2 diabetes mellitus (DM), considerably change not only structural but also functional left ventricle parameters [11–13]. There is evidence that diastolic dysfunction (DD) may be determined by myocyte hypertrophy and cardiac fibrosis [1]. DM patients suffer these changes