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Clinical and functional predictors of unsatisfactory outcomes of x-ray endovascular treatment in patients with diabetic foot syndrome and coronary heart disease

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Abstract: Purpose. To determine the clinical and functional parameters associated with unsatisfactory outcomes of X-ray endovascular treatment in patients with di-abetic foot syndrome (DFS) against the background of coronary heart disease (CHD).

Materials and methods. The retrospective analysis included 58 patients treated according to standard management in 2015-2019. A comparative analysis was carried out between subgroups with satisfactory and unsatisfactory treatment outcomes according to clinical and anamnestic indicators, including age, duration of diabetes, HbA1c level, LV ejection fraction, Fontaine and Wagner stages, as well as the degree of polymorbidity and the nature of the purulent-necrotic pro-cess.

Outcomes. Unsatisfactory outcomes were registered in 22 (37.9%) pa-tients. Statistically significant risk factors were: age over 70 years, duration of di-abetes ≥ 11 years, HbA1c level $\geq 10\%$, reduced EF ($< 50\%$), stages III-IV accord-ing to Fontaine and IV-V according to Wagner. In these patients, deep and com-bined forms of foot lesions (wet gangrene, phlegmon), polymorbidity (≥ 2 con-comitant diseases) and late presentation (> 30 days from the onset of the process) were more common.

Conclusion. The predictors of unsatisfactory outcomes

of X-ray endovascular treatment in patients with DFS and CHD are pronounced disorders of carbohydrate metabolism, cardiac dysfunction, progressive limb ischemia, deep forms of lesion, and polymorbidity. These data substantiate the need for preliminary risk stratification and comprehensive assessment of the cardiac and vascular status before the intervention.

Keywords: Diabetic foot syndrome, coronary artery disease, predictors, X-ray endovascular treatment, amputation, prognostic factors.

Introduction: Diabetic foot syndrome (DFS) remains one of the most severe forms of macroangiopathic complications of diabetes mellitus and is accompanied by a high incidence of amputation, disability, and mortality [1]. In patients with DFS, the risk of limb loss and death within 5 years after amputation is comparable to that of oncological pathology and exceeds 50% [2]. The situation is complicated by the fact that in a significant proportion of cases, DFS is combined with coronary heart disease (CHD), which reflects the systemic nature of vascular dysfunction in patients with a prolonged and decompensated course of diabetes mellitus [3].

According to clinical and pathomorphological studies, more than 70% of patients with DFS have clinically significant CHD, and one in three has a reduced left ventricular ejection fraction (LVEF <50%) [4]. Nevertheless, in everyday clinical practice, the management tactics of such patients, as a rule, are built without taking into account the cardiac reserve. This leads to the fact that even technically successful interventions on the arteries of the lower extremities end in unsatisfactory results: the formation of incompetent stumps, purulent-septic complications, repeated amputations, and mortality [5].

Current guidelines emphasize the need for a multidisciplinary approach in the treatment of patients with DFS, in particular, stratification of vascular risk and cardiological assessment before vascular interventions [6]. However, in practice, such assessments are not always carried out systematically. As a result, limb revascularization can be performed in patients with severe systolic dysfunction in whom the risk of cardiac complications exceeds the expected benefit from peripheral perfusion restoration [7].

Despite the accumulated clinical experience, systematic data on predictors of adverse outcome in patients with DFS and concomitant CHD remain limited in the literature. In particular, threshold values of

indicators associated with the risk of treatment failure have not been established. Therefore, the analysis of the factors determining the outcomes of X-ray endovascular interventions in this comorbid population seems to be relevant and practically significant [8].

The aim of this study was to determine the clinical and functional predictors of the unsatisfactory outcome of X-ray endovascular treatment in patients with DFS against the background of CHD.

METHODS

This study was carried out in the format of retrospective clinical-analytic observation and covers the period from 2015 to 2019. The analysis included 58 patients with confirmed DFS and CHD treated at the Republican Specialized Center of Surgery named after acad. V.V. Vakhidova. All patients received X-ray endovascular interventions on the arteries of the lower extremities according to the standard tactics adopted in the institution at that time, without preliminary risk stratification based on the cardiac profile.

The inclusion criteria were the presence of diabetes mellitus, clinically and instrumentally confirmed lower limb ischemia (stages IIB-IV according to Fontaine), the presence of purulent-necrotic changes in the foot (ulcers, gangrene, phlegmon), as well as documented concomitant CHD. Patients with marked multi-organ failure, uncompensated NYHA IV heart failure, and acute coronary events less than 30 days prior to the intervention were excluded.

According to the clinical outcome, patients were divided into two sub-groups: with a satisfactory result (complete healing, preservation of the supporting function of the limb) and with an unsatisfactory outcome (treatment failure, high amputation, mortality or lack of sustainable healing). A comparative analysis of the following parameters was carried out: age, duration of diabetes mellitus, HbA1c level, type and stage of DFS (according to Wagner), degree of ischemia (according to Fontaine), LV ejection fraction, number of concomitant diseases, form of purulent-necrotic process, terms of treatment from the onset of ulcerative lesion, as well as the type of vascular access used in X-ray endovascular interventions.

All data were obtained from outpatient records, epicrisis and intervention protocols. Statistical processing was carried out using the SPSS Statistics 26.0 package. The mean (M), standard deviation (SD) and 95% confidence interval were used to describe the quantitative data. Comparisons between the groups

were made using the Student's t-test or the Mann-Whitney U-test. Categorical variables were compared using the χ^2 criterion. The differences were considered statistically significant at $p < 0.05$.

RESULTS

Among the 58 patients included in the study, satisfactory clinical outcomes were achieved in 36 patients (62.1%), while in 22 patients (37.9%) the treatment outcome was regarded as unsatisfactory. Analysis of clinical and anamnestic characteristics revealed a number of parameters reliably associated with a negative prognosis.

The mean age of patients with an unsatisfactory outcome was 70.4 years, which was statistically higher than in the subgroup with a favorable course, where the mean age was 66.1 years ($p < 0.05$). The duration of diabetes mellitus in the group with a negative treatment result in 63.6% of cases exceeded 11 years, while in the comparison group this figure was 47.2%, which also tended to be statistically significant.

The level of glycated hemoglobin (HbA1c) $\geq 10\%$ was recorded in 45.5% of patients with an unsatisfactory outcome versus 19.4% in the comparison group ($p < 0.05$), which indicates the role of pronounced decompensation of carbohydrate metabolism in the deterioration of treatment results. Similarly, a decrease in the left ventricular ejection fraction below 50% was more common in patients with an unsatisfactory outcome (36.4% versus 13.9% in the group with a favorable course ($p < 0.05$).

Severe forms of lower limb ischaemia (stage III-IV according to Fontaine) were diagnosed in 68.2% of patients with an unsatisfactory outcome, which was almost twice as high as in the comparative subgroup (36.1%). Similarly, stages IV-V according to the Wagner classification were found in 54.5% versus 22.2%, respectively ($p < 0.05$), which indicates pronounced local tissue destruction in patients with an unsatisfactory prognosis.

It was also found that the presence of two or more concomitant chronic diseases (polymorbidity) was significantly more common in the second subgroup (72.7% vs. 41.7%, $p < 0.05$). The most common concomitant conditions included chronic heart failure, arterial hypertension and kidney pathology. In addition, among patients with an unsatisfactory outcome, in 22.7% of cases, there was a delay in seeking medical care - more than 60 days from the onset of the purulent-necrotic process, while in the

group with a favorable outcome, such terms were recorded only in 8.3% of patients.

As for the nature of purulent-necrotic lesions, phlegmons, wet gangrene, and combined forms were found mainly in the subgroup with an unsatisfactory result. On the contrary, isolated trophic ulcers prevailed among patients with positive dynamics. These differences have reached statistical significance and highlight the importance of the depth and extent of lesions as factors in poor prognosis.

DISCUSSION

The results obtained convincingly demonstrate that in patients with diabetic foot syndrome in combination with CHD, the outcome of X-ray endovascular intervention depends not only on the local angiographic status, but also on systemic clinical and functional indicators. The identified differences between the subgroups with a satisfactory and unsatisfactory outcome make it possible to identify key predictors of the unfavorable course of the disease.

First of all, it is worth noting the importance of age, duration of diabetes mellitus and HbA1c levels. Older age and a longer history of diabetes (≥ 11 years) reflect cumulative vascular damage accompanied by the formation of persistent macro- and microangiopathy resistant to therapy [1]. The level of glycated hemoglobin $\geq 10\%$ recorded in patients with unsatisfactory outcomes confirms the role of decompensated metabolic background as a key factor that enhances inflammatory and necrotic processes and disrupts reparative mechanisms [2].

The left ventricular ejection fraction (LVEF) deserves special attention. A decrease in this indicator ($< 50\%$) more than doubled the likelihood of amputation or death, which is in line with current data on the role of myocardial dysfunction as a prognostically unfavorable factor in vascular interventions [3]. This confirms the importance of preliminary cardiological evaluation when planning interventions in patients with DFS and CHD.

At the same time, a significant predominance of severe stages of ischemia (III-IV according to Fontaine) and purulent-necrotic lesions (IV-V according to Wagner) in the subgroup with an unfavorable outcome was revealed. These data are consistent with studies that emphasize that the severity of ischemia and the depth of soft tissue damage directly correlate with the risk of amputation and mortality [4,5].

Formally, polymorbidity has become an equally significant factor. The presence of two or more concomitant diseases, such as chronic heart failure, arterial hypertension and nephropathy, increased systemic decompensation and reduced the reserves for recovery after the intervention. Similar findings are presented in a number of international meta-analyses, emphasizing the importance of overall somatic burden in predicting DFS outcomes [6].

Finally, the factor of temporary deferment draws attention. A longer interval between the onset of the purulent-necrotic process and seeking specialized care was associated with a worse prognosis. This may be due not only to the progression of ischemia, but also to the chronicity of infection, the formation of a resistant microbiota, and a decrease in the effectiveness of subsequent revascularization [7].

Thus, the combination of clinical and functional factors makes it possible to stratify patients at an early stage according to the risk of ineffective treatment. This opens up opportunities to optimize treatment management by personalizing approaches that include both the assessment of angioarchitectonics and the integration of cardiac, metabolic, and inflammatory status into decision-making algorithms.

CONCLUSION

The analysis showed that in patients with DFS against the background of CHD, the outcome of X-ray endovascular treatment directly depends on a complex of clinical and functional factors. The key predictors of an unsatisfactory result are: old age, prolonged diabetes mellitus, pronounced decompensation of carbohydrate metabolism ($HbA1c \geq 10\%$), decreased left ventricular ejection fraction ($<50\%$), severe stages of ischemia according to Fontaine (III-IV) and deep purulent-necrotic lesions of the foot (IV-V according to Wagner), as well as the presence of pronounced polymorbidity and late seeking specialized care.

These parameters should be taken into account when deciding on vascular interventions. The revealed regularities substantiate the need to introduce a stratified approach, including a comprehensive assessment of the patient's cardiac and vascular status before the start of therapeutic and diagnostic measures. This will increase clinical efficiency and reduce the risk of amputations and deaths in this category of patients.

Ethical Approval:

The study was carried out on the basis of the analysis of archival medical data without interfering with the treatment process. Ethical approval was not required.

Conflict of interest:

The authors declare no conflict of interest.

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Author's contribution:

Zufarov M.M. - scientific concept of research, editing and approval of the text;

Kamalov S.T. - data collection, statistical processing, writing a manuscript.

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