Examination of patients with diabetes mellitus and peripheral arterial disease according to the adapted ischaemic criteria of the WIfI classification

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Abstract

Objective. To combine the determination of ischemia class indicators according to the WIfI classification and simultaneous performance of ultrasound duplex scanning of the arteries of both lower extremities during the initial examination of patients with diabetes mellitus and peripheral arterial disease to predict healing, determine the risk of amputation and the need for revascularisation.

Materials and methods. We treated 74 patients with diabetes mellitus and peripheral arterial disease who had signs of infection, ulceration or destruction of deep foot tissues. Patients were divided into two groups: the main group – 43 patients (ischaemia class was determined by the WIfI classification with simultaneous performance of ultrasound duplex scanning of the lower extremity arteries with assessment of lesions by ultrasound criteria) and the control group – 31 patients (ischaemia class according to the WIfI classification was determined only by portable Doppler). Patients in both groups received comprehensive treatment.

Results. During the 1–year follow–up, the frequency of re–hospitalisation associated with deterioration of the condition due to limb ischaemia in the main group was statistically significantly (p=0.03) lower than in the control group.

Conclusions. The integration of ultrasound duplex scanning at the initial stage of diagnosis allows to determine the degree of ischemia more accurately and to refer the patient for vascular correction in time.

Keywords: diabetes mellitus; peripheral arterial disease; ultrasound duplex scanning; WIfI classification.

Purulent–necrotic complications in the foot, combined with limb ischaemia, in patients with diabetes mellitus (DM) are considered one of the main causes of most major and minor amputations worldwide. Approximately 50% of patients with poor lower limb circulation have an infectious lesion in the foot, and these factors aggravate each other and lead to the loss of part or all of the lower limb [1].

The five–year mortality rate for patients with diabetic foot ulcers is close to 30%, and for those who have undergone major amputation, it exceeds 70%. Among patients with diabetes and the development of foot complications, 231 per 1000 person–years die, and among patients with diabetes without lower extremity damage – 182 per 1000 person–years [1].

Diabetic polyneuropathy and peripheral arterial disease (PAD) are the main pathogenetic factors in the development of lower limb diseases in patients with diabetes mellitus. Due to decreased skin sensitivity on the lower extremities as a result of polyneuropathy, patients seek medical care late, which increases the number of amputations [2].

About 60% of patients with diabetes have PAD of varying severity – obstructive atherosclerotic disease of the aorta, iliac arteries, thigh, leg, and foot, which leads to impaired or deteriorating blood circulation in one or both lower extremities, with clinical symptoms and signs during non–invasive or invasive vascular assessment [3].

Clinical symptoms of PAD include intermittent claudication, pain at rest, hair loss, muscle atrophy, decreased peripheral skin temperature, and absence of pulses in the arteries of the lower extremities. These symptoms are subjective and can be distorted by many factors. The pain syndrome can be reduced or not felt in elderly patients or patients with a sedentary lifestyle [4]. In the presence of peripheral neuropathy, pain may also be reduced, and in the presence of autonomie neuropathy, the foot may feel warm [5]. Palpation of the arteries may be misleading due to the presence of edema or infectious inflammation of the limb. The presence of a trunk pulsation at one level alone does not exclude PAD [6]. Therefore, non–invasive and invasive tests are performed to judge the presence of PAD.

Usually, non–invasive tests – ankle–brachial index (ABI), finger–brachial index (FBI) – are performed at the first stage of examination of a patient with suspected WPD. Unfortunately, these tests are also not absolutely accurate, as patients may have Menkeberg's sclerosis, which significantly distorts the values of the CIP and FPI [7, 8].

According to the 2023 recommendations of the international and European societies of vascular surgery IWGDF (International Working Group of the Diabetic Foot), ESVS (European Society for Vascular Surgery), SVS (Society for Vascular Surgery) on PAD in patients with diabetes and foot ulcers or gangrene, specialists consider using the Wound/Ischemia/ and foot Infection (WIfI) classification to predict the benefit...
of revascularisation and determine the risk of amputation [3].

Despite a significant arsenal of technologies for vascular imaging (digital subtraction, magnetic resonance, computed tomographic angiography), colour ultrasound duplex scanning (USD) remains relevant to this day. This non-invasive method is accurate enough, does not require high costs, can be used by a wide range of doctors and is available for medical institutions of different accreditation levels [9–11].

The aim of the study: to combine the determination of ischemia class according to the WIfI classification with the simultaneous performance of ultrasound of the arteries of both lower extremities during the initial examination of patients with diabetes and PAD to predict healing, determine the risk of amputation and the need for revascularisation.

**Materials and methods**

During the period from January 2023 to December 2023, 74 patients with diabetes and PAD who had signs of infection, ulceration or destruction of deep foot tissues (abscess, phlegmon, purulent tendovaginitis, purulent arthritis gangrene), as well as diabetic osteoarthropathy, at the Department of Surgery No. 2 of Zaporizhzhia State Medical and Pharmaceutical University in the purulent and septic centre with "diabetic foot beds" at Zaporizhzhia City Hospital No. 3. The age of the patients ranged from 39 to 82 years. Patients who had previously undergone an amputation on the forefoot, had significant necrotic lesions or tissue defects in the examination area, severe somatic status, and sepsis were not included in the study.

Patients were divided into two groups: the main group – 43 patients with DM and PAD, examined initially during hospitalisation with the determination of ischemia class indicators using an ultrasound machine, and immediately underwent ultrasound examination of the arteries of both lower extremities using a standard method, and the control group – 31 patients with DM and PAD, examined initially during hospitalisation with the determination of ischemia class indicators using a portable ultrasound Doppler with a pencil probe of 8 MHz (Neaso, China) using a standard method without lesion detailing.

Descriptive statistics were used for statistical analysis. Data are presented as mean ± standard deviation (x ± SD). The normality of the distribution was determined using the Kolmogorov–Smirnov test. The statistical significance of differences was assessed depending on the data analysed using the Student’s t test for data with a normal distribution. For ranked and binary data, Pearson’s coherence criterion ($\chi^2$) was determined to assess the statistical significance of differences in relative indicators. The difference was considered statistically significant if the $p$–value was less than 0.05. Statistical analysis was performed using SPSS v. 24 software (SPSS Inc., USA).

Many patients had a combination of comorbidities, such as coronary heart disease, hypertension, heart rhythm disorders and obesity.

The study groups of patients were comparable in terms of gender and age, as well as the presence of concomitant pathology (Table 1).

Patients were divided according to the clinical characteristics of the wound according to the WIfI classification criteria: Grade 0 – ischaemic pain at rest without ulceration or gangrene; Grade 1 – minor tissue loss (small shallow ulcer less than 5 cm² on the foot or distal part of the leg without gangrene); Grade 2 – a deep ulcer with exposed bone, joint or tendon measuring 5–10 cm² without heel area involvement, gangrene is limited to the toes; Grade 3 – a large ulcer/gangrene measuring more than 10 cm² involving the forefoot or midfoot and heel area involvement. Patients whose clinical characteristics of the wound according to the WIfI classification corresponded to grade 0 and grade 3 were not included in the study groups.

Patients were also divided according to the criteria of manifestations, spread of infection on the foot and its systemic impact on the body according to the WIfI classification criteria: Grade 0 – wound without suppuration or infection; Grade 1 – mild infection, the patient has less than 2 manifestations.

<table>
<thead>
<tr>
<th>Criteria.</th>
<th>Group.</th>
<th>Statistical significance</th>
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<tbody>
<tr>
<td></td>
<td>main, n=43</td>
<td>control group, n=31</td>
</tr>
<tr>
<td>Age, years, x ± SD</td>
<td>56.52 ± 3.53</td>
<td>55.81 ± 3.94</td>
</tr>
<tr>
<td>Quantity</td>
<td>men, n (%)</td>
<td>20 (46,51)</td>
</tr>
<tr>
<td></td>
<td>women, n (%)</td>
<td>23 (53,49)</td>
</tr>
<tr>
<td>Duration of type II diabetes, years, x ± SD</td>
<td>10.40 ± 3.42</td>
<td>11.26 ± 3.46</td>
</tr>
<tr>
<td>Coronary heart disease, n (%)</td>
<td>23 (53,49%)</td>
<td>17 (54,88)</td>
</tr>
<tr>
<td>Hypertension, n (%)</td>
<td>20 (46,51)</td>
<td>15 (48,39)</td>
</tr>
<tr>
<td>Heart rhythm disturbances, n (%)</td>
<td>14 (32,56)</td>
<td>9 (29,03)</td>
</tr>
<tr>
<td>Obesity of II and III degree, n (%)</td>
<td>12 (27,91)</td>
<td>8 (25,81)</td>
</tr>
</tbody>
</table>

Table 1. **Characteristics of the study groups**
Festations (hyperaemia less than 2 cm, hyperthermia, pain, swelling, dysfunction or systemic manifestations); Grade 2 – moderate infection, the patient is stable but has more than 1 manifestation (cellulite more than 2 cm, lymphangitis, spread under the fascia, deep tissue abscess, gangrene, muscle, tendon, joint or bone damage); Grade 3 – systemic infection with significant metabolic disorders and sepsis. Patients whose infectious foot lesions according to the WIfI classification corresponded to grade 0 and grade 3 were not included in the study groups.

According to the WIfI classification criteria for clinical characteristics of the wound and the prevalence of infection, the study groups of patients were comparable (Tables 2, 3).

To determine the degree of ischemia, patients in both groups underwent systolic blood pressure (SBP) at the level of the upper arm (upper arm SBP), SBP in the ankle area of the lower leg arteries (ankle SBP), followed by calculation of the CPI.

Additionally, SBP in the distal phalanx of the first toe (toe SBP) was measured with subsequent calculation of PPI. For technical reasons, measurement of percutaneous oxygen pressure or skin perfusion pressure is not available in our clinic, so these criteria were replaced by equally informative available ones.

To determine the degree of ischaemia according to the WIfI classification criteria in the proposed modification, the following threshold values were used: Class 0 – ankle SBP ≥ 100 mm Hg, KPI ≥ 0.8, finger SBP ≥ 80 mm Hg, PPI ≥ 0.7; Class 1 – ankle SBP 70 – 99 mm Hg, KPI 0.6 – 0.79, finger SBP 50 – 79 mm Hg, PPI 0.4 – 0.69; class 2 – ankle SBP 50 – 69 mm Hg, KPI 0.40 – 0.59, finger SBP 30 – 49 mm Hg, PPI 0.20 – 0.39; class 3 – ankle SBP < 50 mm Hg, KPI < 0.40, finger SBP < 30 mm Hg, PPI < 0.20.

All patients in the main group underwent a standard protocol for duplex examination of the arteries of both lower extremities using a SonoScope E2 Medical Corp (China) digital colour Doppler ultrasound system. The patency and diameter of the vessels, the condition of their walls were determined, subcutaneous tissue, fascia and muscles were visualised. Using the pulsed–wave mode, a spectral Doppler image was obtained, and the flow rate and qualitative analysis were determined. Colour flow mapping, uniformity and homogeneity of filling of the vascular lumen were studied, and zones of turbulence, filling defects or pathological dilation were identified.

Lower extremity arterial ultrasonography was performed in patients of the main group to determine the blood pressure in the extremities and to diagnose the degree of damage to the main arteries.

The criteria used to distribute patients were indices and intravascular changes that prevailed and led to haemodynamic disorders. Ultrasonography allowed to detect changes in vessel patency: stenosis, occlusion, aneurysm, localisation of the lesion: iliac, femoral, popliteal, lower leg and foot arteries.

The unaffected vessels had a homogeneous hypoechoic lumen, smooth contours of the arterial wall, intima–media layer of less than 1 mm, a typical three–phase blood flow spectrum, a clear spectral contour, local blood flow acceleration, and no asymmetry of blood flow on the contralateral side.

Stenosis of the lower extremity arteries was recorded in longitudinal and transverse scans with measurement of the percentage of stenosis by diameter.

Taking into account the general characteristics of ultrasound and total pathology, patients were divided according to the degree of ischemia (Table 4).
Table 4. Distribution of patients taking into account the degree of ischaemia according to the WIfI classification criteria in the proposed modification

<table>
<thead>
<tr>
<th>The degree of ischaemia</th>
<th>Group, n=43</th>
<th>Group, n=31</th>
<th>Statistical significance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>abs.</td>
<td>%</td>
<td>abs.</td>
</tr>
<tr>
<td>1</td>
<td>10</td>
<td>23.26</td>
<td>18</td>
</tr>
<tr>
<td>2</td>
<td>33</td>
<td>76.74</td>
<td>13</td>
</tr>
</tbody>
</table>

Grade 0. Local stenosis of the main vessels is less than 50%, no significant circulatory disorders occurred in the distal arteries.

Grade 1. At a stenosis of 50–60%, the three-phase spectrum changed to biphasic and monophasic, the spectral broadening increased, and the peak systolic velocity increased at the site of local stenosis.

Grade 2. With a stenosis of more than 60% in the distal part of the artery, disorganised blood flow without early diastole was recorded, and with critical stenosis and occlusion, a collateral type of blood flow was recorded. In a number of patients with occlusion of the main arteries due to well-developed collateral circulation, a rather high SBP in the lower leg arteries and a normal CPI were obtained. Menkeberg's sclerosis with varying degrees of severity was detected in almost every patient. Due to increased arterial wall stiffness, falsely high ankle SBP was obtained, sometimes 200 mm Hg and higher.

Grade 3: Absence of main and collateral circulation in the arteries of the lower leg and foot with low SBP, CPI <0.40, PPI <0.20.

Patients with 0 and 3 degrees of ischaemia according to the WIfI classification criteria in the proposed modification were not included in the study groups.

Results

After the initial examination, the surgeon prescribed a comprehensive treatment: drug therapy, foot surgery, local wound treatment, endovascular or vascular intervention (if necessary). The treatment tactics were planned for 3, 5, 7 days and reviewed depending on changes in the patient’s general condition and local condition of the limb.

The combination of ultrasonography data and calculated indices allowed the treating physician to obtain information about the presence of vascular component pathology earlier and to refer the patient for blood circulation correction earlier.

In case of acute purulent–necrotic process on the foot after drainage surgery, antibiotic therapy (5–7 days), the patient was referred for vascular correction (often endovascular), then local wound treatment was continued.

This tactic was followed when ischaemia met the criteria for grade 2 – 33 (76.74%) patients in the main group and 13 (41.94%) patients in the control group.

In 8 (25.81%) patients in the control group, who were initially diagnosed with grade 1 ischaemia, there were no positive changes in the wound and the condition of the limb deteriorated. An additional examination confirmed the presence of grade 2 ischaemia, and the treatment tactics were revised to correct vascular problems.

After complex treatment and discharge from the hospital, patients in both groups were followed up for 1 year. The wound healed completely in 30 days in both groups in 12 (27.91%) patients, in the control group in 7 (22.58%) patients (p=0.61). The wound healed completely in 60 days in the main group in 15 (34.88%) patients, in the control group in 6 (19.35%) patients (p=0.14). Complete wound healing did not occur within a year in the main group in 3 (6.98%) patients, in the control group – in 5 (16.13%) patients (p=0.21). In case of deterioration of the condition due to limb ischaemia within 1 year, 3 (6.98%) patients in the main group were re-hospitalised, and 8 (25.81%) patients in the control group (p=0.03).

After 1 year, 10 (23.26%) patients in the intervention group and 5 (16.13%) patients in the control group were lost to follow-up.

Clinically, the wound healing was better in the main group, although according to the statistical analysis, no statistically significant difference in the results of treatment in the short term was found. However, long-term follow-up showed that in the main group, the number of re-hospitalisations caused by an increase in the degree of lower limb ischaemia decreased statistically significantly (p=0.03).

More accurate and earlier diagnosis of ischaemia in the main group and referral of patients for endovascular correction of blood circulation led to a statistically significant reduction in the number of repeat hospitalisations associated with its disorder.

Discussion

According to the updated diagnostic guidelines of the IWGDF, ESVS, and SVS vascular surgery societies, if a patient with DM is suspected of having PAD, lower extremity ultrasound should be considered in combination with the determination of PDA and PWV. However, no single modality has been proven to be optimal, i.e., above which a value
can rule out PAD. In the presence of a CPI of 0.9 to 1.3, a PPI > 0.70, and a three–phase or biphasic Doppler wave in the arteries of the foot, PAD is less likely (level of recommendation: conditional, low).

In patients with diabetes and foot ulcers or gangrene, the use of ultrasound for diagnosis is only advisory with a low degree of certainty.

Measurement of percutaneous oxygen pressure or skin perfusion pressure helps to determine the degree of ischaemia, the condition of the foot tissue to assess the likelihood of wound healing.

The most popular device on the world market for monitoring percutaneous oxygen pressure is the PeriFlux 6000 (Perimed, Radiometer Medical), which can have up to 8 measurement sensors and automatically generates test reports and reports. Our centre is not equipped with such equipment, so we use other proposed indicators to determine the level of ischaemia.

Routine toe SBP measurement and calculation of PPI can complement the calculation of CPI for numerical characterisation and assessment of ischaemia severity.

In our opinion, the task of any multidisciplinary team treating patients with diabetes and PAD is to determine the degree of ischemia at an early stage and, if necessary, prescribe limb revascularisation, which accelerates wound healing, reduces the number of complications and re–hospitalisations during the follow–up period.

Conclusions

Patients with the same wound characteristics according to the WIfI classification criteria and infectious foot lesions may have different degrees of ischaemia depending on the examination methodology.

Diagnosis of ischemia by means of ultrasound at the initial stage helps to obtain additional information about haemodynamically significant lesions, to identify more severe ischemia in the patient, which, according to the recommendations, already requires revascularisation measures.

Further prospective studies involving a larger sample of patients are needed to judge the likely benefit of mandatory ultrasound in determining the degree of ischemia using the WIfI classification criteria at the initial stage of examination in patients with diabetes and PAD.

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