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Tactical and technical considerations in deploying endovascular procedures for chronic threatening lower limb ischemia

The aim of the work: to evaluate new tactical and technical measures in order to increase the efficiency of endovascular operations in chronic threatening ischemia of the lower extremities.

Materials and Methods. We analyzed postoperative results in 286 patients with TCLLI, average age (62±8.2) years, after an endovascular procedures performed in cardiovascular and endovascular center at Ternopil Municipal Hospital No. 2, for the period of 2012–2022 years. The majority were men (187), 99 were women. Limb ischemia, according to Rutherford's classification, was III stage in 69.1 % and 30.9 % was IV stage. According to our findings, the frequency and localization of occlusive lesions using TASC II classification, type A was found in 9.1 % of patients, type B in 49.7 %, type D – in 41.2 % of patients. The length of atherosclerotic occlusions in 57 (20 %) patients was from 15 to 20 cm, in 121 (42.3 %) patients – up to 15 cm, and in 108 cases (37.7 %) more than 20 cm. To eliminate or reduce the symptoms of TCLLI, the following options of endovascular operations were used: vasoballoon dilatation of arteries using the "sliding" technique or the "drilling" technique followed by stenting with a self-expanding stent, subintimal angioplasty, the SAFARI method, retrograde approaches through the distal part of the tibial or posterior arteries of the foot, the transpedal arch technique, the J-loop technique, and the confluent balloon technique.

Results and Discussion. After gathering postoperative results, we can state that clinical success in the first 6 months was achieved in 234 (81.8 %) patients. Among them, a significant improvement in the condition of the limb occurred in 128 (44.9 %) patients, moderate improvement was noted in 100 (35 %) patients, no changes in 35 (12.3 %) cases, and moderate deterioration in 23 (7.8 %) of patients. calculation of the brachial-peroneal index, studying the intensity of the pain syndrome using a digital rating scale.

Key words: chronic threatening lower limb ischemia; endovascular operations.

Statement of the problem and analysis of the latest research. More than 200 million people worldwide suffer from occlusive peripheral artery diseases, of which chronic threatening lower limb ischemia (CTLLI) accounts for up to 11 % of this population.

It should be noted that patients with CTLLI are at risk of two major complications. First, reduced blood flow in the lower extremity, without adequate revascularization therapy expedites the need of amputation. Thus, the frequency of amputations of limbs without adequate treatment in patients with CTLLI reaches 40 % within 6 months. Secondly, one year after the development of CTLLI, mortality among these patients is from 20 % to 25 %, mainly from cardiovascular diseases. In addition to the serious health consequences associated with CTLLI, the economic impact of the disease is substantial, with an estimated annual cost of approximately $12 billion in the United States alone [1,2,3,4,5].

Despite the negative consequences of CTLLI, the problem of its treatment remains unsolved. The experience of the vast majority of vascular surgeons dealing with this pathology indicates that conservative therapy is ineffective in the treatment of patients with CTLLI. At the same time, the use of revascularization procedures is a promising treatment option for patients with CTLLI, since only the restoration of sufficient blood flow can save the limb and improve patients quality of life [6,7,8].

However, specifics in development of CTLLI, especially: the high prevalence and multilevel atherosclerotic lesions in the femoral-popliteal and distal arterial segments, which is 65–85 % of the total number of all cases of CTLLI; rapid rate of progression to critical ischemia followed by necrosis or gangrene of the distal foot; unviable use of bypass grafting in cases of total lower leg arterial occlusion; concomitant pathology – advanced and senile age of patients, which directly affects the choice of the method of revascularization of the limb and the course of the postoperative period, as well as diabetic foot syndrome, in which distal lower limb arterial damage predominates, affect the choice of certain methods of limb revascularization [6, 7].

Therefore, the choice of surgical tactics in the case of CTLLI is always a choise between the desire to provide maximal blood flow in the diseased limb by expanding the volume of the procedure and the reduction of operational traumasity. In this regard, there is also no definitive answer regarding the use of open (grafting) and endovascular surgical interventions [7, 8, 9, 10, 11].

It should be noted that recently, a number of scientific articles have been published, demonstrating

benefits in using endovascular procedures for revascularization in the conditions of CTLLI, with a predominance of distal occlusive-stenotic arterial lesions [11, 12, 13, 14].

This is also confirmed by the conclusions based on the results of the BASIL 2 study (Bypass versus angioplasty for severe ischaemia of the leg). They indicate a strategy for the first endovascular revascularization in patients with CTLLI – "revascularization first, rather than venous bypass." This conclusion was presented at the International Symposium of Vascular Surgeons (April 25-27, 2023, London) [15,16].

The aim of the work: to evaluate new tactical and technical measures in order to increase the efficiency of endovascular operations in chronic threatening ischemia of the lower extremities.

Materials and Methods. We analyzed postoperative results in 286 patients with TCLLI, average age (62±8.2) years, after an endovascular procedure performed in cardiovascular and endovascular center at Ternopil Municipal Hospital No. 2, for the period of 2012–2022 years. The majority were men (187), 99 were women. Limb ischemia, according to Rutherford's classification, was III stage in 69.1 % and 30.9 % was IV stage. Arterial vessels were evaluated using sonography on a Vivid 3 unit ("General Electric", USA) with a 5–10 MHz sensor and the corresponding standard software package. The extent of the atherosclerotic lesion of aorto-femoral-popliteal-tibial segment and the thickness, shape, structure, diameter of the arterial lumen at the level of the stenotic and post-stenotic areas were assessed in B-mode duplex scanning. Atherosclerotic occlusion and its extent, localization was determined using spiral computer angiography with 3D reconstruction or aorto-arteriography on the angiographic complex "Siemens".

According to our findings, the frequency and localization of occlusive lesions using TASC II classification, type A was found in 9.1 % of patients, type B in 49.7 %, type D – in 41.2 % of patients. The length of atherosclerotic occlusions in 57 (20 %) patients was from 15 to 20 cm, in 121 (42.3 %) patients – up to 15 cm, and in 108 cases (37.7 %) more than 20 cm. Additionaly, 75 % of patients with CTLLI have distal segments lesion, presenting additional tactical and technical challenges for the restoration of blood supply.

Often, long and multi-level atherosclerotic occlusions require creative solutions when performing endovascular surgical interventions in CTLLI and become “a last resort” procedure, which, despite the pros and cons, gives hope for the patient and the surgeon of saving the limb.

To determine the viability of certain endovascular interventions, we used the paradigm of science-based revascularization of the limb in cases of CTLLI - PLAN (Patient risk, Limb severity, and Anatomic complexity). For this, we also performed an assessment of perioperative risk, limb damage, according to GLASS (Global Limb Anatomic Staging System) and WI-FI (wound, ischemia, foot infection), anatomical complexity and angiosomal pattern of ischemic foot damage [17].

In performing balloon dilatation of the infrainguinal arterial segment an antegrade ipsilateral or a contralateral femoral artery, popliteal artery access xia puncture or open incision were used, this allowed manipulation of the proximal and distal segments of femoral and tibial arteries.

In cases of superficial femoral artery occlusios up to 15 cm, balloon dilatation of this segment with the "sliding" or "drilling" technique were used in 111 (38.8.3 %) patients, followed by stenting with a self-expanding stents Terumo Misago (Japan), Palmas Cordis (USA) ets.

Extensive occlusions in the femoral-popliteal-distal (more than 20 cm), intraluminal balloon angioplasty was used in 108 patients (37.6 %) An angiography catheter was placed 1–2 cm above the occlusion, and a microcatheter on a 0.035" hydrophilic guidewire. This allowed reliable occlusions or stenosis crossing. After that, the microcatheter-guidewire system was replaced with a Teflon 0.035” guidewire. The advantages of this method is the possibility to remove the wire and perform angiographic position control and, if necessary, the direction of guidewire movement. Finally, the balloon is introduced and positioned. As a rule, we use balloons of different diameters, starting with a balloon 1–2 cm smaller than the artery diameter, concluding with a nominal balloon diameter. At the same time, dilation is gradual and prolonged (up to 5–10 minutes). In 61 cases, femoral and popliteal arteries required additional stenting. In such cases, one stent or two end-to-end stents were placed and additional posdiltations above, between or under the stents were performed. A recoil phenomenon was observed in 17 cases, also requiring a stent to prevent early restenosis.

Subintimal angioplasty was performed in 31 case (10.8 %) using the Re-Entry Outback device (Cordis, USA). This method was indicated by: a) long occlusions; b) unsuccessful attempt to restore intraluminal blood flow; c) the presence of a large collateral branch with an onset near occlusion site; d) in the absence of a defined "stump" (attempts to cross intraluminally, and up with a guidewire in the collateral branch); e) bifur-

cation occlusions in the superficial femoral artery; f) recanalization after vessel perforation (the use of subintimal technique allows bypassing the perforated area and plot a new course through the occluded area); g) heavily calcified lesions (an attempt at an intraluminal crossing in dense lesion leads the guidewire in the path of least resistance – the subintimal space).

Drug coated or eluting balloons(DCB/DEB), IN. PACT Admiral (Medtronic Inc. USA) etc., with Paclitaxel or sirolimus coating were used in 37 patients. In all cases they were used in femoral and popliteal segments.

SAFARI (subintimal arterial flossing with antegrade-retrograde intervention) with ipsilateral antegrade approach was used in 14 (4.9 %) patients. We used this method in cases of: a) lesions spreading from the popliteal artery to the tibio-peroneal trunk and tibial arteries; b) chronic total occlusions of the tibial arteries; c) unsuccessful intraluminal passage of the tibial arteries.

After an unsuccessful antegrade approach, we used the retrograde approach. The decision was made after a careful evaluation of the wound healing and analyzing the ischemic foot lesion angiosomal picture. Most often retrograde access was gained through the distal posterial tibial or dorsalis pedis arteries (14 cases), transpedal arch technique (3 cases), antegrade and retrograde tracking and dissection (CART) / Reverse CART (3 cases), confluent balloon technique (2 cases).

Postoperative results were assessed after patient discharged from hospital, 3 and 6 months after the operation and was based on clinical data, ultrasound doppler, calculation of the brachial-peroneal index (BPI), transcutaneous oximetry. Changes in the clinical status were assessed according to the Rutherford scale (1997) [18]: 0 – no changes (no changes in the degree of ischemia and no increase in BPI); +1 - minimal improvement (increase in BPI by more than 0.1, but no clinical improvement, or vice versa, clinical improvement without an increase in BPI by more than 0.1) +2 - moderate improvement (at least by 1 degree of ischemia, BPI does not normalized, but increased by more than 0.1), +3 – significant improvement; - 1 – slight deterioration; - 2 - moderate deterioration; - 3 – significant deterioration.

In order to ascertain the microcirculatory status, partial oxygen pressure (transcutaneous oximetry, tcpO2) in the lower limb superficial soft tissues was measured using a RADIMETER (Denmark) device. To obtain tcpO2, the Clark sensor was placed on the foot in the area of the first interdigital space and in the area of the heel. We used the following criteria to assess the degree of preservation of microcirculation: I degree of microcirculation disorders (compensated tissue metabolism) – tcpO2 > 30 mmHg; II degree of microcirculation disorders (subcompensated tissue metabolism) – tcpO2 = 20-30 mmHg; III degree of microcirculation disorders (decompensated tissue metabolism) tcpO2 < 20 mm Hg.

The effectiveness of endovascular revascularization was also assessed by the pain syndrome intensity using a digital rating scale – Verbal Descriptor Scale (Gaston-Johansson F., Albert M., Fagan E. et al., 1990). The verbal descriptor scale allows to quantify pain intensity through quality verbal assessment. According to this scale, six pain rates are possible: 0 – no pain; 2 – weak pain; 4 – moderate pain; 6 – severe pain; 8 – very strong pain; 10 – unbearable pain. Treadmill test (Garduer-Skiner protocol) was also used to evaluate the effectiveness of endovascular operations at TCLLI, which was performed on a treadmill with a zero incline, at a speed of 3.2 km/h, until the patient experienced pain in the lower extremities.

Statistical analysis of the obtained results were carried out using "Microsoft Excel 2010" software, applying the variational statistical method of analysis. Arithmetic mean (X), standard error of arithmetic mean (m), standard deviation (t), and correlation coefficient (r) were calculated. The level of probability (p) was established by testing two sample equality distribution centers (t – Student's test), Laplace normal distribution law and the statistical sign test. In other cases, using the Mann–Whitney U-test (differences at $p < 0.05$ were considered reliable).

Results and Discussion. After gathering postoperative results, we can state that clinical success in the first 6 months was achieved in 234 (81.8 %) patients. Among them, a significant improvement in the condition of the limb occurred in 128 (44.9 %) patients, moderate improvement was noted in 100 (35 %) patients, no changes in 35 (12.3 %) cases, and moderate deterioration in 23 (7.8 %) of patients. According to transcutaneous oximetry data (Table 1), on the 14th day after restoration of blood supply in the limb, an increase in tcpO2 values was noted in the vast majority of patients (219–76.6 %).

Worth noticing is the fact that the biggest increase in tcpO2 occurs 1–2 months after surgery and persisted thought 6 months of observation. These findings can be explained by the presence of postoperative foot and leg soft tissue oedema, which subsides over time, and the possible microcirculatory blood flow restoration, on the other hand. Tissue reperfusion injury and, as a result, local inflammation may be an additional factor in the delayed partial oxygen pressure increase.

Patients in critical limb ischemia preoperative pain intensity was as follows: moderate pain in 176

Table 1. tcpO2 before and 14, 30, and 60 days after revascularization intervention

Measured $tcpO_2$	Patients n=286			
	Before intervention	14 days after	30 days after	60 days after
I degree – ($tcpO_2$>30 mm Hg)	–	31	52	66
II degree – ($tcpO_2$ 20–30 mm Hg)	169	188	213	172
III degree – ($tcpO_2$ 20–30 mm Hg)	117	67	21	48

(61.6%), severe pain in 73 (25.5 %), and very severe pain in 37 (12.9 %) patients. After reconstructive procedure, the intensity of pain significantly decreased 3–4 days in the postoperative period, and after 7–12 days, the majority (213–74.5 %) were pain-free. Treadmill test results showed that pain-free walking distance before the operation in patients with TCLLI was, on average, (64.3±11.5) meters ($p<0.05$). 20 days after endovascular operations, this distance increased to 92.4±8.1 meters, and after 2 months and 6 months walking distance further increased to (115.6±7.9) meters and (131±9.2) meters respectively ($p<0.05$). This shows a clear beneficial limb status effect as well as clinical improvement for the significant majority of patients, regardless of the initial stage of limb ischemia, indicating at high overall efficacy of endovascular procedures, even in the early postoperative period of TCLLI.

Long-term follow-up was performed at 6, 12, 18, 24 and 30 months intervals. For this purpose, patients were divided in 3 groups: in the first (n=111) patient group – only balloon angioplasty was performed; the second group (n=108) – received balloon angioplasty and stenting; the third group of patients (n=37) underwent balloon angioplasty with DCB. Lumen patency was preserved in the first group at 30 months was 39.5 %. Restenosis occurred in 28 (25 %) patients, and reocclusion occurred in 35 (35.3 %) patients. The highest of restenosis rates and reocclusion occurs in the first 6 months – 40 %. Worth noticing that repeated balloon angioplasty and stenting were successfully performed 18 patients with restenosis, while lumen patency was restored only in 12 patients after reocclusion. In the 2nd group, stent patency at 30 months was 48.2 %. Restenosis occurred in 20 (18.5 %) of cases, and reocclusion – in 23 (21.3 %) respectively. The main volume of recurrences also occured in the first 6 months of observation – 39.8%. However, after DCB angioplasty recurrence rates significantly lower. Better long-term results were also noted in this group of patients. Overall lumen patency was found in 58.3 % of cases, restenosis occurred in 13.5 % of patients, and reocclusion in 17.6 % of treated lesions. In general, the cumulative vessel patency after endovascular surgery was: 1 month – 94.5 %, 2 months – 82.3 %, 6 months – 77.4 %, after a year – 58.1 %, after 2 years – 49.8 %. Cumulative limb preservation after endovascular operations was: 1 month – 92.4 %, 3 months – 80.3 %, 6 months – 72.6 %, after a year – 65.1 %.

Conclusions. 1. The use of endovascular surgical interventions is a promising treatment option for threatening critical ischemia of the lower extremities, especially in the elderly and senile, who have a high risk of postoperative complications when using bypass procedures.

2. In the case of threatening critical ischemia of the lower extremities, balloon angioplasty followed by stenting or balloon angioplasty with a drug coated balloon (paclitaxel or sirolimus) is more preferable, based on the results of the early and late postoperative period.

Future development. There is no doubt that positive outcomes of endovascular operations in critical lower limb ischemia will increase the interest of the medical industry in developing more advanced instrumental equipment, new specialized stents, for this further scientific research is needed.

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ТАКТИЧНІ ТА ТЕХНІЧНІ ОСОБЛИВОСТІ ЗАСТОСУВАННЯ ЕНДОВАСКУЛЯРНИХ ОПЕРАЦІЙ ПРИ ХРОНІЧНІЙ ЗАГРОЗЛИВІЙ ІШЕМІЇ НИЖНІХ КІНЦІВОК

Мета роботи: обґрунтувати застосування нових тактичних та технічних заходів для підвищення ефективності ендоваскулярних операцій при хронічній загрозливій ішемії нижніх кінцівок.
Матеріали і методи. Проаналізовано результати ендоваскулярних операцій у 286 пацієнтів із хронічною загрозливою ішемією нижніх кінцівок віком (62±8,2) року, за період 2012–2022 р. Згідно з класифікацією Рутерфорда, 69,1 % пацієнтів мали III стадію, 30,9 % – IV стадію ішемії кінцівки. Згідно зі класифікацією TASC II, за рівнями оклюзій тип А діагностовано у 9,1 % хворих, тип В – у 49,7 % випадків, тип D – 41,2 % пацієнтів. Протяжність атеросклеротичних оклюзій у 57 (20 %) пацієнтів була від 15 до 20 см, у 121 (42,3 %) хворого – до 15 см та у 108 випадках (37,7 %) більше 20 см. У 75 % хворих із хронічною загрозливою ішемією нижніх кінцівок встановлено ураження дистального сегменту, що спричинило певні проблеми тактичного та технічного плану під час відновлення кровопостачання в кінцівці. Для ліквідації або зменшення симптомів хронічної загрозливої ішемії нижніх кінцівок використано такі варіанти ендоваскулярних операцій: вазобалонна дилатація артерій за технікою “ковзання” або технікою “буріння” із наступним стентуванням саморозширюючим стентом, субінтимальна ангіопластика, метод SAFARI, ретроградні доступи через дистальну частину великогомілкової або тильної артерії стопи, техніку транспедальної дуги, техніка J – петлі та техніку конфлюентного балона.
Результати дослідження та їх обговорення. Після аналізів результатів ендоваскулярних операцій встановлено, що клінічний успіх в перші 6 місяців досягнено у 234 (81,8 %) хворого. В тому числі, значне покращення стану кінцівки наступило у 128 (44,9 %) пацієнтів, помірне покращення відмічено у 100 (35 %) хворого, без змін у 35 (12,3 %) випадках та помірне погіршання було у 23 (7,8 %) пацієнтів. Ці дані підтверджені комплексними обстеженнями, що включали: транскутанну оксиметрію, ультразвукову доплерографію артерій із виміром кісточково-плечового індексу, тредміл-тест та вивчення інтенсивності больового синдрому за цифровою рейтинговою шкалою – Verbal Descriptor Scale.

Ключові слова: хронічна загрозлива ішемія нижніх кінцівок; ендоваскулярні операції.