

PERCUTANEOUS TRANSLUMINAL ROTARY ATHERECTOMY IN PATIENTS WITH ATHEROSCLEROTIC LESIONS OF BELOW THE KNEE ARTERIES

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ABSTRACT

The aim: To determine the effectiveness of the combination of the percutaneous transluminal rotational atherectomy (PTRA) techniques with plain old balloon angioplasty (POBA) and POBA monotherapy (POBA-mono) in endovascular treatment (ET) of patients with occlusive-stenotic lesions below the knee (BTK) arteries.

Materials and methods: We studied two groups, the main included patients (n=9) aged who underwent PTRA and POBA of BTK arteries, and the comparative group (POBA-mono) of patients (n=24) who underwent POBA monotherapy of BTK arteries.

Results: Thrombosis of the reconstructed segments in the target arteries after 12 months was diagnosed in 95% of patients of the control and 1 – main groups (Ft, p=0.00001). Healing of trophic ulcers of the foot in the first month after ET was observed in 78% (n=7) of patients of the main group and in 13% (n=3) of the control group (χ^2 (1, n=33) = 10.2961; p=0.0013), and after 3 months – in 100% (n=9) and 83% (n=20) of patients in the respective groups.

Conclusions: The combination of PTRA with POBA reduces the probability of repeated violations of the patency of the target artery. In addition, it increases the healing efficiency of trophic ulcers of the LE compared to POBA monotherapy.

KEY WORDS: endovascular treatment, thrombosis, occlusive-stenotic lesions, trophic ulcer, cardiovascular

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INTRODUCTION

Cardiovascular disease (CVD) is a major cause of disability and mortality worldwide. Despite significant achievements over the past decades in the diagnosis, treatment, and prevention of such diseases, occlusive-stenotic lesions of the arteries of the lower extremities (LE) leads the second place in the structure of CVD due to their contribution to the development of critical ischemia (35.0-64.7%). Furthermore, treatment of such patients is difficult due to the frequency of development of thrombosis and restenosis in them (6.0-42.0%) and the need for repeated surgical interventions in 1/3 of patients [1].

Clinical recurrence of critical limb ischemia (CLI) is associated with a high rate of nonhealing ulcer recurrence, major amputation, and death. Patients with undergoing reinterventions than patients without reinterventions had lower rate of healing (28.5% vs. 71.9% p = 0.0001) higher rate of ulcer recurrence (20% vs. 10.3% p = 0.03), major amputation (24.3% vs. 4.3% p = 0.0005), and death (33.3% vs. 7.9% p = 0.002) [2].

A novel alternative to standard angioplasty and stenting is the excision of the obstructing arterial plaque using a minimally invasive technique, the atherectomy, to improve outcomes and lower re-intervention rate [3]. Atherectomy

is a competing technique that uses a rotating cutting blade or burr to excise the atheroma [4]. Thus, the problem of treatment of occlusive and calcified lesions of BTK arteries remains relevant and requires further study.

THE AIM

The aim was to determine the effectiveness of the combination of the percutaneous transluminal rotational atherectomy (PTRA) techniques with plain old balloon angioplasty (POBA) and POBA monotherapy (POBA-mono) in endovascular treatment (ET) of patients with occlusive-stenotic lesions below the knee (BTK) arteries.

MATERIALS AND METHODS

A comparative analysis of the results of ET of 33 patients (10 women and 23 men; mean age 69.6±8.9 years) of the BTK atherosclerotic occlusive-stenotic lesions with trophic ulcers in the foot was performed (2020-2022). Depending on the application of the percutaneous transluminal angioplasty (PTA) method, 2 groups of patients were distinguished: the main group (PTRA+POBA) included 27% of patients (n=9), who underwent PTRA+POBA of BTK

Table I. Characteristics of atherosclerotic lesions of the BTK arteries in the studied groups of patients, n / %.

LESION LOCALIZATION	Main group (n=9)	Control group (n=24)
Anterior tibial artery	2 / 22	6 / 25
Posterior tibial artery	5 / 56	4 / 17
Peroneal artery	0	2 / 8
Anterior+Posterior tibial artery	1 / 11	5 / 21
Anterior+Posterior tibial+Peronea artery	0	2 / 8
Posterior tibial+Peronea artery	1 / 11	1 / 4
Anterior tibial+Peronea artery	0	4 / 17
Calcification	9 / 100	15 / 63*

Note: * – $p=0,039$ (Ft)

arteries, and the comparative group (POBA-mono) – 73% of patients (n=24), who underwent POBA monotherapy of BTK arteries. Diabetes mellitus was diagnosed in 28 (85%) patients, arterial hypertension – 33 (100%), coronary heart disease – 22 (67%), and atrial fibrillation – in 8 (24%) cases. Six (18%) patients demonstrated the decline of estimated glomerular filtration rate <35 ml/min/1.73 m².

Patients were studied for the primary patency of the target artery and other vessels by preoperative ultrasound. The wound healing, limb amputation, and the development of cardiovascular events during the year were analyzed every 3 months after ET. All patients got optimal medical treatment before and after ET.

PTA was performed by POBA and PTRa with POBA. Rotablation was performed by standard coronary technique, and burr size was selected by Burr/Artery ratio 0,75-0,85/1 [5].

The study was conducted by the principles of the Council of Europe Convention on Human Rights and Biomedicine, the World Medical Association Declaration of Helsinki on the ethical principles for medical research involving human subjects, and current regulations of the Ministry of Health of Ukraine. The study not used new medications, biologics, or devices. Additional risks associated with scientific research, apart from those possible against the background of surgical intervention for lower limb ischemia, are not expected. Examinations and medical procedures were performed in the inpatient department under a doctor's supervision. All patients signed informed consent to participate in the study.

The Mann-Whitney U-test (for quantitative variables), and the Pearson's agreement test (χ^2 test) with Yates correction or Fisher's exact test (Ft) (for qualitative variables) were used to assess the statistical significance of differences between the studied groups. A p-value <0.05 was considered as statistically significant.

RESULTS

The studied groups were comparable by age, sex, and the profile of associated conditions.

According to the data from preoperative ultrasound, which determined the target vessels for endovascular inter-

vention the groups had differences in the topography of the lesions of the BTK arteries and the amount of endovascular intervention (Table I).

In particular, all the patients from the main group presented with the calcification of the BTK arteries, compared with 63 % of the cases in the control group (Ft, $p=0,039$). The studied groups did not differ significantly by the number of affected BTK arteries (Figure 1).

Mortality among 24 patients in the control group was 8% (n=2) during the first 6 months. In 1 patient of the control group, within 3 months, a limb was amputated, on which an endovascular intervention was previously performed. The frequency of cardiovascular events during the year of observation after endovascular treatment in patients of the main group was 11% (n=1) and in patients of the control group – 8% (n=2) which includes ACS and Stroke. The frequency of preservation of the limb during 12 months in patients of the main group was 100% (n=9) and in patients of the comparison group – 96% (n=21).

Thrombosis or reocclusion of the reconstructed segments of the BTK arteries occurred in 4% (n=1) of control group patients in the first month, in 25% (n=6) – after 3 months, in 44% (n=10) – after 6 months and in 86% (n=18) – after 9 months after ET. After 12 months of ET, occlusion in the target artery was diagnosed in 95% of patients in the control group and only 1 in the main group (Ft, $p=0.00001$) (Figure 2).

At the same time, no statistically significant differences between the groups were found in the rate of repeated endovascular interventions during the year, which was performed in 1 patient of the main and 9 of the control groups (Ft, $p=0.20351$).

Healing of trophic ulcers of the foot in the first month after ET was observed in 78% (n=7) of patients of the main group and in 13% (n=3) of the control group (χ^2 (1, n=33) = 10.2961; $p=0.0013$), and after 3 months – in 100% (n=9) and 83% (n=20) of patients in the respective groups (Figure 3).

Despite the fact that calcification of BTK arteries in 100% (n=9) of patients in the main group technical success rate was achieved in 100% of cases.

The complication was 11% (n=1) in the main group: the distal part of the rotawire has been damaged and separated

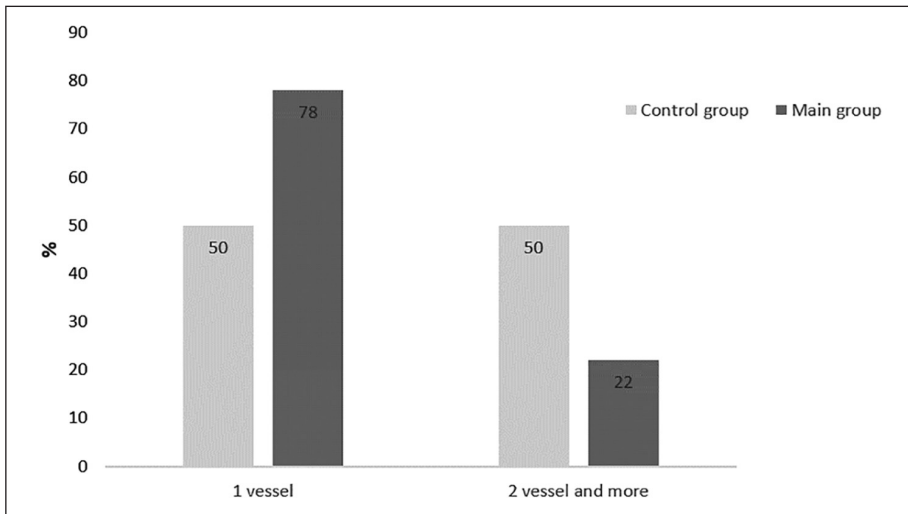


Fig. 1. The number of affected BTK arteries in the studied groups of patients (%) ($\chi^2(1, n=33) = 1.0868; p=0.297$)

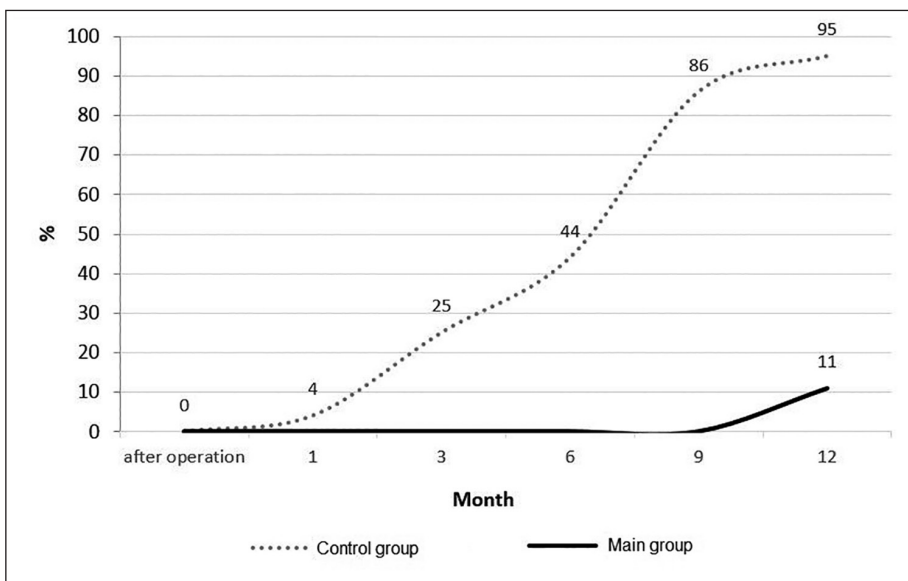


Fig. 2. The frequency (%) of impaired patency of the target artery in the studied groups of patients with BTK lesions (month). The total number of patients in the main group ($n=9$) was 100%. At 1 and 3 months of observation, the total number of patients in the control group ($n=24$) was taken as 100%. At six months, 23 patients were accepted as 100%, and at 9 and 12 months - 21 patients of the control group. ($F_t, p=0.00001$)

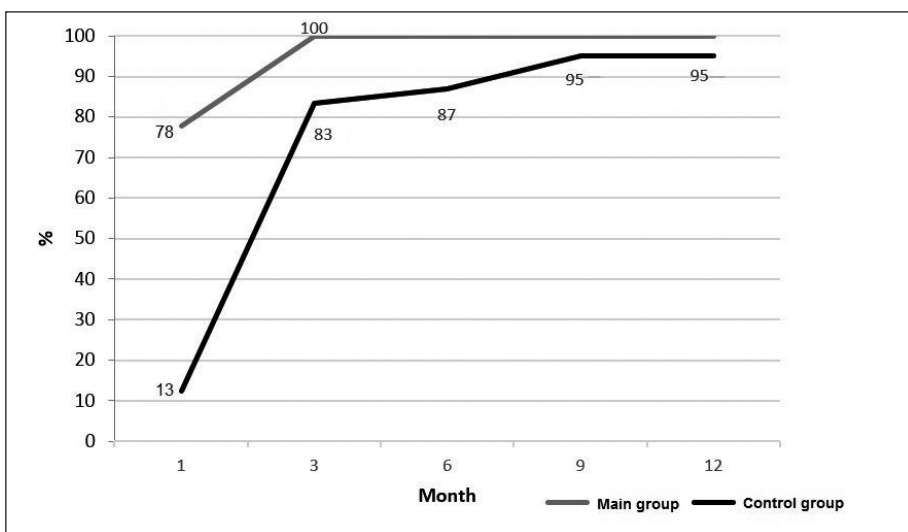


Fig. 3. The frequency (%) of foot trophic changes among patients of the study groups with BTK lesions (month). The total number of patients in the main group ($n=9$) was 100%. At 1 and 3 months of observation, the total number of patients in the control group ($n=24$) was taken as 100%. At six months, 23 patients were accepted as 100%, and at 9 and 12 months - 21 patients of the control group. At 3 months ($p=0.0013$).

from the main body of the wire. The damaged part of the wire was snared and successfully reviewed from the vessel without compromising distal lumen flow. In the control group complications were observed in 13% ($n=3$): 1 case

– vessel perforation of the anterior tibial artery, treated by long-time balloon inflation; 2 cases – bleeding complication of puncture site from the common femoral artery, all treated by prolonged manual compression.

DISCUSSION

Transluminal atherectomy appears to be an effective, predictable, and safe method for removing occlusive atheromatous deposits from peripheral arteries [6]. While established treatments have a solid evidence base and guidelines for their use [7], the outcomes for atherectomy are less well understood [8]. However, unfortunately, there are few high-quality comparative data to guide the choice of a specific endovascular approach [9]. In addition, the PTRAs require a more significant number of observation objects to optimize the performance of the intervention.

Using Rotablation before POBA in calcified BTK lesions in most cases gives the opportunity to reach adequate inflation of the balloon in target arteries for maximum expansion of balloon surface with minimal additional vessel wall trauma [10].

In previous quite old studies where Rotablation used as a stand-alone procedure for ET of BTK lesions reported big complication amount 25-50% of all treated patients. Complications were quite typical for Rotablation atherectomy: arterial spasm, thrombosis, dissection, vessel perforation, distal embolism, and no-reflow [11,12]. That is why new studies and concepts have been performed over the last decades and aim investigators to find new treatment algorithms and methods to reduce complication rates. RESCUE-BTK trial showed that Rotablation was used as an adjunctive device for balloon angioplasty when POBA was unsuccessful. This concept gave a high technical success rate of 94.5% in BTK lesion treatment and much lower complication rates of 1.8% [13]. Our results were almost the same in the technical success rate of 100%, but the complication rate was higher in the main group – at 11%, in the control group – at 13%.

In the last few years, new debulking and plaque modification devices have been developed for endovascular treatment in BTK arteries, such as shockwave balloons, directional atherectomy, laser atheroablation, orbital atherectomy that can tell about the ongoing search for optimal treatment algorithm and optimal devices for BTK lesions.

CONCLUSIONS

Reconstructive endovascular interventions are an effective treatment method for patients with occlusive-stenotic lesions of BTK arteries because they facilitate the healing of trophic ulcers and allow preserving LE with a low risk of developing cardiovascular events. At the same time, using the PTRAs technique improves the treatment results of patients with calcified lesions of the BTK arteries. The probability of target vessel occlusion increases when using POBA-mono compared to combining PTRAs with POBA. In addition, healing trophic ulcers occur more actively in patients with atherosclerosis of BTK when PTRAs is combined with POBA.

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Conflict of interest:

The Authors declare no conflict of interest.

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