YΔK 616.1. 616.13-089

DOI: 10.24884/1682-6655-2024-23-2-60-66

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# Преимущества техники гибридной реваскуляризации при лечении протяженных окклюзий поверхностной бедренной артерии и многоуровневых поражений артерий нижних конечностей

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Статья поступила в редакцию 02.10.23 г.; принята к печати 22.12.23 г.

#### Резюме

Введение. Атеросклеротическое поражение артерий нижних конечностей зачастую носит многоуровневый характер, следствием которого становится инвалидизация населения вплоть до развития постишемического некроза. Общепринятые методы хирургического лечения окклюзии поверхностной бедренной артерии и многоуровневых поражений артерий, тем не менее, характеризуются высокой травматичностью, вызывающей рост летальности среди данной когорты пациентов. Преодоление указанных выше недостатков требовало разработки альтернативных подходов, в частности гибридной реваскуляризации. Цель. Проанализировать собственный опыт проведения указанного выше вмешательства с целью последующей оценки его преимущества. Материалы и методы. В работу включено 80 пациентов, страдающих от хронической ишемии, угрожающей потерей нижней конечности, с окклюзией артерий бедренно-подколенного сегмента длиной >20 см. Исследуемые разделены на две равные группы в зависимости от типа выполненной операции – аутовенозного бедренно-подколенного шунтирования с эндоваскулярной коррекцией каналов оттока (гибридного шунтирования) или аутологичного бедренно-большеберцового шунтирования. Проанализированы клинические и демографические характеристики пациентов, технические особенности вмешательств, а также их прямые и отдаленные эффекты. Оценка проходимости шунта проводилась с использованием таблиц Каплана-Мейера. Различия в показателях между группами определяли при помощи логарифмического критерия. Результаты. Тридцатидневная смертность среди пациентов, относящихся к группе гибридного шунтирования, составила 2,5 % против 4,3 % во второй группе (р>0,05). Частота несостоятельности трансплантата – 5 % против 13 % соответственно. Спустя год после проведенной операции первичная проходимость шунта достигла 77.7 % (95 % ДИ 61.7–93.7) в первой группе. Среди представителей второй группы данный показатель 57,1 % (95 % ДИ 42,9-71,3). Одногодичная выживаемость без ампутации - 82,1 % (95 % ДИ 66,8–97,4) против 69,6 % (95 % ДИ 56,1–83,1) соответственно. Частота ангиосомальной реваскуляризации у больных, которым выполнено гибридное шунтирование, достигла 90,0 %. В другой группе показатель оказался ниже и составил 69,2 % (р=0,006). Выводы. Представленные сведения доказывают высокую эффективность исследуемого способа лечения.

**Ключевые слова:** гибридная реваскуляризация, хроническая критическая ишемия нижних конечностей, атеросклероз, многоуровневое поражение, окклюзия

Для цитирования: Кучай А. А., Липин А. Н., Курьянов П. С. Преимущества техники гибридной реваскуляризации при лечении протяженных окклюзий поверхностной бедренной артерии и многоуровневых поражений артерий нижних конечностей. Регионарное кровообращение и микроциркуляция. 2024;23(2):60–66. Doi: 10.24884/1682-6655-2024-23-2-60-66.

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UDC 616.1. 616.13-089

DOI: 10.24884/1682-6655-2024-23-2-60-66

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# Advantages of the hybrid revascularization technique in the treatment of extended occlusions of the superficial femoral artery and multilevel lesions of the lower extremity arteries

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Received 02.10.23; accepted 22.12.23

#### **Summary**

Introduction. Atherosclerotic lesions of the lower extremity arteries often have a multilevel character, the consequence of which is the disability of the population up to the development of post-ischemic necrosis. Conventional methods of surgical treatment of occlusion of the superficial femoral artery (SFA) and multilevel arterial lesions, however, are characterized by high traumatism causing an increase in mortality in this cohort of patients. Overcoming the above disadvantages required the development of alternative approaches, particularly hybrid revascularization. Objective. To analyze our own experience of the above-mentioned intervention in order to further evaluate its benefits. Material and methods. The study included 80 patients suffering from chronic limb-threatening ischemia (CLTI) with occlusion of the femoral-popliteal segment arteries >20 cm long. The subjects were divided into two equal groups depending on the type of surgery performed – autovenous femoralpopliteal bypass with endovascular correction of outflow channels (hybrid bypass) or autologous femoral-tibial bypass (FTB). We analyzed the clinical and demographic characteristics of the patients, technical features of interventions, as well as their direct and long-term effects. The assessment of the shunt patency was carried out using Kaplan-Meyer tables. The differences in indicators between groups were determined using the logarithmic criterion. Results. Thirty-day mortality among patients in the hybrid bypass group was 2.5% versus 4.3% in the second group (p>0.05). The frequency of graft failure is 5% versus 13%, respectively. A year after the operation, the primary shunt patency reached 77.7% (95% CI 61.7-93.7) in the first group. In the second group, this indicator was 57.1% (95% CI 42.9-71.3). One-year survival without amputation was 82.1% (95% CI 66.8-97.4) versus 69.6% (95% CI 56.1-83.1), respectively. The frequency of angiosomal revascularization in patients who underwent hybrid bypass surgery reached 90.0%. In the other group, the indicator was lower and amounted to 69.2% (p=0.006). Conclusions. The presented information proves the high efficiency of the investigated method of treatment.

Keywords: hybrid revascularization, chronic limb-threatening ischemia, atherosclerosis, multilevel lesion, occlusion

For citation: Kuchay A. A., Lipin A. N., Kurianov P. S. Advantages of the hybrid revascularization technique in the treatment of extended occlusions of the superficial femoral artery and multilevel lesions of the lower extremity arteries. Regional hemodynamics and microcirculation. 2024;23(2):60–66. Doi: 10.24884/1682-6655-2024-23-2-60-66.

#### Introduction

Atherosclerotic affection of the arteries of the lower extremities has very often the character of multilevel disability. The extent of disability is very typical for patients with critical limb ischemia. Solution of extended occlusion of SFA and multilevel affection in the form of extensive vascular-surgical intervention leads to a significant increase in perioperative morbidity and mortality of patients. Efforts to reduce the rate of complications of extensive vascular-surgical procedures with the current rescue of the limb, it was behind the development of the hybrid performance. Hybrid procedure is referred to an intervention, which combines endovascular and open vascular-surgical intervention within one or more follow-up procedures. We divide accordingly hybrid procedures to single-staged or double (2-staged). The author of the first hybrid performance is called Porter, who already combined dilatation in 1973 pelvic arteries with femoro-femoral bypass to rescue the lower limb [1].

Early development phase of hybrid performances took the form of multi-staged interventions. Growing familial vascular surgery with endovascular interventions led to the development of double-staged at the turn of the millennium, simulated hybrid performances [2]. Their advantage is the elimination of the accumulation of complications of 2 isolated interventions, which otherwise arises during multistep implementation. At our site we perform hybrid performances from 2014. The topic of this communication is to present our experience with hybrid performances, evaluation influence of indication and nature of hybrid reconstruction on their results.

#### **Material and Methods**

We were monitoring 80 patients with chronic lower limb ischemia (table 1) who underwent hybrid interventions on the arterial system of the lower limb due to atherosclerotic after disability. Atherosclerosis was the cause of occlusive arterial bed or channel lesion in all

Таблица 1

#### Клинические характеристики пациентов с КИНК, которым выполнены гибридные вмешательства

Table 1

#### Clinical characteristics of patients with CLTI who underwent hybrid interventions

Characteristic	Hybrid intervention, N (%)	Femoral-tibial bypass, N (%)	P	
Males, n (%)	60 (75)	34 (73.9)	0.05	
Age (y), mean (range)	69.5 (45–88)	69 (46–88)		
Coronary artery disease, n (%)	66 (82.5)	37 (80.4)		
Diabetes mellitus, n (%)	36 (42.5)	20 (43.4)		
Chronic renal failure, n (%)	8 (10)	5 (10.8)		
Tissue loss				
Rutherford 5, n (%)	36 (45)	22 (47.8)		
Rutherford 6, n (%)	44 (55)	24 (52.1)		
Angiosome affected				
Posterior/anterior tibial artery, n (%)	74 (92.5)	26 (56.5)		
Peronea alone or in combination with other angiosomes, n (%)	6 (7.5)	20 (43.5)		

#### Таблица 2

#### Результаты предоперационной ангиографии

Table 2

#### Preoperative angiographic findings

Trooperative angrograpme intends		
N ( %)		
80 (100)		
18 (22.5)		
Patent and non-stenotic PA with one of the following		

Three-vessel crural CTO, n (%)	52 (65)
A. peroneal as the only runoff artery, n (%)	14 (17.5)

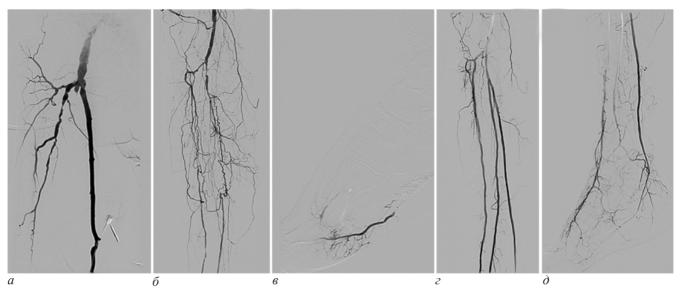
patients. In all patients their pre-operative anamnestic data, results of physical examination were obtained and performed preoperative imaging methods. Information on the nature of hybrid reconstruction, perioperative and postoperative stem of patients was obtained and their post-performance monitoring. Collection the data went prospectively, evaluation later retrospective. The indication of patients to perform was based on the presence of symptomatic arterial affection of the lower extremities (HD) as defined Rutherford [3]. Patients with an image of acute limb ischemia (ALI) based on peripheral atherosclerosis were also included in the study. Demographic data and information on risk factors of atherosclerosis were obtained in patients. Based on the type of indication for hybrid intervention, patients were divided into 2 groups. We used a series of 46 consecutive patients who underwent femoral tibial bypass. In this series there were 34 (73.9 %) male and 12 (26.1 %) female patients.

The average age was 69.5 years, 60 (75 %) men and 20 (25 %) women. The detection of occlusion or hemodynamically meaningful stenosis in the infrainguinal arterial segment, along with long-standing occlusion of the SFA and crural arteries, served as evidence for surgical treatment. Hybrid procedures were also performed for cases with a substantial and prolonged lesion of the SFA. It is well known that stenting of the specified ves-

sel carries a significant risk of stent rupture and arterial occlusion [4].

Significant proportion of patients had profound necrotic changes involving toes and commonly extending to metatarsus. Preoperative digital subtraction angiography (DSA) (table 2) revealed long (>20 cm) SFA chronic total occlusion (CTO) in all cases (n=80; 100 %) with proximal (above the knee) popliteal artery (PA) always being patent and non-stenotic. Distal (at or below the knee) PA CTO was found in 18 (22.5 %) patients, threevessel crural CTO – in 52 (65 %), CTO of anterior and posterior tibial arteries (with peroneal as the only runoff vessel) – in 14 (17.5 %).

Postoperative follow-up of patients was performed by clinical examination and ultrasonographic duplex follow-up at intervals of 2, 6, 12, 24 months after hybrid intervention and further at annual intervals. In case of worsening of clinical symptomatology, clinical finding or Pathology of duplex ultrasonography was indicated by CT angiography for diagnosis and assessment of possibility of reintervention, or digital subtraction angiography commonly associated with percutaneous reintervention. An unfractioned heparin (UFH) dose of 60 IU/kg was administered during single-step hybrid interventions. For staged hybrids 30 IU/kg UFH was used during open and 60 IU/kg at the endovascular step.



Пример симультанного дистального гибридного вмешательства, выполненного пациенту возрастом 64 года с критической ишемией нижней конечности и глубокими трофическими изменениями в бассейне латеральной подошвенной артерии: 
а – интродьюсер 6F установлен антеградно через боковую ветвь функционирующего бедренно-подколенного шунта; б – селективная прямая ангиография артерий подколенно-большеберцового сегмента, выполненная через интродьюсер: окклюзия всех артерий голени; в – реканализация задней большеберцовой артерии: введение контрастного вещества в латеральную подошвенную артерию через просвет баллонного катетера; 
г – окончательный результат эндоваскулярного вмешательства: все три артерии голени функционируют; д – прямая ангиосомная реваскуляризация стопы

Example of a simultaneous distal hybrid intervention performed on a 64-year-old patient with CLI and deep trophic changes in the lateral plantar artery: a – the introducer 6F is placed antegradely via the lateral branch of the functioning femoral-popliteal shunt/bypass (FPB);  $\delta$  – selective direct angiography of the arteries of the popliteal-tibial segment performed through the introducer: occlusion of all tibial arteries;  $\epsilon$  – recanalization of the posterior tibial artery: injection of contrast agent into the lateral plantar artery through the lumen of the balloon catheter;  $\epsilon$  – the final result of the endovascular intervention: all three tibial arteries are functioning;  $\delta$  – direct angiosomal foot revascularization

	Таблица 3		
Тридцатидневная смертность и осложнения			
	Table 3		
Thirty-day mortality and complications			
Mortality, n (%)	1 (1.25)		
Graft failure, n (%)	4 (5)		
Crural artery thrombosis, n (%)	2 (2.5)		
Major amputation, n (%)	1 (1.25)		
Thrombotic occlusion of CFA used for endovascular access, n (%)	1 (1.25)		

The analysis of the patency of reconstructions and limb-salvage analyzes were performed using Kaplan–Meier life tables. Differences in clearance between patient groups were assessed by use of the log-rank test. P values <0.05 were regarded as statistically significant. The continuities of hybrid reconstructions were evaluated for the performance as a whole, i.e., simultaneously for its endovascular and vascular-surgical intervention.

#### **Results**

The analysis was performed in 80 patients and all the patients underwent hybrid revascularization procedures (figure). The mean age of patients in the study was 69.5 years (range: 50–87 (years) with a predominance of men (60; 75%). The incidence of cardiovascular comorbidities was: diabetes 42,5% of patients, hypertension 85,8% of patients, ischemic heart disease 48,0% of patients, history of myocardial infarction 19,7% of patients, stroke history of event 16,5% of patients, hyperlipidemia 55,9% of patients, chronic renal insufficiency 10% patients, active smokers 90% and stop-smokers 20,2% of patients.

Thirty-day mortality after hybrid interventions was 1.25 % (1 death due to acute coronary syndrome) (table 3). Four patients (5 %) had early graft failure, both occurred 1 day after a single-step hybrid. There were no cases of early graft failure during (between open and endovascular steps) or after staged hybrid interventions. Two (2.5 %) patients had early thrombosis of a crural artery after balloon angioplasty (BAP) with stenting. The bypass, however, remained functional and the signs of chronic limb ischemia (CLI) resided. One (1.25 %) above-knee amputation was performed within 30 days after revascularization. Access site complications included one (1.25 %) case of contralateral common femoral artery (CFA) thrombosis successfully treated with endarterectomy.

A year after the operation, the primary patency of the shunt reached 77.7 % (95 % CI 61.7–93.7) in the first group. Among the representatives of the second group, this indicator is 57.1 % (95 % CI 42.9–71.3). One-year survival without amputation was 82.1 % (95 % CI 66.8–97.4) versus 69.6 % (95 % CI 56.1–83.1), respec-

tively. The frequency of angiosomal revascularization in patients who underwent hybrid bypass surgery reached 90.0 %. In the other group, the indicator was lower and amounted to 69.2 % (p=0.006).

When monitoring the effect of comorbidities on the patency of reconstruction, we reached several paradoxical findings, although below the limit of statistical significance. Patients with diabetes, hyperlipidemia and active smokers showed improved reconstruction clearance compared to patients who did not have the indicated comorbidities.

#### Discussion

Hybrid revascularization procedures are already an integral part of the treatment of vascular Workplaces not only in the world, but also in the Russian Federation [5]. They allow multilevel revascularization of the limb affected by ischemia, in a very gentle way for the patient, with minimization of the extent of vascular-surgical interventions. Patients with multilevel disability of leg arterial disease represent comorbidities in very affected patient population. Because of their restricted capacity to undergo substantial surgical revascularization as a substitute for hybrid intervention, perioperative morbidity and mortality are disproportionately increased in real-world settings. For these reasons, hybrid performance is attractive, less invasive form of revascularization [6]. The advantage of simultaneous intervention is the elimination of risk hematomas, pseudo development and other complications after percutaneous transluminal angioplasty. Listed the procedure also eliminates the risk of failed percutaneous cannula of the arterial bed.

Hybrids of this sort are seldom done in CLI patients [7]. Published studies contain small numbers of patients and don't include any relevant comparators. Therefore, trying to define indications to this type of interventions we relied on two well-known and widely adopted principles. First, we preferred bypass to peripheral vascular intervention (PVI) in long (>20 cm) SFA CTOs. This was due to lower patency of PVI in extensive SFA disease as compared to open surgery [8]. As well, the outcome of SFA BAP/stenting is worse in patients with severe crural disease [9].

A matter of discussion here, of course, is the choice of a hybrid approach with femoropopliteal bypass and crural BAP instead of simply performing femoral tibial/ pedal bypass, the latter being the method of choice for the majority of vascular surgeons. Indeed, most would opt to provide direct flow to the foot at the expense of increased bypass length, avoiding the need for any PVI. Indirect evidence to support this is the high proportion of FTB (12 % to 40–50 %) in large studies and registries of open reconstructions in CLI [10]. The reverse side of such practice, however, might be more early failures (up to 9 %), major amputations (4.7–8.3 %) [11], early revisions (13.3 %) [12] and, finally, higher mortality (4.6–6.8 %). This became one of the things for us favoring FPB. In fact, our study showed the rate of early failures after distal hybrids being lower compared to the published studies of open infrainguinal interventions.

Trying to address this issue we reviewed publications concerning infrainguinal bypass with distal anastomosis at the genicular, sural or isolated («blind») popliteal arteries [13]. These studies commonly enrolled several dozens of patients. Most authors used vein conduit [14], others implanted even PTFE grafts [15]. No double antiplatelet therapy or anticoagulation were used. Early failure rate of vein grafts was 0-3.3 %. Primary patency of vein bypass at 1 year was 73 % to 94 % [16], at 3 years – 65–84.1 % [17], at 5 years – 72–74 % [18]. Limb salvage at 3 years reached 68–90 % and up to 78 % at 5 years. Importantly, no author measured healing time. Despite functioning bypass, 3.3 to 6.3 % patients [19] still had progressive CLI and required below-knee amputation. Therefore, even complete occlusion of all crural arteries didn't seem to be linked to an increased early failure rate or any decline in the long-term patency as compared to the results obtained in large studies of infrainguinal reconstructions. Lastly, recent guidelines on peripheral arterial disease treatment [20] recommend considering bypass to an isolated popliteal artery in case of insufficient conduit length or no other recipient vessels present. At the same time, there's been no trial comparing FPB with 3-vessel crural CTO to FTB. In addition, we haven't found any published data on the volume flow through FPB to a «blind» popliteal segment.

Another important principle that led us to the concept of distal hybrids was angiosomic revascularization [21] achieved through crural BAP. Here it's worth mentioning that, despite affirmative conclusions made in large metaanalyses [22], the need for direct foot revascularization is still a matter of debate. Thus, some authors found no benefit of direct angiosomic revascularization (DR) over the indirect (IR) [23]. Others showed improved healing time for DR vs IR with no difference in limb salvage rates [24] or vice versa [25]. As for the method of revascularization, there were studies that included only bypass reconstructions, or, on the contrary, solely PVI. Finally, some authors studied both open and endovascular interventions. Publications varied in the proportion of superficial and profound tissue loss, the per cent of minor amputations vs debridement and even the very definition of DR: Fossaceca R. et al. [26]; Kabra A. et al. [24]; Soderstrom M. et al. [27] and Lejay A. et al. [28] used «classic» layout of foot angiosomes; others regarded revascularization of toes through plantar arch and/or heel area revascularization via peroneal artery as DR [29, 30, 31]. A common trait of all studies reviewed was the presence of at least one patent crural artery in the IR cohort. Similarly, the published data on distal hybrid interventions mostly include cases with a minimum of one crural runoff vessel [32]. Our own series, however, is remarkable for the high proportion of patients (65 %) with three-vessel crural CTO. Therefore, the above studies (particularly those showing no benefit of DR vs IR) are unlikely to reflect the prospects of healing in our patients. The three-vessel crural CTO can by itself cause CLI and this, we believe, also created grounds for performing runoff CLI after an FPB.

An important reason for us to choose hybrid approach was the high proportion of deep necrotic changes eventually requiring minor amputation. In such settings, failure to achieve foot healing might lead to a below-knee amputation even with a functioning bypass. And, with a distal anastomosis located above the knee, you avoid the otherwise inevitable bypass ligation and preserve good perfusion of the stump [33].

Hybrid reconstruction clearance results in our file fall into the dispersion of the results of published works. A relatively high percentage (19,7 %) patients with a short follow-up interval are considered to be a factor that adversely affected the results statistics. The effectiveness of hybrid intervention to deal with multilevel lesions and the impact of the arterial system is also proven by the results of both groups, which is typical population of patients with multiple-stage disability. The paradox of the favorable effect of the presence of diabetes, hyperlipidemia and the status of active smoking on the patency of reconstruction is not clearly explained. Although the data do not reach statistical significance, at the same time, however, they are not explained by the representation of favorable or unfavorable types of performances. Thirtyday mortality and complications show's table 3. The average patient follow-up interval is short and negatively affected by a relatively high number of patients with a short monitoring period [34].

All these considerations, of course, need to be confirmed by comparative studies. Though, it can be concluded that hybrid approach to long SFA CTO with extensive crural runoff disease is a viable and effective strategy in patients with CLI.

#### Conclusion

Hybrid revascularization is a combination of vascularsurgical and endovascular types of treatment the effective use of which permit to achieve a clinically significant regression of long SFA CTO and multilevel disability of leg arterial system in one or two sessions. It is loaded low risk of periprocedural mortality and morbidity for the patient. It can achieve good results of the continuity of the arterial system and the rescue of the limb, regardless of the type of chronic ischemia (claudication, severe limb ischemia). Results in patients with acute limb ischemia, they are inferior. As the best performance is the combination the two-step interventions of the arteries associated with transluminal angioplasty of the tibial arteries or outflow tract of the limb. Hybrid performance allows us to reduce invasiveness vascular-surgical intervention with subsequent positive impact on perioperative complications of patients. Larger comparative studies using intraoperative flowmetry to measure the volume flow are needed.

#### Конфликт интересов / Conflict of interest

Авторы заявили об отсутствии конфликта интере-COB. / Authors declare that they have no conflicts of interest.

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