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COMPARISON OF CLINICAL OUTCOME OF BYPASS SURGERY VERSUS BELOW-THE-KNEE ANGIOPLASTY AND STENTING IN INFRAPOPLITEAL LESIONS THAT RESULTS IN ULCER OR TOE GANGRENE

© Arshed A. Kuchay[1, 3], Alexander N. Lipin[2, 3], Nikita N. Gruzdev[3], Aleksey G. Borisov[3], Ilyas S. Kashapov[4], Kirill A. Atmadzas[3], Anton G. Orlov[3], Hudayberdi A. Muhamedov[5]

[1] Med2 clinic. 11 Vosstaniya str., Saint Petersburg 191036 Russian Federation
[2] Military Medical Academy named after S.M. Kirov. 6 Akademician Lebedev str., Saint Petersburg 194044 Russian Federation
[3] City Hospital No. 14, Limb Salvage Center. 19/9 Kosinov str., Saint Petersburg 198099 Russian Federation
[4] Saint Petersburg City Polyclinic No. 120. 4/1 Lenskaya str., Saint Petersburg 195426 Russian Federation
[5] Belgorod State National Research University. 85 Pobeda str., Belgorod 308015 Russian Federation

Contact information: Arshed A. Kuchay — Cardiovascular Surgeon, Clinical Researcher of the City Limb Salvage Center.
E-mail: drarshedcvs@gmail.com ORCID: https://orcid.org/0000-0002-7974-9369 SPIN: 5455-9033

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Abstract. ***Introduction.*** Chronic limb-threatening Ischaemia (CLTI) is a manifestation of peripheral arterial disease (PAD) that includes chronic ischemic rest pain or Ischaemic skin lesions, ulcers, or gangrene for longer than two weeks. Although infrapopliteal angioplasty may salvage the majority of limbs under threat of amputation. Endovascular interventions in the infrapopliteal vasculature may improve symptoms in patients with CLTI by re-establishing in-line blood flow to the foot. The optimal revascularization strategy for patients with severe leg ischemia remains uncertain. ***The purpose*** of this study was to compare outcomes of bypass surgery and angioplasty in isolated below-the-knee lesions. ***Materails and methods.*** Patients with ulcers or toe gangrenes, undergone below-the-knee bypass surgery or angioplasty and stenting from 2022 to 2023, were included in the study. Amputation-free survival (AFS) and overall survival (OS) were assessed using the Kaplan–Meier and Cox regression tests. ***Results.*** Three hundred ten (310) patients were included in this study, of which 259 patients underwent balloon angioplasty and popliteal artery stenting, 51 patients underwent bypass surgery. The mean age in the bypass group was 73.1 (±7.1) years and 73.9 (±7.2) years in the angioplasty and stenting group. There were no significant differences in gender, diabetes, hypertension, history of smoking, history of stroke, and renal insufficiency between the three groups. AFS was 43.4 (±8.5) months in the bypass group and 39.8 (±8.9) months in the angioplasty and stenting group which was significantly better in the bypass group (p=0.05). OS was 49.6 (±10.6) months in the bypass group and 46.2 (±11.7) months in the angioplasty and stenting group but did not differ statistically significant (p=0.32). ***Conclusion.*** AFS was significantly higher in the bypass group. Thus, bypass surgery seems preferable to angioplasty for all patients with severe leg ischemia except those with multiple comorbidities and those whose vein is not adequate for bypass.

Keywords: below-the-knee angioplasty, below-the-knee bypass, lower limb ischemia, toe gangrene

СРАВНЕНИЕ КЛИНИЧЕСКИХ РЕЗУЛЬТАТОВ ШУНТИРОВАНИЯ ПО СРАВНЕНИЮ С АНГИОПЛАСТИКОЙ И СТЕНТИРОВАНИЕМ НИЖЕ КОЛЕНА ПРИ ПОРАЖЕНИИ ИНФРАПОПЛИТЕАЛЬНОЙ АРТЕРИИ, ПРИВОДЯЩЕМ К ЯЗВЕ ИЛИ ГАНГРЕНЕ СТОПЫ

© Аршед Ахмад Кучай[1, 3], Александр Николаевич Липин[2, 3], Никита Николаевич Груздев[3], Алексей Геннадьевич Борисов[3], Ильяс Салаватович Кашапов[4], Кирилл Александрович Атмадзас[3], Антон Георгиевич Орлов[3], Худайберды Азаткулиевич Мухамедов[5]

[1] Клиника Мед2. 191036, г. Санкт-Петербург, ул. Восстания, 11
[2] Военно-медицинская академия им. С.М. Кирова. 194044, г. Санкт-Петербург, ул. Академика Лебедева, 6
[3] Городская больница № 14, Центр спасения конечностей. 198099, г. Санкт-Петербург, ул. Косинова, 19/9
[4] СПб ГБУЗ «Городская поликлиника № 120». 195426, г. Санкт-Петербург, ул. Ленская, 4/1
[5] Белгородский государственный национальный исследовательский университет. 308015, г. Белгород, ул. Победы, 85

Контактная информация: Аршед Ахмад Кучай — врач сердечно-сосудистый хирург, клинический исследователь Городского центра спасения конечностей. E-mail: drarshedcvs@gmail.com ORCID: https://orcid.org/0000-0002-7974-9369 SPIN: 5455-9033

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Резюме. ***Введение.*** Хроническая ишемия, угрожающая потерей конечностей (ХИУПК), представляет собой конечную стадию заболевания периферических артерий (ЗПА), которое включает хроническую ишемическую боль в покое или ишемические поражения кожи, язвы или гангрену продолжительностью более двух недель. Хотя инфрапоплетиальная ангиопластика может спасти большинство конечностей при угрозе ампутации, эндоваскулярные вмешательства на инфрапоплитеальном сосудистом русле могут улучшить симптомы у пациентов с ХИУПК за счет восстановления магистрального кровотока в стопе. Оптимальная стратегия реваскуляризации у пациентов с тяжелой ишемией ног остается неопределенной. ***Целью*** данного исследования было сравнение результатов шунтирования и ангиопластики при изолированных поражениях ниже колена. ***Материалы и методы.*** В исследование были включены пациенты с язвами или гангреной пальцев ног, перенесшие операцию шунтирования ниже колена или ангиопластику и стентирование в 2022–2023 гг. Выживаемость без ампутаций (ВБА) и общая выживаемость (ОВ) оценивались с использованием регрессионных тестов Каплана–Мейера и Кокса. ***Результаты.*** В исследование были включены 310 пациентов, из них 259 пациентам была выполнена баллонная ангиопластика и стентирование подколенной артерии (ПкА), 51 пациенту — шунтирование. Средний возраст в группе шунтирования составил 73,1 (±7,1) года, а в группе ангиопластики и стентирования — 73,9 (±7,2) года. Между двумя группами не было существенных различий по полу, диабету, гипертензии, курению, инсульту и почечной недостаточности в анамнезе. ВБА составила 43,4 (±8,5) месяца в группе шунтирования и 39,8 (±8,9) месяца в группе ангиопластики и стентирования, что было достоверно лучше в группе шунтирования (p=0,05). Общая выживаемость (ОВ) составила 49,6 (±10,6) месяца в группе шунтирования и 46,2 (±11,7) месяца в группе ангиопластики и стентирования, но статистически значимо не отличалась (p=0,32). ***Заключение.*** ВБА была значительно выше в группе шунтирования. Таким образом, операция шунтирования представляется предпочтительнее ангиопластики для всех пациентов с тяжелой ишемией ног, за исключением пациентов с множественными сопутствующими заболеваниями и тех, чья вена не подходит для шунтирования.

Ключевые слова: ангиопластика ниже колена, шунтирование ниже колена, ишемия нижних конечностей, гангрена пальца стопы

INTRODUCTION

Atherosclerosis is the most common cause of peripheral arterial disease (PAD) of the lower extremities. Acute ischemic limb is an advanced stage of peripheral vascular disease, which is characterized by pain during rest and night pain (requiring opioid analgesics), for >2 weeks. This condition results in ulcers and gangrene in the limbs, and if left untreated, it will cause permanent disability, even amputation, and mortality in patients. It also imposes a heavy burden on the society and health system [1]. This condition is now cured using various revascularization technics [2]. Although surgical bypass is regarded as the gold standard due to better anatomical and clinical durability relative to the other revascularization methods for critical lower limb ischemia (CLI) [14–16], percutaneous transluminal angioplasty (PTA) in peripheral vascular disease (PVD) is a feasible method of treating CLI, and has similar outcomes to those of bypass surgery [17, 18, 23–30] (Fig. 2).

Several studies have been published about the outcomes of surgical and endovascular interventions all around the world, presenting various views on these two approa-

ches. Although both surgery and angioplasty methods are suggested for these patients, there are still significant controversies regarding the best one [1, 3–9].

Infrapopliteal bypass is one of the major methods in lower limbs, which targets to reestablish blood flow to the tibial, peroneal, or pedal arteries. The primary indication for this method is critical limb ischemia (CLI) due to atherosclerotic events [3]. In general, venous grafts, regardless of the target site, are preferred over artificial grafts in all below-the-knee bypasses. The large saphenous vein is most commonly used; however, small saphenous vein, superficial femoral vein, and venous parts of the upper limbs can also be used [4, 8, 23–30].

Endovascular treatment is often the first choice in the treatment of peripheral vascular diseases of the lower extremities [2]. New advances in endovascular treatments have made it possible to treat complicated vascular lesions. Patients with multiple underlying illnesses or those who do not have proper veins for the surgery will benefit most from endovascular therapies [2, 6].

Despite extensive studies for determining the best way to treat these patients, there is no consensus on which surgical or angioplasty is preferred (Fig. 3).

THE AIM OF THE STUDY

This study aimed to compare the results of bypass and angioplasty in patients with lesions below the knee due to ischemia, to determine which method gives better outcomes.

MATERIALS AND METHODS

In this retrospective cohort study, 310 patients who were treated by bypass surgery or angioplasty or stenting from 2022 to 2023 were included in the study. The criteria for entering the study were having obstruction or stenosis of distal to popliteal artery confirmed by duplex or triplex ultrasonography and computed tomography angiography. The exclusion criteria of patients were being unable to walk due to advanced underlying disease or due to severe deformities in the knee or ankle joints.

The patients were interviewed and examined to collect their demographic, pre and post-medical history information, including gender, age, smoking status, background illnesses, having ulcers, gangrene, or pain during rest, level of amputation, glycated hemoglobin level, and type of their surgeries (Fig. 1). Confidence interval in this study was 95%.

RESULTS

A total number of 310 patients who were undergone below-the-knee bypass surgery or angioplasty or stenting of PopA during the years of 2022–2023 because of foot ulcers or gangrene were enrolled in this study. The mean age in

Possibility of PAD
Medical history, Risk factors of atherosclerosis,
Arterial pulse palpitation, Vascular bruit, ABI

↓

Foot evaluation (WIfi classification) *Toe pressure, SSP,TcPO2, CRP, WBC, Bacterial culture*

I grade	*W grade*	*Fi grade*
Grade 3 with rest pain	*W3*	*Fi2,3*
Grade 2 with tissue loss	*Deep infection evaluation*	*Deep infection evaluation*

Diagnosis as CLI

↓

Systemic evaluation	**Vascular evaluation**	**Differential diagnosis of disease etiology**
Cardiac function, coronary circulation	Anatomy of arterial lesions	Buerger's disease
Cerebral and neck arteries	Hemodynamics (duplex)	Other vasculitis
Lung, kidney, liver function	Vein material evaluation	Collagen disease
Coagulation and fibrinolysis system	Limb function evaluation	Rare diseases involving popliteal artery
Status of lifestyle disease management	Daily activity	Other vascular disease

Fig. 1. Diagnostic steps for patients with rest pain or chronic wounds of foot: PAD — peripheral arterial disease; CLI — critical limb ischemia

Рис. 1. Диагностические этапы для пациентов с болью в покое или хроническими ранами стопы

Table 1

Demographic and descriptive statistics about age, amputation-free survival, and overall survival of patients groups

Таблица 1

Демографическая и описательная статистика о возрасте, без ампутационной выживаемости и общей выживаемости групп пациентов

Variable	Groups	N	Mean	SD	SEM
Age	Angioplasty+stenting	259	73.95	7.22	1.07
	Bypass	51	73.11	7.10	1.08
AFS	Angioplasty+stenting	259	39.82	8.98	1.33
	Bypass	51	43.44	8.57	1.30
OS	Angioplasty+stenting	259	46.28	11.76	1.75
	Bypass	51	49.67	10.68	1.62

Note: AFS — amputation-free survival; OS — overall survival: SD — standard deviation: SEM — standard error of mean.

Table 2

Таблица 2

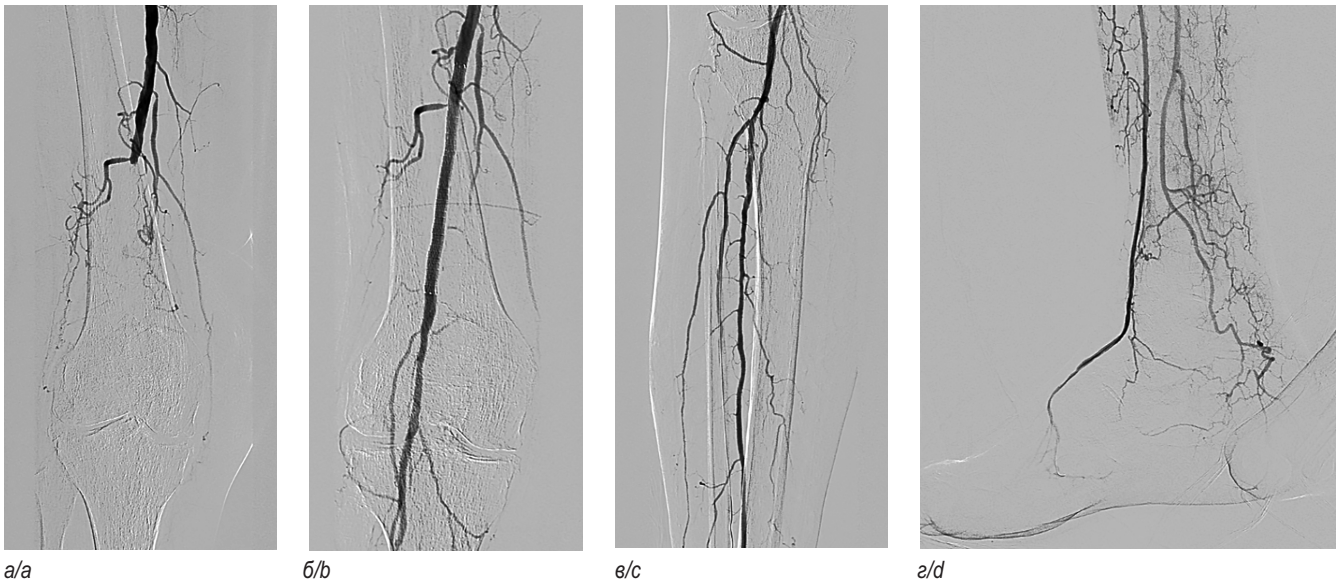
Классификация А.В. Покровского
A.V. Pokrovsky classification

Stage	Symptoms
I	Asymptomatic or pain in calf muscles (>1 km)
IIA	Intermittent claudication (>200 meters)
IIB	Intermittent claudication (<200 meters)
III	Intermittent claudication, rest pain
IV	Ulceration or gangrene

the bypass group was 73.1 (±7.1) years, and in the angioplasty group was 73.9 (±7.2) years. Amputation-free survival (AFS) in the bypass group was 43.5 (±8.5) months and 39.8 (±8.9) months in the angioplasty group. AFS was significantly higher in the bypass group compared to the angioplasty group (p=0.05) (Table 1). In addition, the AFS survival survey showed that in the bypass group, the predicted survival rate was 45.1±4.29 (42.87–47.95) months, and in the angioplasty group was 41.1±7.27 (39.24–44.25) months, which showed a significant difference between the two groups (p=0.05). Patients' overall survival (OS) was 49.6±10.6 and 46.2±11.7 months in the bypass and angioplasty groups, respectively. There was no significant difference between the groups (p=0.32) (Table 1). The OS survey of patients indicated that the average predicted survival in the bypass group was 54.1±6.7 months (51.13–58.09) and in the angioplasty group was 52.2±2 months (48.3–56.1). Despite >4 months difference, it was not statistically significant (p=0.3).

DISCUSSION

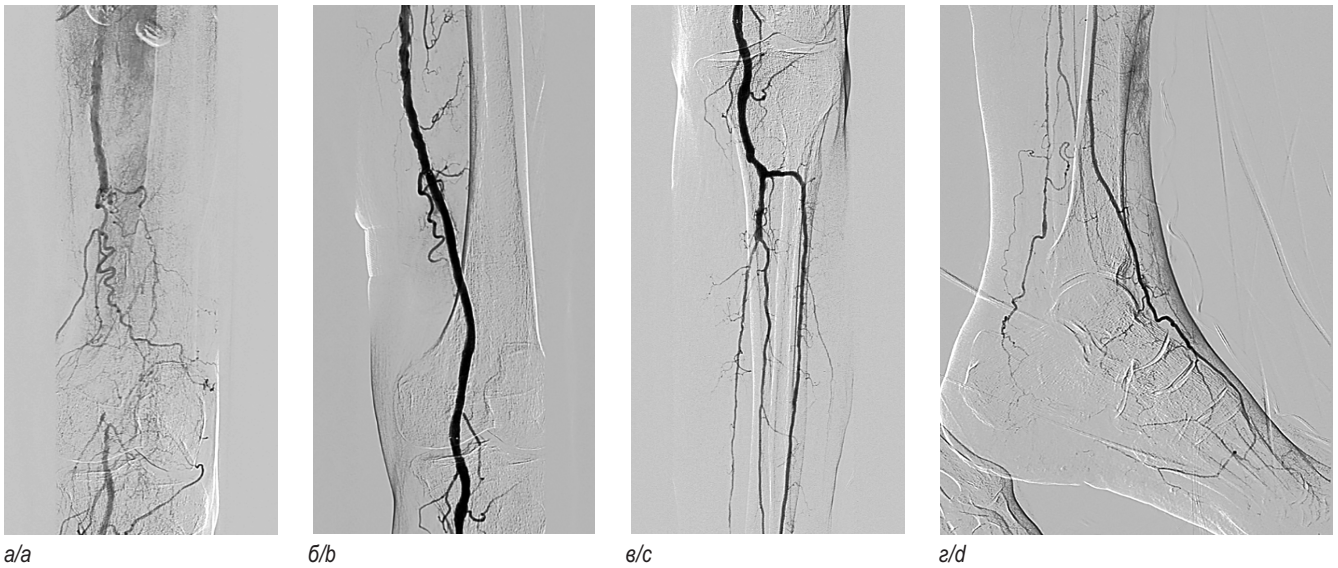
Choosing the best type of treatment for patients with lower limb ischemia is still a question. According to the Bypass versus Angioplasty in Severe Ischemia of the Leg's (BASIL's) randomized controlled trial (RCT), there was no significant difference between the results of surgical bypass and angioplasty up to 2 years. However, patients who lived >2 years benefited from bypass surgery. To the best of our knowledge, BASIL's RCT is the only one that its results are available in this regard [1]. Although BASIL 2, and BEST-CLI studies are in progress, their results have not been released yet. Therefore, considering that there is still no certainty about treatment selection, the current study aimed to collect, analyze, and report the results of both bypass and angioplasty patients with lower limb ischemia. The main goal was to answer the question of which method is better for below-the-knee lesions. Although the definition of "better" is not easy, we chose AFS as the main criterion, which is also the US Food and Drug Administration's criterion for such studies. The reason for not considering other criteria such as vascular patency and arterial pressure in the ankle (ankle pressure) was that we wanted to compare two therapeutic strategies, not just comparing bypass and angioplasty techniques. Morbidity was not evaluated in this study due to the controvert results reported in various studies pertaining to morbidity. For example, an article published by Siracuse et al.



а/a *б/b* *в/c* *г/d*

Fig. 2. Occlusion of the PopA, crural arteries on the right: *a* —initial angiogram; *b–d* — after transluminal balloon angioplasty with stenting of the PopA and lower leg arteries

Рис. 2. Окклюзия подколенной артерии (ПкА), артерий голени справа: *а* — исходная ангиограмма; *б–г* — после транслюминальной баллонной ангиопластики со стентированием ПкА и артерий голени



а/a *б/b* *в/c* *г/d*

Fig. 3. Occlusion of the PopA, crural arteries on the left: *a* — initial angiogram; *b–d* — after transluminal balloon angioplasty with stenting of the PopA and lower leg arteries

Рис. 3. Окклюзия подколенной артерии (ПкА), артерий голени слева: *а* — исходная ангиограмма; *б–г* — после транслюминальной баллонной ангиопластики со стентированием ПкА и артерий голени

indicated endovascular procedures had been associated with lower 30-day mortality rate and 3-year worse survival compared to surgical bypass [10]. In another study by Tsai et al., no significant difference was reported between these two methods regarding the 30-day mortality [11]. Moreover, studies often suggest that mortality and morbidity of the endovascular method are reduced within short-term periods. Thus, they are less indicative to determine the effectiveness of these methods, especially in long-term periods [12, 13].

The examinations showed that all of the patients, who participated in this study, had normal aortic, iliac, and femoral vessels or had no significant lesions. To the best of our knowledge, most of the previous studies analyzed the lesions under the groin area, while the current study for the first time compared these two methods in lesions below the knee. AFS in the bypass group was 43.5±8.5 and in the angioplasty group, it was 39.8±8.9 months, which showed a significant difference with p=0.05

(Table 1). In addition, OS in bypass patients was 49.6±10.6 months and 46.2±11.7 months in the angioplasty patients. There was no significant difference between the two groups regarding OS (p=0.32). Regarding the fact that the mean and frequency of demographic variables such as age and gender in the two groups did not differ significantly. Thus, it cannot be hypothesized that the patients in the bypass group had better physical status. Indeed, the effects of the demographic factors were minimized. Due to the increasing prevalence of diabetes, high blood pressure, and tobacco consumption, limb ischemia appears to be one of the major problems in health systems, both in developed and developing countries.

Currently, most studies emphasizing vascular reconstruction for patients with severe lower limb ischemia are reporting very good results. However, a significant percentage of these patients undergo medical treatments. Although AFS was a clear and relevant measure in this study, it did not provide much information about the quality of life of patients after vascular reconstruction. It is quite acceptable that sometimes amputation in the early phase of the disease improves the patient's quality of life, but on the other hand, chronic pain, and wound care reduce the quality of life of the patients. As a result, this issue should be taken into attention by vascular surgeons and intervention specialists, to not only consider vascular lesions in the treatment of these patients but also patients' needs and expectations.

Although bypass surgery using outflow vessels below the ankle should be considered the standard treatment in patients with CLI due to infrapopliteal arterial disease [20], this requires a good vein conduit and at least one open foot artery and is associated with considerable perioperative mortality, postoperative complications, myocardial infarction, and early reoperation for graft thrombosis [21]. Recanalization temporarily increases blood flow to the foot and has a positive effect in eradicating infection and healing ulcers and surgical wounds. Because foot tissue healing reduces oxygen demand, less blood flow is generally required to maintain tissue integrity and keep the limb asymptomatic [19, 22].

CONCLUSION

The main finding of this study was that the surgical bypass procedure had a significantly higher AFS compared to angioplasty in the two examined groups during the follow-up period. Therefore, it is recommended for all patients with below-the-knee ischemic lesions to have surgical bypass procedures, except for patients with multiple underlying diseases, who have a high-risk condition for surgery, as well as for patients with veins not suitable for bypass.

ДОПОЛНИТЕЛЬНАЯ ИНФОРМАЦИЯ

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Конфликт интересов. Авторы декларируют отсутствие явных и потенциальных конфликтов интересов, связанных с публикацией настоящей статьи.

Источник финансирования. Авторы заявляют об отсутствии внешнего финансирования при проведении исследования.

Информированное согласие на публикацию. Авторы получили письменное согласие пациентов на публикацию медицинских данных.

ADDITIONAL INFORMATION

Author contribution. Thereby, all authors made a substantial contribution to the conception of the study, acquisition, analysis, interpretation of data for the work, drafting and revising the article, final approval of the version to be published and agree to be accountable for all aspects of the study.

Competing interests. The authors declare that they have no competing interests.

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