



Risk of infection of textile vascular prostheses in the aorto-iliac-femoral position in patients with chronic obliterating diseases of the arteries of the lower extremities

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Abstract

Objective. Evaluate the risk of textile vascular prosthesis infection in patients with peripheral artery disease (PAD) after reconstruction in the aortoiliac-femoral position.

Materials and methods. At the first stage, a retrospective analysis of the medical history of 317 patients who had tissue vascular prostheses implanted without antibacterial treatment during reconstructive operations on the aortoilioemoral segment was performed.

The operations were carried out at the Gomel Regional Clinical Cardiological Center. The patients were monitored for up to five years. At the second stage, patients who were scheduled for implantation of a woven prosthesis and had grade 4 chronic arterial insufficiency with purulent necrotic lesions of the feet and/or shins according to the Pokrovsky classification were selected.

Results. In all cases of prosthetic infection (100%), clinical signs were observed: from local inflammatory foci to systemic reactions caused by bacteria of the genus *Staphylococcus*. Thus, isolated paraprosthesis abscess occurred only once (5%), a combination of abscess and lymphorrhea – in eight cases (40%), and a combination of abscess, lymphorrhea and septic process – in two cases (10%). In eight cases (40%), a paraprosthesis hematoma with signs of infection was diagnosed, accompanied by arrosive hemorrhage.

Conclusions. In 100% of cases in patients with a high risk of infection, the textile vascular prosthesis was accompanied by characteristic local changes below the inguinal crease on the side of the affected lower limb, as well as the detection of *Staphylococcus* bacteria.

Keywords: *textile vascular prosthesis, infection, chronic obliterative diseases of lower limb arteries*

Author contributions. Doroshko Ya.Y., Kaplan M.L., Lyzikov A.A.: conception and design of the study; Doroshko Ya.Y., Charnabayeu M.I.: collection and processing of material; Doroshko Ya.Y., Kovaleu I.U.: statistical processing; Doroshko Ya.Y., Kaplan M.L.: writing; Lyzikov A.A.: editing.

Conflict of interest. The authors declare no conflict of interest.

Funding. Grant from the President of the Republic of Belarus for 2025 (Order No. 15pn dated January 27, 2025).

For citation: Doroshko YaYu, Kaplan ML, Kavaleu IU, Charnabayeu MI, Lyzikov AA. Risk of infection of textile vascular prostheses in the aorto-iliac-femoral position in patients with chronic obliterating diseases of the arteries of the lower extremities. *Health and Ecology Issues*. 2026;23(2):47–53. DOI: <https://doi.org/10.51523/2708-6011.2026-23-2-05>

Риск инфицирования текстильных сосудистых протезов в аорто-подвздошно-бедренной позиции у пациентов с хроническими облитерирующими заболеваниями артерий нижних конечностей

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Резюме

Цель исследования. Оценить риск инфицирования текстильных сосудистых протезов у пациентов с хроническими облитерирующими заболеваниями артерий нижних конечностей после реконструкции в аорто-подвздошно-бедренной позиции.

Материалы и методы. На первом этапе выполнен ретроспективный разбор 317 карт стационарных пациентов, которым при реконструктивных операциях на аорто-подвздошно-бедренном сегменте имплантировали тканевые сосудистые протезы без антибактериальной обработки. Операции проводились в учреждении «Гомельский областной клинический кардиологический центр». Наблюдение за пациентами продолжалось до пяти лет. На втором этапе были отобраны пациенты, планировавшие к имплантации тканого протеза и имевшие хроническую артериальную недостаточность 4-й степени с гнойно-некротическими поражениями стоп и/или голей по классификации Покровского.

Результаты. Во всех случаях протезной инфекции (100 %) наблюдались клинические признаки - от локальных воспалительных очагов до системных реакций, что было вызвано бактериями рода *Staphylococcus*. Так, изолированный парапротезный абсцесс встречался лишь однажды (5 %), комбинация абсцесса и лимфореи — в восьми случаях (40 %), а сочетание абсцесса, лимфореи и септического процесса — в двух (10 %). В восьми наблюдениях (40 %) диагностировалась парапротезная гематома с признаками инфекции, сопровождающаяся аррозивным кровотечением.

Заключение. В 100 % случаев у пациентов с высоким риском инфицирования текстильного сосудистого протеза сопровождалось характерными локальными изменениями ниже паховой складки на стороне пораженной нижней конечности, а также выявлением бактерий рода *Staphylococcus*.

Ключевые слова: текстильный сосудистый протез, инфекция, хронические облитерирующие заболевания артерий нижних конечностей

Вклад авторов. Дорошко Е.Ю., Каплан М.Л., Лызигов А.А.: концепция и дизайн исследования; Дорошко Е.Ю., Чернобаев М.И.: сбор и обработка материала; Дорошко Е.Ю., Ковалёв И.В.: статистическая обработка; Дорошко Е.Ю., Каплан М.Л.: написание текста; Лызигов А.А.: редактирование.

Конфликт интересов. Авторы заявляют об отсутствии конфликта интересов.

Источники финансирования. Грант Президента Республики Беларусь на 2025 г. (распоряжение № 15рп от 27 января 2025 г.).

Для цитирования: Дорошко ЕЮ, Каплан МЛ, Ковалёв ИВ, Чернобаев МИ, Лызигов АА. Риск инфицирования текстильных сосудистых протезов в аорто-подвздошно-бедренной позиции у пациентов с хроническими облитерирующими заболеваниями артерий нижних конечностей. Проблемы здоровья и экологии. 2026;23(2):47–53. DOI: <https://doi.org/10.51523/2708-6011.2026-23-2-05>

Introduction

The primary factor in the development of occlusive conditions of the leg vessels is associated with atherosclerosis of the arterial pathways [1]. Surgical treatment of patients with peripheral artery disease (PAD) using vascular prostheses, despite achieved successes, is associated with the risk of postoperative complications. The most formidable of these is prosthesis infection, which occurs in up to 6 % of cases and carries the threat of limb loss (up to 70 %) and high mortality (up to 100 %) [2–5].

The clinical signs of prosthesis infection are directly related to when it develops. Recommenda-

tions distinguish between early prosthesis infection, which manifests clinically up to four months, and late infection, which arises after this period [6]. Early vascular prosthesis infection is characterized by clinical symptoms such as fever, chills, bacteremia, prosthesis occlusion, and local inflammatory changes in the groin (hematoma, abscess, pseudoaneurysm). Late prosthesis infection is more often accompanied by «subtle» symptoms, such as chest pain, groin pain, vascular prosthesis occlusion, and the formation of pseudoaneurysms and fistulas [2, 7, 8].

Determining the true incidence and risk of infection of vascular prostheses is problematic, as this complica-

tion is relatively rare and can remain latent for many years after reconstruction. The most realistic results are only possible with retrospective analysis of large groups with a follow-up period of at least five years [9].

Objective

Evaluate the risk of textile infection of vascular prostheses in patients with peripheral artery disease (PAD) after reconstruction in the aortoiliac-femoral position.

Material and methods

The study was conducted retrospectively and without randomization in order to analyze data from 317 patients underwent reconstruction of aorto-ilio-femoral segment using standard polyester textile vascular prostheses without antibacterial impregnation in the period from 2015 to 2020 at the Gomel Regional Clinical Cardiological Center (GRCCC). The main indication for surgery was chronic obliterating artery disease of the lower extremities. The follow-up of the patients lasted up to 5 years (60 months). Permission for research from the hospital (2021) and the ethics committee of the Gomel State Medical University dated June 20, 2022, protocol №2.

At the beginning of the work, the participants were divided into two categories. The first group included 297 patients who underwent vascular reconstructions without developing prosthetic infection. The second group consisted of 20 patients who had an infection of the prosthesis sometime after the operation.

The Samson classification was used to assess the incidence of infections and the degree of damage to the prosthesis. In our study, prosthetic infection was considered confirmed when belonging to groups 3-5 on this scale [2, 9].

The diagnosis of infection associated with a textile prosthesis was based on a clinical analysis of local inflammatory processes in the wound area after surgery, as well as an assessment of systemic symptoms of inflammation. Ultrasound diagnostics and multispiral computed tomography were used to accurately determine the location of the infection — above or below the inguinal fold, or in a mixed version covering the distal and/or proximal anastomosis. The isolation of pathogenic microorganisms was carried out using bacteriological analysis of wound discharge.

At the second stage, the main task was to identify patients who were scheduled for implantation of

a textile polyester vascular prosthesis and who met the following criteria for high risk of infection: grade 4 chronic arterial insufficiency with purulent-necrotic lesions of the feet and/or shins according to the Pokrovsky classification.

A comparative analysis was carried out to identify differences in the risk of infection of prostheses installed in the aorto-ilio-femoral region. Prosthetic infections were divided into early (which occurred before 4 months after surgery) and late (which developed after 4 months). When calculating the time, the interval between the day of surgery and the date of infection diagnosis was taken into account, including both dates as one day.

The Statistica software package was used for data processing; the database was created in Excel 2013. The absolute risk of infection was calculated as the proportion of cases in each group, while the relative risk was the ratio of infection rates between groups. Fourfold table method: the statistical significance of the relationship was determined by 95 % confidence interval (CI) for relative risk: if the interval did not include one, the relationship was considered significant ($p < 0.05$). A relative risk value above 1 meant an increase in the probability of an outcome in the presence of a factor.

The results and their discussion

The study revealed twenty cases of infection of vascular prostheses used in reconstructions of the aorto-ilio-femoral segment, which is 6.31 % of the total number of studied individuals. A significant part of the infections affected the prosthesis directly, belonging to groups 3-5 according to the Samson classification [2, 9].

In the first group of patients with CSF, 38 people (12.8 %) were identified as having a high risk of infection with a woven vascular prosthesis due to the presence of stage 4 chronic arterial insufficiency with complications in the form of purulent-necrotic lesions of the feet and/or shins. The remaining 259 patients (87.21 %) did not meet this high-risk criterion.

The analysis of the second group of subjects showed that 6 people, equivalent to 30 %, met the established criterion. At the same time, 14 participants representing 70% of the group did not demonstrate compliance with this criterion (table 1).

Table 1. Analysis of infection in textile vascular prostheses: association with high-risk criteria during implantation

Таблица 1. Анализ инфицирования текстильных сосудистых протезов: связь с критериями высокого риска при имплантации

The presence of criteria	1st group (n=297)	2nd group (n=20)	p
Yes	38 (12,79 %)	6 (30 %)	<0,05
No	259 (87,21 %)	14 (70 %)	

As a result of the study, it was found that the incidence of infection of textile prosthetics of blood vessels in patients with chronic peripheral artery disease (PAD) who met certain criteria reached 13.64 %, while in those who did not meet these criteria, this figure was 5.13 %. Statistical processing of the data revealed significant differences in the degree of infection of textile vascular prostheses between the compared groups ($p < 0.05$; 95 % confidence interval (lower bound) = 1.08; 95 % confidence interval (upper bound) = 6.55). Consequently, in patients with PAD who meet the established criterion, the relative probability of infection of a textile vascular prosthesis increases statistically significantly by 2.7 times compared with patients who do not meet this criterion.

Clinical manifestations of prosthetic infection were represented by local changes (paraprosthetic abscess, lymphorrhea, paraprosthetic hematoma with signs of infection) in 20 cases (100 %). At the same time, only paraprosthetic abscess was detected in one case (5 %), paraprosthetic abscess and lymphorrhea were detected in eight cases (40 %), paraprosthetic abscess, lymphorrhea and sepsis were detected in two cases (10 %), paraprosthetic hematoma with signs of infection and erosive bleeding in eight cases (40 %). It should be noted that in patients with a given criterion in the second group, only a paraprosthetic abscess was detected in one case, paraprosthetic abscess and lymphorrhea were detected in three cases (50 %), paraprosthetic abscess, lymphorrhea and sepsis were detected in one case, paraprosthetic hematoma with signs of infection and erosive bleeding were detected in one case.

By localization, an isolated prosthetic infection of textile vascular prostheses below the inguinal fold involving distal anastomosis was detected in 95 % of cases (19 out of 20), and in 5% of cases (1 out of 20) a mixed type involving proximal and distal anastomosis. There was no isolated prosthetic infection above the inguinal fold. It should be noted that in the second group, according to the specified criterion, in one (16.67 %) of the six cases, there was a mixed type of prosthetic infection localization. The localization of prosthetic infection of textile vascular prostheses below the inguinal fold in 100 % (20 out of 20 cases) corresponded to the side of the lesion of the lower limb.

In 45 % of bacteriological analyses, staphylococcus aureus (*Staphylococcus aureus*) was detected from the foci of infection, which corresponds to nine cases. In three cases (15 %), epidermal staphylococcus epidermidis was identified. In a single case (5 %), hemolytic staphylococcus (*Staphylococcus haemolyticus*) was found. No microflora growth was observed in four samples. No other pathogens were identified during the bacteriological analysis, but in three situations there were no research results. It should be noted that in the second group, according to the specified criterion, in five cases (83.33 %) the causative agent was *Staphylococcus aureus*, in one case (16.67 %) *Staphylococcus haemolyticus* (in a patient with a mixed type of prosthetic infection).

The time interval between the implantation and the manifestation of infection of the textile vascular prosthesis was analyzed based on the timing of the development of early (up to 4 months) and late prosthetic infection (more than 4 months) (table 2).

Table 2. Number of early and late infections of textile vascular prostheses, depending on the presence of a high-risk infection criterion during textile vascular prosthesis implantation

Таблица 2. Количество ранней и поздней инфекции текстильных сосудистых протезов в зависимости от наличия критерия высокого риска инфицирования при имплантации текстильного сосудистого протеза

The period of development of prosthetic infection	The presence of criteria	
	Yes (n=6)	No (n=14)
Early (up to 4 months)	5 (83.33 %)	8 (57.14 %)
Late (after 4 months)	1 (16.67 %)	6 (42.86 %)

Overall, the results show that in most cases (13 out of 20, which is 65 %), clinical manifestations of infection occur in the first 4 months after surgery (which corresponds to an early prosthetic infection). Moreover, in patients with this criterion, early infection of the textile vascular prosthesis develops in 83.33 % of cases (table 2).

The risk of early infection of vascular textile prostheses in patients who met the established cri-

terion reached 11.36 %, whereas in the absence of it – 2.93 %. The study of the data revealed a statistically significant difference in the incidence of infection of textile vascular prostheses at the initial stages of infection associated with compliance with the criterion ($p < 0.05$; 95 % CI (lower bound) = 1.33; 95 % CI (upper bound) = 11.32). Consequently, in patients with critical lower limb ischemia who meet a certain criterion, the relative risk of early infection of a textile

vascular prosthesis is statistically 3.9 times higher than the same risk in patients who do not meet this criterion. At the same time, it should be noted that in patients according to the specified criterion, early manifestation of prosthetic infection occurred in the postoperative period up to 7 days in three or 60 % of cases, and up to 14 days in five or 100 % of cases, whereas in the group of patients who did not meet the criterion of infection with early prosthetic infection up to 14 days was not recorded. The risk of late infection of textile vascular prostheses in a group of patients meeting the specified parameters was 2.27 %.

At the same time, among patients who did not meet the criterion, the same indicator was 2.2 %. The analysis of the relative risk of late infection of a textile vascular prosthesis, depending on compliance with the criteria, did not reveal statistically significant differences ($p > 0.05$; 95 % confidence interval: lower bound=0.13; upper bound=8.39).

The novelty of this work lies in the analysis of the risk of infection, the pathogen, the symptoms and the time of infection of textile prostheses that do not have antimicrobial properties after operations to restore the aorto-ilio-femoral region. The short duration of clinical manifestation, infection with bacteria of the genus *Staphylococcus* in patients with a high risk of prosthetic infection revealed the need for antimicrobial prophylaxis. The most common way to reduce the risk of purulent complications in high-risk conditions is to use autografts in the form of subcutaneous veins, however, these veins cannot always be used, and their diameter is inadequate for reconstruction of the aorto-iliac segment [10]. Xenotransplantation of prefabricated bovine pericardial grafts and the use of homographs (allographs) represent promising treatment options for an existing prosthetic infection of the aorto-ilio-femoral segment [11, 12].

A promising method of prevention in cases of high risk of infection is the use of vascular prostheses with antimicrobial potential. It has been clinically proven that in cases of aortic infection, in situ reconstruction using dacron impregnated with rifampicin is no less effective than extraanatomic bypass surgery [13]. Effective attempts are being made to protect grafts from microbial exposure by soaking them in a mixture of chlorhexidine, rifampicin and minocycline, triclosan, and silver gel [14, 15]. As a result of the use of a polyester graft and a polyester silver-triclosan graft, infection was observed in 3.3% of cases and 1.8% of cases, respectively [16]. The use of domestic textile prostheses and "BASEX" patches

shows good results with the development of superficial suppuration in 4.1 % of cases, and deep suppuration in 1.4 % of cases [3]. The Omniflow II bio-synthetic transplant also shows good resistance to infection even in the presence of a source of infection with a 3.4 % incidence of prosthetic infection [17].

Based on the results of the performed study, it is recommended to take into account the presence of stage IV chronic arterial insufficiency in the patient, accompanied by purulent-necrotic lesions of the feet or legs, as a criterion for a high risk of infection when using a textile vascular prosthesis. Therefore, the unjustified use of textile vascular prostheses without antimicrobial protection in such clinical situations is not recommended.

Conclusions

1. After reconstructive interventions in the aorto-ilio-femoral area, the incidence of infectious complications associated with the use of textile vascular prostheses was 6.31 % of the total number of patients treated.

2. In the vast majority of situations (95 %), the infectious process was localized exclusively in the area of distal anastomosis. Damage to the proximal anastomosis was observed much less frequently (5 %).

3. In people with stage IV chronic arterial insufficiency accompanied by purulent necrosis of the foot or shin, the risk of developing an infectious process in textile prostheses increases 2.7 times compared with patients without such lesions ($p < 0.05$).

4. In patients with a high risk criterion for infection of textile vascular prostheses, local changes under the inguinal folds of the affected lower limb and the presence of *Staphylococcus* bacteria.

5. In the first four months, the probability of infection of textile vessels among patients suffering from purulent lesions of the tissues of the lower extremities increases more than threefold (coefficient 3.9) when compared with those who do not have such processes ($p < 0.05$).

6. Manifestation of early prosthetic infection in patients with a high risk of infection textile vascular prosthesis in the postoperative period up to 14 days occurred in 100 % of cases.

7. The risk of developing late infection (after 4 months) of textile vascular prostheses was 2.27 %. There was no statistically significant difference in the risk of infection compared with patients without purulent-necrotic lesions ($p > 0.05$).

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Поступила в редакцию / Received 05.02.2026

Поступила после рецензирования / Accepted 12.02.2026

Принята к публикации / Revised 20.05.2026