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RESEARCH ARTICLE

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# Hybrid vascular approach reduces the length of hospital stay in patients with chronically threatening limb ischemia and multilevel atherosclerotic lesions

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## ABSTRACT

**Introduction.** Chronic limb-threatening ischemia represents the advanced stage of atherosclerosis and is often associated with significant cardiovascular morbidity, resulting in high mortality rates. The hybrid approach combines surgical and endovascular techniques, allowing for optimal revascularization of multilevel lower limb atherosclerotic lesions. Additionally, the hybrid approach offers the advantages of shorter procedure times and reduced trauma compared to the classical method. It is also expected to result in a shorter length of hospital stay for patients. Therefore, the aim of this study is to analyze the relationship between the hybrid approach and the length of hospital stay compared to the classical vascular surgical approach in patients with chronic limb-threatening ischemia, multilevel atherosclerosis, and a high anesthesiologic risk.

**Material and methods.** The study compares the total and postoperative lengths of stay between two groups: a prospective group (N = 48) of patients treated with hybrid revascularizations, and a control group (N = 50) treated with classical vascular revascularizations. The included patients in both groups had multilevel atherosclerotic lesions (including aortoiliac, femuro-popliteal, and runoff) and chronic limb-threatening ischemia (Fontaine grade III and IV).

**Results.** The study analyzed the total and postoperative lengths of stay in both groups, including ischemia-based subgroups. The results showed that both the total and postoperative lengths of stay were significantly shorter in the hybrid approach group compared to the control group.

**Conclusions.** In cases where hybrid revascularizations were used, the length of hospital stay for patients with chronic limb-threatening ischemia and multilevel atherosclerosis is significantly shorter compared to the classical vascular surgical method.

**Key words:** multilevel atherosclerotic lesions, chronic limb-threatening ischemia, hybrid revascularizations, length of stay..

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## Key messages

### What is not yet known on the issue addressed in the submitted manuscript

Until now, there has been a dearth of objective data comparing the length of hospital stay between patients treated with hybrid revascularizations for chronic limb-threatening ischemia and multilevel atherosclerotic lesions, and those treated using the classical method of surgical revascularization.

### The research hypothesis

Patients treated with hybrid revascularizations for chronic limb-threatening ischemia and multilevel atherosclerotic lesions experience a shorter length of hospital stay compared to those treated using the classical method of surgical revascularization.

### The novelty added by manuscript to the already published scientific literature

Endovascular surgery is a relatively new specialty in the Republic of Moldova, while hybrid revascularization itself represents a novel treatment approach for patients with multilevel atherosclerotic lesions. Therefore, conducting an analysis of the length of hospital stay for patients undergoing hybrid revascularizations compared to classical surgical revascularizations would contribute valuable data to the existing literature.

## Introduction

In 2010, estimates suggested that over 200 million people worldwide were living with PAD. This represented a 23.5% increase since 2000, which is largely attributed to aging populations and the growing prevalence of risk factors, particularly diabetes mellitus [1]. While CLTI is widely recognized as a significant global healthcare issue, reliable epidemiological data on CLTI are scarce [1]. CLTI likely accounts for less than 10% of all PAD cases, and individuals undergoing amputation due to CLTI face a significantly higher risk of premature death [1]. Without treatment, the risk of lower limb loss in CLTI patients is approximately 25% within one year [2]. CLTI represents the advanced stage of atherosclerosis and is often accompanied by significant cardiovascular morbidity, resulting in high mortality rates due to stroke and myocardial infarction [2]. Without timely identification of risk factors and effective management of comorbidities, the prognosis for CLTI patients is generally unfavorable, with a mortality rate ranging from 20% to 26% within one year of diagnosis [2, 3]. A study conducted on 574 CLTI patients who did not undergo limb revascularizations revealed that 31.6% of patients died from cardiovascular causes, while 23% required major amputations [2, 4]. Hence, the objective of this study is to analyze the impact of hybrid revascularizations on the length of hospital stay for patients with CLTI, multilevel atherosclerosis, and a high anesthesiological risk.

## Materials and methods

This study utilized a prospective, superiority design, comprising a study group (N = 48) and a historical control group (N = 50) from the period of 2010-2015. The primary objective of the study was to compare the efficacy of the hybrid vascular approach with the classical vascular surgical treatment for patients with multilevel atherosclerosis and CLTI. The ultimate endpoint of the study was to assess the impact of the hybrid approach on reducing morbidity and mortality within the study group. The sample size for the study group was determined using the "Mureşanu formula." The study was conducted at the Republican Clinical Hospital, while the control group was formed by selecting every 5th patient file from the anonymized and codified records of 250 patients in the hospital archive from the 2010-2015 period. Inclusion criteria for the study were as follows: (1) men and women aged over 50 years old; (2) presence of multilevel atherosclerotic lesions; (3) diagnosis of CLTI based on Fontaine grades III and IV or Rutherford 4-6 classification. Exclusion criteria for the study were: (1) presence of an aortic infrarenal aneurysm greater than 5.5cm; (2) inoperable patients; (3) patients in terminal stages; (4) allergic to iodinated contrast material;

(5) presence of isolated atherosclerotic lesions; (6) absence of CLTI; (7) refusal to sign the informed consent; (8) non-compliant patients.

The study group consisted of all consecutive patients meeting the inclusion criteria, with a total of N = 50. These patients underwent hybrid interventions, which involved a combination of one open surgical reconstruction and another endovascular procedure. Two patients were excluded from the analysis due to their failure to attend the follow-up visits. The follow-up assessments were conducted at one month and three months post-treatment. Additionally, two subgroups were formed based on the severity of ischemia, categorized as Fontaine grade III and IV. The study analyzed both the total length of hospital stay and the postoperative length of hospital stay for the patients. A database was created to store the collected data, which was subsequently subjected to statistical analysis using the "SPSS" software. The statistical tests employed in the analysis included chi-square, p-value calculations, and frequency analysis. The study obtained ethical approval from the Ethics Committee on 14.11.2016, with reference number 17.

## Results

Demographic data analysis revealed an equal distribution between men and women in the study population, with no significant statistical difference observed ( $\chi^2 = 0.004$ ,  $df = 1$ ,  $p = 0.952$ ). In both the study group and the control group, the majority of patients were men: 44 patients (91.7%; 95% CI [84.0-98.0]) in the study group and 46 patients (92.0%; 95% CI [84.0-98.0]) in the control group. The most common age group among the patients was 60-69 years, comprising 21 patients (43.8%; 95% CI [29.4-57.8]) in the study group and 28 patients (56.0%; 95% CI [40.1-70.0]) in the control group. The next most prevalent age group was 50-59 years, with 17 patients (35.4%; 95% CI [22.2-50.0]) in the study group and 13 patients (26.0%; 95% CI [14.0-38.0]) in the control group. However, the data did not reveal any significant statistical difference between the two groups in terms of age distribution ( $\chi^2 = 1.979$ ,  $df = 3$ ,  $p = 0.577$ ).

The most prevalent comorbidity among the patients was arterial hypertension, with a higher rate observed in the study group (44 patients; 91.7%; 95% CI [83.3-98.1]) compared to the control group (36 patients; 72.0%; 95% CI [59.1-85.1]). This difference between the two groups was statistically significant ( $\chi^2 = 6.317$ ,  $df = 1$ ,  $p = 0.012$ ). Ischemic heart disease was the second most frequent comorbidity, with similar rates observed in both the study group (30 patients; 62.5%; 95% CI [49.0-77.8]) and the control group (32 patients; 64.0%; 95% CI [51.0-77.8]), showing no

significant statistical difference ( $\chi^2 = 0.024$ ,  $df = 1$ ,  $p = 0.878$ ). Chronic obstructive pulmonary disease was the third most common comorbidity, being more prevalent in the control group (32 patients; 64.0%; 95% CI [51.0-77.8]) compared to the study group (23 patients; 47.9%; 95% CI [32.6-62.7]), but this difference did not reach statistical significance ( $\chi^2 = 2.573$ ,  $df = 1$ ,  $p = 0.109$ ). Cerebrovascular disease, the fourth comorbidity analyzed, was identified at similar rates in both the study group and the control group. In the study group, 20 patients (41.7%; 95% CI [27.7-56.5]) had cerebrovascular disease, while in the control group, 16 patients (32.0%; 95% CI [19.6-44.7]) had the same condition. However, there was no significant statistical difference between the two groups ( $\chi^2 = 0.985$ ,  $df = 1$ ,  $p = 0.321$ ). The prevalence of DM was relatively equal in both groups. In the study group, 17 patients (35.4%; 95% CI [21.2-50.0]) had DM, while in the control group, 13 patients (26.0%; 95% CI [13.7-37.5]) had DM. The statistical analysis showed no significant difference between the two groups ( $\chi^2 = 1.022$ ,  $df = 1$ ,  $p = 0.312$ ). The majority of patients in both the study group (42 patients; 87.5%; 95% CI [76.5-95.9]) and the control group (41 patients; 82.0%; 95% CI [72.0-92.0]) had an anesthesiological risk score of ASA 3 (Severe systemic disease that is not incapacitating, mortality 1.8%) based on the ASA grading scale. However, there was no significant statistical difference observed between the groups ( $\chi^2 = 0.571$ ,  $df = 1$ ,  $p = 0.450$ ).

Analyzing the total length of hospital stay in the two groups in relation to the grade of limb ischemia, it was found that the highest frequency for Fontaine grade III consisted of lengths of stay within the period of 9-12 days. Out of 32 cases in the study group, 11 cases fell within this period, compared to the control group where the period with the highest frequency was more than 14 days. Out of 22 cases in the control group, 11 cases had a length of hospital stay exceeding 14 days (Table 1). Thus, there was a significant statistical difference between the groups ( $\chi^2 = 10.53$ ;  $df = 4$ ;  $p = 0.03$ ). Furthermore, a moderately significant statistical difference was observed ( $\chi^2 = 15.53$ ;  $df = 4$ ;  $p = 0.004$ ; V. Cramer = 0.536).

**Table 1.** Overall length of hospital stay in groups for Fontaine grade III limb ischemia.

Length of hospital stay periods	Study group (N = 32)	Control group (N = 22)	p
3-5 days	3	-	
6-8 days	8	-	$\chi^2 = 15.53$
9-11 days	11	4	$df = 4$
12-14 days	5	7	$p = 0.004$
> 14 days	5	11	

**Note:** p – significance level;  $\chi^2$  – Pearson test; df – degrees of freedom.

Regarding the length of hospital stay after the intervention, it was found that patients with Fontaine grade III limb ischemia from the study group required a period of 3-5 days in 17 out of 32 cases. In contrast, patients from the control group required 6-8 days in 7 out of 22 cases and 9-11 days in 7 out of 22 cases (Table 2). A moderately significant statistical difference was observed between the groups ( $\chi^2 = 12.73$ ;  $df = 4$ ;  $p = 0.013$ ; V. Cramer = 0.486).

**Table 2.** Postoperative length of hospital stay in groups for Fontaine grade III limb ischemia.

Length of hospital stay periods	Study group (N = 32)	Control group (N = 22)	p
3-5 days	17	4	
6-8 days	12	7	$\chi^2 = 12.73$
9-11 days	2	7	$df = 4$
12-14 days	1	3	$p = 0.013$
> 14 days	-	1	

**Note:** p – significance level;  $\chi^2$  – Pearson test; df – degrees of freedom.

When comparing the length of hospital stay of patients with Fontaine grade IV limb ischemia, it was discovered that the study group had the highest frequency for the period of 6-8 days, with 5 out of 16 cases falling within this range. Conversely, in the control group, the majority of patients required more than 14 days, specifically 18 out of 28 cases (Table 3). This difference between the groups was found to be statistically significant with a moderate level of significance ( $\chi^2 = 10.93$ ;  $df = 4$ ;  $p = 0.027$ ; V. Cramer = 0.498).

**Table 3.** Overall length of hospital stay in groups for Fontaine grade IV limb ischemia.

Length of hospital stay periods	Study group (N = 16)	Control group (N = 28)	p
3-5 days	1	-	
6-8 days	5	1	$\chi^2 = 10.93$
9-11 days	2	2	$df = 4$
12-14 days	4	7	$p = 0.027$
> 14 days	4	18	

**Note:** p – significance level;  $\chi^2$  – Pearson test; df – degrees of freedom.

Regarding the postoperative length of hospital stay in patients with Fontaine grade IV limb ischemia, a significant statistical difference was observed between the study and control groups ( $\chi^2 = 10.53$ ;  $df = 4$ ;  $p = 0.032$ ; V. Cramer = 0.489). Among patients with Fontaine grade IV limb ischemia, the highest frequency was found in the 3-5 day period, with 6 out of 16 cases in the study group. In the control group, the majority of cases were in the 9-11 day period, with 10 out of 28 cases (Table 4).

**Table 4.** Postoperative length of hospital stay in groups for Fontaine grade IV limb ischemia.

Length of hospital stay periods	Study group (N = 16)	Control group (N = 28)	p
3-5 days	6	1	
6-8 days	5	7	$\chi^2 = 10.53$
9-11 days	2	10	$df = 4$
12-14 days	2	7	$p = 0.032$
> 14 days	1	3	

**Note:** p – significance level;  $\chi^2$  – Pearson test; df – degrees of freedom.

## Discussions

Hybrid interventions have become an integral part of the strategy for limb salvage in patients with multilevel arterial occlusive disease. Technical success, early results, as well as long-term results, have shown to be at least comparable to conventional endovascular and open vascular procedures.

Hybrid revascularization offers the efficiency and convenience of a single-stage revascularization [5]. Currently, most of the combined procedures are performed by vascular surgeons trained in both open and endovascular surgery. Simultaneous hybrid interventions are associated with potential benefits such as decreasing the length of stay, the absence of the need to delay complete revascularization of the ischemic limb, avoidance of puncture site complications due to direct surgical access, and the possibility of open surgical correction of inadequate endovascular revascularization sites [6, 7]. In a study by Peter L. Faries et al., all the combined interventions were performed in a staged manner, with an interval of 3.1 days between the open and endovascular stages. When comparing simultaneous and staged hybrid procedures, factors such as patient comfort and convenience, length of stay, procedure costs, and the possibility of staging the procedure were taken into consideration. These factors demonstrate the advantages of choosing the simultaneous hybrid procedure over the staged approach [8]. Elbadawy A. et al., in their study, recommend decision-making based on the patient's risk and the severity of limb ischemia when determining the appropriate strategy [9]. In a review conducted by Christos D. Liapis and Elias A. Tzortzis, it was concluded that combining open vascular and endovascular techniques yields greater benefits compared to using each technique alone [10]. James L. Ebaugh et al., in their study, identified 5 variables as confounders in the relationship between staged and same-day procedures. Patients with the following conditions were excluded from the final subgroup analysis: (1) gangrene; (2) ischemic rest pain; (3) non-elective admission; (4) chronic heart failure; and (5) renal failure. After excluding patients with these confounders, hospital charges and length of hospital stay were compared once again. The results indicate that when performing elective hybrid procedures in patients without gangrene, ischemic rest pain, chronic heart failure, or renal failure, conducting both the endovascular and open portions on the same day significantly reduces total hospital charges by 78% and length of hospital stay by 133% [11]. Therefore, compared to the staged hybrid procedure, the simultaneous procedure may lead to a shorter length of stay, reduced procedural costs, and a broader range of revascularization options by combining open and endovascular techniques [12, 13, 14].

### Conclusions

The length of hospital stay for patients with CLTI and multilevel atherosclerotic lesions is significantly reduced when hybrid revascularizations are used compared to conventional revascularizations.

### Abbreviations

CLTI – chronic limb-threatening ischemia; PAD – peripheral arterial disease; DM – diabetes mellitus.

### Ethics approval

This study was approved by the Research Ethics Committee (the name of the ethics committee or institutional review board) (Reference No 17 from 14 November 2016).

### Declaration of conflict of interests

Nothing to declare.

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