Long-term results of treatment of iliofemoral segment by hybrid and endovascular methods

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Abstract

Introduction. The significance of this study lies in its lack of clear guidelines for the selection of surgical treatment options for patients with iliofemoral occlusive disease.

Objective. The objective of this study was to evaluate the long-term outcomes of endovascular and hybrid interventions for the treatment of occlusive lesions in the iliofemoral artery segment.

Methods. A total of 62 patients were randomized (n = 31 in the endovascular treatment (EVT) group, n = 31 in the hybrid treatment (HT) group). In the EVT group, an interwoven nitinol stents were implanted in patients after recanalization and balloon angioplasty of the iliac and common femoral arteries. In the HR group, patients underwent endarterectomy from the common femoral artery with xenopericardial patch repair, recanalization and stenting of the iliac arteries with using an interwoven nitinol stent. The follow-up period was 3 years.

Results. Thirty-day complications occurred in 3 (9.7 %) of the EVT group and 7 (22.6 %) of the HT group. The primary patency rate after 36 months was 60 % in the EVT group and 80 % in the HT group. Secondary patency rates at 36 months were 83 % and 87 %, respectively. Survival and limb preservation rates did not differ significantly between the groups at 36-month follow-up.

Conclusion. This study supports the use of hybrid treatment over endovascular stenting, as it provides greater safety and primary patency during a three-year follow-up period.

Keywords: atherosclerosis; endarterectomy; endovascular therapy; nitinol stent; vascular surgery

Отдаленные результаты лечения артерий подвздошно-бедренного сегмента гибридным и эндоваскулярным методами

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Аннотация

Актуальность. Актуальность исследования заключается в отсутствии четких рекомендаций для выбора оперативного лечения у пациентов с подвздошно-бедренными окклюзионными поражениями.

Цель. Цель данного пилотного рандомизированного исследования – сравнение отдаленных результатов эндоваскулярного и гибридного лечения сочетанных окклюзионных поражений артерий подвздошно-бедренного сегмента с использованием плетеного нитинолового стента.

Методы. Всего были рандомизированы 62 пациента ($n = 31$ в группе эндоваскулярного, $n = 31$ в группе гибридного лечения). В группе эндоваскулярного лечения пациентам после реканализации и баллонной ангиопластики подвздошной и общей бедренной артерий были имплантированы плетеные нитиноловые стенты. В группе гибридного лечения пациентам были выполнены эндартерэктомия из общей бедренной артерии с пластикой заплатой из ксеноперикарда, реканализация и стентирование подвздошных артерий с плетеным нитиноловым стентом. Время наблюдения составило 3 года.

Результаты. Тридцатидневные осложнения составили 3 (9,7 %) в группе эндоваскулярного лечения и 7 (22,6 %) в группе гибридного лечения ($p = 0,17$). Первичная проходимость через 24 и 36 месяцев составила 60 и 46 % в группе эндоваскулярного лечения, 80 и 73 % в группе гибридного лечения ($p = 0,09$ и $p = 0,03$ соответственно). Показатели вторичной проходимости через 36 месяцев в группе эндоваскулярного лечения составили 83 % против 87 % в группе гибридного лечения ($p = 0,64$). Уровни выживаемости и сохранения конечностей не различались между группами через 36 месяцев наблюдения ($p = 0,97$ и $p = 0,31$ соответственно).

Заключение. Данное исследование подтверждает, что гибридное лечение имеет преимущество перед эндоваскулярным стентированием с точки зрения безопасности и первичной проходимости в трехлетнем периоде наблюдения.

Ключевые слова: атеросклероз; нитиноловый стент; сосудистая хирургия; эндартерэктомия; эндоваскулярное лечение

Introduction

In recent years, endovascular interventions have become an important part of the treatment for patients with peripheral artery disease [1]. Despite the expanded indications for an endovascular strategy, open endarterectomy from the common femoral artery (CFA) remains the method of choice. However, open CFA repair carries a risk of perioperative surgical complications [2–4].

Due to the high mobility of the transition zone between the external iliac artery (EIA) and the CFA, endovascular treatment for occlusive lesions of the iliofemoral segment using self-expanding stents has shown unsatisfactory long-term effectiveness [5]. This is related to stent fracture beneath the inguinal ligament, leading to subsequent restenosis and reocclusion of the stented arteries [6].

New-generation braided nitinol stents may expand the possibilities of endovascular treatment (EVT) under complex physical conditions due to their resistance to compression, fracture, elongation, and shortening in the EIA-CFA transition zone [7; 8].

A hybrid approach involving CFA endarterectomy and EIA stenting represents another promising treatment method. Primary patency following hybrid procedures is characterized by better patency rates compared to EVT, although both methods have similar limb salvage rates [9; 10].

Furthermore, there are no prospective randomized trials comparing EVT and hybrid treatment (HT) using braided nitinol stents in patients with combined iliac artery lesions extending into the CFA.

Methods

Study Design and Sample Size Calculation

A pilot single-center prospective randomized trial was conducted to compare the three-year safety and efficacy of EVT and HT procedures in patients with concomitant occlusive-stenotic lesions of the iliofemoral segment. The sample size was calculated based on the results of the study by Soga Y. et al. [11] and the study by Piazza M. et al. [12], where patency rates after CFA stenting and CFA endarterectomy were 66.7 % and 97 %, respectively. To obtain reliable data with a 95 % probability, 24 patients needed to be included in each group. However, due to potential patient loss to follow-up, we decided to include a total of 62 patients, with 31 in each group.

Patient Enrollment

Patients presenting with combined atherosclerotic occlusive lesions of the iliac arteries and the CFA between February 2018 and February 2021 were considered potentially eligible for this study.

Inclusion/Exclusion Criteria

Inclusion criteria:

- Concomitant lesions of the iliac arteries and CFA lesions (occlusion/stenosis ≥ 70 % of the proximal and middle third);
- Chronic lower limb ischemia grade 2b–4 according to the A.V. Pokrovsky classification;
- Age between 45 and 85 years;
- Patent (stenosis ≤ 50 %) ipsilateral superficial femoral artery and/or deep femoral artery.

Exclusion criteria:

- Aortic thrombosis, concomitant aneurysms of the abdominal aorta, iliac artery, or CFA, acute limb ischemia, or vasculitis;
- Type 3 and 4 CFA lesions according to the Azema classification [10];
- Refusal to participate in the study;
- Stroke or myocardial infarction within the previous 3 months;
- Coronary heart disease and chronic heart failure class IV according to the New York Heart Association classification;
- Malignancy;
- Previous ipsilateral or contralateral surgery (bypass, hybrid procedure, or stenting);
- Hepatic or renal failure (bilirubin > 35 mmol/L, glomerular filtration rate < 60 mL/min/1.73 m2);
- Severe calcification of the aorta and iliac arteries, intolerance to balloon angioplasty (according to the Peripheral Arterial Calcification Scoring System (PACSS) based on computed tomography as interpreted by a radiologist): unilateral calcification ≥ 5 cm (grade 2), bilateral calcification ≥ 5 cm (grade 4), or circumferential calcification, defined as 270–360° of the circumference of the aorta and/or iliac arteries.

Demographic Data

A total of 80 patients were considered for inclusion in the study, but 18 patients were excluded due to the concomitant presence of an abdominal aortic aneurysm ($n = 1$), stroke or myocardial infarction within the previous 3 months ($n = 3$), previous ipsilateral/contralateral bypass surgery or hybrid procedure ($n = 4$), CFA stenosis < 50 % ($n = 2$), and lack of consent to participate in the study ($n = 8$).

Ultimately, 62 patients were randomized into the study, with 31 patients randomized to the EVT group and 31 to the HT group. Figure 1 shows the study design (CONSORT diagram), which details the flow of patients throughout the study.

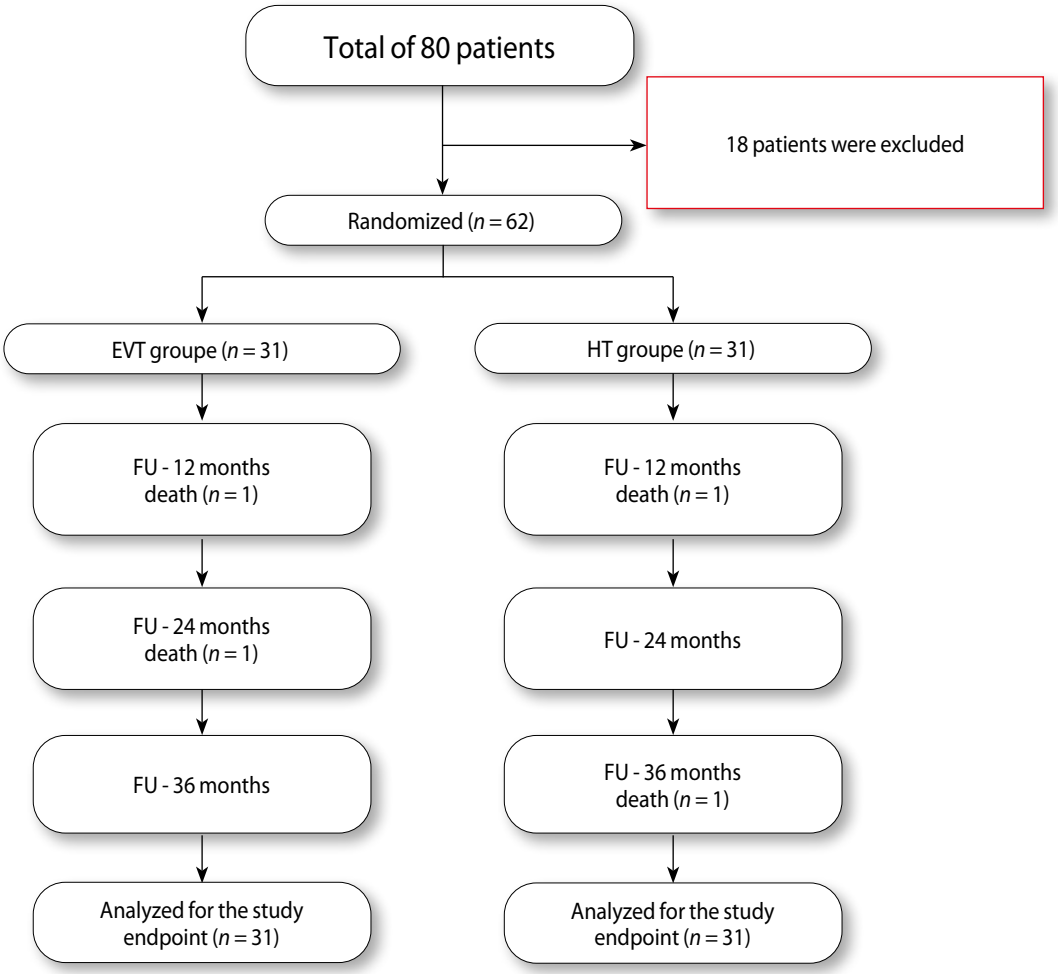

Fig. 1. Study design

Surgical Technique

Surgical revascularization was performed either by stenting of the CFA and iliac arteries using the Supera stent (Abbott, USA) or by CFA endarterectomy with xenopericardial patch plasty and stenting of the iliac arteries using the Supera stent (Abbott, USA) (Fig. 2).

Stenting of the common femoral artery and iliac arteries using a braided nitinol stent

All procedures were performed under local anesthesia. Prior to intervention, systemic anticoagulation was achieved with intravenous heparin sulfate (70–100 IU/kg). Endovascular procedures in the EVT group were conducted in an angiographic suite using a GE Innova system (General Electric, USA).

Access strategy in the EVT group was tailored to the clinical scenario, utilizing either a contralateral CFA or brachial approach. Following placement of a 6Fr introducer sheath, antegrade recanalization of the ipsilateral iliac arteries was performed using a 0.018"(300 cm) or 0.035" (260 cm) hydrophilic guidewire. Lesion predilation was carried out with a plain balloon catheter sized 1 mm larger than the nominal outer diameter of the stent. Following predilation, the 0.035" guidewire was exchanged for a 0.018" (300 cm) guidewire via the balloon delivery system, with the wire tip positioned in the deep femoral artery (DFA) or superficial femoral artery (SFA).

Through-and-through stenting of extensive occlusions was performed using the Supera stent (Abbott, USA). In cases with an intact CFA bifurcation, stent deployment began in the distal third of the CFA. In patients with CFA

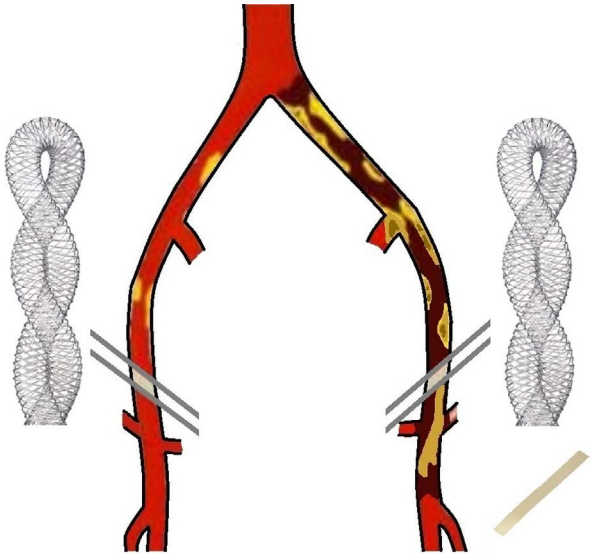

Fig. 2. Occlusion of the iliac arteries and common femoral artery. Supera stents (Abbott, USA) and xenopericardial patch (KemPeriplast-Neo, NeoCor, Russia)

bifurcation involvement and SFA occlusion, the stent was extended into the DFA. Stent diameters were 6.5 mm or 7.5 mm, with lengths ranging from 80–120 mm and 80–100 mm, respectively. Technical success was defined as residual stenosis <30 % on control angiography performed in three projections (anteroposterior, right anterior oblique, and left anterior oblique).

Medication Regimen

Patients received a loading dose of clopidogrel (300 mg) 3–24 hours prior to stenting. Postoperatively, all patients received daily acetylsalicylic acid (ASA, 75 mg) and prophylactic doses of low molecular weight heparin (LMWH) for 3 days. Thereafter, dual antiplatelet therapy (DAPT) with ASA 75 mg and clopidogrel 75 mg daily was continued for a minimum of 3 months, after which clopidogrel was discontinued.

Hybrid Procedure: Common Femoral Artery (CFA) Endarterectomy with Xenopericardial Patch Plasty + Iliac Artery Angioplasty and Stenting with a Braided Nitinol Stent

In patients randomized to the HT group, either local or spinal anesthesia was used. After isolation and control of the CFA in the groin region, an anticoagulant (heparin sulfate 70–100 IU/kg) was administered intravenously. Hybrid procedures were performed in an angiographic suite using a GE OEC 9900 Elite system (General Electric, USA).

For catheterization of the target iliac arteries and CFA, either a contralateral CFA access (6Fr, 45 cm introducer sheath) or a brachial access (6Fr, 11 cm introducer sheath) was selected. Following antegrade recanalization and balloon predilation of the iliac artery, CFA endarterectomy with xenopericardial patch plasty (KemPeriplast-Neo, NeoCor, Kemerovo, Russia) was performed. In cases of SFA occlusion, endarterectomy of the CFA was extended into the DFA. Predilation was performed using a non-coated balloon sized 1 mm larger than the nominal outer diameter of the stent. In all cases, stenting of the iliac arteries was performed using the Supera stent via either the contralateral CFA or brachial access. Stent diameter was 6.5 mm (length 80–120 mm) or 7.5 mm (length 80–100 mm). Technical success was defined as the absence of residual stenosis greater than 30 % on control angiography performed in three projections (anteroposterior, right anterior oblique, and left anterior oblique).

Medication Regimen

Antiplatelet therapy was discontinued 5 days prior to surgery, and prophylactic doses of LMWH were administered. In the postoperative period, patients in both groups received 75 mg of ASA daily and prophylactic doses of LMWH for 3 days. Thereafter, patients were prescribed DAPT: ASA 75 mg and clopidogrel 75 mg daily for at least 3 months after the procedure, after which clopidogrel was discontinued.

Randomization

After obtaining informed consent, an independent clinician provided the researchers with sealed envelopes, each indicating one of the two treatment groups. The patient was then assigned to a specific group on the day before surgery based on the contents of the envelope.

Study Endpoints

Primary endpoints: patency rates at 36 months of follow-up (primary and secondary patency).

Secondary endpoints: complication rates, mortality, and limb salvage at 36 months.

Postoperative follow-up visits (at 1, 12, 24, and 36 months after surgery) included physical examination, blood pressure measurement, and duplex ultrasound scanning of the stent in the iliac artery and CFA. If restenosis of the stent or CFA ≥ 70 % (peak systolic

Table 1. Baseline demographic and clinical characteristics

Characteristic	EVT (*n* = 31)	HT (*n* = 31)	*p*
Demographic data			
Sex, male/female	26 (84) / 5 (16)	31 (100) / 0	0.02
Age, years	63.74 ± 5.1	65.61 ± 4.7	0.53
CLI classification (according to A.V. Pokrovsky)			
Grade 2b	26 (84)	24 (77)	0.37
Grade 3	4 (13)	5 (16)	0.50
Grade 4	1 (3)	2 (6)	0.50
Risk factors			
Arterial hypertension	24 (77)	22 (71)	0.38
Coronary heart disease	19 (61)	11 (35)	0.08
Stroke > 3 months	5 (16)	3 (9.7)	0.35
Diabetes mellitus	4 (13)	8 (26)	0.16
Obesity	7 (23)	9 (29)	0.38
Dyslipidemia	4 (13)	5 (16)	0.50
History of smoking	4 (13)	9 (29)	0.11
Anatomical data			
Aortic stenosis < 50 %	31 (100)	31 (100)	>0.99
Ipsilateral iliac artery			
Stenosis ≥ 70 % / occlusion	17 (55) / 14 (45)	12 (39) / 19 (61)	0.15
Contralateral iliac artery			
Stenosis ≤ 60 %	31 (100)	31 (100)	>0.99
Ipsilateral internal iliac artery			
Stenosis ≥ 70 % / occlusion	9 (29)	14 (45)	0.11
Contralateral internal iliac artery			
Stenosis ≤ 70 %	13 (42)	9 (29)	0.20
Ipsilateral common femoral artery			
Stenosis 70–99 % / occlusion	18 (58) / 13 (42)	17 (55) / 14 (45)	0.50
Contralateral common femoral artery			
Stenosis < 70 %	31 (100)	31 (100)	>0.99
Ipsilateral deep femoral artery			
Patent / stenosis 50–99 %	29 (94) / 2 (6)	24 (77) / 7 (23)	0.14
Contralateral deep femoral artery			
Patent / stenosis < 70 %	31 (100)	31 (100)	>0.99
Ipsilateral superficial femoral artery			
Patent	18 (58)	11 (35)	0.12
Stenosis 50–99 %	3 (9.7)	5 (16)	0.71
Occlusion	10 (32)	15 (48)	0.30
Contralateral superficial femoral artery			
Patent	20 (65)	18 (58)	0.79
Stenosis 50–99 %	2 (6)	2 (6)	>0.99
Occlusion	9 (29)	11 (35)	0.78
Calcification			
Unilateral calcification < 5 cm (grade 1)	4 (13)	6 (19)	0.36
Bilateral calcification < 5 cm (grade 3)	0	0	>0.99
Unilateral calcification ≥ 5 cm (grade 2)	0	0	>0.99
Bilateral calcification ≥ 5 cm (grade 4)	0	0	>0.99
Circumferential calcification	0	0	>0.99
Mean length of ipsilateral iliac segment lesion, mm	156 ± 21.8	161 ± 34.1	0.83

Note. HT – hybrid treatment; CLI – chronic lower limb ischemia; EVT – endovascular treatment. Data are presented as *n* (%) or mean ± standard deviation (SD).

Table 2. Early postoperative complications (30-day follow-up period)

Complication	EVT (*n* = 31)	HT (*n* = 31)	*p*
Stent thrombosis	1 (3)	0 (0)	0.31
Hematoma	1 (3)	5 (16)	0.09
Groin seroma	0 (0)	2 (6)	0.15
Transient ischemic attack	1 (3)	0 (0)	0.31
Myocardial infarction / stroke / mortality	0 (0)	0 (0)	>0.99
Total	**3 (9.7)**	**7 (22.6)**	**0.17**

Note. HT – hybrid treatment; EVT – endovascular treatment. Data are presented as *n* (%).

velocity ≥ 2.5 m/s) [13] or reocclusion was suspected, MSCT angiography of the abdominal aorta and lower limb arteries was performed for further evaluation.

Statistical Analysis

Quantitative data with normal distribution are presented as mean ± standard deviation using the Shapiro – Wilk test; data with non-normal distribution are presented as median with 95 % confidence interval. Statistical differences between groups were determined using the Mann – Whitney *U* test and two-sided *F*-test. Pre- and postoperative survival rates (mean and standard deviation) between the two procedures were compared using the two-sample *t*-test. Statistical significance of intergroup differences in nominal data was assessed using the χ^2 test or Fisher's exact test. Kaplan – Meier survival curves were calculated for primary patency, primary assisted patency, and secondary patency, and the log-rank test was applied. Probability values of $p < 0.05$ were considered significant. Statistical calculations were performed using Statistica 8.0 (StatSoft, USA).

Results

Patients in both study groups were comparable in demographic and clinical characteristics, except for one parameter. In the HT group, 100 % of the randomized patients were male. The data are presented in Table 1.

Technical success was 100 % in both groups. Procedure duration was statistically significantly shorter in the EVT group (68.4 [45–110] minutes vs. 200.3 [164–221] minutes, $p = 0.0001$). The mean length of the stented segments in the HT group was 108.4 ± 39.5 mm. The mean length of stented segments in the EVT group was greater, at 153.9 ± ± 35.2 mm, due to stenting of the CFA ($p < 0.05$).

Perioperative Follow-up Period

No deaths or injuries were recorded in either group within 30 days after surgery. Overall, 30-day complications

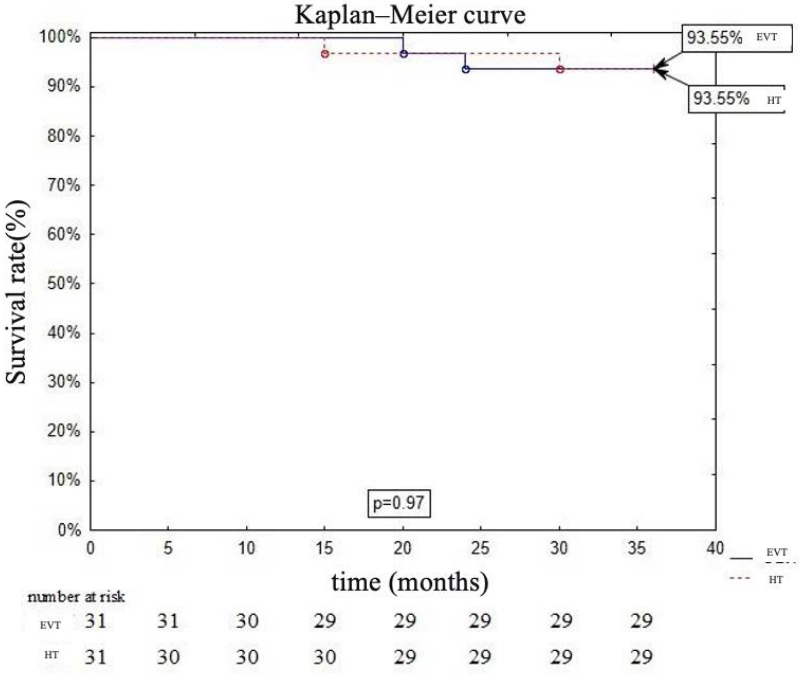

Fig. 3. Kaplan – Meier curve calculated for survival rates

Note. HT – hybrid treatment; EVT – endovascular treatment.

Table 3. Long-term complications in both groups (3-year follow-up period)

Complication	EVT (*n* = 31)	HT (*n* = 31)	*p*
Mortality	2 (6)	2 (6)	0.97
Amputation	1 (3)	0	0.31
Stroke	1 (3)	0	0.31
Reocclusion	6 (19)	3 (10)	0.47
Restenosis	10 (32)	5 (16)	0.23
Total	**20 (65)**	**10 (32)**	**0.02**

Note. HT – hybrid treatment; EVT – endovascular treatment. Data are presented as *n* (%).

occurred in 9.7 % of patients in the EVT group and in 22.6 % of patients in the HT group ($p = 0.17$) (Table 2).

In the EVT group, 1 (3 %) case of pseudoaneurysm at the CFA puncture site was recorded after intervention, which was successfully managed with conservative treatment (ultrasound-guided manual compression). Transient ischemic attack occurred in 1 (3 %) case in the EVT group in a patient with right brachial access. Additionally, 1 (3 %) case of 30-day stent thrombosis occurred in the EVT group and was successfully treated with a hybrid procedure (thrombectomy and iliac artery stenting).

Postoperative hematoma occurred in 5 (16 %) cases in the HT group. No surgical intervention or blood transfusion was required. Groin seromas occurred in 2 (6 %) patients in the HT group, all of whom were obese (body mass index > 30). Both cases were managed conservatively. No other complications occurred in either group during the 30-day postoperative period.

36-Month Follow-up Period

Over the 3-year follow-up period in this study, 2 deaths were recorded in the EVT group and 2 deaths in the HT group ($p = 0.97$) (Fig. 3).

In two cases, the cause of death was cancer, and in two cases the cause of death was unknown. In the EVT group, 1 (3 %) minor stroke was recorded. One case of amputation in the EVT group occurred in a patient with grade 4 ischemia prior to surgery. Postoperative complications and outcomes over three years are presented in Table 3.

The cumulative primary patency rates at 24 and 36 months were 60 % and 46 % in the EVT group, and 80 % and 73 % in the HT group ($p = 0.09$ and $p = 0.03$) (Fig. 4).

During the 36-month follow-up, stent thrombosis was detected in 6 (19 %) patients in the EVT group. Hybrid procedures (thrombectomy and balloon angioplasty of

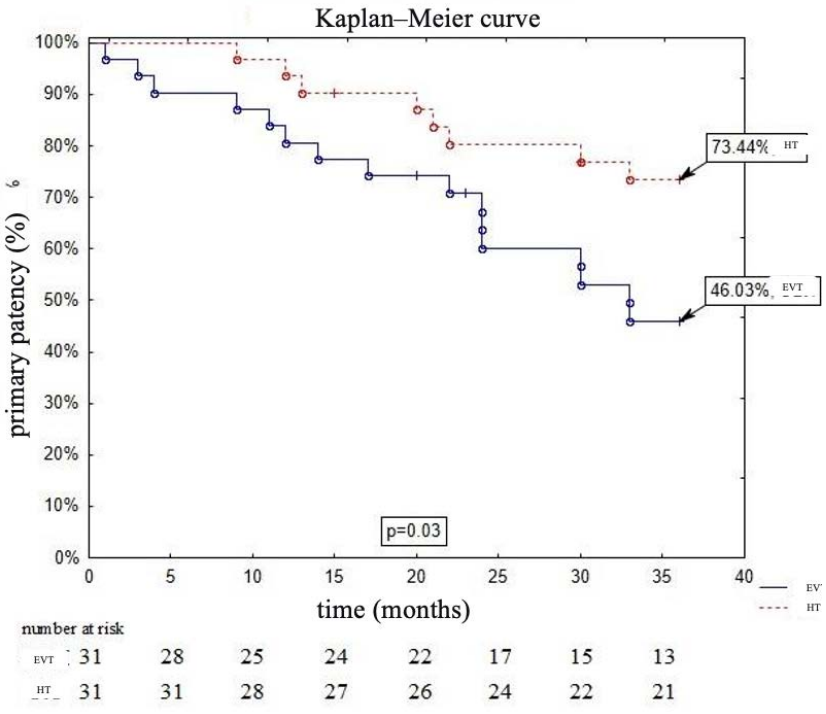

Fig. 4. Kaplan – Meier curve calculated for primary patency rates

Note. HT – hybrid treatment; EVT – endovascular treatment.

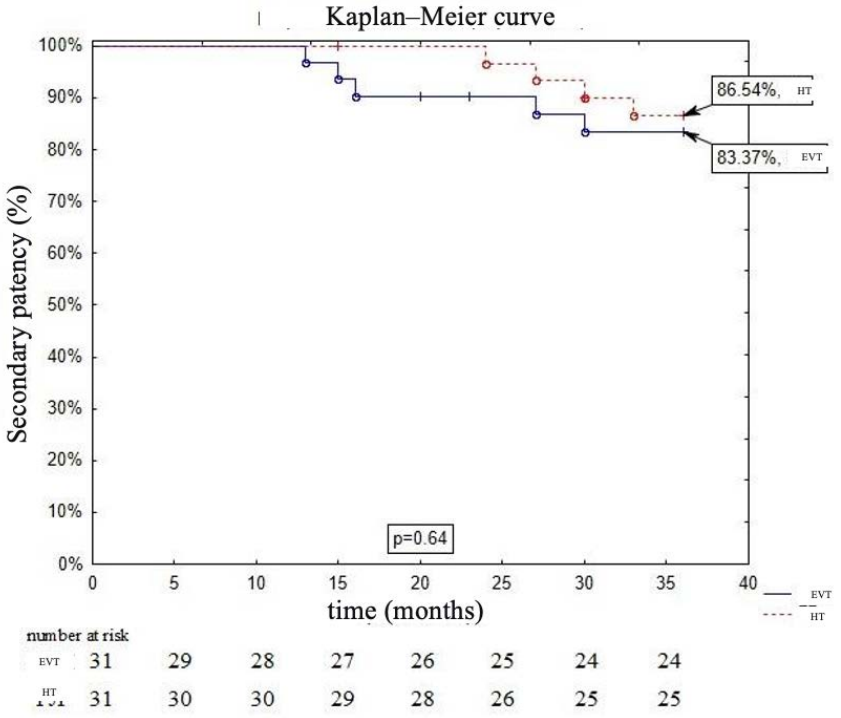

Fig. 5. Kaplan – Meier curve calculated for secondary patency rates

Note. HT – hybrid treatment; EVT – endovascular treatment.

the external iliac artery) were successfully performed. It should be noted that during thrombectomy, Supera stents were removed in three cases. In one case, residual stenosis (> 70 %) in the EIA was detected after stent removal, necessitating stenting of the EIA. An AbsolutePro (Abbott, USA) 8×40 stent was used. Additionally, repeat endovascular interventions were also performed in 10 (32 %) cases in the EVT group (where restenosis > 70 % was detected in the iliac segment stent).

It should be noted that during the 36-month follow-up, reocclusions of the iliofemoral segment arteries in the HT group were observed in 3 (9.7 %) cases. All three patients underwent aortobifemoral bypass surgery. In the HT group patients, four cases of stent restenosis were detected in the EIA (> 70 %) and DFA (80 %). Repeat endovascular interventions were performed.

Secondary patency rates at 36 months were 83 % in the EVT group versus 87 % in the HT group ($p = 0.64$) (Fig. 5).

Ankle-brachial index (ABI) values at 3 years post-surgery significantly increased in all patients in both groups. In the EVT group, pre- and postoperative ABI values were 0.54 ± 0.15 and 0.74 ± 0.06 (mean ± standard deviation, ipsilateral), respectively ($p = 0.0001$). In the HT group, pre- and postoperative ABI values were 0.53 ± 0.13 and 0.77 ± 0.03 (ipsilateral), respectively ($p = 0.0001$). Data on symptom improvement of chronic lower limb ischemia (CLI) according to grade in patients over three years in both groups are presented in Table 4.

Table 4. Long-term outcomes and symptom improvement (36 months)

Parameter	EVT (*n* = 31)	HT (*n* = 31)	*p*
Statin therapy	31 (100)	31 (100)	>0.99
Smoking	4 (13)	9 (29)	0.11
CLI according to A.V. Pokrovsky classification			
Grade 1	14 (45)	17 (55)	0.61
Grade 2a	13 (42)	9 (29)	0.42
Grade 2b	4 (13)	5 (16)	>0.99

Note. HT – hybrid treatment; CLI – chronic lower limb ischemia; EVT – endovascular treatment. Data are presented as *n* (%).

Discussion

This pilot prospective randomized study compared endovascular intervention and hybrid surgery using braided nitinol stents in patients suffering from combined occlusive-stenotic lesions of the iliac and common femoral arteries. The study results demonstrated that after 36 months of follow-up, the hybrid treatment group showed higher primary patency rates and a lower incidence of

postoperative complications compared to the group receiving a purely endovascular approach.

In our study, 30-day complications occurred in 9.7 % of patients in the EVT group and in 22.6 % of patients in the HT group (p = 0.17). These results are similar to those reported in studies showing postoperative 30-day complication rates [14–18]. According to the literature, the most frequent complications were access site hematomas, distal embolizations, arterial ruptures, and dissections.

The study results revealed a significantly higher primary patency rate in the hybrid treatment group at 36 months of follow-up compared to the endovascular intervention group – 73 % versus 46 % (p = 0.03). However, no statistically significant differences were found in secondary patency rates (p = 0.64). The high secondary patency in the EVT group, comparable to that in the HT group, was achieved due to the technical feasibility of performing repeat hybrid and endovascular interventions after reocclusion. According to various studies, the 4-year primary patency rate ranged from 60 % to 88 % [15; 17; 19]. Meta-analysis results demonstrated that primary patency rates at 1, 3, and 5 years in EVT patients were 86 %, 80 %, and 71.4 %, respectively. However, in these studies, CFA stenting was not performed. In various studies, the 1-year primary patency rate ranged from 78 % to 91 % in HT patients [20]. In another randomized trial, primary patency rates at 12 and 36 months were 93 % and 91 %, respectively, in the HT group [21]. It should be noted that after isolated common femoral artery endarterectomy, primary patency at 3 years was 85–94 % [9; 22].

There are novel endovascular techniques, such as subintimal angioplasty, the use of laser technologies, and endovascular atherectomy. These methods may potentially be more effective than CFA stenting. There have been reports of successful stent implantation in the CFA [23; 24]. For example, Stricker et al., after 33 cases of stent placement at the CFA bifurcation, reported that primary patency at one and three years was 87 % and 83 %, respectively. However, the majority of these cases (82 %) were associated with claudication, and only one short stent (up to 4 cm) was used in each case. Until additional data on these novel endovascular techniques become available, endarterectomy remains the preferred treatment method for CFA lesions in our practice [25–29].

Study Limitations

The limitations of this study include its single-center focus, which may introduce patient selection bias. Furthermore, this was a pilot study conducted at a single center. Data on buttock claudication, impotence, or lower limb neuropathy were not collected, and exercise testing was not performed before or after surgery. Additionally, the study did not utilize high-pressure balloons or cutting balloons, drug-coated technologies, or vascular closure devices.

Conclusion

In this single-center randomized pilot study, we compared the outcomes of EVT and HT procedures using a braided nitinol stent in patients with concomitant occlusive lesions of the iliac and common femoral arteries. This study supports the hypothesis that hybrid treatment offers advantages in terms of safety and primary patency compared to endovascular treatment in the mid-term follow-up period. Larger multicenter randomized clinical trials based on these findings are required to obtain robust results for establishing clear revascularization method recommendations for patients with iliofemoral lesions.

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