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Comparative Evaluation of Endovascular Treatment Methods in Patients with Aortoiliac Lesions of Moderate and High Cardiovascular Perioperative Risk

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Abstract

Objective. Comparative evaluation of efficacy and safety of the kissing-stent technique and covered endovascular reconstruction of the aortic bifurcation (CERAB) in patients with aortoiliac lesions of moderate and high cardiovascular perioperative risk. **Material and Methods.** A total of 105 patients with hemodynamically significant aortoiliac atherosclerotic lesions of moderate and high cardiovascular perioperative risk were included in this ambispective cohort study. The Duke Activity Status Index (DASI) and the Gupta MICA scale (Gupta Perioperative Risk for Myocardial Infarction or Cardiac Arrest) were used to assess cardiovascular perioperative risk. III stage chronic lower limb ischemia according to Fontaine–Pokrovsky classification was observed in 84 patients (80.0%) and stage IV in 21 patients (20.0%). A total of 66 patients (62.9%) had infrarenal aortic occlusion. A total of 49 patients underwent CERAB, and 56 patients underwent kissing-stent treatment with bare-metal stents. The severity of calcification in the aortoiliac segment was assessed using the PACSS (Peripheral Arterial Calcium Scoring System) based on computed tomography data. Primary endpoint included primary patency. Secondary endpoint included technical success, operation time, intraoperative blood volume loss, adverse cardiovascular events (local and systemic complications, cardiovascular mortality) in the early postoperative period, intensive care unit (ICU) length of stay, hospital length of stay, long-term postoperative complications, secondary patency, freedom from amputation, and survival rate. **Results.** The median follow-up duration was 48.0 [interquartile range (IQR) 33.0; 54.0] months. The median operation time was 73.5 [IQR 60.0; 100.0] minutes in the CERAB group and 67.5 [IQR 45.0; 95.0] minutes in the kissing-stent group ($p = 0.723$). The median intraoperative blood volume loss was 80.5 [IQR 75.4; 110.0] mL in the CERAB group and 81.4 [IQR 68.2; 105.0] mL in the kissing-stent group ($p = 0.865$). Technical success was 98.0% in the CERAB group and 92.9% in the kissing-stent group ($p = 0.369$). The median ICU length of stay was 1.54 [IQR 1.0; 2.0] days in the CERAB group and 1.67 [IQR 1.0; 2.0] days in the kissing-stent group ($p = 0.968$). The median hospital length of stay was 5.0 [IQR 4.0; 7.0] days in the CERAB group and 6.4 [IQR 4.5; 7.8] days in the kissing-stent group ($p = 0.744$). In the early postoperative period, complications occurred in three patients (6.1%) from the CERAB group and in five patients (8.9%) from the kissing-stent group ($p = 0.721$). In the long-term postoperative period, complications occurred in one patient (2.0%) from the CERAB group and in two patients (3.6%) from the kissing-stent group

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($p = 1.000$). Primary patency at 60 months was 85.1% in the CERAB group and 59.4% in the kissing-stent group ($p = 0.047$). Secondary patency at 60 months was 92.9% in the CERAB group and 91.3% in the kissing-stent group ($p = 0.883$). Freedom from amputation at 60 months was 95.4% in the CERAB group and 93.3% in the kissing-stent group ($p = 0.985$). Survival rate at 60 months was 95.7% in the CERAB group and 96.0% in the kissing-stent group ($p = 0.772$). Predictors of loss of primary patency of the aortoiliac segment after kissing stent included grade 3–4 calcification according to the PACSS, the presence of thrombotic masses in the lumen of the infrarenal aorta, and hemodynamically significant damage to the outflow arteries. **Conclusions.** The results of this study demonstrated the advantage of CERAB over kissing-stent technique in terms of five-year primary patency with comparable safety. The predictors of loss of primary patency after kissing-stent treatment identified in this study indicate the need for more careful patient selection and a personalised approach to treatment selection.

Keywords: aortoiliac segment; ambispective cohort study; chronic lower limb ischemia; CERAB; endovascular treatment; kissing stent

1. Introduction

Aortoiliac atherosclerotic occlusive disease increasingly affects patients of working age, including those aged 40–60 years, representing a substantial clinical and socioeconomic burden. For patients with extensive disease of the aortoiliac segment, open aortobifemoral bypass (AFB) has traditionally been regarded as the reference standard for revascularisation, owing to its established durability and favourable long-term patency. However, AFB is associated with considerable operative trauma, prolonged recovery, and a substantial risk of perioperative complications, including cardiovascular and pulmonary events. These limitations are particularly relevant in patients with elevated cardiovascular perioperative risk [1,2]. Consequently, advances in endovascular technology have progressively shifted the treatment paradigm towards less invasive strategies, a trend that has also become increasingly evident in the Russian Federation.

Accumulating clinical evidence suggests that covered endovascular reconstruction of the aortic bifurcation (CERAB) may achieve primary patency comparable to that of open AFB, while offering the potential advantages of reduced procedural invasiveness, shorter hospitalisation, and lower early postoperative morbidity [3,4]. However, the current evidence base remains limited. Most published studies are retrospective, single-centre investigations or relatively small case series, with considerable heterogeneity in patient selection, lesion complexity, procedural techniques and follow-up duration. Furthermore, robust prospective comparative evidence directly evaluating CERAB against conventional kissing-stent reconstruction is lacking.

This evidence gap is particularly important in patients with intermediate-to-high cardiovascular perioperative risk, in whom the balance between the durability of revascularisation and the physiological burden of the intervention is critical. For these patients, an endovascular strategy capable of providing durable patency while reducing perioperative morbidity could offer a clinically meaningful alternative to open surgery. At the same time, the potential technical advantages of CERAB over kissing-stent reconstruction require prospective evaluation before its routine use can be more broadly recommended.

Therefore, prospective comparative studies are warranted to determine whether CERAB provides clinically relevant advantages over kissing-stent reconstruction in patients with complex aortoiliac disease. Comparative assessment of procedural outcomes, perioperative safety, primary patency, and the need for repeat intervention may help define

the optimal endovascular strategy for different patient subgroups and contribute to a more individualised approach to aortoiliac revascularisation.

The aim of this study was to compare the efficacy and safety of kissing-stent reconstruction and CERAB in patients of moderate and high cardiovascular perioperative risk with haemodynamically significant atherosclerotic disease of the aortoiliac segment.

2. Materials and Methods

This ambispective (retrospective–prospective) cohort study included 105 consecutive patients of moderate and high cardiovascular perioperative risk with hemodynamically significant atherosclerotic disease of the aortoiliac segment who were admitted to the Department of Vascular Surgery at the Almazov National Medical Research Centre, Ministry of Health of the Russian Federation, between February 2021 and March 2026 for elective endovascular revascularisation. Aortoiliac lesions included hemodynamically significant atherosclerotic disease, defined as 70–99% stenosis or occlusion of the infrarenal abdominal aorta and/or both common iliac arteries (CIAs).

All patients provided written informed consent before enrolment. The study was conducted in accordance with the principles of the Declaration of Helsinki and applicable national regulations.

Before intervention, all patients underwent a comprehensive clinical and instrumental assessment, including medical history, physical examination, routine laboratory investigations, and multidetector computed tomography angiography (MDCTA) of the abdominal aorta and lower-extremity arteries with three-dimensional reconstruction. MDCTA was performed to confirm the diagnosis, determine the anatomical extent and severity of aortoiliac disease, assess arterial calcification, and guide procedural planning.

The severity of calcification of the abdominal aorta and iliac arteries was assessed using the Peripheral Arterial Calcium Scoring System (PACSS) on MDCTA, according to the established classification [5,6].

Calcification was graded as follows: grade 0, no calcification; grade 1, unilateral calcification < 5 cm; grade 2, unilateral calcification ≥ 5 cm; grade 3, bilateral calcification < 5 cm; and grade 4, bilateral calcification ≥ 5 cm or circumferential calcification involving 270–360° of the arterial circumference.

For the purposes of the present analysis, the PACSS score was determined for the arterial segment relevant to the planned endovascular reconstruction. The presence of severe calcification (PACSS grade 4) was considered a marker of advanced arterial wall calcification and increased anatomical complexity.

Patients were divided into two groups according to the revascularisation technique used. The CERAB group comprised 49 patients who underwent CERAB. The kissing-stent group comprised 56 patients who underwent conventional bilateral iliac stent implantation using bare-metal stents in a kissing configuration.

The choice of endovascular technique was based on the anatomical characteristics of the aortoiliac lesion, extent and severity of calcification, lesion morphology, and clinical characteristics of the patient. All procedures were performed by experienced vascular specialists using standard endovascular techniques.

The required sample size was calculated using G*Power version 3.1.9.7. The anticipated allocation ratio between the CERAB and kissing-stent groups was 7:8. The calculation was based on a two-sided log-rank test with a statistical power of 80% and a significance level of 0.05.

The expected primary patency at 60 months was assumed to be 85% in the CERAB group and 58% in the kissing-stent group. Based on these assumptions, the minimum

required sample size was estimated at 46 patients for the CERAB group and 53 patients for the kissing-stent group, corresponding to a total of 99 patients.

The final cohort consisted of 105 patients, exceeding the prespecified minimum sample size.

The primary endpoint was primary patency of the treated aortoiliac segment during follow-up.

Secondary endpoints included technical success, procedure duration, intraoperative blood loss, early postoperative complications within 30 days, cardiovascular and procedure-related adverse events, cardiovascular mortality, intensive care unit (ICU) length of stay, total hospital length of stay, late postoperative complications occurring after 30 days, secondary patency, freedom from amputation, and overall survival.

Primary patency was defined as uninterrupted patency of the treated aortoiliac segment after the index procedure, without the need for any additional endovascular or open surgical intervention to restore blood flow.

Secondary patency was defined as patency of the treated aortoiliac segment maintained or restored following a secondary intervention after loss of primary patency. Technical success was defined as successful completion of the planned endovascular procedure with restoration of adequate luminal patency and without the need for conversion to open surgery during the index procedure.

Early adverse events were defined as complications occurring within 30 days after the index intervention, whereas late complications were defined as events occurring thereafter.

In the long-term postoperative period late thromboses were reported as adverse events, not as local complications.

2.1. Assessment of Perioperative Cardiovascular Risk

Perioperative cardiovascular risk was assessed using the Duke Activity Status Index (DASI) and the Gupta Myocardial Infarction or Cardiac Arrest (MICA) risk model.

The DASI is a validated 12-item questionnaire designed to assess functional capacity across a range of everyday activities, from personal self-care to more physically demanding recreational activities. The questionnaire generates a DASI score, which can subsequently be converted into an estimated peak oxygen consumption and metabolic equivalents of task (METs). Functional capacity was interpreted according to established clinical thresholds. A capacity of >10 METs was considered excellent, 4–10 METs satisfactory, and <4 METs poor, with poor functional capacity indicating the potential need for additional cardiovascular assessment and optimisation before elective intervention [7].

The Gupta MICA risk model was used to estimate the probability of myocardial infarction or cardiac arrest within 30 days after non-cardiac surgery. The model incorporates age, functional status, type of surgical procedure, serum creatinine concentration, and American Society of Anesthesiologists (ASA) physical status classification. Patients were categorised according to the estimated 30-day risk as low (<1%), intermediate (1–1.9%), or high (≥2%) [7].

The DASI and Gupta MICA assessments were performed before the index procedure and were used to characterise the baseline cardiovascular risk profile of the study population.

2.2. Eligibility Criteria

2.2.1. Inclusion Criteria

Patients were eligible for inclusion if they met all of the following criteria:

- Age ≥ 18 years;
- Hemodynamically significant atherosclerotic disease of the aortoiliac segment, defined as 70–99% stenosis or occlusion of the infrarenal abdominal aorta and/or both CIAs, confirmed by MDCTA;
- Symptomatic chronic lower limb ischemia, classified as stage III or IV according to the Fontaine–Pokrovsky classification;
- Intermediate-to-high cardiovascular perioperative risk, defined as a DASI-derived functional capacity of ≤10 METs and a Gupta MICA-predicted risk of ≥1%.

2.2.2. Exclusion Criteria

Patients were excluded if they met any of the following criteria:

- Acute lower limb ischemia;
- Previous surgical or endovascular intervention involving the aortoiliac segment, including the abdominal aorta or iliac arteries;
- Confirmed or suspected infection of the soft tissues of the limb undergoing intervention, including phlegmon, abscess, or erysipelas;
- Systemic coagulopathy;
- Expected life expectancy of <12 months;
- Intolerance or contraindication to aspirin, clopidogrel, or heparin;
- Aneurysmal dilatation involving the target arterial segment;
- Chronic kidney disease (CKD) stage 5;
- Acute myocardial infarction or acute cerebrovascular event within the preceding 12 months;
- Terminal-stage malignant disease;
- Refusal to participate in the study.

2.3. Study Flow

The overall study design and patient flow are presented in Figure 1.

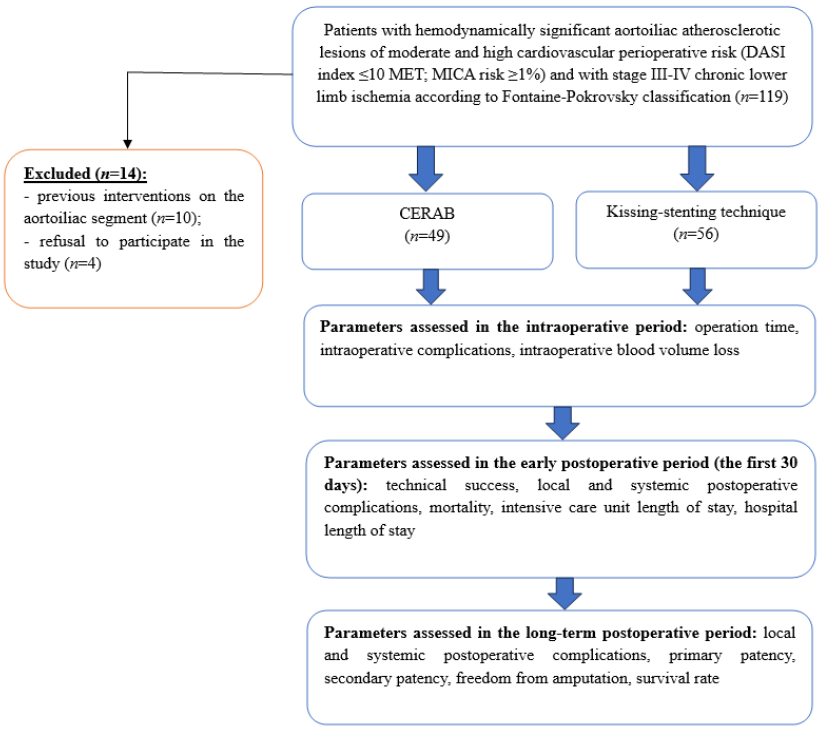

Figure 1. Overall study design.

Patients with haemodynamically significant atherosclerotic disease of the aortoiliac segment, intermediate-to-high cardiovascular perioperative risk (DASI-derived functional capacity ≤ 10 METs and Gupta MICA risk ≥ 1%), and stage III–IV chronic lower limb ischemia according to the Fontaine–Pokrovsky classification were assessed for eligibility.

Following application of the predefined eligibility criteria, patients who met the exclusion criteria were excluded from the study. The remaining patients underwent endovascular revascularisation and were analysed according to the treatment strategy used: CERAB or conventional kissing-stent reconstruction.

Complications were classified as intraoperative and early and long-term postoperative. The threshold between early and long-term postoperative complications was 30 days.

Primary patency was defined as the interval from the time of the intervention until the first occurrence of any of the following: thrombosis/occlusion, a procedure to restore or maintain patency, or measurement of a hemodynamically significant stenosis (≥50% by MDCTA) in the aortoiliac segment.

2.4. Intraoperative Assessment

The following intraoperative parameters were recorded:

- Procedure duration;
- Intraoperative complications;
- Estimated intraoperative blood loss.

2.5. Early Postoperative Assessment

Early postoperative outcomes were assessed during the first 30 days after the index procedure and included:

- Technical success;
- Local and systemic postoperative complications;
- Cardiovascular mortality;
- Intensive care unit (ICU) length of stay;
- Total hospital length of stay.

2.6. Long-Term Follow-Up

During long-term follow-up, the following outcomes were assessed:

- Local and systemic postoperative complications;
- Primary patency;
- Secondary patency;
- Freedom from amputation;
- Overall survival.

Figure 1 provides a schematic overview of the study design, patient selection, treatment allocation, and assessment of perioperative and long-term outcomes.

Baseline demographic, clinical, and anatomical characteristics of the study population are presented in Table 1.

Table 1. Baseline demographic, clinical, and anatomical characteristics of the study population.

Variable	Kissing-Stent Group (n = 56)	CERAB Group (n = 49)	p-Value
Age, years, median [Q1; Q3]	62.0 [55.5; 65.0]	63.0 [59.0; 71.0]	0.221
Body mass index, kg/m^2, median [Q1; Q3]	26.1 [24.0; 30.1]	26.2 [23.1; 29.7]	0.987
Male sex, n (%)	50 (89.3)	42 (85.7)	0.768

Table 1. *Cont.*

Variable	Kissing-Stent Group (n = 56)	CERAB Group (n = 49)	p-Value
Current smoking, n (%)	46 (82.1)	39 (79.6)	0.806
Comorbidities			
Dyslipidaemia, n (%)	52 (92.9)	46 (93.9)	1.000
Diabetes mellitus, n (%)	45 (80.4)	38 (77.6)	0.812
Arterial hypertension, n (%)	49 (87.5)	42 (85.7)	1.000
Coronary artery disease, n (%)	50 (89.3)	46 (93.9)	0.498
Multilevel atherosclerotic disease, n (%)	48 (85.7)	40 (81.6)	0.605
Previous myocardial infarction, n (%)	40 (71.4)	34 (69.4)	0.834
Previous stroke, n (%)	24 (42.9)	22 (44.9)	0.846
Atrial fibrillation, n (%)	21 (37.5)	18 (36.7)	1.000
Chronic heart failure, n (%)	46 (82.1)	41 (83.7)	1.000
Chronic kidney disease, n (%)	22 (39.3)	18 (36.7)	0.842
Cardiovascular perioperative risk			
DASI-derived functional capacity, METs, median [Q1; Q3]	4.36 [3.28; 5.82]	4.20 [3.59; 5.67]	0.584
Gupta MICA risk, %, median [Q1; Q3]	2.34 [1.75; 4.01]	2.15 [1.88; 3.77]	0.745
Fontaine–Pokrovsky stage of chronic lower limb ischemia, n (%)			
Stage III	46 (82.1)	38 (77.6)	0.559
Stage IV	10 (17.9)	11 (22.4)	
Aortoiliac lesion anatomy, n (%)			
Isolated bilateral CIA occlusion	6 (10.7)	3 (6.1)	0.498
Infrarenal abdominal aortic occlusion	31 (55.4)	32 (65.3)	0.325
Isolated bilateral 70–99% CIA stenosis	8 (14.3)	5 (10.2)	0.568
Unilateral CIA occlusion with 70–99% stenosis of the contralateral CIA	11 (19.6)	9 (18.4)	1.000
TASC II classification, n (%)			
C	12 (21.4)	13 (26.5)	0.541
D	44 (78.6)	36 (73.5)	
Aortoiliac lesion dimension			
The extent of aortoiliac lesions, mm median [Q1; Q3]	40.5 [25.0; 51.4]	42.8 [27.5; 53.0]	0.244
Concomitant lesion of the EIA, n (%)			
70–99% stenosis/occlusion of the external iliac artery	28 (50.0)	23 (46.9)	0.845
Aortic and iliac artery calcification according to PACSS, n (%)			
Grade 1	11 (19.6)	4 (8.2)	0.268
Grade 2	23 (41.1)	21 (42.9)	
Grade 3	15 (26.8)	13 (26.5)	
Grade 4	7 (12.5)	11 (22.4)	

Table 1. *Cont.*

Variable	Kissing-Stent Group ($n = 56$)	CERAB Group ($n = 49$)	p-Value
Outflow arterial disease			
70–99% stenosis/occlusion of the femoropopliteal arteries, n (%)	13 (23.2)	7 (14.3)	0.321

Abbreviations: CIA, common iliac artery; CERAB, covered endovascular reconstruction of the aortic bifurcation; DASI, Duke Activity Status Index; MICA, Myocardial Infarction or Cardiac Arrest; MET, metabolic equivalent of task; PACSS, Peripheral Arterial Calcium Scoring System; Q1, first quartile; Q3, third quartile. Data are presented as median [Q1; Q3] or *n* (%), as appropriate.

2.7. Previous Cardiovascular Interventions and Baseline Hemodynamic Characteristics

Previous coronary revascularisation was frequent in both study groups. A history of coronary artery bypass grafting (CABG) was reported in 15 patients (30.6%) in the CERAB group and 22 patients (39.3%) in the kissing-stent group ($p = 0.415$). Previous percutaneous coronary intervention with coronary stent implantation had been performed in 26 patients (53.1%) in the CERAB group and 35 patients (62.5%) in the kissing-stent group ($p = 0.428$).

One patient (2.0%) in the CERAB group had previously undergone combined CABG, aortic valve repair, and replacement of the aortic root and ascending aorta with a vascular graft (David I procedure, Kouchoukos modification) under cardiopulmonary bypass with blood cardioplegia. Three patients (5.4%) in the kissing-stent group had previously undergone CABG combined with mechanical aortic valve replacement.

The preprocedural ankle–brachial index (ABI) was 0.57 [0.43–0.62] in the CERAB group and 0.54 [0.48–0.69] in the kissing-stent group ($p = 0.754$). All aortoiliac lesions were de novo.

2.8. Endovascular Procedure

All procedures were performed under local anaesthesia using three arterial access sites. Arterial puncture was performed under ultrasound guidance. A 6 Fr sheath was introduced through the left brachial artery and used for angiographic guidance and procedural imaging. Bilateral common femoral arterial access was obtained using 8 Fr sheaths.

In patients with chronic aortoiliac occlusion, retrograde recanalisation of the target lesion was performed. Following successful wire passage, simultaneous bilateral balloon angioplasty of the infrarenal abdominal aorta and iliac arteries was performed using Mustang balloon catheters (Boston Scientific, Marlborough, MA, USA) in a kissing configuration.

2.9. Kissing-Stent Reconstruction

For conventional kissing-stent reconstruction, the angioplastied segments were subsequently treated with bilateral iliac stents deployed in a kissing configuration, with the proximal portions extending into the distal abdominal aorta.

In patients with advanced arterial calcification (PACSS grade III–IV), balloon-expandable bare-metal Express Vascular LD stents (Boston Scientific) were preferentially used ($n = 22$, 39.3%). In the remaining patients, self-expanding nitinol stents were implanted: SMART Control (Cordis, Miami Lakes, FL, USA; $n = 7$, 12.5%), Epic (Boston Scientific; $n = 12$, 21.4%), or Protégé EverFlex (ev3 Endovascular Inc., Plymouth, MN, USA; $n = 15$, 26.8%).

Additional stenting of the external iliac artery (EIA) was performed in 28 patients (50.0%) in the kissing-stent group.

2.10. Covered Endovascular Reconstruction of the Aortic Bifurcation

For CERAB, the iliac branch (cuff) of Ankura covered stent-graft (Lifetech, Shenzhen, China) was advanced over 0.035-inch, 300 cm Lunderquist Extra Stiff guidewires and deployed within the infrarenal abdominal aorta under angiographic guidance via the common femoral artery. The proximal diameter of the Ankura stent-graft was 14 mm, distal diameter 12–14 mm, and its length 60 cm.

Two BeGraft balloon-expandable covered stent-grafts (Bentley, Hechingen, Germany) were then simultaneously advanced over hydrophilic guidewires into the right and left iliac arteries, positioned, and deployed to complete reconstruction of the aortic bifurcation. The diameter of the peripheral stent-grafts was 6–10 mm and their length 37–58 mm. The overlap of the aortic body with the iliac limbs was 1.5–2 cm. The Ankura stent-graft delivery system was 14 Fr in diameter.

Additional EIA stenting was performed in 23 patients (46.9%) in the CERAB group.

The CERAB technique is presented in Figure 2.

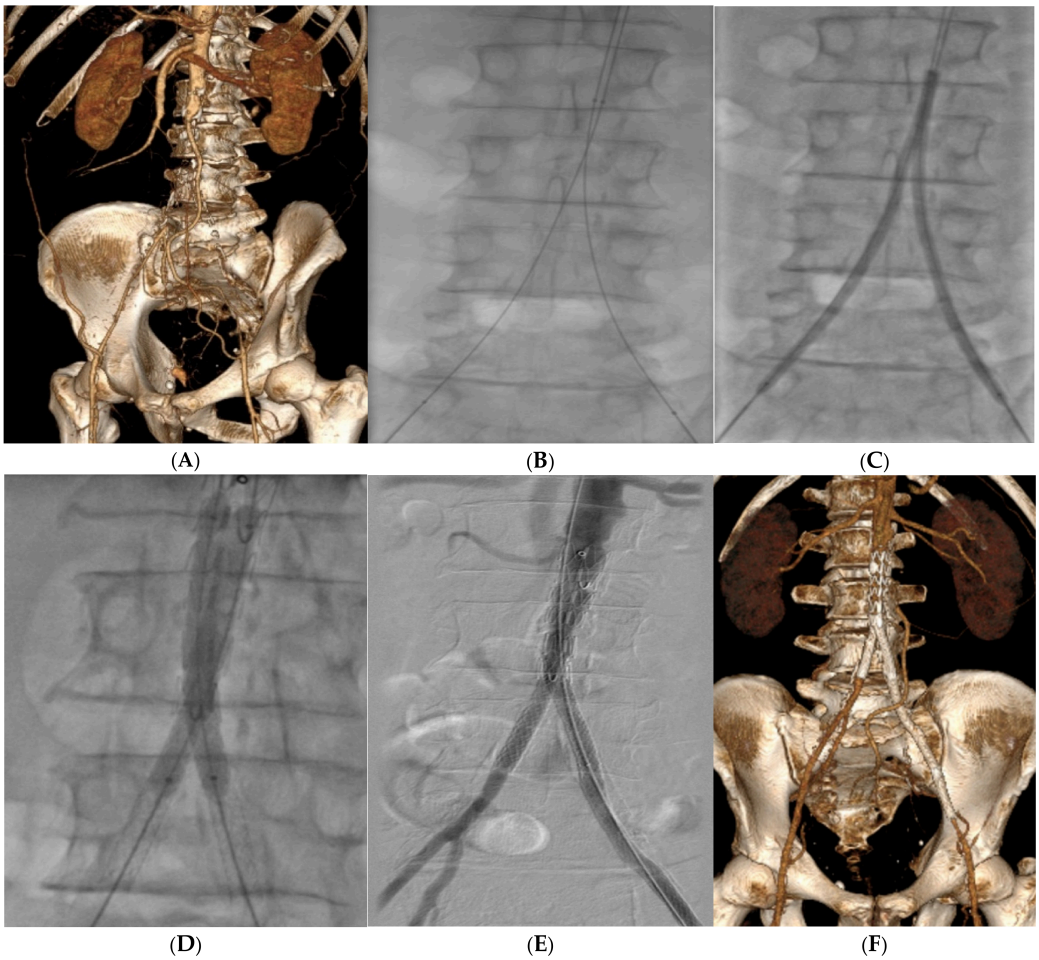

Figure 2. Covered endovascular reconstruction of the aortic bifurcation (CERAB). A 72-year-old patient with infrarenal abdominal aortic occlusion, both common iliac arteries (CIAs) and the left external iliac artery (EIA): preoperative MDCTA (**A**); retrograde recanalisation of the left EIA, both CIAs and the infrarenal abdominal aorta with access to its true lumen, guidewire recrossing using the "Rendez-vous" technique (**B**); balloon angioplasty of the infrarenal abdominal aorta and both CIA using the "kissing" technique (**C**); the iliac branch (cuff) of the stent-graft was implanted in the infrarenal abdominal aorta, and balloon-expandable peripheral stent-grafts were implanted in both CIA (**D**); a self-expanding bare-metal stent was implanted in the left EIA, control angiography: optimal result (**E**); control MDCTA 6 months after surgery: optimal result (**F**).

Stent and stent-graft diameter and length were determined on the basis of preprocedural MDCTA measurements and confirmed by intraoperative angiography.

Concomitant treatment of femoropopliteal outflow disease was performed when clinically indicated and included endarterectomy, balloon angioplasty, and/or stenting. Such additional interventions were performed in 7 patients (14.3%) in the CERAB group and 13 patients (23.2%) in the kissing-stent group ($p = 0.321$).

2.11. Assessment of Procedural Success and Follow-Up

Technical success was defined as successful completion of the intended endovascular reconstruction, with restoration of flow through the treated aortoiliac segment and without conversion to open surgery or the need for immediate repeat intervention.

Patency of the reconstructed segment was assessed by MDCTA on postoperative day 7, at 6 months, and annually thereafter. Imaging was performed to assess stent/stent-graft patency, identify restenosis or occlusion, and detect procedure-related complications. Serial CTA examinations were performed to specifically assess if the new aneurysmal dilatation at or above the proximal kissing-stent segment was present.

After hospital discharge, patients were followed by vascular surgeons at the Almazov National Medical Research Centre. In the prospective phase, clinical follow-up was scheduled at 3, 6, and 12 months after the index procedure and annually thereafter. For patients included retrospectively (February–October 2021), follow-up data were extracted from the existing medical records; where available, the same follow-up schedule (3, 6, and 12 months and annually thereafter) was applied, and all available clinical and imaging data were used for the analysis.

At each follow-up visit, clinical status was assessed according to the Fontaine–Pokrovsky classification of chronic lower-limb ischemia, and the ABI was measured. These assessments were performed at 3, 6, and 12 months and annually thereafter.

Follow-up was closed on 31 May 2026. Patients were considered lost to follow-up if contact was lost for more than 6 months.

2.12. Antithrombotic Treatment

Following endovascular reconstruction, patients in both treatment groups received dual antiplatelet therapy with aspirin 100 mg bid indefinitely and clopidogrel 75 mg bid for 6 months.

Patients with non-valvular atrial fibrillation (18 patients in the CERAB group and 18 patients in the kissing-stent group) received triple therapy (apixaban 5 mg bid, aspirin 100 mg bid, and clopidogrel 75 mg bid) for 7 days, followed by dual therapy (apixaban 5 mg bid and clopidogrel 75 mg bid) for 6 months with subsequent transition to monotherapy (apixaban 5 mg bid) indefinitely. In cases of high haemorrhagic risk, the decision to prescribe aspirin was made on an individual basis as well as the dosage of apixaban. Although the dosage of apixaban depended on the GFR level. The dosage of 5 mg bid was administered to patients with glomerular filtration rate (GFR) $\geq$ 30 mL/min and the dosage of 2.5 mg bid to patients with GFR 15–29 mL/min. Additionally, apixaban 2.5 mg bid was prescribed if the patient had two or more of the following criteria: age $\geq$ 80 years, body weight $\leq$ 60 kg, and plasma creatinine concentration $\geq$ 1.5 mg/dL (133 µmol/L).

In the CERAB group, one patient with a history of a David I procedure modified according to Kouchoukos received aspirin 100 mg bid once daily indefinitely, clopidogrel 75 mg bid once daily for 1 month, and long-term apixaban 5 mg bid.

Three patients in the kissing-stent group with a history of mechanical aortic valve replacement (5.4%) received triple therapy with the same duration and usage of warfarin as an anticoagulation agent.

The choice and duration of antithrombotic therapy were determined according to the patient's cardiovascular comorbidities, prior interventions, and thrombotic and bleeding risks.

Bleeding after CERAB or kissing stent was defined as any clinically significant acute or delayed bleeding or hematoma within 30 days after the index procedure (in hospital or after discharge), identified clinically, by laboratory testing, or by imaging, if at least one of the following was present: visible bleeding from the vascular access site or another source; hematoma or swelling at the access site with pain, tension, increase in size, or ≥5 cm, or confirmed by ultrasound/CT; unexplained decrease in haemoglobin ≥1 g/dL; transfusion of ≥1 unit of packed red blood cells; retroperitoneal, intraperitoneal, or other haemorrhage on ultrasound or CT; need for compression, reversal of anticoagulation, embolisation, vascular intervention, or surgery; death attributable to bleeding.

Bleeding events were defined during the physical examination and patient interview. These events were assessed during the follow-up at each patient visit. Against the background of the antiplatelet and anticoagulant therapy used, the patients in both groups did not experience any bleeding.

2.13. Statistical Analysis

Statistical analyses were performed using MedCalc® Statistical Software version 23.4.9 (MedCalc Software Ltd., Ostend, Belgium; 2026).

Continuous variables were assessed for normality. As the distributions were non-normal, continuous data are presented as medians with interquartile ranges (IQRs), expressed as Q1 and Q3. Categorical variables are presented as counts and percentages.

Between-group comparisons of continuous variables were performed using the Mann–Whitney U test. Categorical variables were compared using Fisher's exact test.

Time-to-event outcomes, including overall survival, primary patency, secondary patency, and amputation-free survival, were analysed using the Kaplan–Meier method. Differences between survival curves were assessed using the two-sided log-rank test. In the survival analysis, patients were considered "censored" in the following cases: at the time of the last contact, if the target event (e.g., relapse, death) did not occur; upon withdrawal of informed consent; upon loss to follow-up (loss of contact for a period of more than 6 months); and upon the occurrence of a competing event (e.g., death from non-cardiovascular causes).

Univariable Cox proportional hazards regression was used to identify factors associated with loss of primary patency. Hazard ratios (HRs) with corresponding 95% confidence intervals (CIs) were reported. The proportional hazards assumption was assessed before interpretation of the Cox regression models. All statistical tests were two-sided, and a p-value < 0.05 was considered statistically significant.

3. Results

3.1. Periprocedural and Early Postoperative Outcomes

The overall median follow-up duration was 48.0 [33.0; 54.0] months: 38.0 [26.0; 52.0] months in the CERAB group and 50.0 [41.5; 55.0] months in the kissing-stent group. The number of patients who reached the 12-month period was 44 (89.8%) in the CERAB group and 54 (96.4%) in the kissing-stent group, the 24-month period—40 (81.6%) in the CERAB group and 53 (94.6%) in the kissing-stent group, the 36-month period—29 (59.2%) in the CERAB group and 44 (78.6%) in the kissing-stent group, the 48-month period—19 (38.8%) in the CERAB group and 37 (66.1%) in the kissing-stent group, and the 60-month period—5 (10.2%) in the CERAB group and 11 (19.6%) in the kissing-stent group. Follow-up was closed on 31.05.2026. Loss to follow-up (loss of contact >6 months) occurred in 10 patients (20.4%) in the CERAB group and 8 patients (14,3%) in the kissing-stent group. The remaining censoring was due to withdrawal of consent or competing events.

The median procedure time was 73.5 [60.0; 100.0] min in the CERAB group and 67.5 [45.0; 95.0] min in the kissing-stent group ($p = 0.723$). Median intraoperative blood loss was 80.5 [75.4; 110.0] mL and 81.4 [68.2; 105.0] mL, respectively ($p = 0.865$).

No intraoperative complications occurred in the CERAB group, whereas two patients (3.6%) in the kissing-stent group experienced intraoperative complications. Both events were distal thromboembolism and were successfully managed by thrombectomy.

Technical success was achieved in 98.0% of patients in the CERAB group and 92.9% of those in the kissing-stent group ($p = 0.369$).

The median ICU stay was 1.54 [1.0–2.0] days in the CERAB group and 1.67 [1.0–2.0] days in the kissing-stent group ($p = 0.968$). The median hospital length of stay was 5.0 [4.0–7.0] days and 6.4 [4.5–7.8] days, respectively ($p = 0.744$).

The median ABI measured during the early postoperative period was 0.91 [0.89–1.10] in the CERAB group and 0.95 [0.85–1.00] in the kissing-stent group ($p = 0.678$).

During the first 30 days after the index procedure, local complications occurred in two patients (4.1%) in the CERAB group and four patients (7.1%) in the kissing-stent group. Systemic complications occurred in one patient (2.0%) and one patient (1.8%), respectively.

In the CERAB group, one patient (2.0%) developed a common femoral artery pseudoaneurysm, which was successfully managed conservatively. One patient developed early thrombosis of the iliac limb of the endograft on postoperative day 2, resulting in acute lower limb ischemia and requiring emergency thrombectomy. One patient developed acute myocardial infarction on postoperative day 7, which resulted in fatal outcome.

In the kissing-stent group, two patients (3.6%) developed early thrombosis of the treated CIA segment and underwent thrombectomy. One patient developed a CFA pseudoaneurysm, which resolved with conservative management. One patient developed femoral lymphorrhoea on postoperative day 6 and was successfully managed conservatively. One patient, who had an otherwise satisfactory clinical condition, developed a stroke approximately 10 days after the procedure, resulting in death.

The overall incidence of any early postoperative complications was 6.1% (3/49) in the CERAB group and 8.9% (5/56) in the kissing-stent group ($p = 0.721$). Thirty-day mortality was 2.0% (1/49) and 1.8% (1/56), respectively ($p = 1.000$).

A detailed comparison of early postoperative complications and mortality between the two groups is presented in Table 2.

Table 2. Early postoperative complications and mortality within 30 days after the index procedure.

Outcome	CERAB ($n = 49$)	Kissing Stent ($n = 56$)	p-Value
All-cause mortality, n (%)	1 (2.0)	1 (1.8)	1.000
Any complication, n (%)	3 (6.1)	5 (8.9)	0.721
Local complications, n (%)	2 (4.1)	4 (7.1)	0.683
Common femoral artery pseudoaneurysm	1 (2.0)	1 (1.8)	1.000
Femoral lymphorrhoea	0	1 (1.8)	1.000
Thrombosis of the treated segment	1 (2.0)	2 (3.6)	1.000
Systemic complications, n (%)	1 (2.0)	1 (1.8)	1.000
Acute myocardial infarction	1 (2.0)	0	0.467
Stroke	0	1 (1.8)	1.000

3.2. Late Postoperative Outcomes

During long-term follow-up, no local complications were observed in either treatment group.

In the CERAB group, one patient (2.0%) experienced a systemic complication, namely stroke, which resulted in death. In the kissing-stent group, two patients (3.6%) experienced systemic complications: one developed acute heart failure resulting in death, and the other experienced a non-fatal stroke.

During follow-up, no patient developed new aneurysmal dilatation at or above the proximal kissing-stent segment.

The incidence of late complications did not differ significantly between the groups: 1/49 patients (2.0%) in the CERAB group versus 2/56 patients (3.6%) in the kissing-stent group ($p = 1.000$).

A detailed comparison of late postoperative complications is presented in Table 3.

Table 3. Late postoperative complications (more than 30 days) during follow-up.

Outcome	CERAB ($n = 49$)	Kissing Stent ($n = 56$)	p-Value
Any complication, n (%)	1 (2.0)	2 (3.6)	1.000
Local complications, n (%)	0	0	—
Systemic complications, n (%)	1 (2.0)	2 (3.6)	1.000
Acute heart failure	0	1 (1.8)	1.000
Stroke	1 (2.0)	1 (1.8)	1.000

In the long-term postoperative period, adverse events (late thrombosis) occurred in 6 patients from the CERAB group (12.2%) and in 19 patients from the kissing-stent group (33.9%), which required reinterventions ($p = 0.011$). Two of these patients (one patient in the kissing-stent group and one patient in the CERAB group) had previously experienced early thrombosis of the treated CIA segment.

3.3. Primary Patency

A significant difference in primary patency was observed between the treatment groups during follow-up (log-rank $p = 0.047$; HR 2.24; 95% CI 1.01–4.96; Figure 3). Restricted mean survival time at time point 60 months was 53.8 (95% CI 49.2–58.4) in the CERAB group and 47.5 (95% CI 42.7–52.2) in the kissing-stent group.

In the CERAB group, estimated primary patency was 95.7% at 12 months, 93.3% at 24 months, 85.1% at 36 months, 85.1% at 48 months, and 85.1% at 60 months. In the kissing-stent group, estimated primary patency was 96.4% at 12 months, 87.0% at 24 months, 68.6% at 36 months, 63.2% at 48 months, and 59.4% at 60 months. In the CERAB group, estimated primary patency was 95.7% at 12 months, 93.3% at 24 months, 85.1% at 36 months, 85.1% at 48 months, and 85.1% at 60 months. In the kissing-stent group, estimated primary patency was 96.4% at 12 months, 87.0% at 24 months, 68.6% at 36 months, 63.2% at 48 months, and 59.4% at 60 months. Complete data: 6 (12.2%) in the CERAB group, 19 (33.9%) in the kissing-stent group. Censored data: 43 (87.8%) in the CERAB group, 37 (66.1%) in the kissing-stent group.

Thus, although primary patency was comparable between groups during the first 12 months, a progressive divergence of the Kaplan–Meier curves was observed thereafter, with a more pronounced decline in patency in the kissing-stent group.

All patients who experienced loss of primary patency underwent repeat revascularisation. One patient in the kissing-stent group, who had intermediate cardiovascular

perioperative risk, subsequently underwent aortobifemoral bypass (AFB). All other patients with loss of primary patency in both groups were successfully managed with repeat endovascular intervention.

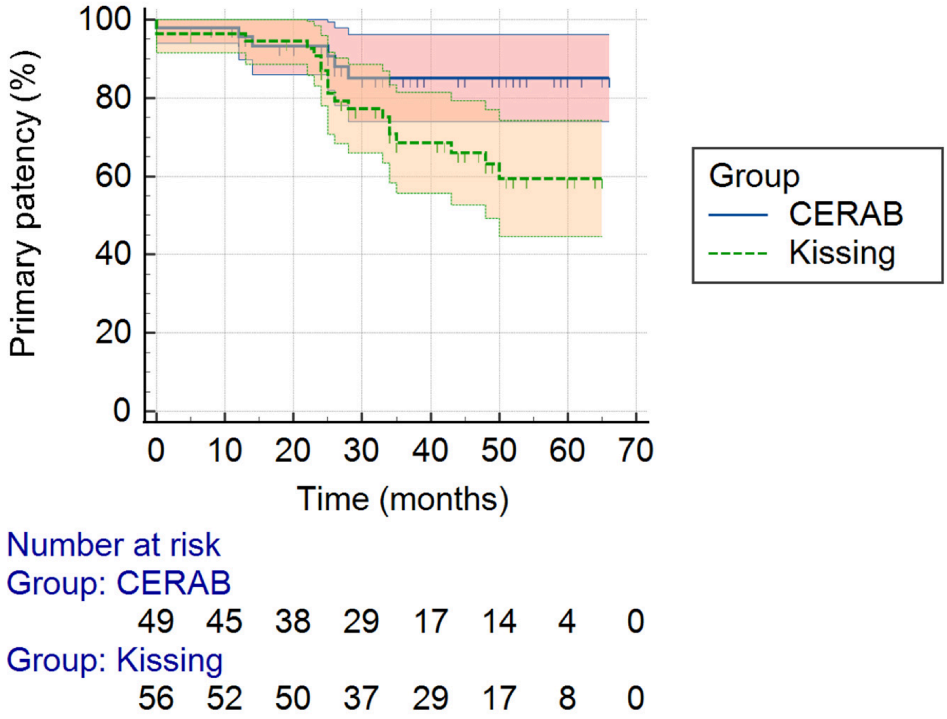

Figure 3. Primary patency with 95% confidence intervals: statistically significant differences were observed between the study groups ($p = 0.047$).

3.4. Secondary Patency, Freedom from Amputation, and Overall Survival

Secondary patency remained high throughout follow-up in both treatment groups. In the CERAB group, estimated secondary patency was 97.8% at 12 months, 95.4% at 24 months, 92.9% at 36 months, 92.9% at 48 months, and 92.9% at 60 months. In the kissing-stent group, the corresponding estimates were 98.1%, 98.1%, 96.1%, 93.9%, and 91.3%, respectively. No significant difference in secondary patency was observed between the groups (log-rank $p = 0.883$; HR 0.89; 95% CI 0.20–4.08; Figure 4). Restricted mean survival time at time point 60 months was 57.0 (95% CI 53.7–60.3) in the CERAB group and 57.7 (95% CI 55.4–60.0) in the kissing-stent group. Complete data: 3 (6.1%) in the CERAB group, 4 (7.1%) in the kissing-stent group. Censored data: 46 (93.9%) in the CERAB group, 52 (92.9%) in the kissing-stent group.

Freedom from amputation was also comparable between the treatment groups. In the CERAB group, estimated freedom from amputation was 97.8% at 12 months and 95.4% at 24, 36, 48, and 60 months. In the kissing-stent group, the corresponding estimates were 98.1% at 12, 24, and 36 months and 93.3% at 48 and 60 months. No significant between-group difference was observed (log-rank $p = 0.985$; HR 0.98; 95% CI 0.16–5.99; Figure 5). Restricted mean survival time at time point 60 months was 57.9 (95% CI 55.1–60.7) in the CERAB group and 58.4 (95% CI 56.4–60.3) in the kissing-stent group. Complete data: 2 (4.1%) in the CERAB group, 3 (5.4%) in the kissing-stent group. Censored data: 47 (95.9%) in the CERAB group, 53 (94.6%) in the kissing-stent group.

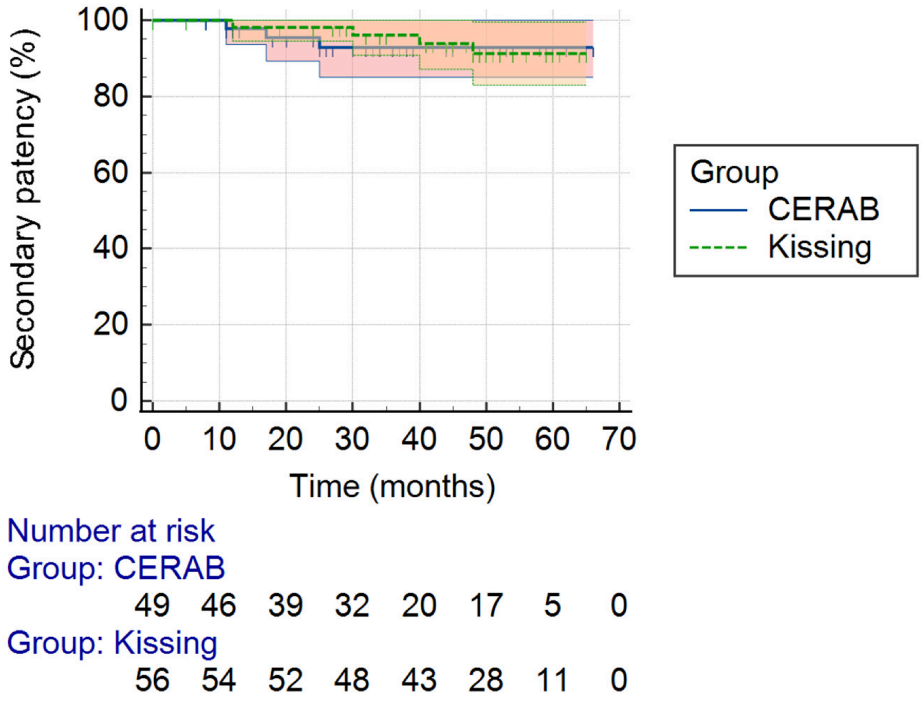

Figure 4. Kaplan–Meier estimates of secondary patency with 95% confidence intervals after CERAB and kissing-stent reconstruction. No significant between-group difference was observed (log-rank $p = 0.883$).

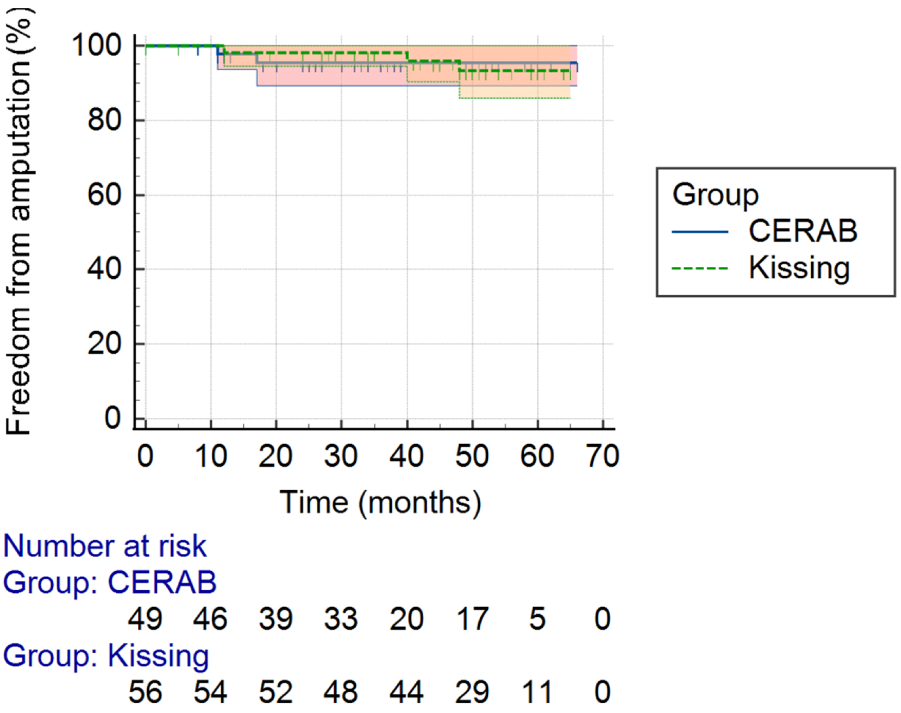

Figure 5. Kaplan–Meier estimates of freedom from amputation with 95% confidence intervals after CERAB and kissing-stent reconstruction. No significant between-group difference was observed (log-rank $p = 0.985$).

One patient in the kissing-stent group underwent a major lower limb amputation during long-term follow-up. The other two patients in the kissing-stent group and two patients in the CERAB group underwent minor lower limb amputation.

Overall survival was similarly high in both groups during follow-up. In the CERAB group, estimated overall survival was 95.7% at 12, 24, 36, 48, and 60 months. In the kissing-stent group, overall survival was 98.2% at 12, 24, and 36 months and 96.0% at 48 and 60 months The difference between the groups was not statistically significant (log-rank $p = 0.772$; HR 0.74; 95% CI 0.10–5.49; Figure 6). Restricted mean survival time at time point 60 months was 57.7 (95% CI 54.6–60.8) in the CERAB group and 58.5 (95% CI 56.2–60.7) in the kissing-stent group. Complete data: two (4.1%) in the CERAB group, two (3.6%) in the kissing-stent group. Censored data: 47 (95.9%) in the CERAB group, 54 (96.4%) in the kissing-stent group.

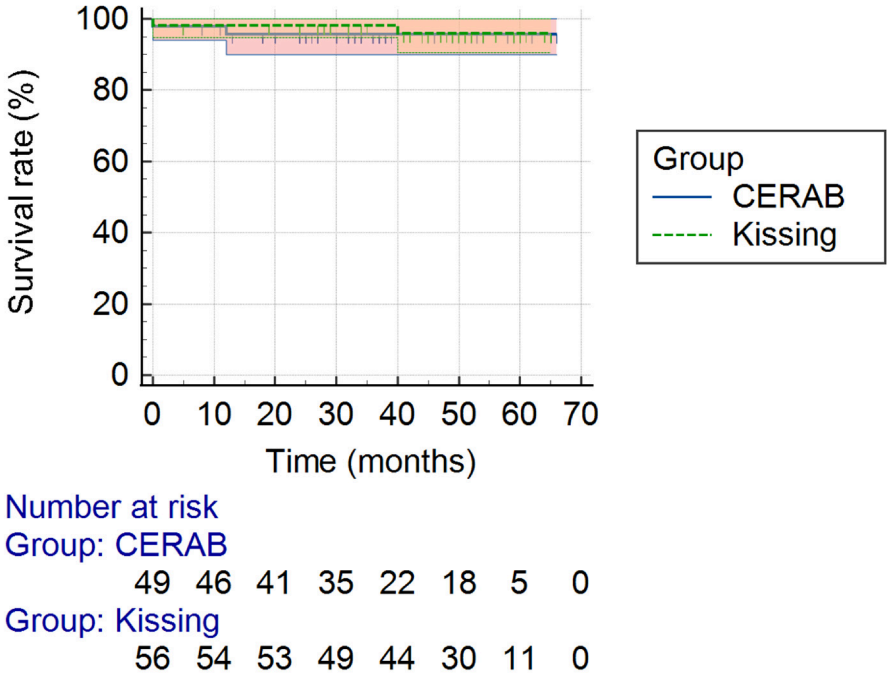

Figure 6. Kaplan–Meier estimates of overall survival with 95% confidence intervals after CERAB and kissing-stent reconstruction. No significant between-group difference was observed (log-rank $p = 0.772$).

Univariable Cox proportional hazards regression was performed to identify predictors of loss of primary patency following kissing-stent reconstruction. A separate regression analysis was not performed in the CERAB group because of the limited number of primary patency loss events ($n = 6$), which was considered insufficient for reliable multivariable modelling.

Among patients undergoing kissing-stent reconstruction, three factors were significantly associated with an increased hazard of primary patency loss. Advanced aorto-iliac calcification (PACSS grade III–IV) was associated with a 2.74-fold higher hazard of primary patency loss (HR 2.74, 95% CI 1.09–6.85; $p = 0.030$). The presence of thrombotic material within the infrarenal abdominal aorta on preprocedural MDCTA was also associated with an increased hazard of primary patency loss (HR 2.84, 95% CI 1.14–7.08; $p = 0.026$). Similarly, haemodynamically significant disease in the arterial outflow tract was associated with a higher hazard of primary patency loss (HR 2.61, 95% CI 1.04–6.50; $p = 0.040$).

Age, body mass index, previous myocardial infarction, and chronic kidney disease were not significantly associated with primary patency loss in the kissing-stent group.

4. Discussion

Endovascular treatment has become an integral component of contemporary management of aorto-iliac occlusive disease. Advances in endovascular devices and techniques have progressively expanded the applicability of minimally invasive revascularisation, allowing complex lesions involving the aortic bifurcation and even chronic infrarenal aortic occlusions to be treated in patients who may be considered at increased risk for open surgery. At the same time, the durability of different endovascular reconstruction strategies remains an important clinical consideration, particularly in patients with extensive aortoiliac disease and substantial cardiovascular comorbidity.

Bilateral iliac stent implantation using the kissing-stent technique is currently one of the most widely used endovascular approaches for reconstruction of the aortic bifurcation. Although technically straightforward and associated with favourable short- and intermediate-term outcomes in appropriately selected patients, its performance may be compromised by extensive aortic bifurcation calcification. Severe calcification can impair complete stent expansion and apposition and may result in suboptimal stent positioning and deformation, including the so-called 'crumple' or 'accordion' effect. These geometric abnormalities can adversely affect haemodynamic flow and potentially increase the risk of stent thrombosis, restenosis, and subsequent reintervention during long-term follow-up. To address these limitations, CERAB was introduced in 2013 as an alternative endovascular strategy for complex aorto-iliac occlusive disease. By using a covered stent configuration designed to reconstruct the aortic bifurcation with a more anatomical flow channel, CERAB aims to restore a more physiologically favourable bifurcation geometry while minimising the extent of arterial manipulation and surgical trauma [8,9]. Despite the increasing use of both CERAB and kissing-stent reconstruction, direct comparative evidence remains limited.

Today, kissing stent with covered stents and unibody stent-grafts are also used in patients with aortoiliac lesions, and it has demonstrated good results. According to Manaki et al. [10], primary patency following bifurcated endograft application was 93.93%, 91.46%, and 90.25% at 12, 24, and 36 months, respectively. In the ILIACS Registry, after propensity score matching, there was no significant difference in 3-year primary patency between covered and bare-metal kissing stents for TASC II C and D lesions ($92 \pm 7\%$ vs. $92 \pm 8\%$, respectively, $p = 0.38$). However, in the subgroup with moderate to severe iliac calcification, covered stents showed better results than bare-metal stents (100% vs. $89 \pm 9\%$, respectively, $p = 0.048$) [11]. A systematic review and meta-analysis by Fang et al. [12] found that, while covered stents were superior overall, there was no significant difference in 36-month primary patency between covered and bare-metal stents in the subgroup with TASC II D or severe calcified aortoiliac lesions. The study made by Groot Jebbink et al. [13] showed that the bare-metal kissing configuration may have a hemodynamic advantage over the covered kissing configuration, potentially narrowing the performance gap that the stent material alone would create. Both aortoiliac stent configurations demonstrated characteristic zones of flow disturbance that correspond to radial mismatch. Thus, despite the available research, the evidence for covered kissing stents advantage in heavily calcified lesions is not yet definitive.

In the present study, CERAB was associated with significantly superior long-term primary patency compared with kissing-stent reconstruction. At 60 months, estimated primary patency was 85.1% after CERAB versus 59.4% after kissing stent (log-rank $p = 0.047$). Importantly, this difference emerged despite comparable baseline demographic, clinical, haemodynamic, and anatomical characteristics between the treatment groups. These findings suggest that the configuration and mechanical characteristics of the reconstruction may have an important influence on long-term durability in complex aortoiliac disease. These 60-month estimates should be interpreted with caution because only four patients in

the CERAB group and eight in the kissing-stent group remained at risk at this time point, resulting in wide confidence intervals.

Our findings are broadly consistent with previously published data on CERAB. In a meta-analysis by Bontinis et al. [14], primary patency following CERAB was 94.4%, 84.4%, and 83.8% at 12, 24, and 36 months, respectively. De Cort et al. [15] reported a 5-year primary patency of 83.3% following CERAB. The 60-month primary patency of 85.1% observed in the present study is therefore within the range reported in previous series, despite the inclusion of a population with substantial cardiovascular comorbidity and intermediate-to-high perioperative cardiovascular risk.

The durability observed with kissing-stent reconstruction in our cohort was comparatively less favourable. Previous evidence has reported primary patency rates of approximately 81% at 24 months [16] and 69.0% at 60 months [17]. In the present study, primary patency after kissing stent declined progressively from 96.4% at 12 months to 59.4% at 60 months. The progressive divergence between the Kaplan–Meier curves suggests that the principal difference between the techniques may relate not to early technical or clinical outcomes, but rather to long-term durability.

Several mechanisms may account for the observed difference in primary patency. Conventional kissing-stent reconstruction creates two parallel stent columns within the distal aorta, which may result in a non-circular reconstructed lumen and areas of disturbed flow, particularly at the level of the aortic bifurcation. In heavily calcified lesions, incomplete stent expansion and interaction between the two stents may further compromise the geometry of the reconstructed segment. By contrast, CERAB is designed to recreate a more physiological aortic bifurcation with a single proximal covered stent-graft and bilateral iliac limbs. This configuration may provide a larger effective lumen and more favourable flow characteristics while simultaneously excluding the diseased arterial wall from the reconstructed lumen. These anatomical and haemodynamic differences may contribute to the superior long-term primary patency observed with CERAB. However, it should be acknowledged that the observed difference may also reflect, at least in part, differences in stent coverage (covered vs. bare-metal), device platform, and reconstruction geometry, rather than the CERAB technique per se.

Importantly, the advantage of CERAB in terms of primary patency was not accompanied by a statistically significant difference in early postoperative safety outcomes. The incidence of early postoperative complications was comparable between the CERAB and kissing-stent groups, as was 30-day mortality. Previous studies have reported 30-day mortality of approximately 1.3% following CERAB [18] and major perioperative complication rates of approximately 3–5% [4]. For kissing-stent reconstruction, reported 30-day mortality is approximately 3%, with an in-hospital complication rate of approximately 4% [19]. The rates observed in the present study are therefore broadly consistent with the available literature.

The comparable early safety profile is particularly relevant given the cardiovascular risk profile of the study population. All patients had reduced functional capacity and/or an elevated predicted risk of perioperative myocardial infarction or cardiac arrest. Despite this high-risk clinical profile, both endovascular strategies were associated with low early mortality. These findings support the feasibility of endovascular aorto-iliac reconstruction in appropriately selected patients at increased cardiovascular risk, although the absence of statistically significant between-group differences should not be interpreted as evidence of equivalence because of the relatively small sample size.

A further important finding was the absence of a significant difference in secondary patency. At 60 months, secondary patency was 92.9% following CERAB and 91.3% following kissing stent ($p = 0.883$). This finding indicates that, once loss of primary patency occurs, repeat revascularisation can frequently restore and maintain patency irrespective

of the initial reconstruction technique. In practical terms, the major difference between the two strategies therefore appears to concern the need for reintervention rather than the ultimate ability to maintain vessel patency after successful secondary treatment.

The high secondary patency rates observed in both groups are consistent with previous reports. De Cort et al. [15] reported a 5-year secondary patency of approximately 95% following CERAB, whereas Jebbink et al. [16] reported a 5-year secondary patency of approximately 88.8% following kissing-stent reconstruction. Secondary patency reflects the effectiveness of reinterventions. The main reasons for the comparability of secondary patency between CERAB and kissing stents are as follows. Firstly, even if kissing stents are more prone to restenosis, modern endovascular correction methods (balloon angioplasty, restenting) make it possible to restore patency with high efficiency, regardless of the initial technique. Secondly, regular MDCTA (6 months after surgery and annually thereafter) allows for the detection of restenosis at the preclinical stage. Thirdly, reintervention before the development of critical limb ischemia prevents occlusion and preserves patency. Thus, the relatively high secondary patency observed in the present study may reflect close postoperative surveillance and prompt treatment of recurrent stenosis or occlusion.

Freedom from amputation was similarly high in both groups. At 60 months, freedom from amputation was 95.4% after CERAB and 93.3% after kissing stent ($p = 0.985$). Only one patient in the kissing-stent group underwent major lower limb amputation during long-term follow-up. These findings are consistent with the generally favourable limb outcomes reported after endovascular treatment of aorto-iliac occlusive disease. Previous studies have reported freedom from major amputation of approximately 89% at 36 months following CERAB [20] and approximately 82% following kissing-stent reconstruction [21]. Freedom from amputation is determined not only by the patency of the aortoiliac segment, but also by the condition of the distal vascular bed (femoropopliteal segment), as well as the timeliness of reinterventions. Amputations in cases of damage to the aortoiliac segment are extremely rare if at least one of the outflow pathways is preserved.

Overall survival was also comparable between the groups. Five-year survival was 95.7% in the CERAB group and 96.0% in the kissing-stent group ($p = 0.772$). The causes of death were predominantly cardiovascular or cerebrovascular, including acute myocardial infarction, stroke, and acute heart failure. The absence of a significant difference in survival is not unexpected, as long-term mortality in this patient population is likely to be determined predominantly by the systemic burden of atherosclerotic cardiovascular disease rather than by the choice of aorto-iliac reconstruction technique. Previous studies have reported 5-year survival of approximately 80.1% following CERAB [22] and 6-year survival of approximately 83.5% following kissing-stent reconstruction [23]. The higher survival observed in the present cohort may reflect differences in patient selection, baseline risk, follow-up strategy, and study design.

4.1. Predictors of Loss of Primary Patency After Kissing-Stent Reconstruction

The exploratory Cox regression analysis identified three factors associated with loss of primary patency following kissing-stent reconstruction: advanced aorto-iliac calcification (PACSS grade III–IV), the presence of thrombotic material within the infrarenal abdominal aorta, and haemodynamically significant disease in the arterial outflow tract.

Advanced arterial calcification was associated with a more than twofold increase in the hazard of primary patency loss (HR 2.74, 95% CI 1.09–6.85; $p = 0.030$). The relationship between arterial calcification and outcomes after aorto-iliac revascularisation has not been entirely consistent across previous studies. Severe calcification may complicate lesion crossing, balloon expansion, and optimal stent deployment, and may therefore contribute to residual stenosis, mechanical deformation, and subsequent restenosis or thrombosis [24].

Pereira-Neves et al. [25] demonstrated that severe calcification in patients with TASC II type D aorto-iliac lesions was associated with increased risks of major adverse cardiovascular events and amputation following both open and endovascular revascularisation. Similarly, Megale et al. [26] reported an association between severe aortic calcification and increased risks of amputation and repeat revascularisation during the early postoperative period. A systematic review by Fornasari et al. [27] also identified severe iliac calcification as a factor associated with an increased need for repeat aorto-iliac intervention.

The presence of thrombotic material within the infrarenal abdominal aorta was associated with a similarly increased hazard of primary patency loss (HR 2.84, 95% CI 1.14–7.08; $p = 0.026$). Intraluminal thrombotic material may create an irregular luminal surface and interfere with optimal stent expansion and apposition. In addition, the presence of thrombus may increase the risk of distal embolisation during lesion crossing, balloon angioplasty, and stent deployment. Previous observations support the relevance of aortic thrombotic burden to the durability of kissing-stent reconstruction. Mochalova et al. [28] identified the presence of thrombotic material in the infrarenal aorta as an independent predictor of primary patency loss after kissing stent, together with stent configuration and implanted stent diameter.

Significant outflow disease was also associated with loss of primary patency (HR 2.61, 95% CI 1.04–6.50; $p = 0.040$). Impaired distal runoff increases downstream resistance and may adversely affect flow through the reconstructed aorto-iliac segment, thereby promoting low-flow conditions, thrombosis, and recurrent obstruction. This observation is consistent with the findings of Saaya et al. [29], who identified significant outflow disease as a risk factor for loss of primary patency following aorto-iliac endovascular intervention. Collectively, these findings emphasise that successful treatment of the inflow lesion cannot be considered independently of the distal arterial bed.

Interestingly, the influence of severe calcification on primary patency was not consistent across previous studies. While the present study identified PACSS grade III–IV calcification as a significant predictor, Mochalova et al. [28] did not demonstrate a significant association between the severity of aortoiliac calcification and primary patency after kissing-stent reconstruction. Such discrepancies may reflect differences in lesion morphology, calcification assessment methods, stent platforms, patient populations, and follow-up duration.

From a clinical perspective, the present findings support the use of detailed preprocedural anatomical assessment to guide selection of the optimal reconstruction strategy. In particular, the extent and distribution of calcification, the presence of intraluminal thrombotic material, and the quality of distal arterial runoff should be considered when planning endovascular reconstruction of the aortic bifurcation. These factors may be particularly relevant when conventional kissing-stent reconstruction is being considered. In patients with extensive calcification, complex aortic bifurcation anatomy, or compromised outflow, CERAB may offer a more durable reconstruction, although this hypothesis requires confirmation in larger comparative studies.

The small number of women in the presented cohort ($n = 13$) precludes formal sex-stratified analysis, and the reported findings should therefore be considered most applicable to men. Nevertheless, the vascular literature consistently demonstrates that women undergoing endovascular aortic bifurcation interventions experience higher perioperative morbidity despite contemporary device improvements with a recent systematic review of over 500,000 endovascular aortic repair procedures reporting adjusted 30-day mortality odds ratio of 1.73 and persistently elevated access-related complications in women despite contemporary device improvements [30]. While the pathology in the present study (aortoiliac occlusive disease) differs from infrarenal abdominal aortic aneurysm, and sex-specific outcome data for CERAB and kissing stent remain sparse, these observations highlight

the need for sex-aware reporting and dedicated enrolment of women in future studies to determine whether similar disparities exist in this population.

Overall, the present study suggests that the principal potential advantage of CERAB is improved long-term durability rather than a reduction in early procedural morbidity. The comparable secondary patency, limb salvage, and overall survival observed between the groups further indicate that differences in primary patency may primarily translate into differences in the frequency and timing of repeat interventions rather than differences in ultimate limb or survival outcomes.

4.2. Study Limitations

Several limitations should be acknowledged. First, this was a single-centre, non-randomised ambispective (retrospective–prospective) cohort study with a relatively small sample size. The non-randomised distribution of patients into groups (CERAB versus kissing stents) may introduce a systematic selection bias. The lack of equalisation of groups according to known and unknown interfering factors (confounders) does not allow to exclude their influence on the final results of the study, even though the baseline characteristics of the two groups were broadly comparable.

The ambispective design implies that the retrospective component relied on routinely collected clinical data. Although the respective ethics approval was obtained before these data were analysed, the possibility of incomplete or inconsistent recording in the original clinical records cannot be excluded, and potential temporal bias should be considered when interpreting the long-term outcomes. The retrospective inclusion was necessitated by the limited number of patients in the CERAB group.

The exclusive use of bare-metal kissing stents reflects contemporary practice at our centre but introduces a potential confounder, as stent coverage, platform, and geometry may all influence patency. An adjusted comparison was not feasible because the small number of primary patency events in the CERAB group ($n = 6$) precluded a stable multivariable model (fewer than 10 events per variable). Residual confounding by stent coverage, platform, and geometry therefore cannot be excluded, and the conclusions have been moderated accordingly.

The study population consisted exclusively of patients with intermediate or high cardiovascular perioperative risk. Therefore, the findings may not be directly generalisable to patients with low cardiovascular risk or to younger patients with less extensive comorbidity.

The number of primary patency loss events in the CERAB group was limited, precluding reliable Cox regression analysis in this subgroup. The predictor analysis performed in the kissing-stent group should therefore be considered exploratory and hypothesis-generating rather than definitive.

Although the maximum follow-up period was 60 months, the number of patients available for analysis may have decreased over time because of censoring and competing events. Accordingly, the 5-year estimates should be interpreted in the context of the number of patients remaining at risk at each time point.

The study was conducted at a specialised vascular centre with substantial experience in complex endovascular aortoiliac interventions. The observed outcomes may therefore not be fully reproducible in centres with different levels of expertise or access to advanced endovascular technologies.

Larger multicentre prospective studies, ideally with randomised allocation and longer follow-up, are warranted to confirm the superiority of CERAB with respect to long-term primary patency, establish the comparative safety of the two approaches, and validate predictors of patency loss for each reconstruction strategy.

5. Conclusions

In this ambispective cohort of patients with aortoiliac occlusive disease and intermediate-to-high cardiovascular perioperative risk, CERAB was associated with significantly higher 5-year primary patency than kissing-stent reconstruction, while early postoperative complications, secondary patency, freedom from major amputation, and overall survival were comparable between the two techniques. However, this difference may be partly attributable to differences in stent coverage, device platform, and reconstruction geometry, and should therefore be interpreted with caution.

The superior long-term primary patency observed with CERAB suggests that covered reconstruction of the aortic bifurcation may provide greater durability than conventional kissing-stent reconstruction in appropriately selected patients. Among patients treated with kissing stents, advanced aortoiliac calcification, infrarenal aortic thrombotic material, and significant outflow disease were associated with an increased hazard of primary patency loss.

These findings support a patient-specific approach to aortoiliac revascularisation, incorporating both cardiovascular risk and detailed anatomical assessment. Nevertheless, the results should be interpreted in the context of the study's single-centre design, limited sample size, and non-randomised methodology. In particular, the 60-month estimates are exploratory, as only four patients in the CERAB group and eight in the kissing-stent group remained at risk at this time point, resulting in wide confidence intervals. Confirmation in adequately powered multicentre randomised trials is required before definitive conclusions regarding the preferred endovascular strategy can be drawn.

Our findings suggest that CERAB may be associated with improved primary patency compared with kissing-stent reconstruction; however, secondary patency and limb-loss outcomes were comparable between the groups. Therefore, these results should not be interpreted as definitive evidence of the overall superiority of CERAB. Larger prospective and preferably randomised studies are required to confirm these observations and determine whether differences in primary patency translate into meaningful long-term clinical benefit.

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