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Long-Term Outcomes of the Covered Endovascular Reconstruction of the Aortic Bifurcation (CERAB) Technique in Patients With Aorto-Iliac Occlusive Disease

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Abstract

Background: The Covered Endovascular Reconstruction of the Aortic Bifurcation (CERAB) reconstruction is an endovascular technique, developed to reconstruct the aortic bifurcation in the most optimal anatomical and physiological manner. Short-term data were promising, but long-term data are still lacking. The objective was to report the long-term outcomes of CERAB for extensive aorto-iliac occlusive disease and to identify predictors for loss of primary patency. **Methods:** Consecutive electively treated patients with CERAB for aorto-iliac occlusive disease in a single hospital were identified and analyzed. Baseline and procedural data and follow-up were collected at 6-weeks, 6 months, 12 months, and annually thereafter. Technical success, procedural, and 30-day complications were evaluated, as well as overall survival. Patency and freedom from target lesion revascularization rates were analyzed using Kaplan Meier curves. Uni- and multivariate analysis were performed to identify possible predictors of failure. **Results:** One hundred and sixty patients were included (79 male). Indication for treatment was intermittent claudication for 121 patients (75.6%) and 133 patients (83.1%) had a TASC-II D lesion. Technical success was obtained in 95.6% of patients and the 30-day mortality rate was 1.3%. The 5-year primary, primary-assisted, and secondary patency rates were 77.5%, 88.1%, and 95.0%, respectively, with a freedom-from clinically driven target lesion revascularization (CD-TLR) rate of 84.4%. The strongest predictor of loss of primary patency of CERAB was a previous aorto-iliac intervention (odds ratio [OR]=5.36 (95% confidence interval [CI]: 1.30; 22.07), p=0.020). In patients not previously treated in the aorto-iliac tract, 5-year primary, primary assisted, and secondary patency rates were 85.1%, 94.4%, and 96.9%, respectively. At 5-year follow-up, an improved Rutherford was found in 97.9% of patients and the freedom from major amputation rate was 100%. **Conclusion:** The CERAB technique is related to good long-term outcomes, particularly in primary cases. In patients that had prior treatment for aorto-iliac occlusive disease, there were more reinterventions and therefore surveillance should likely be more intense.

Clinical Impact

The Covered Endovascular Reconstruction of the Aortic Bifurcation (CERAB) reconstruction was designed to improve outcomes of endovascular treatment of extensive aorto-iliac occlusive disease. At 5-year follow-up clinical improvement was found in 97.9% of patients without major amputations. The 5-year overall primary, primary-assisted, and secondary patency rates were 77.5%, 88.1%, and 95.0%, respectively, with a freedom-from clinically driven target lesion revascularization rate of 84.4%. Significantly better patency rates were observed for patients that were never treated before in the target area. The data implicate that CERAB are a valid treatment option for patients with extensive aorto-iliac occlusive disease. For patients previously treated in the target area, other treatment options might be considered, or more intensive follow-up surveillance is warranted.

Keywords

aorto-iliac, atherosclerosis, AIOD, peripheral arterial disease, CERAB, balloon-expandable covered stent, endovascular

Introduction

The aortic bifurcation is a predominant location of atherosclerosis, and may elicit intermittent claudication and limb-threatening ischemia. When an intervention is indicated this can be performed by either open surgery or by endovascular means. The latter was traditionally performed using the kissing stent technique.[1] A decade ago the Covered Endovascular Reconstruction of the Aortic Bifurcation (CERAB) technique was first described, with the objective to improve outcomes by reconstructing the aortic bifurcation in a more anatomical and physiological fashion. Since then, various case series have been published showing promising results with regard to patency, reinterventions, and clinical outcomes at the short- and mid-term.[2–8] To date long-term data, however, have not been published.

Based on the available clinical data, the technique was adapted in the latest joined guidelines of the European Society of Cardiology and of the European Society for Vascular Surgery, which state that treatment with the CERAB technique can be considered if an iliac artery occlusion extends to the infrarenal aorta.[1] However, if the occlusion comprises the aorta up to the renal arteries and iliac arteries, an aorto-bifemoral bypass surgery would still be indicated in fit patients. In these extensive lesions, endovascular therapy may also be an option, but it was stated that this is not free of perioperative risk and long-term occlusion.

The aim of the current study was to report on the long-term outcomes of CERAB for extensive aorto-iliac occlusive disease (AIOD) and to identify predictors for loss of primary patency.

Materials and Methods

Consecutive patients that were electively treated with a CERAB configuration for AIOD between October 2010 and May 2020 in 1 single center, were prospectively enrolled and data were retrospectively analyzed. Patients that were treated with CERAB in conjunction with a chimney in either the inferior mesenteric artery or the renal artery were excluded, as were acutely treated cases. Short- and mid-term outcomes of a subset of the study group were previously published.[7,9] For the current study, a waiver from the medical ethical committee (2020-6200) and approval from the local board of directors (2020-1555) was obtained.

Demographic data, medical history, cardiovascular risk factors, procedural data, complications, and follow-up data were all collected in a validated online data management system (Research Manager, Deventer, The Netherlands). The clinical stage was classified using the Rutherford classification.[10] Lesion characteristics were obtained from computed tomography angiography (CTA) and classified according to the TransAtlantic InterSociety Consensus II (TASC II) classification.[11,12] In addition, calcification volumes and scores were obtained for the infrarenal aorta, common iliac arteries, and external iliac arteries using IntelliSpace Portal (Version 11.1, Philips, Best, The Netherlands). The calcification scoring system of Davis et al was used to evaluate the degree and distribution of calcifications in these arteries.[13] This scoring system assigns a numeric score for the morphology, circumference, and length of involvement of the calcifications where morphology is scored as the greatest degree of calcification appearance and pattern within the arterial segment ranging from 0 to 3, circumference is scored as the greatest percentage circumference involvement of the arterial segment ranging from 0 to 4, and length is scored as the percentage length involvement of the arterial segment ranging from 0 to 4. For the runoff score at baseline, a 3-point scale was used in the 3 major outflow vessels, being the external iliac artery, the hypogastric artery, and the common femoral artery.[10] Procedural data consisted of vascular access, complications, technical success, adjunctive treatment, types of stents used, procedure time, closure type, residual stenosis, and contrast agent usage.

Follow-up was performed at 6 weeks, 6 months, 1 year, and annually thereafter, and included clinical assessment, duplex ultrasound study, ankle-brachial indices (ABIs), while changes in medication and, when applicable, interventions performed for peripheral arterial disease were scored.

CERAB Procedure

The technique of CERAB has been previously described.[14,15] Briefly, after crossing the lesion from femoral access, a 9 Fr introducer sheath is inserted above the proximal margin of the aortic lesion. Then, a 12-mm balloon expandable expanded polytetrafluoroethylene (PTFE) covered stent is deployed in the distal aorta 15–20 millimeters above the bifurcation. The proximal part of this aortic stent is flared using an angioplasty balloon, typically to 16–18 mm, in

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order to achieve wall apposition at the proximal end. Subsequently, 2 covered stents, typically 8 mm, are deployed in the distal part of the aortic stent, that is still 12 mm in diameter, and simultaneously deployed. Distal extensions are placed when required. After the procedure, patients are treated with a statin and dual antiplatelet therapy for 6 months, after which single antiplatelet therapy is continued. When other anticoagulation is required for other indications, this is continued.

Outcomes and Definitions

The 5-year primary patency was the primary outcome of this study. Secondary outcome measures, all through 5-years follow-up, were the assisted-primary patency, secondary patency, freedom from target lesion revascularization (TLR) and clinically driven target lesion revascularization (CD-TLR) rates, clinical outcomes, technical success, hospital stay, morbidity, mortality, and secondary interventions, defined according to the Society for Vascular Surgery Reporting Standards.[16] Complications were classified according to the Cardiovascular and Interventional Radiological Society of Europe (CIRSE) Classification System Reporting Standard for complications.[17] Patency was defined according to the reporting standards for endovascular treatment of chronic lower extremity peripheral artery disease.[16] Freedom from CD-TLR was defined as the time between the index procedure and any target lesion revascularization based on restenosis or occlusion for recurrent symptoms.

Statistical Analysis

Normality was tested using Kolmogorov Smirnov test together with visual inspection of the normality graphs. Continuous variables are presented as mean with standard deviation (SD) or median followed by interquartile range (IQR) if applicable. Categorical data are presented as a number followed by percentage. Patency rates are visualized in a Kaplan Meier curve including censoring for patients lost to follow-up. Differences between groups were analyzed using the log-rank test from Kaplan Meier analysis. The Wilcoxon Signed Rank test was used to analyze the Rutherford and ABI before and after the procedure. Patients with a failed patency were compared with patients with a patent graft. Differences were tested using independent student t-test of chi-square test if applicable. Univariate and multivariate binary logistic regression was used to identify possible predictors of failure. Variables with a p-value below 0.05 were included in a multivariate model to identify the optimal set of predictors of failure. Statistical significance was set at a 2-sided $p<0.05$. Statistical analysis was performed using IBM SPSS statistics version 25.0 for Windows (IBM Corporation, Armonk, NY, USA).

Table 1. Patient Characteristics.

	N (%) or mean (SD)
Age (years)	62.0 (10.0)
Gender	
Male	79 (49.4)
Ankle Brachial Index (in rest)	
Left	0.68 (0.26)
Right	0.65 (0.23)
Lowest per patient of left or right	0.58 (0.21)
Cardiovascular risk factors	
Smoking	103 (67.3)
Diabetes mellitus	36 (24.2)
Hypertension	100 (65.8)
Hyperlipidemia	64 (79.0)
Cardiac disease	47 (31.3)
Pulmonary disease	50 (31.8)
Renal disease	24 (15.4)
Carotid disease	10 (6.5)
Rutherford classification	
1	1 (0.6)
2	19 (11.9)
3	101 (63.1)
4	20 (12.5)
5	17 (10.6)
6	2 (1.3)
ASA classification	
2	69 (43.7)
3	76 (48.1)
4	13 (8.2)
Previous treatment AIOD tract	
Number of patients	45 (29.8)
Number of interventions	59
Endovascular intervention	45 (76.3)
Open surgical repair	14 (23.7)
Amputation in medical history	0

Abbreviations: AIOD, aorto-iliac occlusive disease; ASA, American Society of Anesthesiologists; IQR, interquartile range.

Results

A total of 160 patients were enrolled with a mean age of 62.0±10.0 years and 79 being male (49.4%). Patient and lesion characteristics are depicted in Tables 1 and 2, respectively. Thirty-nine patients (24.4%) were treated for critical limb threatening ischemia, and 120 (75.0%) for disabling intermittent claudication, not responding to supervised walking exercise training. The remaining patient was scored as Rutherford 1 as he was preventively treated for a high-grade stenosis of the proximal anastomosis of an aorto-bi-femoral prosthesis that was previously implanted. Overall, 63 previous treatments in the aorto-iliac tract were reported in 45 patients (28.1%), of which 76.3% were endovascular procedures.

Table 2. Lesion Characteristics.

	N (%) or mean (SD)
TASC-II classification	
A	1 (0.6)
B	14 (8.8)
C	12 (7.5)
D	133 (83.1)
Runoff score	
0	73 (48.0)
1–3	41 (27.0)
4–6	23 (15.1)
7–9	12 (7.9)
10–12	3 (2.0)
Calcification volume (mm3)	
Aorta	2919 (2319)
Right CIA	1041 (930)
Left CIA	1051 (1075)
Right EIA	335 (555)
Left EIA	292 (473)
Total	5635 (4586)
Total Calcification Score	36.7 (13.0)

Abbreviations: CIA, common iliac; EIA, external iliac artery; TASC, transatlantic intersociety consensus classification for aortoiliac lesions.

Procedure

Only percutaneous vascular access was used in 112 patients (70.0%). In the other 48 (30.1%) patients, open access was obtained on at least one side. In 26 (16.3%) of them, a thrombo-endarterectomy of the common femoral artery was performed and in the others, the common femoral artery was considered to be too frail for percutaneous access.

The technical success rate was 95.6% (n=153). Technical failure was in all 7 cases (4 in 2012, 1 in 2013, and 2 in 2016) associated with inability to pass the lesion or to acquire re-entry in the distal aorta. In none of these 7 failures a brachial access was attempted, which became part of the treatment strategy in the later years of the study period.

The total number of stents used to reconstruct the aortic bifurcation, was 3 in 71 patients, 4 in 22 patients, 5 in 31 patients, and >5 in the remaining 29 patients. The used balloon expandable covered stents included the Advanta V12 Covered Stent (Atrium Medical Corporation, Merrimack, NH, USA), the BeGraft Stent Graft System (Bentley InnoMed GmbH, Hechingen, Germany), the Lifestream (Bard Peripheral Vascular, Tempe, AZ, USA), the Kebomed (Kebomed, Vantaa, Finland), the Gore Viabahn (W.L. Gore&Associates, Flagstaff, AZ, USA), and the SMART stent (Cordis Corp, Miami Lakes, Florida, USA). In 97 patients (63.4%), only the Advanta V12 Covered Stent, and in 31 (20.3%) only the BeGraft Stent Graft System was used to create the CERAB configuration. The Lifestream was used as aortic stent in 4 cases, combined with different stents for the iliac part. Both self-expanding stents were used solely for extension into the external iliac artery (Viabahn, n=15 and SMART, n=1).

The median procedural time was 101 min (IQR: 57–183 min) with a median volume of contrast agents used of 70 mL (IQR: 49–115 mL). Procedural and 30-day complications are shown in Table 3. The 30-day mortality rate was 1.3% (n=2). One patient died 10 days after procedure from an arterial bleeding in the groin, related to failure of the closure device. The other patient died 1 day after the procedure, due to cardiac failure; this patient had an extensive cardiac history and computed tomography showed no complications with the reconstruction.

Follow-Up

The mean follow-up was 36 months (range: 0–125 months) and 46 patients (30.1%) had completed their 60 months follow-up. The median hospitalization time was 2.0 days (IQR: 1.0–3.0 days). At the first post-procedural assessment, the median Rutherford category had significantly improved from 3 (IQR: 3–3) prior to treatment to 0 (IQR: 0–1) after treatment ($p<0.001$) (Figure 1). At 5-year follow-up, the median Rutherford category was 0 (IQR: 0–0) and still significantly better when compared to baseline ($p<0.001$). Clinical improvement with at least one category in Rutherford classification at 6 weeks was available for 141 patients of which 129 (91.5%) showed an improvement, 9 were equal, and 3 deteriorated. At 5-year follow-up, data were available for 45 patients of which 44 showed an improved Rutherford (97.9%), and 1 had the same Rutherford classification compared to baseline. The lowest measured ABI went from 0.58 ($\pm$0.21) at baseline to 0.92 ($\pm$0.19) at 6 weeks after procedure ($p<0.001$) (Figure 2). No significant differences were observed thereafter during follow-up.

The 5-year all-cause mortality rate was 17.6% (n=27). Besides the 2 early deaths the causes of death were cardiac 1.3% (n=1), malignancy 6.3% (n=10), sepsis 1.3% (n=2), bowel ischemia 0.6% (n=1), and the cause was unknown in 6.9% (n=11). One patient died due to an aortic occlusion 28 months after treatment. No major amputations were reported through 5-year follow-up, and there was 1 minor amputation reported.

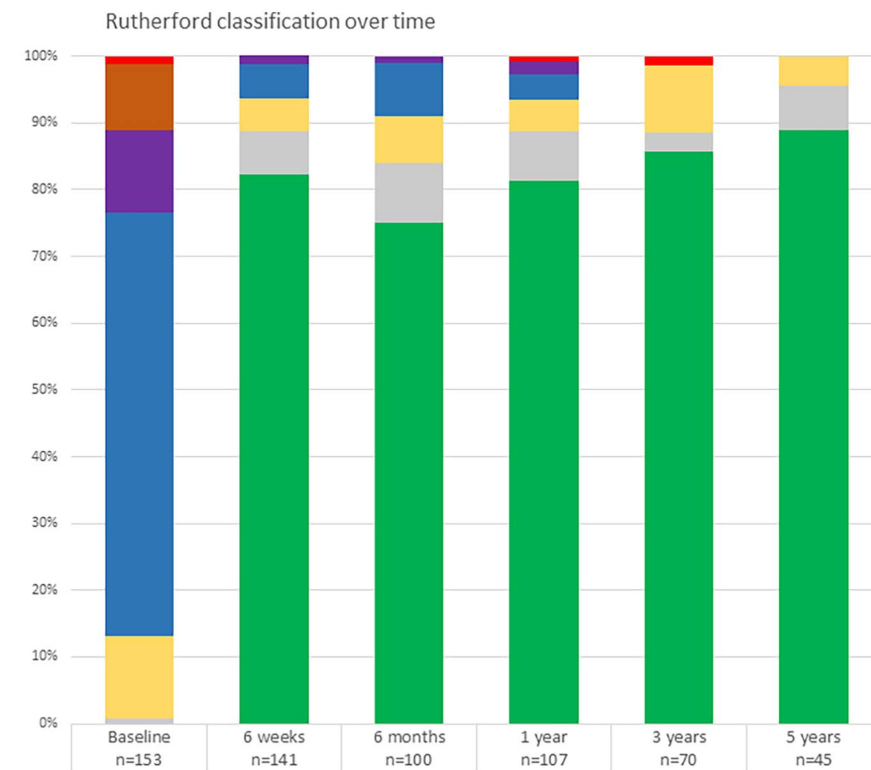
Patency

The overall primary patency was 88.8%, 80.6%, and 77.5% at 1-, 3-, and 5-year follow-up, respectively, with primary assisted patency rates of 94.3%, 89.8%, and 88.1% (Figure 3). The overall secondary patency was 98.7%, 96.6%, and 95.0% at 1-, 3-, and 5-year follow-up, respectively. Patients who underwent an aorto-iliac intervention before CERAB demonstrated significantly lower patency rates, compared to

Table 3. CIRSE Classification of CERAB Related Procedural and Post-Procedural Complications.

	Procedural N (%)	Discharge N (%)	30-day N (%)	Total N (%)
CERAB-related complications	17 (10.6)	32 (20.0)	26 (16.3)	75 (46.9)
Grade I	15 (9.4)	0	0	15 (9.4)
Grade II	1 (0.6)	8 (5.0)	9 (5.6)	18 (11.3)
Grade III	0	17 (10.6)	14 (8.8)	31 (19.4)
Grade IV	0	3 (1.9)	2 (1.3)	5 (3.1)
Grade V	2 (1.3)	1 (0.6)	1 (0.6)	4 (2.5)
Grade VI	0	2 (1.3)	0	2 (1.3)

Abbreviations: CERAB, Covered Endovascular Reconstruction of the Aortic Bifurcation; CIRSE, Cardiovascular and Interventional Radiological Society of Europe.



	Baseline n=153	6 weeks n=141	6 months n=100	1 year n=107	3 years n=70	5 years n=45
6 Major tissue loss	1%	0%	0%	1%	1%	0%
5 Minorfocal tissue loss	10%	0%	0%	0%	0%	0%
4 Ischemic rest pain	12%	1%	1%	2%	0%	0%
3 Severe claudication, walking distance <200m	63%	5%	8%	4%	0%	0%
2 Moderate claudication, walking distance >200m	12%	5%	7%	5%	10%	4%
1 Mild claudication, walking distance unlimited	1%	6%	9%	8%	3%	7%
0 Asymptomatic	0%	82%	75%	81%	86%	89%

Figure 1. Distribution of the Rutherford classification through 5 years follow-up in percentages, including the number at risk for each follow-up period.

patients that were not previously treated (primary treatments), through 5 years of follow-up; 58.5% versus 85.1% for primary patency (p=0.001), 72.2% versus 94.4% for primary assisted patency (p<0.001), and 87.2% versus 96.9% for secondary patency (p=0.029) (Figure 4A–C). When comparing patients in which the CERAB was constructed with only the Advanta V12 Covered Stent, only the BeGraft Stent Graft System, or with a combination of stents, there

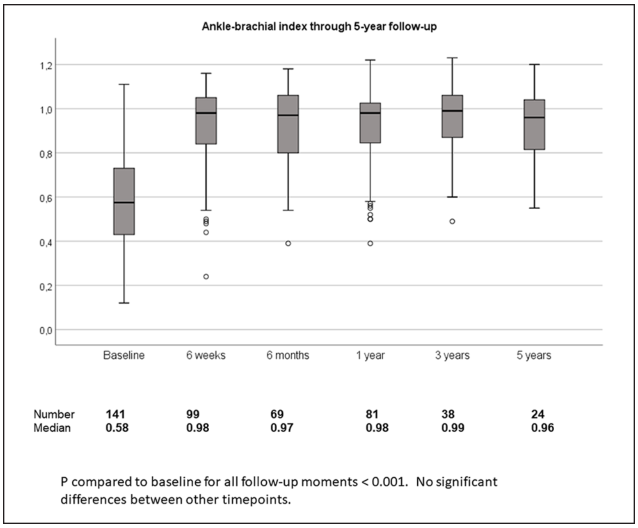


Figure 2. Overview of the median ankle-brachial index through 5 years follow-up.

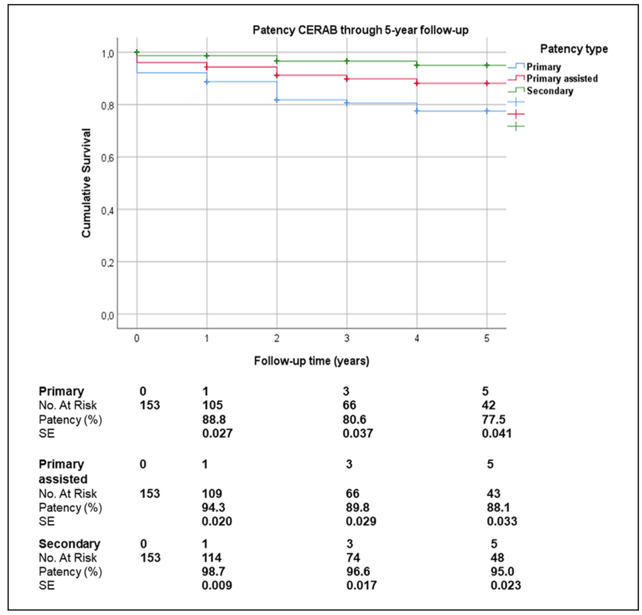


Figure 3. Primary, primary-assisted and secondary patency Kaplan Meier curve through 5-years follow-up, with number at risk and standard error (SE). CERAB, Covered Endovascular Reconstruction of the Aortic Bifurcation.

were no significant differences in patency (p=0.767 for primary, 0.429 for primary assisted, and 0.476 for secondary patency).

Reinterventions

The overall freedom from TLR (Figure 5) at 1-, 3-, and 5-year was 87.3%, 83.0%, and 79.8%, respectively. The freedom from CD-TLR at these time points were 89.4%, 86.0%, and 84.4%, respectively. In total 24 (15.0%) patients underwent a TLR through 5 years of follow-up, of which 19 (11.9%) were CD-TLRs (Table 4). The 5 patients without clinical symptoms all underwent an endovascular intervention with the aim to preserve patency. Of the 19 CD-TLRs, 14 were endovascular procedures, 3 were combined surgical and endovascular procedures; thrombectomy (n=2), endarterectomy of the common femoral artery combined with stent placement in the external iliac artery (n=1), and the remaining 2 were surgical aorto-iliac bypass procedures.

Predictors of Loss of Primary Patency

Patients that suffered from loss of primary patency after CERAB were younger and more often had a history of previous intervention in the aorto-iliac tract. They had less hypertension and hyperlipidemia in medical history and showed a lower calcium volume and calcification score, as shown in Table 5.

Univariate predictors of failure were calcium volumes and scores, a lower age, hypertension, hyperlipidemia, and a previous intervention in the aorto-iliac tract. Since there were 29 failures, a maximum of 3 predictors could be entered into the multivariate model. The results are shown in Table 6. The strongest predictor of loss of primary patency of CERAB is a previous intervention in the aorto-iliac tract (odds ratio [OR]=5.36 (95% CI:1.30; 22.07), p=0.020). Other significant predictors but with lower OR included a higher total calcium volume (OR=0.98 (95% CI: 0.97; 1.00), p=0.047) and the presence of hypercholesterolemia (OR=0.24 (95% CI: 0.07; 0.09), p=0.029).

Discussion

Results of the present study demonstrate that the late outcomes of the CERAB configuration are satisfying, particularly in patients that did not have previous treatment in the target area. Recently, a meta-analysis was published[18] comparing open surgical repair with standard endovascular treatment and CERAB. It was concluded that an endovascular strategy was related to lower 30-day morbidity and mortality, but that open surgery had more favorable primary patency rates without a difference in secondary patency rate. In that study, the pooled 5-year primary patency rate of open surgery was 88% (95% CI: 86%–90%), compared to the 94.4% primary assisted patency in the primary cases in the current analysis. It needs to be emphasized that the definition of primary patency may differ from study to study and that duplex follow-up was not always standard practice in the open surgical data. Moreover, no difference is made between primary and primary-assisted patency. Although these differences challenge comparison of open surgical repair with endovascular techniques, this

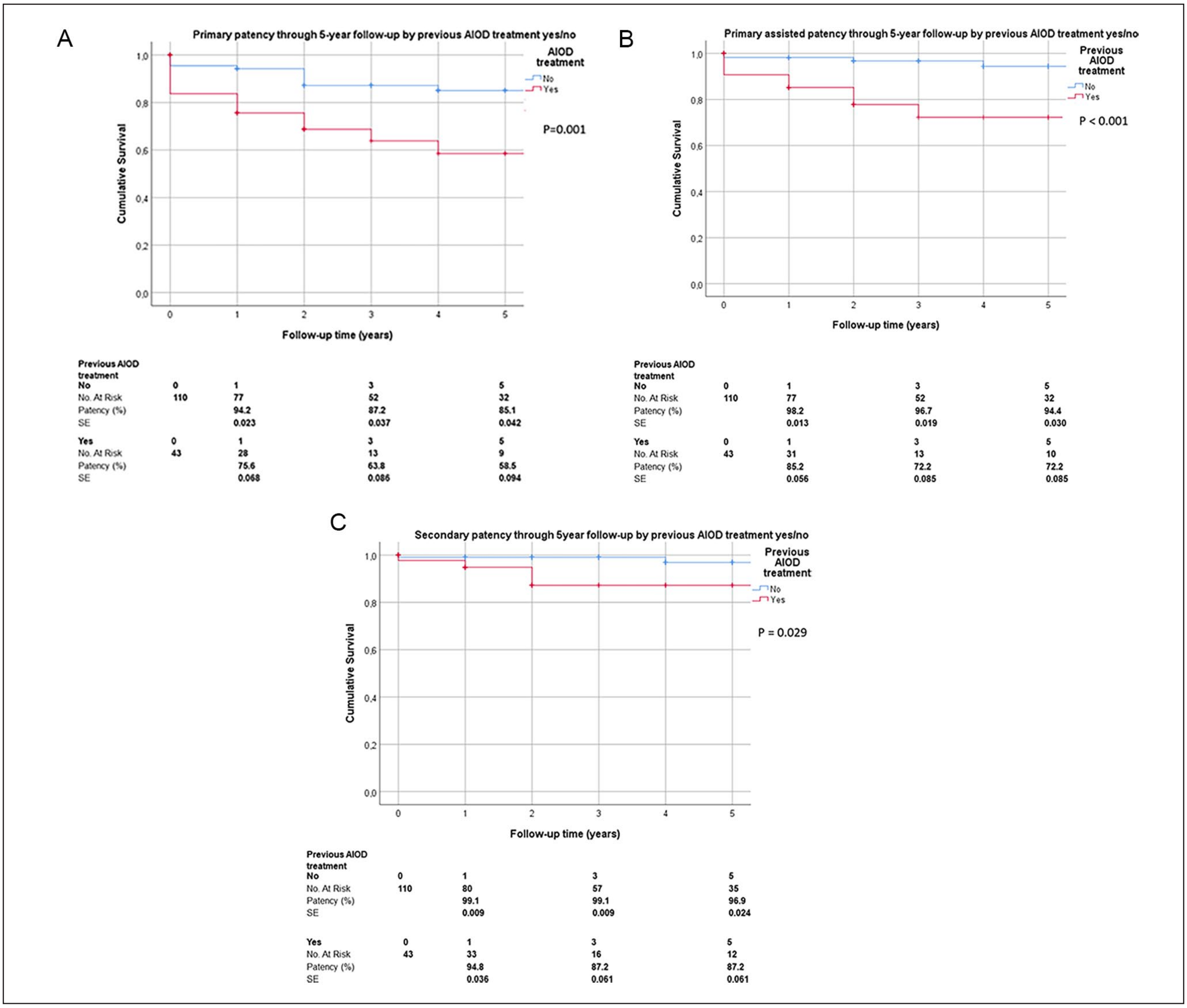


Figure 4. Primary (A), Primary-assisted (B), and Secondary patency (C). Kaplan Meier curves by previous AIOD treatment yes/no through 5-years follow-up, with number at risk and standard error (SE). AIOD, Aorto-iliac occlusive disease.

meta-analysis further supports the choice for CERAB in patients with extensive AIOD.

Whether CERAB is also the most cost-effective treatment remains to be elucidated. Obviously, the procedural costs of CERAB are likely to be higher, related to the costs of the balloon-expandable stents. On the other hand, an admission to the intensive care is hardly ever indicated after endovascular treatment and the overall admission time is shorter. Generally, the follow-up after open surgery is less frequent than after endovascular approaches, but the ratio behind that difference is not evidence-based. With the current data, it might even be defendable that the follow-up regimen after CERAB in primary cases can be limited, but that secondary cases require more frequent surveillance, particularly in the first 3 years after the intervention, when most events occur. This strategy may further reduce costs and make CERAB an even more attractive option.

The optimal treatment algorithm of AIOD remains matter of debate and likely there is a role for kissing stents, CERAB and open surgery. A randomized trial comparing these treatment options unfortunately is still not available to date. In a meta-analysis of patients treated with kissing stents, it was shown that this technique is related to a primary and secondary patency estimate of 81% and 95% at 2-years, respectively.[19] In this study, any previous endovascular intervention was the main predictor for loss of secondary patency. Data cannot reliably be compared to the current data as half of cases in that analysis were treated for TASC A and B lesions, whereas in the current study 83% was treated for a TASC-II D lesion. Stent protrusion of 2 cm or

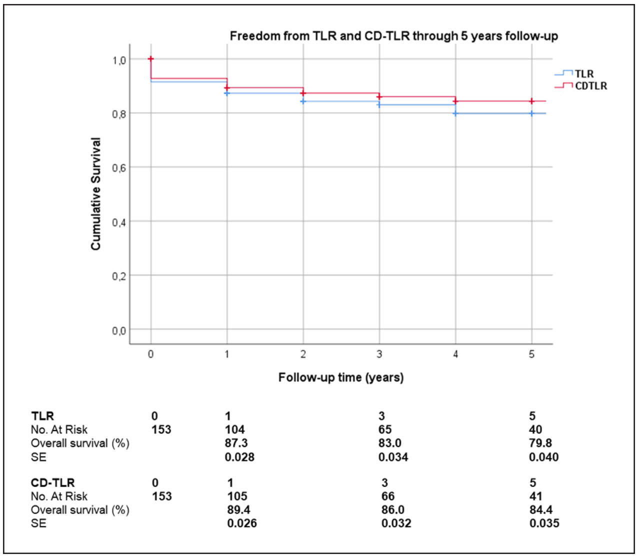


Figure 5. Freedom from target lesion revascularization (TLR) and clinically driven target lesion revascularization (CD-TLR) through 5-years follow-up, with number at risk and standard error (SE).

Table 4. Secondary Interventions During Follow-Up After CERAB.

	CD-TLR n	No CD-TLR n
Plain Balloon Angioplasty CIA	2	1
Plain Balloon Angioplasty EIA	1	
Plain Balloon Angioplasty CIA and EIA	2	
Stenting of the CIA and EIA	1	
Aorto-iliac bypass	2	
Kissing Plain Balloon Angioplasty of the CIA	1	1
Kissing stent placement of the CIA	1	
Thrombolysis	4	
Plain Balloon Angioplasty CIA and stenting of the EIA	2	3
Thrombectomy	2	
Endarterectomy CFA + stenting of the EIA	1	
TOTAL	19	5

Abbreviations: CD-TLR, clinically driven target lesion reintervention; CERAB, Covered Endovascular Reconstruction of the Aortic Bifurcation; CFA, common femoral artery; CIA, common iliac artery; EIA, external iliac artery.

more in the distal aorta was previously identified as a risk factor for failure of kissing stents. Based on that, one may postulate that a kissing stent might be preferred in those lesions that can be treated with KS that protrude less than 2 cm and that in the other cases CERAB should be the preferred endovascular technique. The CERAB can be used in lesions that include the entire infrarenal aorta. However, when the lesion is close to the renal arteries, protection balloons may be indicated to prevent embolization. This, in turn, may increase the morbidity rate, related to a brachial access. The CERAB has also been successfully used in conjunction with chimney grafts in either renal artery for proximal lesions.[8] In these cases, open surgery may remain to be the preferred technique, particularly in fit patients, in order to avoid stenting of the renal arteries. The chimney technique can also be used to preserve the inferior mesenteric artery, when patent, but the necessity of this unclear. It might be indicated in arteries with a diameter of ≥4mm particularly with diseased superior mesenteric artery and/or celiac trunk. In the current series, no ischemic bowel complications occurred, indicating the safety of the technique.

It needs to be addressed that the current data were achieved in a single high-volume center that has been involved in the technique from the start. Therefore, the data might not reflect the real-world outcomes, also as several patients were treated as part of a second opinion (scheduled for open repair or rejected for treatment in other hospitals). However, the published early and midterm outcomes of the CERAB technique in patients treated in the United Kingdom, Italy, and Latin America are comparable to our data, supporting the applicability of the technique in common clinical practice.[2,3,5] No other long-term data are currently available. In the current data, the majority of CERAB-related reinterventions were performed within 12-months follow-up. Therefore, close surveillance during this period is advocated, particularly in patients that had previous treatment for AIOD, using repeated duplex ultrasound studies. Early intervention of outflow stenosis might prevent failures as the impact of an outflow stenosis on the local wall shear stress is likely to be more extensive, as was previously demonstrated in an in vitro set-up.[20]

Besides of the previous treatment, we could not identity strong predictors for loss of primary patency. The study from the United Kingdom identified the following features to be associated with a need for TLR; TASC D disease (OR=2.45, 95% CI: 1.44; 3.71), severe aortic calcification (OR=2.01, 95% CI: 1.03; 2.20), and presence of tissue loss at baseline (OR=1.43, 95% CI: 1.01;4.63). We could not confirm these observations in the current study. In contrast, the burden of calcium appeared to be protective for loss-op primary patency in our series, although with an OR of only 0.98. The relatively low sample size may have contributed to this, although the sample size was even lower in the study from the United Kingdom, with 116 patients. An individual patient-level meta-analysis may overcome this issue and could aid in further improving the decision-making process. Another factor contributing to the CERAB outcomes might be the

Table 5. Patient and Lesion Characteristics for Patients With Preserved and Loss of Primary Patency Through 5-Year Follow-Up.

	Preserved primary patency (N=125)	Loss of primary patency (N=28)	
	N (%) or mean (SD)	N (%) or mean (SD)	p value
Age (years)	63.2 (9.4)	55.9 (10.8)	<0.001
Gender (male)	64 (51.2)	13 (46.4)	0.648
Ankle Brachial Index (at rest)			
Left	0.69 (0.26)	0.66 (0.29)	0.699
Right	0.66 (0.23)	0.64 (0.23)	0.714
Lowest per patient of left or right	0.59 (0.21)	0.53 (0.19)	0.221
Cardiovascular risk factors			
Current smoking	82 (68.9)	19 (67.9)	0.914
Diabetes mellitus	30 (26.3)	4 (14.3)	0.181
Hypertension	83 (70.3)	13 (46.4)	0.017
Hyperlipidemia	55 (85.9)	9 (56.3)	0.008
Cardiac disease	38 (32.5)	7 (26.9)	0.581
Pulmonary disease	42 (34.3)	7 (25.0)	0.337
Renal disease	17 (14.0)	4 (14.3)	0.974
Carotid disease	8 (6.7)	1 (3.6)	0.537
Rutherford classification			0.245
1	-	1 (3.6)	
2	18 (14.4)	1 (3.6)	
3	80 (64.0)	17 (60.7)	
4	24 (11.2)	5 (17.9)	
5	12 (9.6)	3 (10.7)	
6	1 (0.8)	1 (3.6)	
TASC classification			0.953
A	1 (0.8)	-	
B	11 (8.8)	3 (10.7)	
C	10 (8.0)	2 (7.1)	
D	103 (82.4)	23 (82.1)	
ASA classification			0.238
2	53 (43.1)	14 (50.0)	
3	60 (48.8)	14 (50.0)	
4	10 (8.1)	-	
Previous treatment AIOD tract	28 (22.4)	15 (53.6)	0.001
Runoff score			0.337
0	61 (51.7)	8 (29.6)	
1–3	31 (26.3)	10 (37.0)	
4–6	15 (12.7)	7 (25.9)	
7–9	8 (6.8)	2 (7.4)	
10–12	3 (2.5)	-	
Calcification total volume (mm^3)	6028 (4661)	3578 (3490)	0.010
Aorta	3125 (2323)	1868 (1948)	0.009
Right CIA	1120 (967)	671 (701)	0.022
Left CIA	1085 (1090)	781 (802)	0.169
Right EIA	383 (606)	115 (216)	0.023
Left EIA	319 (506)	145 (288)	0.088
Total calcification score	37.9 (12.3)	30.9 (13.4)	0.008

Abbreviations: AIOD, aorto-iliac occlusive disease; ASA, American Society of Anesthesiologists; CIA, common iliac artery; EIA, external iliac artery; N, number; TASC, transatlantic intersociety consensus classification for aortoiliac lesions.

effectiveness of the various available balloon-expandable stents. Several stents are currently in use that differ significantly in design; they are either made of stainless steel or cobalt chromium, with connected or independent stent frames, and the PTFE coverage encapsulated or applied on the outside. Obviously, these design differences impact

Table 6. Predictors for Loss of Primary Patency.

	Univariate predictors				Multivariate predictors			
		95% CI for OR				95% CI for OR		
	OR	Lower	Upper	p value	OR	Lower	Upper	p value
Age (years)	0.927	0.886	0.969	0.001				
Total calcium volume (mm^3/100)	0.984	0.972	0.997	0.013	0.983	0.966	1.000	0.047
Calcium score	0.960	0.930	0.991	0.011				
History of AIOD treatment (no)	3.997	1.703	9.385	0.001	5.357	1.300	22.068	0.020
Hypertension (no)	0.365	0.158	0.848	0.019				
Hypercholesterolemia (no)	0.210	0.063	0.708	0.012	0.238	0.066	.0861	0.029
Constant (multivariate only)					1.019			0.977

Abbreviations: AIOD, aorto-iliac occlusive disease; CI, confidence interval; OR, odds ratio.

the properties of the various stents, for example, its trackability and flexibility. In the current study, we did not find a difference in patency between the 2 most commonly used stents. Flaring of the aortic stent is an important feature of CERAB in order to get appropriate wall apposition at the proximal edge. Flaring, however, is outside the current instructions for use of the available stent options, and therefore CERAB is also outside instructions for use. Therefore, the development of dedicated devices would be preferred, having all the advantages of CERAB, yet preserving the option for future cross-over procedures.

A limitation of this study is that it is a retrospective analysis of a prospectively collected cohort without a control group, and therefore, the data should be interpreted with care. As consecutive patients were enrolled, the data reflect both the early and late experience of the technique. Although being the largest study with the longest follow-up, appropriate subgroup analysis was still impossible and the clinical need for them is obvious. Comparative studies with both open surgery and endovascular alternatives are also clearly indicated to develop an evidence-based treatment algorithm for (extensive) AIOD.

In conclusion, the CERAB technique is related to good long-term outcomes, particularly in primary cases. In patients that had prior treatment for AIOD, there were more reinterventions and therefore surveillance should be more intense.

Clinical Perspectives

Endovascular treatment options continue to evolve and have become the predominant treatment modality for most patients with aorto-iliac occlusive disease. Surgery, however, was always related to better long-term outcomes. The current data show that the Covered Endovascular Reconstruction of the Aortic Bifurcation (CERAB) reconstruction is challenging surgery with comparable long-term outcomes, albeit with less morbidity at the short-term. This would validate an endovascular first strategy also in patients with extensive aorto-iliac occlusive disease.

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