Initial experience with the CERAB technique: case series

P. Nana[1], K. Spanos[1], G. Kouvelos[1], M. Mpareka[2], K. Mpatzalexis[1], N. Rousas[1], E. Arnaoutoglou[2], A. Giannoukas[1], M. Matsagkas[1]

[1]Department of Vascular Surgery, Faculty of Medicine, School of Health Sciences, University of Thessaly, Larissa, Greece
[2]Department of Anesthesiology, Faculty of Medicine, School of Health Sciences, University of Thessaly, Larissa, Greece

Abstract:

Open surgical repair with aorto-bifemoral bypass grafting is considered as the standard of care for the aorto-iliac occlusive disease involving the abdominal aorta, at least in fit patients. On the other hand, substantial risk of peri-operative morbidity and mortality may tarnish the good technical outcomes in higher risk patients. The covered endovascular reconstruction of aorto-iliac bifurcation (CERAB) is a novel minimal invasive approach for aorto-iliac occlusive disease treatment, offering good early- and mid-term outcomes so far. The procedure consists of the implantation of a wide diameter aortic stent graft and the expansion of two iliac covered stents according to the kissing-technique inside the aortic graft. We report an initial case series of 4 patients treated with the CERAB technique for aorto-iliac occlusive disease treatment.

INTRODUCTION

Current ESVS guidelines recommend the endovascular approach as a first line treatment for occlusions extending to the infrarenal aorta (IIb, B).[1] However, traditionally open surgical repair with aorto-bifemoral bypass grafting has been considered as the standard of care for the aorto-iliac occlusive disease involving the abdominal aorta, at least in fit patients. Recently, the covered endovascular reconstruction of aortic bifurcation (CERAB) has been considered as a novel and viable solution for aorto-iliac occlusive disease treatment, especially in high-risk patients.[1] Evidence has shown that the two-year primary patency rate may be estimated at 82% in patients treated using the CERAB technique for such lesions.[2] Despite the minimal approach, in these cases, the peri-operative morbidity and mortality risk exists as well as the risk of long-term restenosis or occlusion.[1]

In terms of anatomical and hemodynamic characteristics, it seems that the CERAB configuration is, geometrically, more similar with the native aortic bifurcation in comparison to kissing stents alone.[3] The configuration of the iliac kissing stents is associated with a lower mismatch rate when they are tapered by an aortic cuff.[3] While kissing stents technique with self or balloon expandable stents is reported to be related with flow disturbances, the CERAB technique is associated with less flow perturbations, diminishing in this way the risk of stent thrombosis or distal embolization.[4]

Herein, the aim of the study was to evaluate our initial experience of CERAB technique for the treatment of high-risk patients with aorto-occlusive arterial disease.

Author for correspondence:

Miltiadis Matsagkas, MD, PhD, FEBVS

Professor of Vascular Surgery, Department of Vascular Surgery, Medical School, University of Thessaly, Mezourlo, Larissa, Greece
Tel: +30 2413501739
E-mail: milmats@gmail.com
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METHODS

Patients' characteristics and pre-operative evaluation

Between September 2018 and September 2019, 4 patients were treated using the CERAB technique. All patients suffered from restrictive intermittent claudication. All patients were considered as high-risk for conventional aorto-bifemoral reconstruction (ASA IV). Considering their anatomical aspects and the risk of an aorto-bifemoral bypass, an endovascular approach was decided in all cases. Demographics, clinical evaluation, anatomical characteristics, intra-operative details and patients' outcomes were recorded prospectively. Pre-operative evaluation included computed tomography angiography (CTA) of the abdominal aorta down to the tibial arteries, in order to verify in and outflow lesions. Sizing and planning were performed using a workstation with 3Mensio dedicated reconstruction software (Medical Imaging B.V., Bilthoven, Netherlands). Pre-operative CTA confirmed the presence of aorto-iliac occlusive disease extended up to the infra-renal aorta.

Technical details

All patients were treated in an adequately equipped operating room using a mobile digital angiographic system (Philips BV Endura, Philips Medical Systems, Release 2.2.3, the Netherlands). Access was achieved with open trans-femoral exposure or ultrasound-guided percutaneous puncture (5:3 femoral artery access sites), according to the need for simultaneous common femoral endarterectomy or the presence of anterior

atherosclerotic plaque in the common femoral artery, which was considered as a contraindication for percutaneous access.

A hydrophilic 0.035'' or/and 0.014'' and 0.018'' guidewire was inserted to overcome bilateral iliac occlusions or stenoses and it was exchanged with a standard PTFE guidewire after accessing the abdominal aorta. A 0.014'' and 0.018'' guidewire was initially used as a step of the standard procedure in order to achieve intra-luminal access. In case where a sub-intimal access was demanded to complete the intervention, a hydrophilic 0.035'' was preferred. An upper access site from the left brachial artery was also available in all patients, in case of failure of passage the lesion through femoral access. After the insertion of an 8Fr x 45cm sheath (Arrow, Teleflex, USA) into the aorta, a diagnostic arteriography was accomplished. A balloon expandable aortic stent graft (Be-Graft, Aortic, Bentley, Innomed, Germany) was, then, deployed into the infrarenal aorta down to the bifurcation through a 12Fr x 33cm sheath over a stiff guidewire (Gore, W.L. Gore & Associates Inc. Delaware, USA). Two balloon-expandable covered stents (Be-Graft, Aortic, Bentley, Innomed, Germany) were then deployed with the kissing stent technique starting 10-20mm into the aortic stent graft, creating a new aortic bifurcation. In case of extended disease, down to the external iliac arteries, self-expandable stents or just balloon angioplasty was used to complete the procedure. Final angiography was used to confirm adequate placement and patency intra-operatively.

Post-operative surveillance and follow-up

Double anti-platelet therapy was initiated the day of the procedure. Clinical evaluation and ankle-brachial pressure index (ABPI) measurements were assessed the first post-operative day. 30-day, 6-month and 1st-year follow-up was undertaken with CTA at the first instance and duplex ultrasonography in subsequent ones in order to evaluate the flow and any stent-graft malformation or other complication (Figures 3 and 4).

RESULTS

All patients were males with a mean age 65 years (range 58-69 years). The clinical presentation was restrictive intermittent claudication at 100m or lower (Rutherford Classification 3 and 4), affecting their daily routine. Femoral artery pulses were absent during clinical evaluation. Pre-operative ABPIs were ranging between 0.36-0.54 (Table I). Comorbidities and pre-operative antithrombotic treatment are presented in Table II. All patients were previous smokers. All of them were presented with significant coronary artery disease. The first patient had a severe infrarenal aortic stenosis and concomitant bilateral common iliac and right common femoral artery stenosis (Figure 1A-D).

The second and third cases were treated for an occlusion of the aorto-iliac bifurcation extending to bilateral common iliac arteries. The second patient had a concomitant severe stenosis of the right external iliac and both common femoral arteries while the third patient suffered a unilateral common femoral artery stenosis. The last case was the most challenging as an infrarenal aortic and bilateral common iliac arteries occlusion was diagnosed. Furthermore, both external iliac and left common femoral arteries had severe atheromatosis; the left external iliac artery with important stenosis of its lumen while the right one was totally occluded (Figure 2A-D). Patients' pre-operative characteristics are summarized in Table III.

Patients	ABPI pre-operatively	ABPI post-operatively
No 1	(R) 0.54 (L) 0.5	(R) 1.00 (L) 1.12
No 2	(R) 0.53 (L) 0.53	(R) 1.08 (L) 1.16
No 3	(R) 0.36 (L) 0.45	(R) 0.95 (L) 1.00
No 4	(R) 0.45 (L) 0.37	(R) 1.20 (L) 0.90

Table I. ABPI measurements pre and post-operatively

Comorbidities	No of patients
Tobacco use	4
Hypertension	4
Dyslipidemia	4
Coronary artery disease (CAD)	4
Coronary artery bypass grafting (CABG)	0
Percutaneous coronary angioplasty (PTCA)	2
Previous ischemic stroke	1
Chronic obstructive pulmonary disease (COPD)	4
Diabetes Mellitus	1
Renal insufficiency (GFR<30ml/min/1.73m^2)	1
Antiplatelet treatment	4
Aspirin 100mg once daily	2
Clopidogrel 75mg once daily	1
Aspirin 100mg plus Clopidogrel 75mg once daily *due to recent PTCA	1

Table II. Patients' comorbidities

Patients	Pre-operative anatomic characteristics	Access sites	Stent grafts
No 1	Severe infrarenal aortic & bilateral CIA and right CFA artery stenosis	Percutaneous LCFA RCFA endarterectomy	14x57mm aortic stent-graft & 8x38mm covered balloon expandable at CIAs (Be-Graft, Bentley, Innomed, Germany)
No 2	*Occlusion* of the aorto-iliac bifurcation extending to bilateral CIAs & right EIA and CFA stenosis	Bilateral CFA endarterectomy	Pre-dilatation of REIA with 7x80mm angioplasty balloon; 16x38mm aortic stent-graft & 9x57mm & 8x57mm balloon expandable covered stents at the right and left CIA, respectively (Be-Graft, Bentley, Innomed, Germany)
No 3	*Occlusion* of the aorto-iliac bifurcation extending to bilateral CIA & unilateral CFA stenosis	Percutaneous LCFA RCFA endarterectomy	16x38mm aortic stent-graft & 8x57mm balloon expandable covered stents at CIAs (Be-Graft, Bentley, Innomed, Germany)
No 4	*Occlusion* of the infrarenal aorta, bilateral CIA & right EIA and CFA artery; diffused severe atheromatosis	Percutaneous RCFA LCFA endarterectomy	14x38mm aortic stent-graft & 8x57mm balloon expandable covered stents at CIAs (Be-Graft, Bentley, Innomed, Germany); *sub-intimal re-canalization* of right EIA with self-expanding stents 8x60mm& 8x40mm (E-Luminexx, Bard Peripheral Vascular, Arizona, USA)

Table III. Pre-operative anatomical and intra-operative patients' characteristics. CFA: common femoral artery; CIA: common iliac artery; EIA: external iliac artery

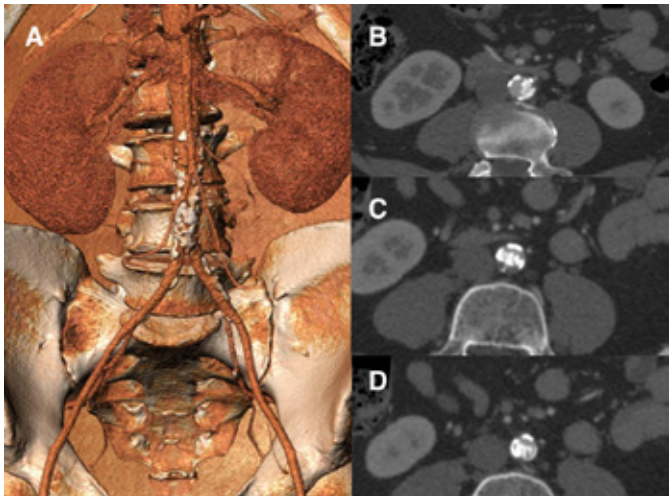

Figure 1. The first patient had a severe infrarenal aortic stenosis and concomitant common iliac artery stenosis bilaterally. In Panel A, 3D reconstruction and in B-D, axial view of the aortic stenosis.

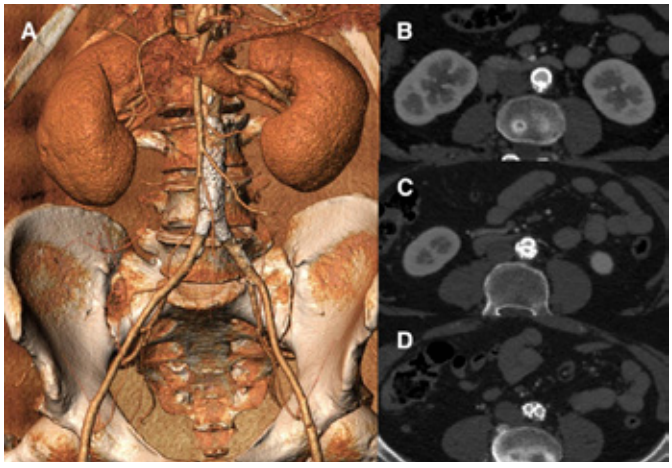

Figure 2. The fourth case suffered from an infra-renal aortic and bilateral common iliac arteries occlusion. Furthermore, both external iliac arteries had severe atheromatosis; the left one with important stenosis of its lumen while the right one was totally occluded. In Panel A, 3D reconstruction and in B-D, axial view of the aortic and iliac occlusions.

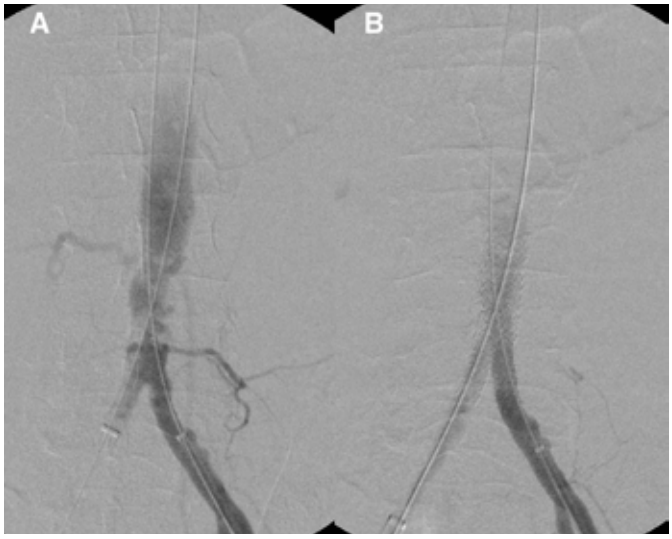

Figure 3. Aortic stenosis is confirmed during diagnostic angiography intra-operatively (A), revealing important collateral vessel (A). Completion angiography confirmed the patency of aortic reconstruction (B).

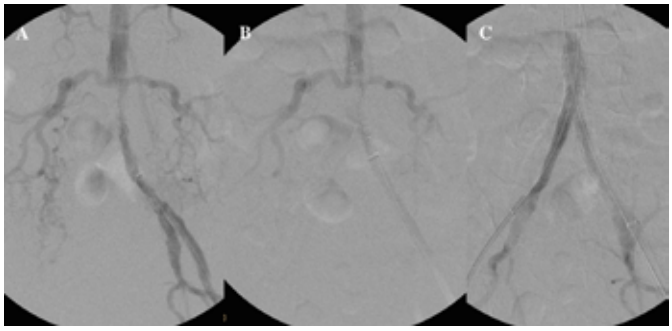

Figure 4. The intra-operative angiography confirmed the occlusion of the infra-renal aorta (A) while an impressive collateral net of lumbar arteries was revealed (B). The completion angiography showed stent patency of the aortic reconstruction (C).

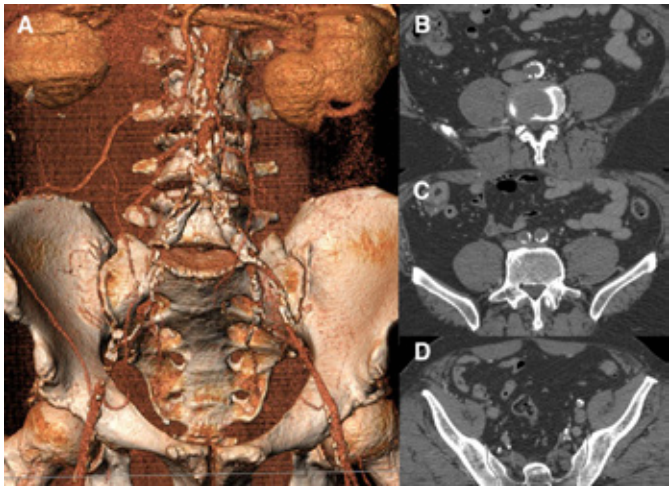

Figure 5. Post-operative CTA of the 1st patient treated with the CERAB technique; Panel A, 3D reconstruction and B-D, axial views.

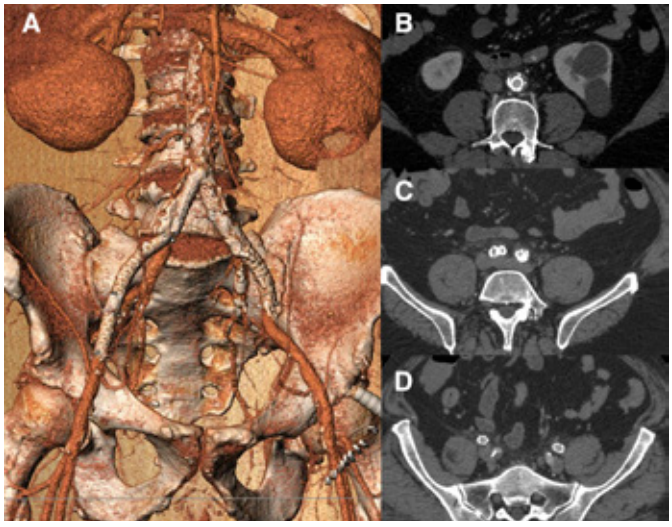

Figure 6. Post-operative CTA of the 4th patient treated with the CERAB technique. Right external iliac artery stenting was accomplished to treat a residual stenosis; Panel A, 3D reconstruction and B-D, axial views.

All cases were undertaken under general anesthesia. Systemic heparinization was administrated in all patients after sheath insertion (50-100IU/kg). In the first case, an ultrasound-guided percutaneous approach was used for the left femoral access while an open transfemoral exposure was used on the right side. Using the technique described above, an aortic stent-graft 14x57mm (Be-Graft, Bentley, Innomed, Germany) was deployed while two balloon expandable covered stents (Be-Graft, Bentley, Innomed Germany) 8x38mm were deployed like kissing stents in the common iliac arteries. In the second patient, after a bilateral femoral artery endarterectomy, endovascular access of the aortic bifurcation was achieved. In this case, a pre-dilatation of the right external iliac artery was performed using a 7x80mm angioplasty balloon. An aortic graft of 16x38mm and 2 covered balloon expandable stents, 9x57mm at the left and 8x57mm at the right common iliac artery were deployed (all Be-Grafts, Bentley, Innomed, Germany). In the third case, a right femoral artery endarterectomy was performed initially; while an aortic-bifurcation reconstruction was achieved using a 16x38mm aortic stent-graft and two 8x57mm balloon expandable covered stents (all Be-Grafts, Bentley, Innomed, Germany). In the last case, a percutaneous approach was used for the right femoral access. An open transfemoral exposure, associated with endarterectomy and patch closure was performed at the left common femoral artery. For the aortic occlusion, an aortic stent-graft 14x38mm was used, while balloon expandable covered stents 8x57mm were deployed in the common iliac arteries (all Be-Grafts, Bentley, Innomed, Germany). A sub-intimal re-canalization of the right external iliac artery was treated using two self-expanding stents 8x60mm and 8x40mm (E-Luminexx, Bard Peripheral Vascular, Arizona, USA) (Figure 3A-C). All intra-operative details are summarized in Table III. The mean operational time was 95 min (90-120), while the mean contrast volume was 45ml (40-50ml) and the mean dose area product was 48mGy (21 min). Technical success was 100%. One patient underwent a synchronous bilateral common femoral artery endarterectomy, while another one a unilateral one. All patients were transferred post-operatively to the ward. Post-operative ABPIs are presented in Table I. Pulses were detected in all femoral arteries post-operatively. All patients became asymptomatic after treatment (Rutherford's 0 from Rutherford's 3and 4). Two patients discharged home the 1st and the other two the 2nd post-operative day in a good general status.

Follow-up was ranging between 1 and 12 months. All patients remained asymptomatic (0 Rutherford's Class) and ABPIs were stable. No renal function deterioration or colonic ischemia event was record. No re-intervention, limb adverse event, major cardiovascular adverse event or death was recorded. One patient suffered from a clopidogrel allergic reaction; presenting only severe exanthema without systemic complications; clopidogrel was withdrawn and patient has been continuing only on aspirin. All patients underwent a 30-day CTA which revealed no complication while one completed the 6-month and another the 12-month follow-up using DUS. Flow patterns were within normal limits and no restenosis was detected so far. No stent compression, restenosis or migration was revealed in CTAs.

DISCUSSION

Aorto-bi-femoral bypass grafting has been used as the treatment of choice in patients with aorto-iliac occlusive disease involving the abdominal aorta during the last decades. The endovascular treatment of this complex disease was initially presented as an alternative option to open surgical repair in high comorbid patients.[5] The latest ESVS guidelines recommend that the endovascular approach may be the first line treatment for the aorto-iliac occlusive disease, preserving the open repair only for fit patients.[1] In 2016, the initial results of CERAB, presented by Dijkstra et al[6]., fostered the widespread use of endovascular procedures for aortoiliac recanalization for TASC C and D lesions using covered balloon-expandable stents. High technical success and 12-month patency rate presented in these series offered an alternative viable endovascular approach for this group of patients.[6] In our opinion, when there is a substantial distal aortic lesion (severe stenosis or occlusion), or severe lesions on both iliac arteries, aortic bifurcation reconstruction with the use of covered balloon expandable stents may be more safe and durable. Along this line, in this small study the technical success was 100% with good outcomes in terms of morbidity and mortality.

The technical success rate has been demonstrated to be high in different case series, ranging between 76% (in initial experience studies) up to 100%, as in this analysis.[3,7,8] Primary, primary assisted and secondary patency are highly acceptable and estimated at 86%, 91%, and 97% at 1 year; and 82%, 87%, and 97% at 3 years of follow-up.[8] Restenosis was observed in rates up to 20%, with a successful re-vascularization in 85% of them while distal embolization was present in up to 8%.[3,7] At 5-year follow-up, primary patency was estimated at 70% and secondary patency rate at 77%.[9] In this study, no restenosis, thrombosis or stent compression was revealed during a very early follow-up. Additionally, no intervention was needed during this follow up period. In the literature, factors that have been associated with lower patency rate are age, subsequent tobacco use and\ previous aorto-iliac interventions.[10] At least theoretically; the decreased radial mismatch presented in covered stent reconstruction of the aortic bifurcation is expected to be associated with an improved flow pattern and subsequent better clinical outcome.[11,12]

The low mortality and morbidity rate of the endovascular aortic reconstruction enforces the application of the technique in high risk patients.[13] There was no early post-operative mortality using the CERAB technique, reported so far in the literature.[2] The lack of high quality data comparing endovascular and open surgery precludes any strict conclusion at the moment. Real-world data are encouraging in terms of early and mid-term follow-up. The 30-day major complication rate was highly acceptable (1-7%).[2,8] Concerning local complications, groin hematoma is present in 15% of patients while the evolution of post-operative pseudo-aneurysm rate was abscent.[2] In terms of systematic morbidity; major complication rate is expected at 2%.[2] In this study, no major complication was recorded post-operatively. A patient suffered an allergic reaction to clopidogrel with exanthema which was treated successfully by discontinuation of the drug. Renal insufficiency is a rare complication after CERAB.[7] Inferior mesenteric artery (IMA) and lumbar arteries occlusion, when is required, seems to have no impact in the post-operative period.[6] No colonic ischemic events were recorded in the current literature, affirming the safety of the technique in case of pre-operatively

patent IMA.[5] However, there is no evidence to indicate the preservation or over-stenting of an IMA >3-4 mm (very rare in any case), while the risk of peri and post-operative complications during endovascular canalization and stenting should not be ignored.[5]

Concerning clinical improvement, in a small case series, an improvement by 2 categories in more than 50% of patients has been recorded.[14] In mid-term follow-up, 96% of the patients are expected to improve at least one more Rutherford's category.[8] In this case series, all patients were asymptomatic after treatment (Rutherford's 0 from Rutherford's 3-4). Following this clinical improvement, ABPI was also significantly increased.[8,14] In patients treated with endovascular means for TASC C and D lesions, the overall survival without restenosis, amputation, or surgery was acceptable (62.8±1.9%) but significantly lower than type A and B lesions (69.6±1.5%).[15] The estimated limb salvage rate was 98% and 97% at 1 and 3 years of follow-up, respectively.[8] During the early follow-up of this case-series, no major adverse limb event was recorded.

Despite the encouraging patency and morbidity-mortality rates, the cost-effectiveness of the technique is still controversial. Endovascular materials and sophisticated covered balloon expandable stents are more expensive than standard stents and conventional Dacron or PTFE grafts.[2] The need for re-interventions may increase the costs in the long-term.[2] However, the low morbidity and mortality rate and the minimal duration of hospitalization and ICU admission may decrease the total cost of the procedure.[2] It is difficult to evaluate accurate this cost because a direct comparison of those two options is not available nowadays. In this case series, the total duration of hospitalization was 2-3 days and no patient was transferred to the ICU. Financial data cannot be extracted in our country in order to support the hypothesis of the cost-effectiveness.

CONCLUSION

The CERAB technique seems to be safe and feasible in patients with aorto-iliac occlusive disease. Early patency rates as well as patients' clinical improvement demonstrated favorable outcomes of endovascular approach in TASC C and D lesions.

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