Covered stents in aortoiliac occlusive disease
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Covered Endovascular Reconstruction of Aortic Bifurcation (CERAB) technique: A new approach in treating extensive aortoiliac occlusive disease

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SUMMARY

Endovascular treatment of occlusive disease of the aortic bifurcation is challenging. We developed the Covered Endovascular Reconstruction of Aortic Bifurcation or CERAB-technique, as a new approach for extensive and/or recurrent aortoiliac occlusive disease using three covered balloon expandable stents to reconstruct the aortic bifurcation. This configuration provides the ability to deal with TransAtlantic Inter-Society Consensus (TASC II) C and D lesions, simulating a neo-bifurcation or flow divider in combination with the benefits of covered stents. The intervention can be performed percutaneously or as a hybrid procedure. Initial results are encouraging and further studies are indicated.
INTRODUCTION

Balloon angioplasty and stenting of iliac occlusive lesions has become an accepted treatment modality with acceptable results. The role of endovascular approach of more extensive aortoiliac occlusive disease (AIOD) is expanding, due to the introduction of new stent technologies and the development of dedicated devices. Reports focusing on the endovascular treatment of TransAtlantic Inter-Society Consensus (TASC II) type C and D iliac artery lesions, mainly using bare stents, have shown promising results regarding safety, midterm durability, technical success and morbidity. Endovascular treatment for AIOD appears to be more suitable than open repair for the older and higher-risk patients and for those who require urgent treatment. Furthermore, endovascular repair is associated with lower complication rates, shorter length of stay and lower inpatient costs. Endovascular treatment gets more complex when the aortic bifurcation is involved in the lesion. Kissing stents have been used for this indication, but results were often disappointing.

The covered endovascular reconstruction of aortic bifurcation (CERAB) technique aims to improve results of endovascular treatment of lesions involving the aortic bifurcation by mimicking the anatomical and physiological situation of the aortic bifurcation using three covered stents.

TECHNIQUE

Preoperatively, patients receive 5000 I.U. heparin intravenously. Access to both common femoral arteries is acquired either percutaneously or by surgical cut down and two sheaths are introduced (9 Fr and 7 Fr, respectively). After endovascular recanalization of both iliac axes, with or without brachial access, a 12mm Advanta V12 LD balloon expandable ePTFE covered stent (Atrium Medical, Maquet Getinge Group, Hudson, NH, US) is expanded in the distal aorta approximately 20mm above the bifurcation through the 9 Fr introducer sheath (fig.1A). The already expanded covered stent is then picked up with a larger balloon and proximally adapted to the aortic diameter, by positioning the distal balloon marker about 15 to 20mm proximal to the distal stent margin. After optimal positioning and complete expansion, the distal stent part becomes funnel-shaped (fig. 1B). Then, two iliac covered stents are placed in this conic segment, in the distal 1/3 of the cuff, in a kissing stent configuration and simultaneously inflated. Both covered stents are now making a very tight combination with the aortic stent, as were
they moulded together, simulating a new bifurcation with the hemodynamic aspect of a flow-splitter (fig. 1C).

Figure 1A During the first step of the CERAB procedure a 12-mm balloon expandable stent is positioned and deployed 15-20mm above the aortic bifurcation

Figure 1B During second step of the CERAB procedure the proximal part of the aortic covered stent is overdilated to adapt to the aortic wall

Figure 1C The CERAB configuration is completed by simultaneous inflation of two iliac covered stents in the conic segment, thereby moulding the first one around the latter two

Case 1
A 57-year old male patient with a history of pancreatitis, supraventricular tachycardia, hypertension, diabetes mellitus, dyslipidemia and alcohol- and nicotine abuse was referred with disabling claudication classified as Rutherford category 3. Duplex ultrasound showed a lesion in the distal aorta together with a bilateral stenosis in the proximal common iliac arteries of 75-99% on the left side and more than 50% on the right side, with an Ankle Brachial Index (ABI) of 0.60 and 0.94, respectively. The ABI after walking exercise decreased to 0.20 and 0.52, respectively. Conservative treatment with supervised walking exercise was unsuccessful. A computed tomography (CT)-angiography was performed showing a highly calcified lesion in the distal aorta extending into both common iliac arteries (fig. 2A). It was decided to perform a CERAB procedure. Patient was operated upon under general anesthesia. After gaining percutaneous access to both common femoral arteries 5000 IU of heparin was administered. Both lesions were passed using a Terumo wire and the intraluminal position proximal to the lesion was confirmed using contrast media. Then, an angiography was made that confirmed the results of the CT scan (fig. 2A). The CERAB configuration was created by first inserting a 12x41mm Advanta V12 LD covered stent through a 9 Fr sheath in the distal aorta that subsequently was overdilated for the proximal 2/3 to 16mm using a regular angioplasty balloon. Then two 8x38mm covered
stents were inserted in the distal part of the aortic covered stent and simultaneously inflated, thereby moulding the first one around the latter two. Control angiography showed a patent reconstruction without remaining stenosis (fig. 2B).

The procedure was completed in 63 minutes and 57mL of contrast media was used. The postoperative course was uneventful and the patient was discharged at day one postoperatively. He was treated with acetylsalicylic acid 80mg daily. The postoperative ABI had increased to 1.1 bilaterally. At five months follow-up the patient was free of symptoms. Duplex ultrasound showed a patent CERAB construction without re-stenosis.

Figure 2A  Angiography of a 57-year old male patient showing a highly calcified lesion in the distal aorta extending into both common iliac arteries

Figure 2B  Completion angiography after construction of a CERAB configuration showing adequate flow thought the bifurcation without any remaining stenosis

Case 2

A 50-year old male patient was referred with bilateral chronic critical limb ischemia, classified as Rutherford category 4, with a right-sided and left-sided ABI of 0.41 and 0.47, respectively. He had a history that included a balloon angioplasty and bare stenting of an occluded left common iliac artery. The stent reoccluded and was revascularized again endovascularly. After one year, a recurrent occlusion occurred that was treated with an ileofemoral cross-over bypass. Then he developed a subtotal stenosis of the right common iliac artery that was treated with a balloon expandable stent. Approximately 18 months later, he developed an occlusion of the aortoiliac bifurcation including the
ileofemoral crossover bypass (fig. 3A). We decided to perform a CERAB procedure. The patient was treated under general anesthesia and 5000 IU heparin. First, a recanalization of both common iliac arteries and the distal aorta was performed, through a 7 Fr and 9 Fr femoral access. The CERAB configuration was then constructed using an Advanta V12 LD 12 x 61mm covered stent (Atrium Medical) that was proximally dilated to 16mm, using a 16 x 40mm semicompliant Cristal balloon (Balt Extrusion, Montmorency, France). Afterwards, the construction was completed by the placement of two Advanta V12 8 x 59mm covered stents in a kissing stent configuration (fig. 3B). The treatment time was 63 min and 100 mL of contrast media was used. There were no postoperative events, the ABI had improved to 0.89 and the patient was discharged the third postoperative day with acetylsalicylic acid 80 mg and clopidogrel 75 mg daily. After 7 months of follow-up there were no signs of re-stenosis on duplex ultrasound and the patient was free of symptoms with a right-sided and left-sided ABI of 0.88 and 0.91, respectively.

Figure 3A  CT-angiographic reconstruction of a 50-year old patient, that had been previously treated with bare stents in the iliac arteries and an ileofemoral cross-over bypass, showing complete occlusion of the aortic bifurcation and bypass

Figure 3B  Postoperative angiographic result after revascularization using the CERAB-technique showing a patent aortoiliac tract without remaining stenosis
DISCUSSION

In the present paper we have shown that the CERAB technique is a minimal invasive alternative for surgical reconstruction of the aortic bifurcation, which is still the gold standard for extensive aortoiliac lesions, according to the TASC-II guidelines. The technique was developed in order to optimize endovascular results by mimicking the anatomical and physiological situation. We hypothesized that using this strategy the outcome would be favourable compared to kissing stents and that the risk of complications would be lower compared to surgical reconstruction. Obviously, additional studies are indicated to assess the indications and outcome of this novel technique.

The reason to choose for ePTFE covered balloon expandable stents for this technique was threefold. First, various case series and the randomized Covered versus Balloon Expandable Stent Trial (COBEST) have reported promising results that outline the benefit of covered stents in both iliac arteries and distal aorta. The COBEST trial has shown the superiority of covered stents for TASC-II C and D lesions above bare stents. Second, because these lesions may be tough to cross, there is always an imminent risk of complications like flow limiting dissection, perforation and embolization. Covered stents may deal immediately with these complications when they appear, thereby possibly reducing morbidity and mortality. Third, the outcome of the simultaneous placement of two kissing stents for the treatment of complex AIOD has been less than satisfactory. The reported poor patency is thought to be the result of thrombus formation and neointimal hyperplasia due to stagnant blood flow owing to residual vascular space outside the kissing stents. Moreover, the protrusion of the stents into the distal aortic lumen, creating a new flow divider within the opposing stents, the stent overlap and other geometric determinants may all affect the patency rates. Saker et al. reported the presence of immature mesenchymal tissue, intimal hyperplasia and organizing thrombus in the space between the opposing stents, within the lumen of the stents and at the level of the free floating intra-aortic portion of the devices. Sabri et al. have shown that with the use of covered stents the outcome is improved compared to bare stents, but still the configuration is far from physiological.

The CERAB technique appears to be a safe and feasible alternative and may be performed percutaneous or in combination with other revascularization techniques as a hybrid procedure. Distal outflow seems to be crucial and needs to be sufficient to maintain arterial flow in the reconstruction and has to be improved when needed. The CERAB technique may facilitate the treatment of recurrent or in-stent disease at the
level of the aortic bifurcation and may prove to be a valid alternative for surgery and/or kissing stents. Critical issues include cost effectiveness, patient selection, fine-tuning of the technique and defining the optimal medical support.

CONCLUSION
The CERAB technique is a safe and feasible alternative for open surgical reconstruction of the aortic bifurcation and/or kissing stents in aortoiliac occlusive disease. Obviously larger series with a longer follow-up are needed to compare the technique with the current gold standards, but initial results are encouraging.
REFERENCES
