Primary Covered Stent For Management Ofinfrarenalaortic and Aortoiliac Occlusive Disease; Pilot Study

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ABSTRACT

Introduction: *Surgery for focal infrarenal aortic stenosis or occlusive aortoiliac lesions has been the traditional standard of care with good long-term patency rates. Numerous encouraging reports about endovascular revascularization, mainly by using bare metal stents, on TASC II class C and D aorto-iliac lesions were very promising regarding safety, mid-term durability.* ***Objectives:****This is a pilot study with the assumption of non-inferiority of covered stent endovascular reconstruction for focal infrarenal aortic and aortoiliac lesions to current endovascular bare metal stent therapy.* ***Methods:*** *Patients with aortic occlusive disease ranging from isolated focal infrarenal aortic stenosis to total occlusion of the infra-renal aorta extending or not to the iliac arteries were treated by covered stents during the period from January 2014 to December 2015. Our Exclusion criteria included: Patients with iliac occlusive diseases with no involvement of infra-renal aorta (bifurcation only), associated extensive infra-inguinal occlusive disease, chronic renal impairment and those with connective tissue disorders or history of previous endovascular intervention.* ***Results:*** *Seven patients met our inclusion criteria, six patients (85.7%) were men. Two patients had isolated mid infrarenal aortic focal stenosis (both were > 3 cm in length)without bifurcation involvement. One patient had rather focal near bifurcation stenosis with length ≤ 3cm. Four patients had chronic total aortobiiliac occlusion (TASC II D). Rest pain was the most common (57%), while minor tissue loss (2 patients) and severe claudication (1 patient) constitute the rest of patient's presentation. Pre-procedural mean resting ABIs were 0.55 ± 0.15 at the right side and 0.59 ± 0.15 at the left side. In the three patients with focal stenosis of the aorta, mean aortic stenosis before the procedure was 70% (range, 60%-80%). We used total of 15 stents with diameter range (8-12mm) and length range (41-61mm). Technical and immediate clinical success were achieved in all our patients (100%) as confirmed by palpable distal pulses, improvement of walking distance and absence of rest pain. Trophic changes were healed completely 3- 4 months after the procedure. The immediate hemodynamic results showed mean resting ABI to increase to 0.95± 0.05 on the right side and to 0.96 ± 0.04 on the left side. No deaths were observed in the first 30 days. During a mean follow up of 10.5 months (range, 9-12 months), five patients had their stented arterial segments patent (The primary patency rate at 3, 6 and 12 months were: 85%, 85% & 71% respectively). One patient developed significant instent stenosis in one iliac stent after 3 months and was treated balloon angioplasty using a drug coated balloon (DCB). Another patient, at 6 months follow up, developed symptom recurrence due to tight bilateral ostial stenosis at the new bifurcation following CERAB technique and was treated by kissing drug eluting stents (DES). At 12 months' follow up no patient showed symptoms of limb ischemia or recurrence of trophic changes.* ***Conclusion****:Covered stent therapy for occlusive aortoiliac diseases is a technically feasible and potentially safe procedure that demonstrates very good early and mid-term patency. Based on the available data, covered stents may be considered the best and unavoidable technical solution in restoring blood flow through occluded infrarenal aorta and iliac arteries.*

INTRODUCTION

Two different formsof aorto-iliac occlusive disease (AIOD) may affectthe infra-renal aorta eitherlocalized lesions of the aorticbifurcation involving one or both common iliac arteries,or relatively rare focal lesions of the infra-renal aorta withoutinvolvement of the aortic bifurcation.AIODis more frequently observed inheavysmokers, women aged 30 to 50 years.[1]Surgery, either by bypass graftor aortic endarterectomy,has been the standard of care for these lesions with good long-term patencyrates of 70% to 75% at 10 years, yetwith a 5% to 10% earlycomplication rate.[2-3]

Percutaneous transluminal angioplasty (PTA) has been proposed as an alternative to surgery,and several reports have demonstrated the safety and efficacy of PTA for focal stenoses of the infrarenalaortaas wellas in lesions involving the aortic bifurcation.[4]Stenting has several documented advantages over PTA alonewithexcellent both primary and secondary patency rates.[5]In the infra-renal aorta, however,only a small number of studies have evaluated theresults of primary stenting for focal aortic stenoses.[6-7]Until recently, total occlusions of aortaand aorto-iliac occlusions have been considered as a relative contraindication for endovascularmanagement.[7]

Growing number of publications confirmed good results of endovascular aorto-iliac stenting with superiority of covered stents over bare metal ones in this regard.[8-9]Reports regarding the use of bare metal stents, on TASC II (TransAtlantic Inter-Society Consensus) class C and D aorto-iliac lesions were very promising in regard to safety, mid-term durability, technical success and low morbidity as compared to surgical intervention.[9,10] According to IndesJ.E et al., en-dovascular treatment for aorto-iliac occlusive disease (AIOD) appears to be more suitable than open repair for high risk patients. Furthermore it is associated with lower complication rates, shorter length of stay and lower inpatient costs.[11]

In this series, we report about the use Advanta V12® balloon expandable ePTFE covered stent (Atrium Medical©, Maquet Getinge Group, Hudson, NH, US) to reconstruct the infra-renal aorta with or without simultaneous reconstruction of the aortic bifurcation. The choice of this ePTFE covered balloon expandable stents was intrigued by the very promisingresults from the COBEST (**C**overed versus **B**alloon **E**xpandable **S**tent **T**rial) reported by Mwipatayi[8] as well asother additional clinical data.[12,13]Furthermore, most lesions in the infrarenal aorta or aortoiliac vessels are tough and difficult to cross during endovascular therapy, consequently, there is a genuinerisk of intra-procedural complications like flow-limiting dissection, vessel perforation and/or distal embolization; the use of covered stents would allowfor immediate management of such complications, thereby reducing the possible morbidity and mortality risks.Finally, the outcome of the simultaneous placement of two "kissing" bare metal stents (BMS) for the treatment of complex aorto-iliac occlusive lesions has been plagued by some mid and long-term complications, according toSaker et al.,who reported the presence of immature mesenchymal tissue, neointimal hyperplasia and organized thrombus in the space between the two opposing stents, within the lumen of the stents and at the level of the free floating intra-aortic portion of the stents.[14]Covered stentswould prevent such adverse hemodynamic and pathological changes.

PATIENTS AND METHODS

Patients with aorto-iliacocclusive disease ranging from isolated focalinfra-renal aorticstenosis to total occlusion of the infra-renal aorta with or without involvement ofthe iliac arteries were treated by covered stent(s) repair duringthe period from January 2014 to December 2015. Our Exclusion criteria included: Patients with iliac occlusive disease with no involvement of infra-renal aorta (bifurcation only), associated extensive infra-inguinal occlusive disease, chronic renal impairment and thosewith connective tissue disorders or history of previous endovascular intervention.

A written informed consent was obtained from all patients.Demographic data and co-morbid diseases, atherosclerosis risk factors were all reported. All patients were preoperatively evaluated with multi detector computed tomography angiography (MD-CTA). Clinical and hemodynamic assessments were judged by pre and post-procedural clinical symptoms and Ankle-brachial indices (ABIs) at rest.

Procedure

All procedures were performed in the interventional radiology suite under local anesthesia supplemented with intravenous sedation and analgesia whenever indicated. The patients were fully monitored with pulse oximetry, electrocardiography, and blood pressure during whole precedure. All patients were receiving anti-platelet therapy (Colpidogrel 300 mg) the night before the intervention.

Due to the large size of the sheath required for delivery of the covered stent device, all our femoral exposures were surgical cut down ones. According to lesion characteristics we employed three different approaches;where in focal aortic stenosis situated well above the bifurcation a

suitable single retrograde femoral accesswas used for stent delivery.

In focal lesions nearby or involving the bifurcation, bilateral retrograde femoral accesses were used for deployment of three covered stents in a kissing fashion with flow divider principle as described by P. Goverde et al for **C**overed **E**ndovascular **R**econstruction of **A**ortic **B**ifurcation or CERAB-technique

While in patient with infrarenal aortic occlusion extending into one or both iliac arteries the duplex guided bilateral retrograde femoral access was obtained with sometimes additional left brachial access to facilitate lesion crossing. Upon initial successful recanalization with undersize non-compliant balloons the procedure continued as described above adopting the CERAB technique

In all cases our initial access was obtained with 6 Fr regular sheath which would be exchanged upon successful lesion crossing and preparation to 9 Fr sheathes to allow for Advanta V12(Atrium Medical, Maquet Getinge Group, Hudson, NH, US) balloon expandable ePTFE covered stent's delivery

In case of stenosis a standard 0.035-inch J-tip, hydrophilic Terumo guidewires (Terumo Corp, Tokyo, Japan) alone or with the aid of a suitable selective catheter was used for lesion crossing. While in occlusion, they werecrossed using0.035-inch straight, medium support hydrophilic Terumo® guidewire combined with straight 4F hydrophilic catheters. Neither angled guidewires nor angled catheterswere usedto prevent subintimal passage.

No predilation was needed for covered stents deployment in stenotic lesions while in total occlusion predilation with suitable length but under sized, non compliant balloons was employed to minimize the resultant atheromatous debris with the risks of distal embolization and to avoid the possibilities ofvessel rupture.

In focal aortic stenosis not involving the bifurcation, the stent deployment was straight forward, insuring total lesion's length coverage with adequate proximal and distal attachmentto healthy aortic segments. Post deployment expansion to the required diameterwith appropriate size non-compliant balloon was carried out with max 5% over-sizing.

While in near or at bifurcation lesions, the kissing techniquewas used, where after lesion preparation if needed, a12 mm Advanta V12 balloon expandable covered stent-graft of suitable length was inserted across the aortic lesion; then theproximal part of the stent was dilated to the diameter of the nativeaorta taking care thatthe distal balloon's marker is positioned about 15 mm proximal to the distal stent margin which, in turn, is positioned around 20 mm above the bifurcation thus the distal end of stent becomes conical in shape.Cannulation of this stent from the contralateral side was the performed. Then bilateral V12 covered stent-grafts of suitable size are placed within this conical segment, in a "kissing" fashion and were deployed simultaneously. A tight seal is now formed between the two iliac stents and the aortic stent, creating a new bifurcation abiding the hemodynamic concept of "new" flow divider similar to that of the EVAR stent, the so called CERAB-technique. At the end of the procedure, a completion angiogramwas performed for confirmation of the final result andscreening of possible distal embolization. Hemostasiswas achieved by primary closure of the femoral arteriotomies. Technical success was considered if the residual stenosisas measured on angiogram was $\leq$ 30% or the mean pressuregradient across the lesion was <10 mm Hg.[15]

After the procedure, dual antiplatelet therapy withaspirin (100 mg/d) and clopidogrel (75 mg/d) was given for 1 month, and then monotherapy with clopidogrel(75 mg/d) was continued long-term unless contraindicated. Follow-up consists of clinical assessment, duplex ultrasound and ankle-brachial indices at 3, 6 and 12 months and annually afterwards. Plain abdominal X-ray was performed at 6 and 12 months to assess for material breakdown or migrationandCT-angiography was performed at 6 and 12months. Clinical success was defined as improvement in walkingdistance, absence of resting pain, and healing of trophicchanges whilehemodynamic success was determined by an increase inABI of $\geq$ 0.10 from baseline at the first clinical follow-up[15].

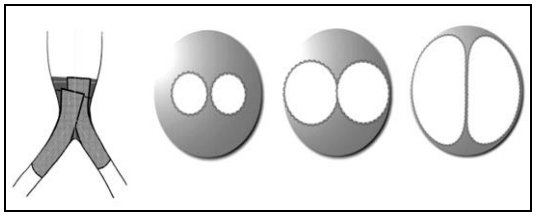

Fig. 1: diagrammatic representation of the kissing stent graft technique for aortoiliac occlusive lesions(quoted from**:**Verma, N., Nanavati, A., &Kluck, B. (2013).Endovascular management of aortoiliac occlusive disease.Poster presentation.)

RESULTS

Seven patients metour inclusion criteria.Two patients had isolatedmid aortic focal stenosis without bifurcationinvolvement both were >3 cmin length. One patient had rather focal near bifurcation stenosis with length ≤3cm (TransAtlantic Inter-Society Consensus [TASC II] B). Four patients had chronictotal aortobiiliac occlusion (TASC II D).Patients' characteristics are summarized in table 1.

Rest pain was the most common, (57%), while minor tissue loss (2 patients) and severe claudication (1 patient) constitute the rest of patient's presentation.Pre-procedural mean resting ABIs were 0.55± 0.15 at the right side and 0.59 ± 0.15 at the left side.

Table 1: Patients' characteristics

age	Range: 42-57 Avg: 50 ± 8 years
sex	6 males 1 female
smoking	5 (71.4%)
hypertension	3 (42.8%)
Diabetes mellitus	1 (14.2%)
Coronary heart disease	4 (57%)
Hypercholesterolemia	3 (42.8%)

We used total of 15 stents with diameter range (8-12mm) and length range (41-61mm).

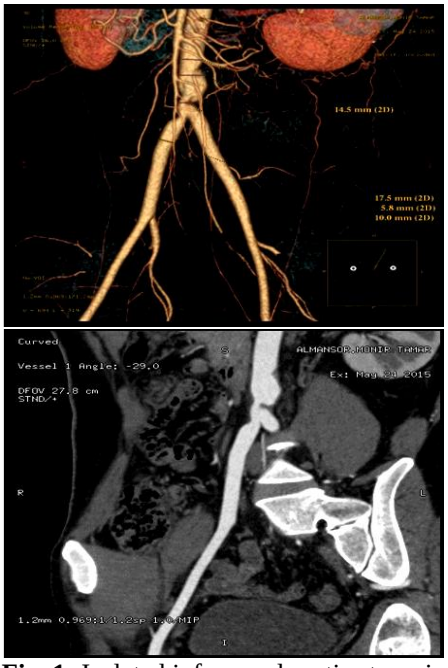

Fig. 1: Isolated infra-renal aortic stenosis

Technical and immediate clinical successwereachieved in all our patients (100%) as confirmed by palpable distal pulses, improvement of walking distance and absence of rest pain. Trophic changes were healed completely within 3-4 months after the procedure.The immediatehemodynamic results showed mean resting ABI toincrease to 0.95± 0.05 on the right side and to 0.96 ± 0.04on the left side. No 30 daysmortality was observed. Mean hospital stay was4.5 ± 1.5 days. Three patients were hospitalized for 3 days, and another three for 2 days, and one for 6 days owing to an access site hematoma

After 3 months, one patient developed significant hemodynamic stenosis at the right common iliac artery stent which was treated drug coated balloon (DCB); (In-PACT Admiral, Medtronic USA). Another patient, at 6 months follow up, reported recurrence of symptoms (rest pain and numbness) his CT-angiography revealed tight ostial stenosis at the new bifurcation (CERAB kissing technique) and was treated by kissing drug eluting stents(Zilver PTX Cook Medical USA). At 12 months' follow up no patient showed symptoms of limb ischemia or recurrence of trophic changes.

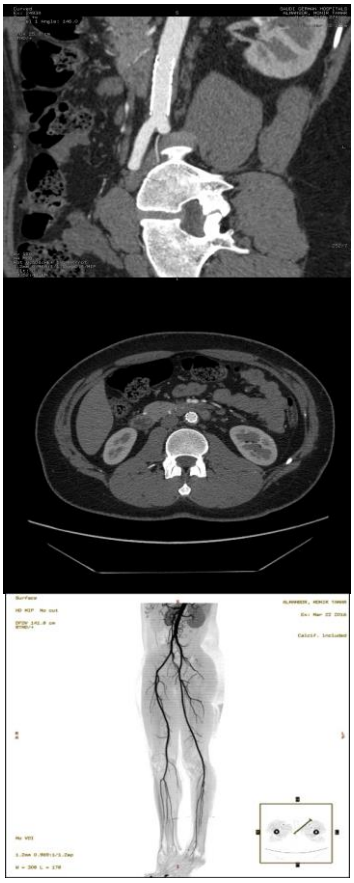

Fig. 2: The case of isolated infra-renal aortic stenosis, 1 year after stent placement.

DISCUSSION

Aortobifemoral bypass or aortic endarterectomy has been the standard treatment of choice for infra-renal aortic occlusive disease with well-documented long term results,[3,16] Long-term patency after localized endarterectomy or aortobifemoral bypass is reported to be up to 90% at 5 years and 75% at 10 years.[17,18]

These procedures, however, are associated with significant morbidity and mortality[19, 20]and may also lead to erectile dysfunction in up to one third ofmalepatients.[16]

PTA (Percutaneous Transluminal Angioplasty), which was initially introduced for aortic lesions in1980 by Grollmann et al,[21] Velasquez et al, [22] and Tegtmeyeret al, [23] has been proposed as an alternative to surgery.Since that time, several series have been published demonstratingsuccessful results of PTA in localized stenoses involvingthe infrarenal aorta[24-30]as well as the aortic bifurcation.[24-26,29]Aortic PTA has a satisfactory immediate outcome, withinitial technical success up to 95% to 100%[26]however,its mid- and long-term efficacy is frequently compromiseddue to re-stenosis mostly from neointimal hyperplasia.[29]

By utilizing graft material to prevent intimal hyperplasia and reduce long-term restenosis, covered stents were developed with the prospect of improving pre-existing stent technology. Although early studies of polyester-covered stents yielded poor results because implantation was associated with low patency rates and a significant post-procedural inflammatory response, the use of expanded polytetrafluoroethylene (e.PTFE)-covered stents has shown favorable outcomes in infrainguinal peripheral interventions.[31-34].The covered stentoffers the unique combination of a primary result that is similar to traditional stenting yet with low and length-independent re-stenosis rate due to its permanent exclusion of the stented segment thus preventing progression of disease from affecting mid and long-term patencies. No other interventional device offers all 3 of this advantages.[32-34]

The Advanta V12balloon expandable ePTFE covered stent (Atrium Medical, Maquet Getinge Group, Hudson, NH, US); is a balloon-expandable stainless steel stent that is fully encapsulated in two layers of PTFE. The PTFE has a porosity of 100 to 120 µm. The system is pre-mounted on a noncompliant balloon catheter with gold markers embedded at the ends of the balloon. The current-generation is available in diameters of 12, 14, and 16 mm with the ability to be postdilated up to 20 mm. Available lengths include 29, 41, and 61 mm and compatible with 9 to 11-Fr. sheaths with 80 and 120 cm shaft lengths. This particular device is approved for restoring and improving patency of iliac arteries.[13]

The largest cohort study on endovascular treatment of infrarenal aortic occlusive lesions to date was published by Kim et al.In his study both balloon-expandable and self-expanding bare metal stents were used to treat 49 lesions. Complications occurred in 16.3% of the patients and distal embolization was reported in 10.2%[35]the overall 30-day complication rate was 14.2%, which is lowerthan other studies (0-28.5%). [36-42]

In theory, eccentric and heavily calcified lesions are more prone to rupture during endovascular intervention. One of the advantages of the use of covered stentsis that they would treatany rupture instantly. The diameter of the native infrarenal segment of the aorta should be taken into account when choosing the stent diameter. A 12-mm Advanta V12 is inserted through a 9-Fr sheath and can subsequentlybe flared to 20 mm, or not flared at all. Therefore, there are no limits to the possibilities of adjusting the diameter of the covered stentto the aortic wall. A possible complication of the use of covered stents is the exclusion of arterial collateral channels, in particular, the inferior mesenteric artery (IMA).However, in stenotic lesions, these arteries are commonly found occluded.

Our patency rateswere found almost comparable to the results seen in previous similar studies. Goverde P., et al used covered stents totreat 44 patientswith acute, chronic or recurrent aortoiliac occlusive disease with TASC II C & Dlesions**.** Technical success rate was 96% with follow up for 3 months up to 38 months. Four patients died of causes not related to the procedure. Ultrasound and CT-angiography were used for follow up. Four patients re-occluded due to progression of the disease in the distal peripheral vascular bed or hematological disorders. Managed successfully by thrombolysis or mechanical thrombectomy and treatment of the outflow problems, with patency rate 90%at 6 months and 84.4% at 12 months.[8]

Also, Piotr Ciosteket al, published the results of treating 14 patients with juxta-renal aortoiliac occlusions from 2012 to 2014 using Viabhan self-expanding stent graft; technical success was 100% and patency rate of 100% was demonstrated over a period of 3-34 months follow -up (average 1.8 month), and the only complications seen was one groin hematoma and one death from unrelated causes.[43]

The relatively small number of the patients in our series, due to the low prevalence of isolated aortic lesions and high cost of the intervention, makes our results rather early outcomes only,moreover, it lacks randomization with our evident bias towards this technique which adds to the study limitations. Although this was set as a feasibility study, our preliminary data show that this approach is feasible as well as effective in achieving excellent anatomical and hemodynamic improvement regardless of the lesion extent.

In our study, no visceral or spinal cord ischemic events occurred.Post-procedural complications included one groin hematoma, which was treated conservatively and did not cause any clinical impairment, no distal embolization occurred, together with no 30-day mortality indicating the safety of the technique. Obviously, the study results should be furtherly emphasized by a randomized study, but again the high cost of the stent graft will limit conduction of such a trial in view of our limited resources. The cost effectiveness of covered stents for aorto-iliac occlusive disease has not been discussed in this study, as these stent grafts are more expensive than the standardvascular grafts commonly used during open surgical repair or bare metal stents.

However, a recent analysis by Indes JE et al., showed a significantly lower complication rate for endovascular procedures with a shorter hospital stay which may compensate for the high cost of such procedures.[12] However, in this series, we found a significantly lower inpatient cost for endovascular repair compared with openrepair especially in aorto-iliac occlusive diseases which usually needs admission into intensive care units andconsequent longer hospital stay. Also, with improvement in patency rates and the possible advantage of lower long term morbidity, and as experience grows, the need for follow up imaging may be reduced, further reducing costs for the endovascular repair.

From our experience gained from this cohort, we can highlight the major advantages of PTFE covered stents over the bare metal stents in management of aorto-iliac occlusive diseases which include: 1) the immediate covering of ulcerated plaques and vessel wall thrombus, thereby possibly preventing distal embolization, moreover, the “dog-bone” shape inflation of the balloon may catch emboli behind the covering material, thus further reducing the chances of embolization, 2) Separates lumen of a new vessel from instable atheromatous plaques or thrombus so guarantees easy flow, 3) Prevents the hemorrhage in case of rupture of aorta or iliac artery.

CONCLUSION

Covered stents for occlusive aortoiliac diseases is a technically feasible and potentially safe procedure and demonstrates very good mid term patency. Based on the available data,covered stents may be considered the best and unavoidable technical solution in restoring blood flow through occluded infrarenal aorta and iliac arteries. Although larger prospective randomized studies with long-term follow-up are necessary to compare to surgery, PTA, and primary stenting, our preliminary findings along with that of other series indicate that primary covered stents may have a significant role in the management of the whole range of infrarenal aortic occlusive disease.

Conflict of Interests

The authors declare no association with any company having a financial interest in the products and the covered stents mentioned in this paper.

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