Percutaneous revascularization as a feasible option for complex aortoiliac occlusive disease with fair 1-year outcome

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Background
Aortoiliac arterial occlusive disease (AIOD) is one of the commonest patterns of systemic atherosclerosis with a spectrum of chronic symptoms from intermittent claudication to critical limb ischemia, which is a common therapeutic challenge. A meaningful shift has evolved in treating symptomatic AIOD from open to endovascular repair, which are becoming an attractive treatment option even in complex lesions, especially in patients with considerable risk.
Aim
The aim of this study was to assess the feasibility, that is, technical success rates, primary patency, and safety outcome for Trans-Atlantic Inter-Society Consensus (TASC) D lesions treated endovascularly with analysis of outcome of stent graft versus bare metal stent in patients with advanced Leriche syndrome.
Patients and methods
A prospective case series study: over 30 months, our case study was conducted on 22 patients with TASC D lesion morphology undergoing treatment for symptomatic chronic AIOD at the Vascular Unit, General Surgery Department, Benha University Hospitals, Vascular Surgery Department, Nile Insurance Hospital and Vascular Surgery Department, Security Forces Hospital and Al-Noor Specialist Hospital, Makkah, Saudi Arabia. The patients were enrolled from April 2015 until October 2016 with a 12-month follow-up period from the last patient enrolled. SPSS, version 20.0 for Windows was used for statistical analysis.
Results
Our study had a technical success rate of 95.5% in crossing TASC D lesion with immediate angiographic success (91%). The 12-month primary patency rate was 85% for TASC D lesions with a target lesion revascularization of 15%. Stent grafts had a higher 1-year patency rate (91.7%) versus bare metal stent (75%). The total procedure-related complications rate was 18.1% and 30 days procedure-related mortality was 4.7%.
Conclusion
Our study shows that technical success of endovascular therapy for TASC D lesions was 95.5% with a 1-year primary patency of 85% and a complication rate of 22.7% in TASC D lesions. Utilizing more than one access with antegrade crossing the lesion through brachial access was paramount for technical success. Long-term follow-up is mandatory to support the durability of the procedure.

Keywords:
aortoiliac arterial occlusive disease, Leriche syndrome, stent graft, Trans-Atlantic Inter-Society Consensus D

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Introduction

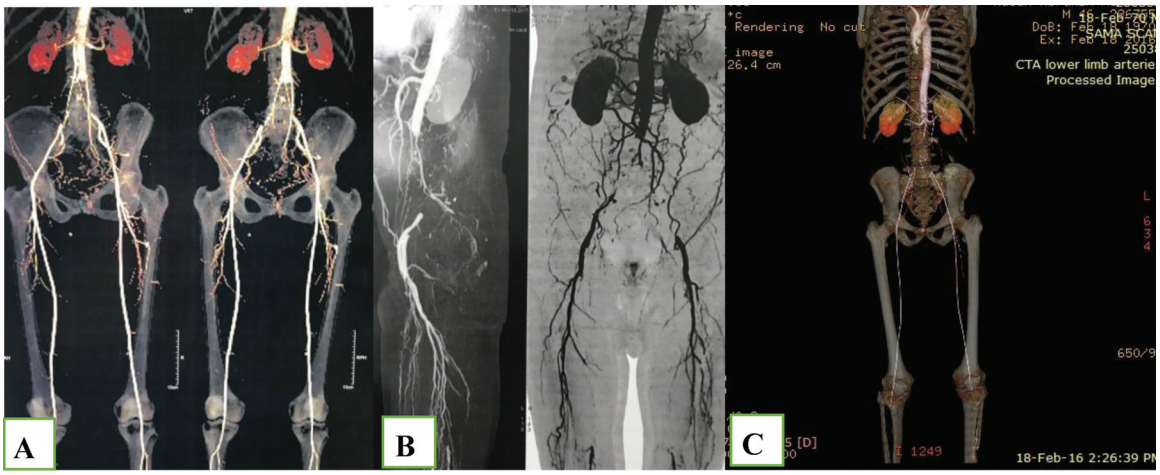
Symptomatic peripheral arterial disease may be frequently observed as cardiac angina. The infrarenal abdominal aorta and iliac arteries are recognized as the most habitual sites for obliterative atherosclerotic lesions and representing about one-third of all symptomatic peripheral arterial disease cases [1]. Disabling intermittent claudication, diminished or absent distal pulses, erectile dysfunction and often a global atrophy of both lower limbs with or without tissue loss are the main symptoms of severe aortoiliac occlusive disease (AIOD) [2]. Complex aortoiliac lesions are a specific type known as Leriche syndrome [3]. It is diffuse and contiguous or multilevel aortoiliac steno-obstructive disease and are much more likely to be associated with atherosclerosis of the coronary or cerebral arteries. They are classified as TASC C and D lesion according to the Trans-Atlantic Inter-Society Consensus II Working Group (TASC-II) which recommended surgical revascularization for extensive and bilateral lesions (TASC C/D) [4]. In the past, surgical revascularization for aortoiliac occlusion was mainly with aortofemoral or aortoiliac bypass. Occasionally,

extra-anatomical revascularization was utilized in patients with associated severe comorbidities; femoro-femoral crossover bypass was also a considerable option in patients with unilateral iliac disease [5]. Percutaneous endovascular therapy is increasingly being used with the stent deployment instead of surgical bypass, even in complex aortoiliac lesions such as bifurcation disease, long-segmental occlusion, and aortic occlusion, due to surgical reconstruction-related complications and mortality rates. In addition, laparotomy may be associated with delayed complications like incisional hernia and adhesions resulting in small bowel obstruction. [6]. Endovascular therapy modalities were furtherly upgraded with improvements in its technology like higher resolution imaging, balloon-mounted stents and self-expanding stents, which has resulted in better outcomes for the endovascular treatment of AIOD [7]. Endovascular procedures are upcoming although open surgical repairs have shown their value, even though endovascular devices are usually more expensive. With significant improvement in patency rates, endovascular modalities are becoming an attractive alternative to open repair [6]. Many different techniques have been used for the reconstruction of AIOD such as 'kissing stent', and 'kissing stent graft' techniques [8]. The covered endovascular reconstruction of the aortic bifurcation technique is a new one that aims to improve the outcomes of endovascular option for lesions involving the aortic bifurcation by simulating the anatomical and physiological situation of the aortic bifurcation using three covered stents. The covered endovascular reconstruction of the aortic bifurcation technique may prove to be a valid alternative for surgery and/or kissing stents [9]. The use of a bifurcated aortic endograft as an alternative therapeutic option in the treatment of complex AIOD TASC C and TASC D-type lesions show promising good short-term outcomes [10].

Patients and methods

From April 2015 to October 2017, 22 consecutive symptomatic patients due to complex TASC D aorto-iliac occlusion underwent percutaneous recanalization at Vascular Surgery Department, Nile Insurance Hospital & Vascular Surgery Unit, Benha University/ Department of Surgery, Egypt & two tertiary referral centers in Saudi Arabia (Security Forces Hospital Program & Al-Noor Specialist Hospital – Makkah). The study protocol was approved by the local hospital's Ethical and Scientific Review Board in the enrolled hospitals. Patients were informed of the risks and benefits of participating to the study and given written informed consent for all to sign. We studied 22 patients for 18 months who were followed up for another 12 months from the last patient who underwent revascularization. All the studied patients were symptomatic with disabling claudication of pre-dominantly Rutherford category 3 with limited walking capacity ranging from only 15 to 100 m and critical ischemia rest pain and minor tissue loss, Rutherford categories 4 and 5 due to aortoiliac occlusive TASC D lesion. Three patients had been previously operated upon for aortobifemoral bypass surgery with subsequent reocclusion of the grafts. Preprocedural diagnostics included in all patients were duplex ultrasonography of the abdominal aorta and iliac/infrainguinal arteries, echocardiography to evaluate left ventricular function, an assessment of the ankle–brachial pressure index, and computed tomography angiogram (CTA) (Fig. 1) to estimate the occlusion lengths in the aorta and iliac

Figure 1



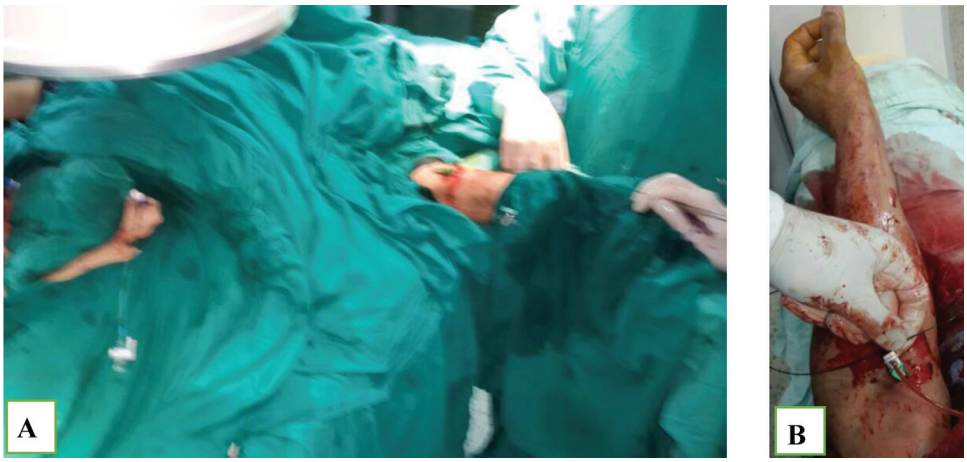
(a–c) Baseline computed tomography angiography (CTA) of three patients with Leriche syndrome.

arteries, as well as to assess femoral, popliteal, and infrapopliteal runoff.

Procedure

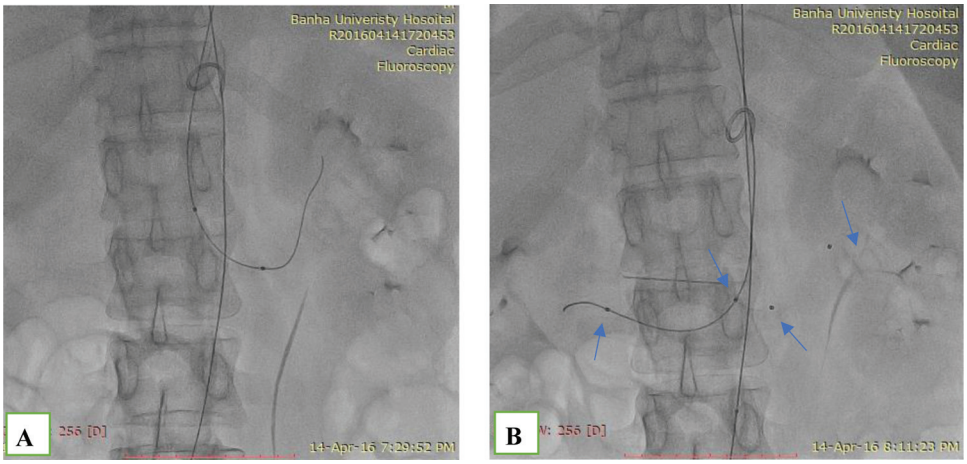
The patients were premedicated with acetylsalicylic acid (aspirin, 81 mg/day) and a loading dose of 600 mg of clopidogrel immediately before the intervention. Our strategy comprised antegrade (transbrachial) recanalization of the occluded segments through the brachial artery followed by retrograde (transfemoral) angioplasty to reduce the risk of subintimal stenting. Following local anesthesia, access to the target lesions was by means of the 6 Fr sheath placed in the left brachial artery in 18 patients (Fig. 2b). Through this access, diagnostic angiography was performed to identify the extent of the disease from the aorta to the iliac/femoral arteries visualized via collaterals. Heparinization was begun with 100 U/kg administered through the 6 Fr sheath; a second bolus of 5000 U of heparin was given after 2 h. Throughout the procedure, no patient required general anesthesia. In two patients in whom preprocedural CTA had revealed juxtarenal occlusion, bilateral brachial access was achieved with two hydrophilic 0.014 inch wires (Nitrex; Covidien, Plymouth, MN, USA), which were introduced into both renal arteries through the 7 Fr sheath in the right arm, while the left brachial access was used for control angiography and lesion navigation (Fig. 3). This protective measure would allow accessing the two renal vessels in case of an unexpected plaque shift or a dissection compromising their blood supply. Once the proximal fibrous cap of the occlusion was penetrated, we exchange the multipurpose catheter for a 135-cm, 0.035 inch support catheter (CXI; Cook Medical Inc., Bloomington, Indiana, USA). We penetrate all the lesions using a 260-cm hydrophilic stiff angled guidewire (AqWire; ev3 Inc., Plymouth, Minnesota, USA and Terumo Cardiovascular Systems Corp., Ann Arbor, Michigan, USA), supported by a 125-cm 5-Fr multipurpose catheter (MPA; Cordis Corp., Miami Lakes, Florida, USA). Recanalization of the aorta was

Figure 2



(a) Combined brachial and femoral access and (b) brachial access through 6 Fr sheath.

Figure 3



(a, b) Bilateral renal cannulation with 0.014 inch hydrophilic wires with balloon protection.

monitored by fluoroscopy in antroposterior and lateral projections, whereas recanalization of the iliac arteries was better monitored in the 30° contralateral anterior oblique projection. When the two wires were successfully passed into the femoral arteries, each artery was punctured under fluoroscopic guidance (because of absent femoral pulses), targeting the endoluminal wire. By way of 8 Fr sheaths, the hydrophilic stiff wires were exteriorized by the rendezvous technique. Femoral cut-down and common femoral artery exposure were performed in four patients due to heavily calcified atherosclerotic femoral access and previous aortobifemoral bypass (hybrid procedure). Starting from the aortic occlusion, the entire occluded segment was predilated with an 8.0/80 mm balloon (Admiral Xtreme, Invatec; Medtronic Inc., Minneapolis, Minnesota, USA). Balloon inflation pressure was restricted to 6 atm to minimize the risk of vessel rupture. Both hydrophilic stiff wires were then exchanged for stiffer wires (Amplatz wire; Boston Scientific Corporation, Natick, Massachusetts, USA) over which the subsequent stents deployment were performed retrograde via the sheathless technique from both groins. For aortic stenting covered self-expandable and balloon-mounted stents (Fluency Plus and LifeStream; Bard Inc., Murray Hill, New Jersey, USA) and bare metal stents was placed. Its correct position with its proximal end extending for about 1 cm beyond the aortic occlusion and post-dilated with either two 8 mm balloons in a kissing-balloon manner. For the reconstruction of the iliac limbs, a self-expanding nitinol stent (Everflex, Covidien, Plymouth, MN, USA; and Wallstent, Boston Scientific, Natick, Mass, USA) was advanced from either groin and deployed such that it overlapped the distal end of the aortic stent by about 3 mm diameter of either iliac stent or oversized the respective iliac-artery reference diameter by 1 mm. Both self-expandable stents were post-dilated in a kissing-balloon manner. An angiogram was taken to document the result. 'Procedural success' was defined as restored vessel patency with a residual diameter stenosis of less than 30% (Figs 5–8). In all patients, both groins were sealed by the tamponade action of inflated common femoral balloon for 5–10 min to avoid vessel compression and ensure unimpeded distal runoff (Fig. 4) with completion angiogram to confirm puncture site sealing. Patients were discharged on an oral regimen of aspirin (81 mg/day) and clopidogrel (75 mg/day for 6 months). A clinical as well as a duplex ultrasonographic examination was done before discharge, after 30 days, at 3 and 6 months, and every 6 months thereafter. CTA was performed at 12 months to exclude aneurysms, dissections, and stent dislocations (Fig. 9).

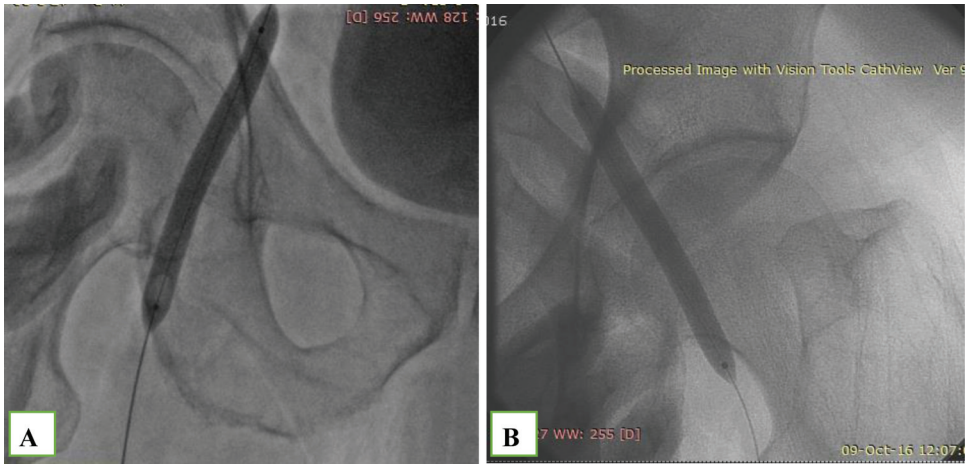
Study endpoints

The primary efficacy endpoints were acute technical success in the revascularization of TASC D AIOD and primary patency at 12 months following the index procedure, defined as freedom from clinically driven target lesion revascularization. The reintervention was due to the clinically recurred symptoms. Safety endpoints included 30-day procedure-related death, all-cause death, major target limb amputation, and target vessel thrombosis. Additional efficacy endpoints included primary clinical improvement (freedom from target limb amputation and upgrading to Rutherford class at 12 months).

Results

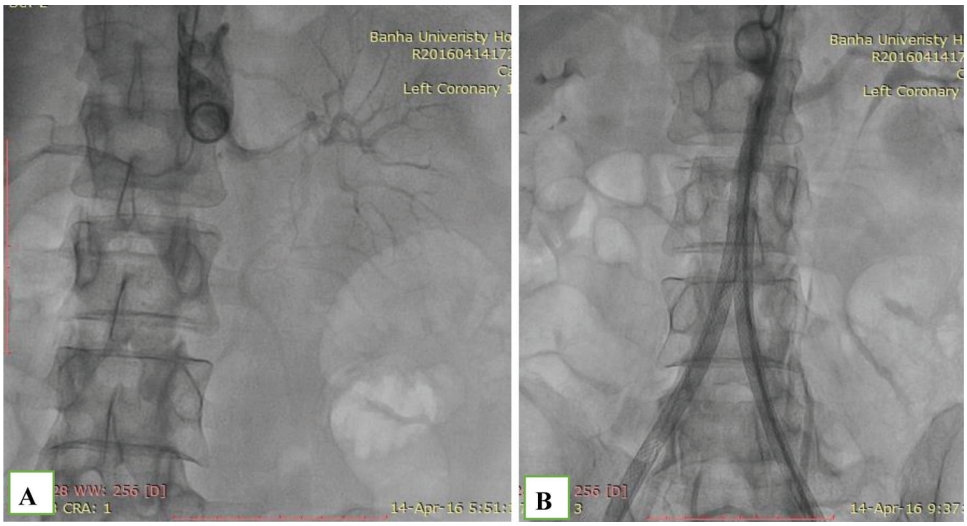
This study is a prospective case serious study. In all, 22 patients were enrolled from April 2015 to October 2016 with a 1-year follow-up from the last enrolled

Figure 4



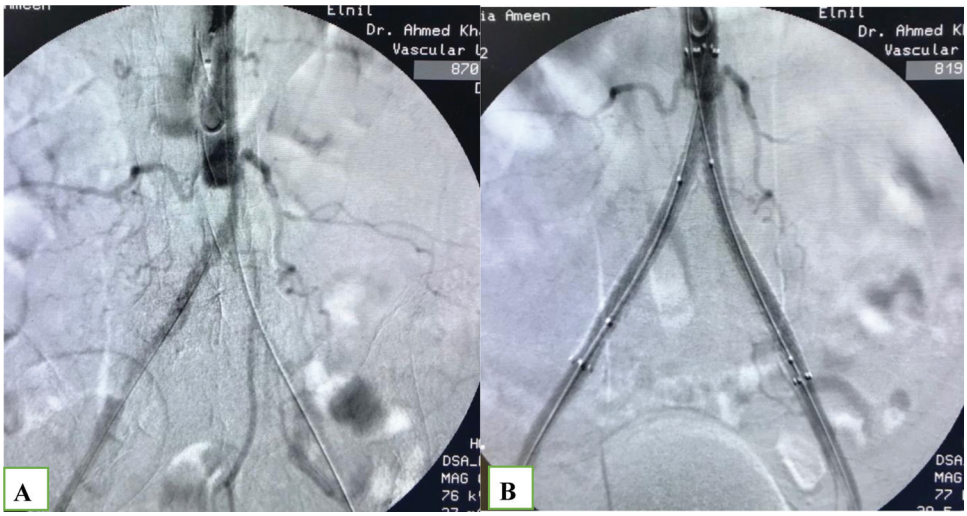
(a, b) Groin puncture sealing by common femoral artery balloon inflation for 5–10 min.

Figure 5



(a) Juxtarenal aortoiliac occlusion, (b) revascularization with two balloon-mounted stent grafts and iliac limb reconstruction with two bare metal stents.

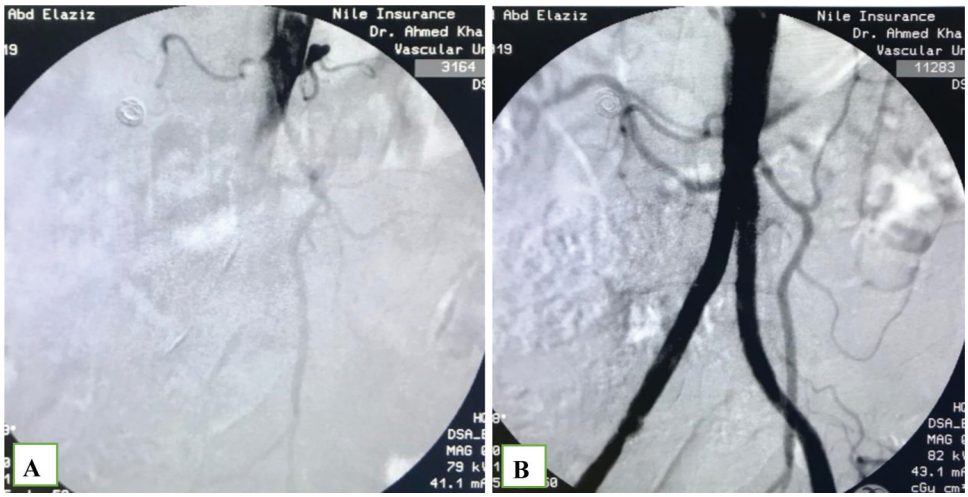
Figure 6



(a) Infrarenal aortoiliac occlusion and (b) revascularization with two stent grafts.

patient. Patient detailed characteristics are shown in Table 1. The main associated risk factors were diabetes mellitus (100%) and smoking (90.9%). All patients were symptomatic for chronic limb ischemia with reduced walking distance of 15–100 m. The majority – 40.9% of the patient population was classified as category 3 according to the Rutherford classification. Complete recanalization of the aortic bifurcation with reestablishment of uninterrupted blood flow to both legs were achieved in 20 (91%) patients. In one (4.5%) patient, the procedure was aborted, and the patient was referred to aortobifemoral bypass due extensive aortoiliac dissection and failure of true lumen reentry. In the second patient (4.5%), the total iliac outflow thrombosis was due to distal iliac dissection, we regained the flow by using the local thrombolytic therapy for 24 h and then stenting of the dissected segment. Procedure results are shown in Table 2. Aortic stents were deployed in 21 (95%) patients, with the total length of the stented segment being 120–220 mm. The completion angiogram showed no vessel perforation with uninterrupted distal flow except in one patient. Regarding safety and efficacy outcome data are shown in Tables 3 and 4. The hospitalization period ranged from 1 to 4 days. Four (19%) patients developed acute renal impairment that was managed with saline infusion and acetyl cysteine 600 mg, three times orally/day; three (14.2%) patients were temporary; and one patient was on regular dialysis due to chronic renal impairment. There was no

Figure 7



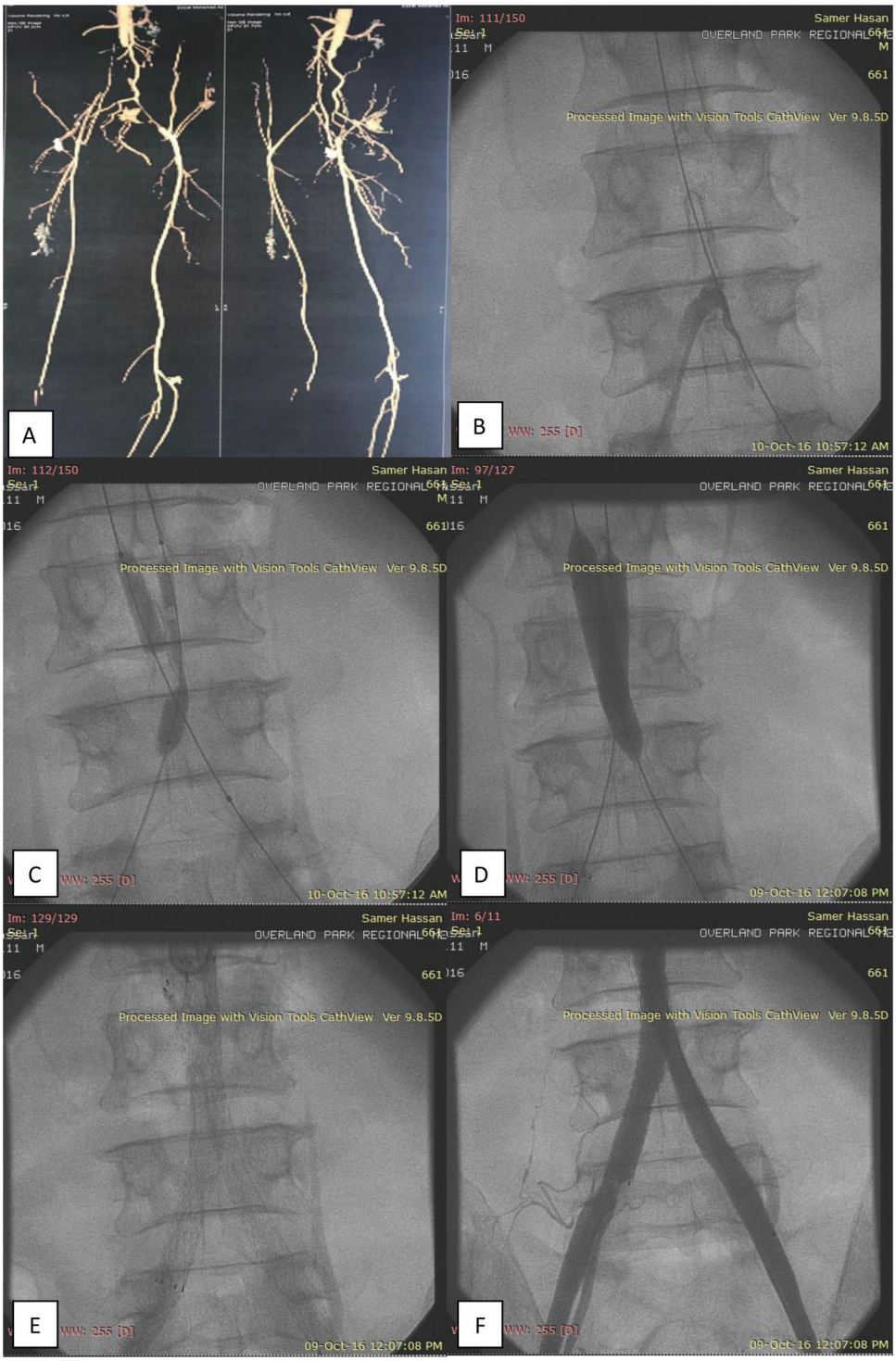
(a) Infrarenal aortoiliac total occlusion and (b) revascularization with four bare metal stents.

access-related complications in our patients. Covered stents are deployed in 13 (62%) patients (Figs 10 and 11, whereas bare metal stents are used in eight (38%) patients. Total 12 months primary patency was 85% with a target lesion revascularization of 15% (Table 5). Covered stents were associated with a superior primary patency of 91.7% in comparison to bare metal stent (75%). There was no significant difference in 1-year clinical improvement between both types of stents (Table 6 and Fig. 12).

Discussion

Over 30 months of the duration of our study, 22 consecutive patients presented with severe and complex aortoiliac occlusion in the form of disabling claudication, rest pain, and minor tissue loss. Patients with Leriche syndrome were usually associated with reduced quality of life due to their lower limb pain and tissue loss that negatively reflected on their social life and mental health [5]. We treated 21 patients of 22 by percutaneous endovascular techniques. All preoperative CTA showed TASC D pattern of the occlusion that involved infrarenal aorta and both iliac arteries. Although this pattern of lesion is recommended to be treated with open surgical repair in the form of aortobifemoral bypass by TASC II of 2007 [3], we decided to conduct them endovascularly for most of them were high-risk patients. In this study, only left brachial artery accesses were performed in 20 (90.9%) patients; unilateral left brachial access was in 18 (81.8%) patients; and bilateral brachial access was in two (9.1%) patients. There were no complications related to the use of brachial access and all lesions were successfully navigated through this access. The brachial approach offered better pushability in complex endovascular procedures but much less used in noncoronary procedures. The main causes for reluctant utilization of brachial access are complications, such as arterial thromboembolism and hematoma. These complications were reported in 6–8% of cases [11]. Overall, 21 (95.5%) patients out of 22 were successfully treated endovascularly with angiographic success achieved in 20 (91%) patients. One patient showed iliac outflow thrombosis due to dissection that was treated with 24 h catheter direct thrombolysis followed by bare metal stenting with optimum angiographic results. One patient died within 30 days of the procedure due to myocardial infarction. One patient underwent below knee amputation due to massive soft tissue infection in association with chronic osteomyelitis. The follow-up period was 12 months through which all successfully treated patients showed an increase in walking distance of up to 500–700 m; three (15%) patients showed a slight increase of ankle–brachial index with delayed wound healing in one of them necessitating secondary tibial intervention. The high technical success rate of 95.5% achieved in our study was comparable to the results of Schmalstieg *et al.* [12] which was 85%. Regarding the safety outcome of the procedure, 30 days procedure-related mortality was 4.7% with a short hospitalization period of 2–4 days. Previous meta-analysis demonstrated a mortality rate of between 3.3 and 4.6% for surgically revascularized patients [13]. In comparison to the studies that utilized endovascular maneuver for aortoiliac occlusion, the rate of complications in our study appeared to be low or similar although we treated complex TASC D lesions [13,14]. Neither iliac perforation nor distal embolization in hospital death occurred in our studies, similar to the results of Schmalstieg *et al.*

Figure 8



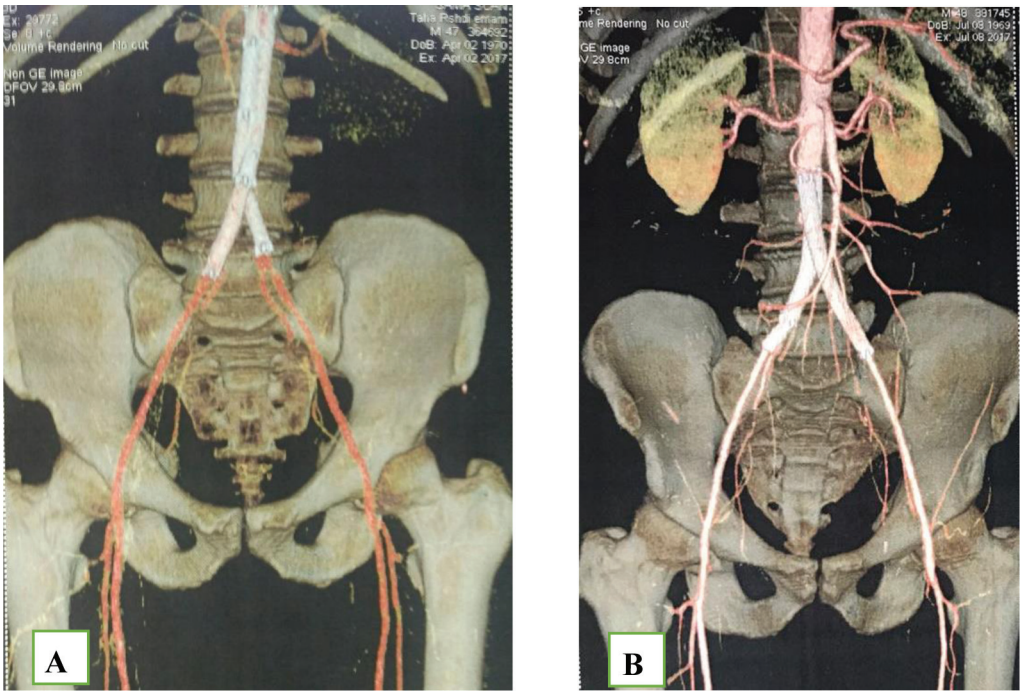
(a–f) Complete recanalization of the aorto-iliac bifurcation with seamless contrast flow in the postprocedural completion angioraphy.

[12]. Primary patency was 100, 95, and 85% at 1, 6, and 12 months, respectively, in our study, which is comparable to open surgery and superior to endovascular results reported by Jongkind *et al.* [15]. Our study shows that stent grafts were superior to bare metal stents in primary patency, but not statistically significant or different in clinical outcome or safety; this may be due to the small number of treated patients and short-term results.

Limitations

Our study presents a case series of solely endovascularly treated patients with complex aortoiliac occlusive lesion. Nevertheless, the patient population is still relatively small, but this is especially due to the pattern rarity of this atherosclerotic occlusive disease (TASC D lesion) and this represents the actual number of patients who were accepted to be enrolled for this management procedure. This prospective study was not randomized between

Figure 9



(a, b) One-year follow-up computed tomography angiography of two of our patients.

Table 1 Patient demographics and clinical characteristics

Patients	*N*=22 [*n* (%)]
Age (years)	
50–60	2 (9.1)
60–70	12 (54.5)
>70	8 (36.4)
Male	19 (86.4)
Female	3 (13.6)
Diabetes mellitus	22 (100)
Hypertension	11 (50)
Hyperlipidemia	16 (72.7)
Smoking	20 (90.9)
Chronic obstructive pulmonary disease	8 (36.4)
Coronary artery disease	10 (45.5)
Complex risk factor	5 (22.7)
Prior aortobifemoral bypass surgery	3 (13.6)
Juxtarenal occlusion	2 (9.1)
Age of occlusion [mean±SD (range)] (months)	25.64±5.76 (15–36)
Length of occlusion [mean±SD (range)] (cm)	
Infrarenal aorta	6.27±1.03 (5–8)
Left iliac artery	7.05±1.81 (4–10)
Right iliac artery	8.5±1.92 (5–12)
Rutherford category of peripheral arterial disease	
Rutherford 3(severe claudication)	9 (40.9)
Rutherford 4 (ischemic pain at rest)	8 (36.4)
Rutherford 5 (minor tissue loss)	5 (22.7)
Absolute walking distance [mean±SD (range)] (m)	54.45±23.07 (15–100)
Ankle–brachial index (mean±SD)	
Left lower limb	0.47±0.07
Right lower limb	0.49±0.08

Table 2 Procedure characteristics and results

Procedures	*N*=22 [*n* (%)]
Initial access	
Left brachial	18 (81.8)
Bilateral brachial	2 (9.1)
Bilateral femoral	22 (100)
Percutaneous	18 (81.8)
Surgical cut-down	4 (18.2)
Procedural success, complete (bilateral)	21 (95.4)
Lesions not recanalized	1 (4.5)
Lesions treated with covered stents	13 (62)
Lesions treated with bare metal stents	8 (38)
Lesions treated with two stents	10 (47.6)
Covered stent (*n*)	7
Bare metal stent (*n*)	3
Lesions treated with three stents	6 (28.5)
Covered stent (*n*)	3
Bare metal stent (*n*)	3
Lesions treated with four stents	5 (23.8)
Covered stent	3
Bare metal stent	2
Nominal stent diameter (mm)	8 (7–10)
Total stented lesion length (mm)	120–220
Procedural success	
Successful lesion crossing	21 (95.5)
Immediate angiographic success	20 (91)
Procedure-related death	0
Iliac stent thrombosis	1/21 (4.7)

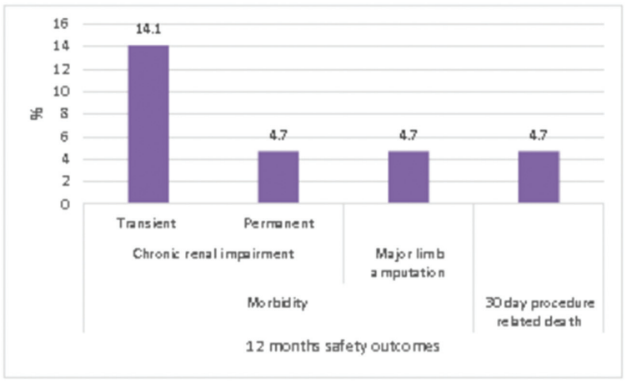
Table 3 Safety outcomes

Safety outcomes [*n* (%)]	
Hospitalization period (days)	1–4
30 days procedure-related death	1/21 (4.7)
Major limb amputation	1/21 (4.7)
Renal impairment	4/21 (19)
Transient	3/21 (14.3)
Permanent	1/21 (4.7)

Table 4 Efficacy outcomes

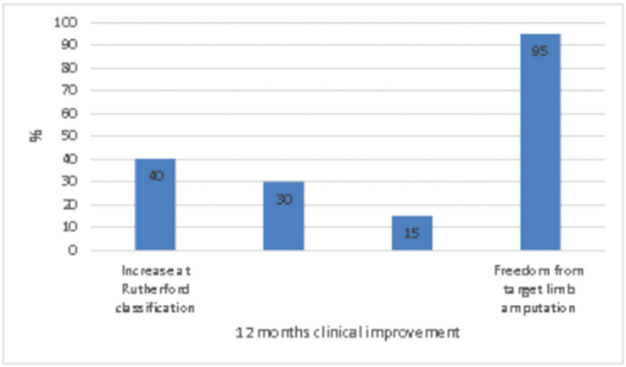
12 months clinical improvement [*n* (%)]	
Increase at Rutherford classification	17/20 (85)
Improvement of claudication	8/8 (100)
Improvement of rest pain	6/8 (75)
Healing of wound	3/4 (75)
Freedom from target limb amputation	19/20 (95)
Increase of ankle–brachial index value [mean±SD, *n* (%)]	
Right lower limb	0.88±0.05, 18/20 (90)
Left lower limb	0.83±0.07, 19/20 (95)

Figure 10



Twelve months of safety outcome.

Figure 11



Twelve months of clinical outcome.

endovascular treatment and open surgery; however, this would be difficult to manage because of the low prevalence of this disease. Meta-analysis of retrospectively enrolled patients with the same disease pattern for open surgical repair could be available when the long-term results of our study will be established. Therefore, it would be mandatory to evaluate a much larger series with long-term follow-up to receive significant results.

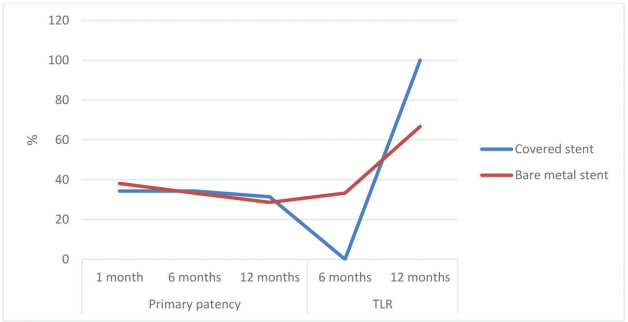
Table 5 Primary patency and target lesion revascularization

Primary patency [*n* (%)]	
1 month (total)	20 (100)
6 months (total)	19 (95)
12 months (total)	17 (85)
Target lesion revascularization	
1 month (total)	0
6 months (total)	1 (5)
12 months (total)	3 (15)

Table 6 Primary patency and target lesion revascularization for covered and bare stents

	Covered stent (*N*=13) [*n* (%)]	Bare metal stent (*N*=8) [*n* (%)]	Fisher's exact test	*P* value
Number of stents				
2	7 (53.8)	3 (37.5)	0.83	0.85
3	3 (23.1)	3 (37.5)		
4	3 (23.1)	2 (25.0)		
Primary patency				
1 month	12 (34.3)	8 (38.1)	χ^2=0.09	0.96
6 months	12 (34.3)	7 (33.3)		
12 months	11 (31.4)	6 (28.6)		
Target lesion revascularization				
6 months	0 (0.0)	1 (33.3)	0.0	1.0
12 months	1 (100)	2 (66.7)		

Figure 12



Primary patency and target lesion revascularization (TLR) of the covered stent and bare metal stent.

Conclusion

In our case series of percutaneous revascularization of complex AIOD, we showed a high technical success rate with the endovascular therapy option for complex totally occluded aortoiliac bifurcation as a feasible option for patients with high risk for surgical revascularization. Transbrachial access is the keyword for successful and safe lesion crossing. The associated low rate of complications, shorter time of hospitalization, recovery, and also lower

mortality were found for endovascular treatment. Significant clinical improvement in association with advances in endovascular supplies encourage us to utilize this endovascular procedure as a primary option for patients with TASC D aortoiliac occlusion; however, a long-term follow-up is mandatory to support the durability of this percutaneous technique.

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Nil.

Conflicts of interest
There are no conflicts of interest.

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