Endovascular management of Trans-Atlantic Inter-Society Consensus C and D aortoiliac occlusive disease as a feasible, effective, and durable intervention

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Context
The progress and innovations in endovascular tools have replaced standard surgical intervention with endovascular intervention, including long, complex lesions.
Aim
The aim of the study was to evaluate the results of endovascular management as the first-approach intervention for symptomatic extensive Trans-Atlantic Inter-Society Consensus (TASC) C and D aortoiliac disease.
Patients and methods
This was a prospective study. Fifty patients with long, complex TASC C and D aortoiliac lesions underwent revascularization by endovascular-first approach. Technical success and follow-up results after 6, 12, and 24 months were documented. SPSS software version 18 was used for statistical analyses.
Results
Of the 50 patients, 84% were male. All the patients had TASC C and D lesions and 66% of them had critical limb ischemia. All the patients were treated by endovascular-first approach. A total of 92 stents were used, of which 66.3% were balloon mounted, and they were located in the common iliac artery.
The technical success rate was 90%, and the ankle–brachial (A/B) index improved significantly (P=0.0001). The primary patency rates were 100, 81.8, and 80% at 6, 12, and 24 months, respectively. A total of 6.6% of patients developed major complications, which were successfully managed. Mortality rate was 2.2%, which was not procedure related.
Conclusion
The endovascular-first approach could be a good alternative and replace the standard surgical management for long, complex aortoiliac occlusive disease.

Keywords:
angioplasty, aortoiliac disease, endovascular intervention

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Introduction

Peripheral arterial disease (PAD) is pandemic, affecting 200 million people worldwide [1]. Aortoiliac occlusive disease represents 30% of all patients with PAD [2]. Atherosclerosis is the most common cause of occlusive disease affecting aortoiliac segment. It induces ischemia either by flow reduction to the distal arterial bed or by breaking down with embolization of its fragment occluding distal arterial vessels [3]. Atherosclerosis is the third leading cause of cardiovascular morbidity reducing quality of life even in patients classified as asymptomatic [4]. Endovascular approach recomended as a first intervention for aortoiliac occlusive disease by the the Society for Cardiovascular Angiography and Interventions (SCAI) [5], Trans-Atlantic Inter-Society Consensus (TASC) [6], and the American College of Cardiology and American Heart Association (ACC/AHA) guidelines, for TASC A and B [7]. Endovascular interventions performed in the aortoiliac segment offer a good technical success (>90%), low complication rate (2.7%) as compared with the standard surgical intervention, and good durability rate [8]. The aim of this study was to prospectively evaluate the technical and clinical success and patency rate over 24 months of endovascular intervention-first approach for symptomatic extensive TASC C and D aortoiliac disease.

Patients and methods

This was a prospective clinical study conducted at Kasr Ani University Hospital and National Institute of Diabetes and Endocrinology Disease over a 2-year

period starting from September 2014 till the end of September 2016.

This study was approved by the ethical committee of the Department of Vascular Surgery on 2014. All patients were informed about the risks and benefits of the procedure, and the written informed consents were obtained before enrollment.

The number of patients enrolled in this study was 50. All patients had PAD affecting the aortoiliac segment, which could be classified anatomically into either TASC II class C or D aortoiliac lesions. The recruited patients had incapacitating claudication in the buttock, thigh, and calf; ischemic rest pain (Rutherford class IV); tissue loss in the form of small ulcer (Rutherford class V); or gangrene (Rutherford class VI).

Patients who had limbs requiring primary amputation, patients with TASC II A or B aortoiliac lesions, patients who needed extra anatomic procedures for their lesions, patients with all arterial lesions associated with arterial–venous malformation, patients with all arterial lesions associated with aneurysmal dilatation, patients with connective tissue disorder or immunological disease, and patients who refused to participate were excluded from the study. All risk factors including smoking, diabetes, hypertension, ischemic heart disease, renal impairment, and cerebrovascular disease were determined and successfully controlled.

Interventions

All procedures were carried out under local anesthesia except for patients who experienced rest pain; the procedures for those patients were carried out under conscious sedation (midazolam, 1–2.5 mg) and intravenous analgesia.

The types of access were retrograde ipsilateral femoral, contralateral femoral with up and over the aortic bifurcation alone or in combination with antegrade brachial, or bilateral retrograde femoral. A 6-F sheath (Avanti, Cordis; Johnson and Johnson Company) was used; for contralateral cross-over aortic bifurcation approach the sheath was 45 cm long and for straight sheath through the brachial artery it was 90 cm long.

No re-entry devices were used. Hydrophilic normal-angled tip (0.035 or 0.018 inch, 260 cm) (Terumo guidewire; Terumo, Boston Scientific) was used to cross the lesion.

Predilatation was carried out using aortic balloon; 12–16 mm in diameter and 30–60 mm in length for aortic lesions and 5–8 mm in diameter and 20–80 mm length for iliac lesions. Inflation time ranged from 15 to 60 s. Balloon-expandable stents were inserted in the aortoiliac lesions and self-expandable stents in external iliac artery (EIA) lesions.

Technical success was assessed based on the presence of pulse distal to the treated segment. Angiographic success was assessed based on the good flow through the stented segment with no flow-limiting dissection or residual stenosis of more than 30%.

Sheath was removed immediately after the procedure using manual compression for 15–20 min. Patients was prescribed clopedogrel 75 mg once daily and acetylesalsylic acid 75 mg once daily on discharged. Patients were followed up for 1, 3, 6, and 12 months by clinical examination and duplex ultrasonography study. Restenosis was assessed using completion computed tomography angiography; reintervention was done when there was clinical indication.

Data analysis and statistical methods

Technical success was defined as good refilling in completion angiography with no residual hemodynamic (significant stenosis $\leq$30%), return of distal pulse or increase in ankle–brachial (A/B) index by 1.

Primary patency and limb salvage were determined. Loss of primary patency rate was determined based on the loss of previous palpable pulse and duplex ultrasonography findings.

The collected data were tabulated and statistically analyzed using statistical package for the social sciences (SPSS) software (version 18; SPSS Inc., Chicago, Illinois, USA). For quantitate data, mean, SD, median, and range were calculated. For qualitative data, number, percent, and distribution were calculated. Paired *t*-test was used to calculate the difference in the mean values of A/B index before and after intervention. For interpretation of the significance of the results, significance was adopted at *P* value less than or equal to 0.05.

Results

Over a period of 20 months, a total of 50 patients were prospectively enrolled in the treatment of aortoiliac lesions. At 12 months, clinical and duplex ultrasonography follow-ups were obtained for all patients.

Patients demographic, indication, and comorbidity

The number of patients eligible for this study, who fulfilled the inclusion criteria, was 50; of which 42 (84%) were men and 8 (16%) were women (Fig. 1). Their age ranged from 40 to 90 years, with a mean± SD of 58.7±8.9 years. Table 1 summarizes demography and comorbidity in the patients. A total of 22 (44%) patients presented with incapacitating claudication (Rutherford class III), 18 (36%) presented with rest pain (Rutherford class IV), seven (14%) presented with nonhealing ulcer (Rutherford class V), and three (6%) presented with gangrene proximal to metatarsal bone (Rutherford class VI) (Fig. 2).

The frequency of TASC II C and D is illustrated in Fig. 3. The total number of lesions was 113 in 50 patients, of which 86 lesions were total occlusion, whereas 27 were stenosis. Seven (14%) patients had aortic involvement, 13 (26%) had their common iliac artery (CIA) totally occluded, and 22 (44%) had had occlusive lesions involved both EIA and CIA (Table 2).

Technical details

Access

The types of access were single access in 12 (24%) patients, ipsilateral retrograde femoral approach in two (4%), contralateral cross-over approach in four (8%), and brachial approach in six (12%). Double access was used in 35 (70%) patients; bilateral femoral access was used in 21 (42%) patients, whereas combined femoral and brachial access was used in 14 (28%) patients. For three (6%) patients, triple access was used: bilateral femoral, popliteal, and brachial approaches. Hybrid technique was used in two (4%) patients (Table 3).

Crossing the lesion

In 20 (40%) patients lesions were crossed intraluminally and in 26 (52%) patients lesions were crossed subintimally, whereas in four patients lesions were failed to be crossed and they were excluded from further patency and follow-up analyses (Table 3). No re-entry devices were used.

Table 1 Summarizes demography and comorbidity in the patients

Variables	*N* (%)
Smoking habits	
Smoker	29 (58.0)
Nonsmoker	16 (32.0)
Ex-smoker	5 (10.0)
HTN	40 (80.0)
IHD	38 (76.0)
DM	38 (76.0)
Dyslipidemia	15 (30.0
CVS	8 (16.0)
Renal impairment	3 (6.0)

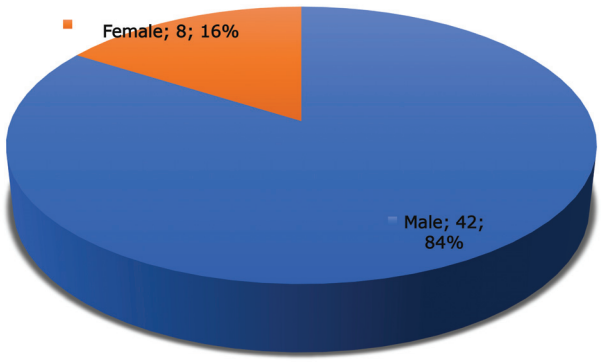
CVS, cerebrovascular stroke; DM, diabetes mellitus; HTN, hypertensive; IHD, ischemic heart disease.

Table 2 Summarizes different locations of the occlusive lesions and its percentages

Lesion positions	*N* (%)
CIA occlusion	13 (26.0)
Unilateral	2 (15.4)
Bilateral	11 (84.6)
CIA and its branches (EIA, CFA)	22 (44.0)
Unilateral	15 (68.2)
Bilateral	7 (31.8)
Occlusion below CIA (EIA, CFA, IIA)	8 (16.0)
Right	7 (87.5)
Left	1 (12.5)
Diffuse occlusive disease including aorta and iliac vessels	7 (14)

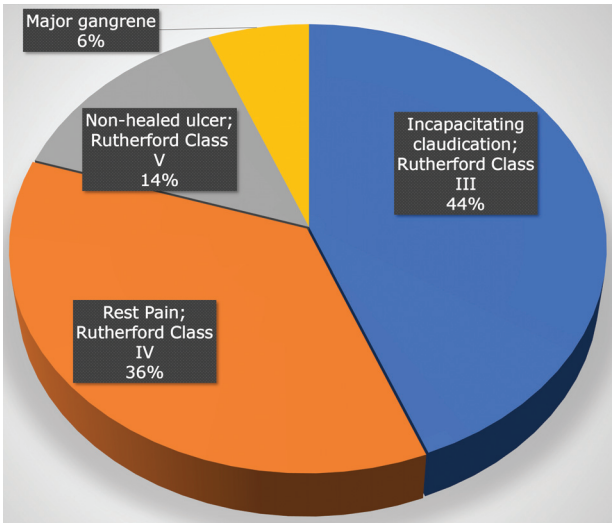
CFA, common femoral artery; CIA, common iliac; IIA, internal ilac artery.

Figure 1



Illustrates demography of the study group.

Figure 2



Illustrates the percentage of patients according to TASC classification.

Angioplasty and stenting

Balloon angioplasty was performed for all cases. A total of 95 stents were inserted in 50 patients; of which 63 (66.3%) stents were balloon-expandable and 25 (26.3%) were self-expandable stents inserted in iliac lesions. One of those stents was covered stent, which was inserted after the artery was injured during angioplasty. Seven (7.4%) stents were self-expandable stents inserted in the aortic lesions (Fig. 4).

Table 3 Illustrates details of intervention; access site location, method of recanalization, and the procedure done

Variables	*N* (%)
Number of access [median (range)]	2 (1–3)
Used access	
Ipsilateral femoral only	2 (4.0)
Contralateral femoral only	4 (8.0)
Brachial access only	6 (12.0)
Two access	
Bilateral access	21 (42)
Femoral/popliteal+brachial	14 (28)
Three access	3 (6)
Crossing the lesion	
Subintimal	26 (52.0)
Intraluminal	20 (40.0)
Failed to cross the lesion	4 (8.0)
Angioplasty	
Done	47 (94.0)
Failed	3 (6.0)

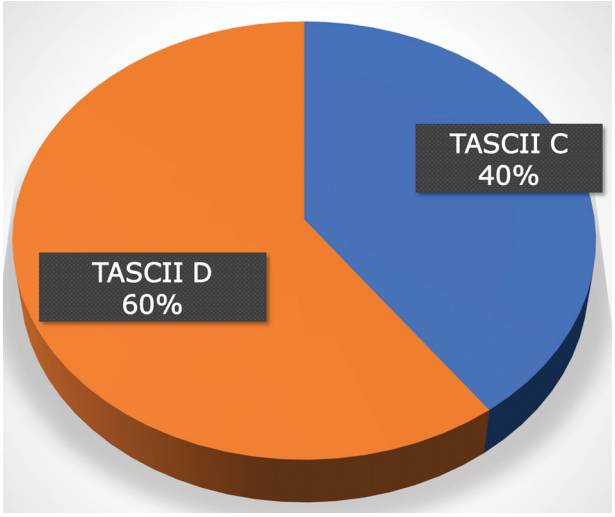
Success rate

Technical success was achieved in 45 of 50 (90%) patients (Table 4). All 45 patients completed follow-up of 6 months, 33 patients completed follow-up of 12 months, and 10 patients completed follow-up of 24 months (Fig. 5). The primary patency rates were 100, 81.8, and 80% for 6, 12, and 24 months, respectively (Table 5). Limb salvage rate was 91.1% (Table 6) and the A/B index increased significantly from 0.39±0.07 to 0.73±0.08 ($P \leq 0.0001$) (Table 7). Three of 50 (6.6%) patients experienced major complications including acute renal failure (2.2%) and retroperitoneal hematoma (2.2%). Eleven of 50 (22.2%) patients had minor complications: 8.9% had access-site hematoma and 13.3% had minor dissections, which were treated with prolonged balloon inflation and/or stenting (Table 8).

Table 4 Illustrate percentage of both technical and clinical success rates

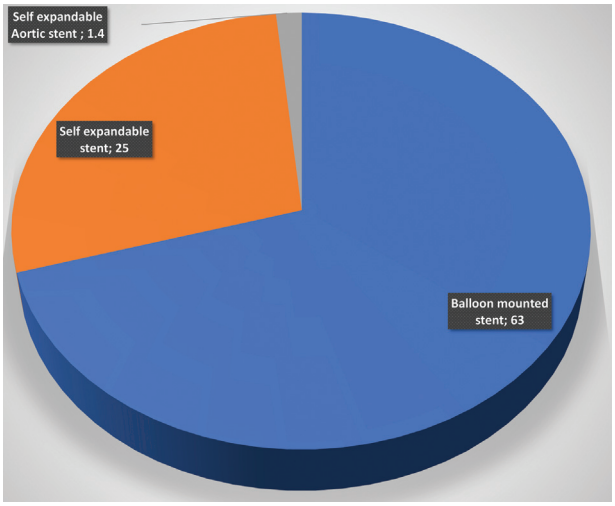
Variables	*N* (%)
Technical success	
Regain femoral pulse in one limb	18 (36.0)
Regain femoral pulse in both	27 (54.0)
Failed	5 (10.0)
Clinical success	
Successful	45 (90)
Failed	5 (10)

Figure 3



The frequency of TASC II C and D.

Figure 4



Percentage of type of inserted stent.

Table 5 Illustrate the patency rate in the follow up period

	Follow-up period				
	1 month	2 months	6 months	12 months	24 months
N	45	45	45	33	10
Patency rate [*n* (%)]	45 (100)	45 (100)	45 (100)	27 (81.8)	8 (80)

Discussion

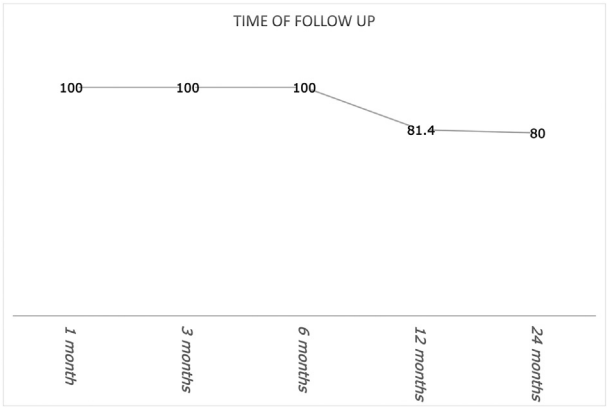
Although endovascular approach as the first approach for aortoiliac atherosclerotic occlusive disease is the standard, TASC II recommends surgical intervention for TASC C and D lesions, which are long, complex, and extensive, because of its durability [9]. Multiple meta-analysis studies encourage endovascular intervention for long, complex TASC C and D lesions. These studies as well as other studies have documented high technical success rate and good primary and secondary patency rate [4], which was comparable to the results of this study.

Sophisticated analysis of the results of this study confirmed better technical and clinical success and extended primary patency rate up to 24 months; and limb salvage rate was better than what published in literature insite of the high percentage of patients had critical limb ischemia (CLI) (66%) included in this study compared to what published literature (20–42%) [10,11]. In this study the limb salvage rate was high (91.1%) and the A/B index significantly improved after intervention (P=0.0001). The prognosis of diagnosed patients with CLI is dismal; the rate of major amputation and limb loss is about 10% per year. All-cause mortality rate is very high and reaches up to 26.8% in 2 years [12]. Endovascular-first approach improved the rate of limb loss (2.2%) and mortality (4.4%) in the population of this study.

Ante-grade approach was preferred in complex lesions (where distal aorta involved in the occlusive lesion); recanalization using brachial access allows successful recanalization, with less complication at the targeted segment and the access site [10,13–16]. In spite that recanalization devices were not used, the technical success rate was 90%. Failure rate was due to complete total occlusion (CTO) lesion in CIA with no proximal stump, and heavily calcified aorta precluded retrograde ipsilateral femoral access in those patients.

EIA perforation and retroperitoneal hematoma occurred in 2.2% of cases, which was managed using

Figure 5



Illustrates the follow up patency rate.

Table 6 Illustrate the limb salvage rate

Limb salvage	*N* (%)
Limb salvage	41 (91.6)
Metatarsal amputation	3 (6.7)
Above-knee amputation	1 (2.2)

Table 7 Illustrate the significance of improved Ankle/brachial index with the intervention

	Ankle–brachial index
Preintervention	0.39
Postintervention	0.73
P value	0.0001

Table 8 Illustrates the percentages of morbidities in the study group

Variables	Cases with success (*N*=45) [*n* (%)]	Cases with failure (*N*=5) [*n* (%)]
Major morbidities	6.6	
No major morbidities	42 (93.4)	4 (80.0)
Retroperitoneal hematoma and perforation	1 (2.2)	0 (0.0)
Thrombosis and intestinal ischemia	0 (0.0)	1 (20.0)
Acute stent thrombosis	1 (2.2)	0 (0.0)
ARF	1 (2.2)	0 (0.0)
Minor morbidities	22.2	
No minor morbidities	35 (77.8)	4 (80.0)
Dissection	6 (13.3)	1 (20.0)
Access hematoma	3 (6.7)	0 (0.0)
Access hematoma and dissection	1 (2.2)	0 (0.0)
Mortality		
Alive	43 (95.6)	5 (100.0)
Dead (cases of multiple organ failure, MI)	2 (4.4)	0 (0.0)

MI, myocardial infarction.

covered stent. One case developed extensive dissection in the aortoiliac segment, which was later complicated by acute ischemia, for which the patient was transferred to surgery. A total of 13.3% of the treated vessels had minor dissection managed with stent deployment. Access-site hematoma was seen in 8.9%, which was managed conservatively. The increasing innovations in endovascular tools extend the application of endovascular intervention, encourage surgeon, and release their fear of surgical conversion in cases where endovascular complications occur.

Conclusion

Endovascular-first approach for the management of complex aortoiliac lesions is effective, feasible, with high success rate and less complication rate. Endovascular management of TASC C and D iliac lesions could be an alternative to standard surgical approach. The evolution in endovascular tools and expertise allow successful management of complicated revascularization of aortoiliac segment.

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Nil.

Conflicts of interest

There are no conflicts of interest.

References

1 Fowkes FG, Rudan D, Rudan I, Aboyans V, Denenberg JO, McDermott MM, *et al.* Comparison of global estimates of prevalence and risk factors for peripheral artery disease in2000 and 2010: a systematic review and analysis. Lancet 2013; 382:1329–1340.

2 Zeller T. Current state of endovascular treatment of femoropopliteal artery disease. Vasc Med 2007; 12:223–234.

3 Nagarsheth KH, Talavera F, Rowe VL, McIntyre KE, Kaufman JL. Aortoiliac occlusive disease: background, pathophysiology, etiology. Available at: https://emedicine.medscape.com/article/461285-overview. [Last accessed 2017 Aug 21].

4 Klein AJ, Ross CB. Endovascular treatment of lower extremity peripheral arterial disease. Trends Cardiovasc Med 2016; 26:495–512.

5 Klein AJ, Pinto DS, Gray BH, Jaff MR, White CJ. SCAI expert consensus statement for aorto-iliac arterial intervention appropriate use. Catheter Cardiovasc Interv 2014; 84:520–528.

6 Goode SD, Cleveland TJ, Gaines PA; STAG Trial Collaborators. Randomized clinical trial of stents versus angioplasty for the treatment of iliac artery occlusions (STAG trial). Br J Surg 2013; 100:1148e53.

7 Rooke TW, Hirsch AT, Misra S, Sidawy AN, Beckman JA, Findeiss LK, *et al.* 2011 ACCF/AHA focused update of the guideline for the management of patients with peripheral artery disease (updating the 2005 guideline): are port of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines: developed in collaboration with the Society for Cardiovascular Angiography and Interventions, Society of Interventional Radiology, Society for Vascular Medicine, and Society for Vascular Surgery. Catheter Cardiovasc Interv 2011; 79:501–531.

8 Norgren L, Hiatt WR, Dormandy JA, Nehler MR, Harris KA, Fowkes FG. Intersociety consensus for the management of peripheral arterial disease (TASC II). J Vasc Surg 2007; 45(Suppl S):S5–S67.

9 Iida O, Soga Y, Takahara M, Kawasaki D, Yamauchi Y, *et al.* Perioperative complications after aorto-iliac stenting: associated factors and impact on follow-up cardiovascular prognosis. Euro J Vasc Endovasc Surg 2014; 47:131–138.

10 Millon A, Della Schiava N, Brizzi V, *et al.* The anti-grade approach using trans-brachial access improves technical success rate of endovascular revascularization of TASC C and D aortoiliac occlusion in case of failed femoral access. Ann Vasc Surg 2015; 29:1346–1352.

11 Balzer JO, Gastinger V, Ralf R, Herzog C, Martin G, Mack MG, *et al.* Percutaneous intervention reconstruction of iliac arteries: primary and long-term success rate in selected TASC C and D lesions. Eur Radiol 2006; 16: 124–131.

12 Cooper KJ, Peña C, Benenati J. Determining end points for critical limb ischemia interventions. Tech Vasc Interv Radiol 2016; 19:104–112.

13 Douslouglu HH, Lall P, Cherr PS, Harris LM, Dryjski ML. Role of simple hypird revascularization procedures for symptomatic lower extremity occlusive disease. J Vasc Surg 2010; 51:1425–1435.

14 Okan U, Oguzurt L, Tercan F. Technique complication and long-term outcome for endovascular treatment of iliac artery occlusion. Cardiovasc Interv Radiol 2010; 33:18–24.

15 Yuan L, Bao J, Zaho Z, Feng X, Lu Q, ZaipingJing Z. Endovascular therapy for long term atherosclerotic aortoiliac occlusion. J Vasc Surg 2014; 59:663–668.

16 Yuan L, Bao J, Zaho Z, *et al.* Transbrachial and femoral artery approach endovascular therapy for flush infra renal aortic occlusion. Euro J Vasc Endovasc Sur 2010; 48:46–452.