Midterm Outcomes of Endovascular Treatment of TransAtlantic Inter-Society Consensus Class C &D Aortoiliac Occlusions

Ahmed El-Marakby[1], Ahmed Faragaly[1]
Assistant Professor in Vascular Surgery Department,
General Surgery Division, Cairo University

ABSTRACT

Objective: *Management of TransAtlantic Inter-Society Consensus for the Peripheral Arterial Disease (TASC II) class C & D total aortoiliac occlusions is traditionally by open surgery. The aim of this study was to evaluate our centers' outcomes treating TASC II C & D lesions by the endovascular approach.* ***Methods:*** *This is a retrospective review of all percutaneous interventions for TASC II type C & D aortoiliac occlusions performed between Jan 2012 and Dec 2015. Preoperative demographic data, risk factors for atherosclerosis, clinical symptoms, and postoperative follow-up were evaluated.* ***Results:*** *During this time period, 56 patients underwent endovascular repair for symptomatic TASC II type C & D aortoiliac occlusions. Primary technical success was achieved in all patients except one (98%) by percutaneous access via retrograde femoral approach. Additional brachial access in nine of these patients was performed. One patient (2%) had failed recanalization & converted to open surgery. Balloon and self-expandable either bare metal (we used nitinol only) or covered stents were used. The balloon expandable covered stents were V12 (Atrium) and the self-expandable covered ones were the Viahaban (Gore) stents. Average intervention time was 111 minutes; with average 155 mL contrast was used. Minor postoperative complications were observed in 12 of 55 (21.8%) patients. Six patients (10.9%) had major complications that required interventions. We didn't have any peri-intervetoinal mortality. Median length of stay was 2 days. The average follow-up was 10.0 months. Therapy failed in one patient at 20 months his leg became unsalvageable despite revascularization. Primary and secondary patency rates (at one year follow-up) were (48/55, 87.2%) and (50/55, 90.9%) respectively.* ***Conclusions:*** *An endovascular approach to complex total aortoiliac occlusions is feasible and shows promising midterm results with effective resolution of symptoms, low mortality rates, and short hospital stay according to this small series. Further prospective studies and longer-term follow-up are needed to confirm these results.*

INTRODUCTION

In 2007, the Trans-Atlantic Inter-Society Consensus (TASC) classification was revised to TASC-II, in which the adaptive range of lesion morphologies indicated for endovascular treatment was broadened for the aorto-iliac arteries [1, 2].

Table: ITASC morphologic stratification of iliac lesions

Type	*Definition*
A	Single stenosis of CIA or EIA <3 cm long (unilateral or bilateral)
B	Single stenosis 3-10 cm long, not extending into CFA
	Two stenoses of CIA or EIA not involving CFA <5 cm
	Unilateral CIA occlusion
C	Bilateral stenoses of CIA and/or EIA not involving CFA 5-10 cm long
	Unilateral EIA occlusion not involving CFA
	Unilateral EIA stenosis extending into CFA
	Bilateral CIA occlusion
D	Diffuse stenosis of entire CIA, EIA, and CFA of >10 cm
	Unilateral occlusion of CIA and EIA
	Bilateral EIA occlusions
	Iliac stenosis adjacent to aortic or iliac aneurysms

CIA, Common iliac artery; *EIA*, external iliac artery; *CFA*, common femoral artery.

METHODS

Patient population:

According to a review of the endovascular registry database for our department, 56 consecutive patients with iliac occlusive lesions classified TASC II C&D, underwent endovascular recanalization using primary stenting between 2012 and 2015. In our centers, patients with intermittent claudication corresponding to Rutherford class 2 to 3 and patients with critical limb ischemia & major tissue loss corresponding to Rutherford class 4 to 6 are considered to undergo endovascular treatment. 29 of the patients had TASC II D lesions(51.78%). The age of patients ranges between 39 to 71 years. Half of those patients (28) were male. Median duration of follow-up was 12 months (range, 1-37 months). The number of patients with intermittent claudication corresponding to Rutherford class 2 to 3 was 33 (58.9%), and the number of patients with critical limb ischemia & major tissue loss corresponding to Rutherford class 4 to 6 was 23 (41%). Preoperative ankle brachial index (ABI) was 0.56±0.23. Lesion length ranges from 4.2 cm to 10,1.

Table I Showed the summary of patient demographic features & risk factors.

Demographic features	***No.***	***%***
Male	28	50%
Diabetes	22	39.2%
Hypertension	49	87.5%
IHD	41	73.2%
Hyperlipidemia	51	91%
Chronic renal failure (on dialysis)	11	19.6%
Hemodialysis	2	3.5%
Cerebrovascular disease	4	7.1%
Smoking	44	82.1%

Table II showed the Rutherford categories for all patients.

Rutherford category	***No.***	***%***
II	4	7.1%
III	29	51.7%
IV	9	16%
V	11	19.6%
VI	3	5.3%

Table III showed lesions characteristics, stents types & the procedures.

Characteristic features	***No.***	***%***
Lesion site		
Aorto iliac	9	16.3%
CIA	35	61.8%
EIA	5	9%
CIA & EIA	7	12.7%
Lesion type		
Stenosis	7	12.7%
Occlusion	49	87.3%
Lesion classification (TASC II, 2007)		
D	29	51.79%
C	27	48.21%
Number of stents per patient		
1	20 patient	36.3%
2	17 patient	30.9%
3	5 patient	9%
4	8 patient	7.2%
5	1 patient	1.8%
6	4 patient	10.9%
Stent type		
Balloon-expandable nitinol	96	73.8%
Self-expandable nitinol	14	10,8%
Balloon-expandable covered (V12)	12	9.2%
Self-expandable covered (Viahaban)	8	6.2%
Procedure		
Kissing stenting	16	27.2%
Kissing & iliac stenting	4	7.2%
Bilateral iliac stenting	2	3.6%
Unilateral iliac stenting	33	60%

Endovascular procedure & follow up

All patients were done in our angio sweet and all procedures were done under local anesthesia. Percutaneous retrograde femoral approach was our standard access. Puncture of pulseless femoral artery was achieved using one or combination of few techniques; the calcified vessel is often palpable, under fluoroscopic guidance which will show calcium in vessel wall that helps to guide the puncture or under Duplex guidance through percutaneous retrograde femoral artery approach in all patients. We used an additional access through percutaneous antegrade brachial approach only in 6 occasions (10.71%)

Occlusions or stenoses were passed using a 0.035-inch hydrophilic guidewire (Terumo). According to our standard protocol, common iliac artery (CIA) occlusion was treated using a retrograde approach, while external iliac artery (EIA) occlusion was recanalized with either with antegrade approach by brachial access or cross over technique via the contralateral femoral. Recanalization for combined occlusions of both the CIA and EIA was initially attempted using a retrograde approach. In cases of iliac occlusions that were difficult to pass through using only a single approach, bi-directional approaches (ante- and retrograde) with or without the pull-through technique was used. The pull-through technique is the method used in which the guidewire is caught by the snare catheter advanced from the contralateral femoral artery. For all patients, primary stenting was systematically performed with or without pre-dilatation using small-diameter balloons, and with post-dilatation for self-expandable stents. We usually used 4 or 5 mm for pre-dilatation, which was about a half diameter of the targeted vessel. Self-expanding stents were mainly used at diffuse lesions, particularly in the EIA. Conversely, balloon-expandable stents were placed at heavily calcified lesions and/or short segments, particularly in the CIA. Covered stents either self-expandable or balloon ones were selected in some cases with presence of thrombosis or associated with aneurysmal dilatation. During the procedures, heparin was injected at 100 unit/kg body weight. According to our standard protocol, Aspirin 100mg once daily was administered from the initial visit and continued permanently. However, clopidogrel 75 mg once daily was administered for diabetic patients and those with coronary artery disease treated with stent.

Our general follow-up protocol included assessment of symptoms, clinical examination, and ABI before discharge and at 30 days, 3 months and every 3 months after stenting. Duplex ultrasonography was performed before discharge and at 3 months, 6 months, 1 year, and each subsequent year after stenting. Symptoms and resting ABI were mainly used for assessing clinical patency. If resting ABI decreased >0.15 compared with the pre-discharge baseline, duplex ultrasonography was performed to check for restenosis or de novo lesions. For patients showing restenosis >50% or de novo lesions on duplex ultrasonography, computed tomographic angiography (CTA) or angiography was performed to confirm the lesion. If more than 50% stenosis or occlusion was confirmed on the angiography or CTA and the symptom recurred, we planned to perform endovascular reintervention. During the follow up period, the following parameters were investigated including technical success rate; procedure time; prevalence of complications and cumulative patency rates (primary and secondary)

RESULTS

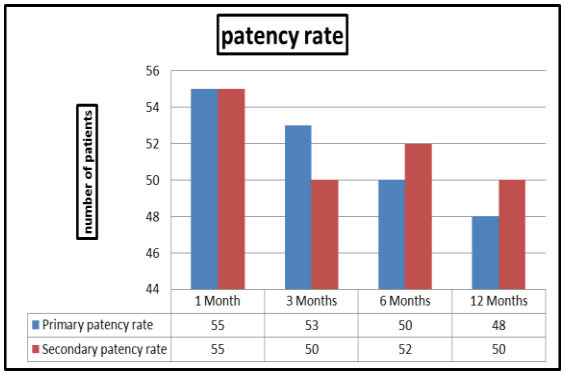
Technical success & complications

Successful primary revascularization with primary stenting was achieved in 55 of 56 patients (98%). The average number of stents used was (2.3)/procedure. The average procedure times were 110±38 minutes and the average amount of contrast was used 150 ml (range 100ml to 300 ml). 12 patients (21.8%) suffered of minor complications that required extension of hospitalization for another 1 or 2 days. These minor complications include 7 patients developed small minor hematomas at access sites and were treated conservatively; three patients suffered of mild contrast induced nephropathy and renal functions returned to normal levels with fluids & N- Aceytal cysteine and Bicarbonate infusion and the other 2 patients developed minor skin allergy from the contrast that resolved by antihistaminic and hydrocortisone administration within 24 hours. Major complications occurred in 6 patients (10.9%). Rupture of the iliac artery in one patient, flow-limiting dissection in one patient, distal embolism in one patient, pseudoaneurysm of the

access site in 2 patients and acute renal failure in one patient. Extravasation from the ruptured iliac artery was successfully treated with placement of an additional covered stent. In the patient with distal embolization during the recanalization procedure, embolectomy was performed using a Fogarty catheter via corresponding common femoral artery, Pseudoaneurysm formation at the access site in two patients were treated successfully with duplex guided compression. No periprocedural deaths were observed. One unilateral above knee amputation was performed during follow up period in spite of revascularization due to severe infection and sepsis.

Mid-term results

Cumulative primary patency rates at 1, 3, 6, and 12 months were (55/55, 100%), (53/55, 96.3%), (50/55, 90.9%), and (48/55, 87.2%) respectively. During follow up of the ankle brachial index (ABI) was measured and if it dropped by more than 0.15, duplex examination is done. Any lesion was detected with recurrent stenosis more than 50%, secondary intervention was carried on either directly or after completion CT angiography. Balloon angioplasty was done in two patients at 6 months follow up increasing the secondary patency rate to 94.5% (52/55). Another two patients required balloon angioplasty with stenting at 1 year follow, increasing the secondary patency rate to 90.9% (50/55).



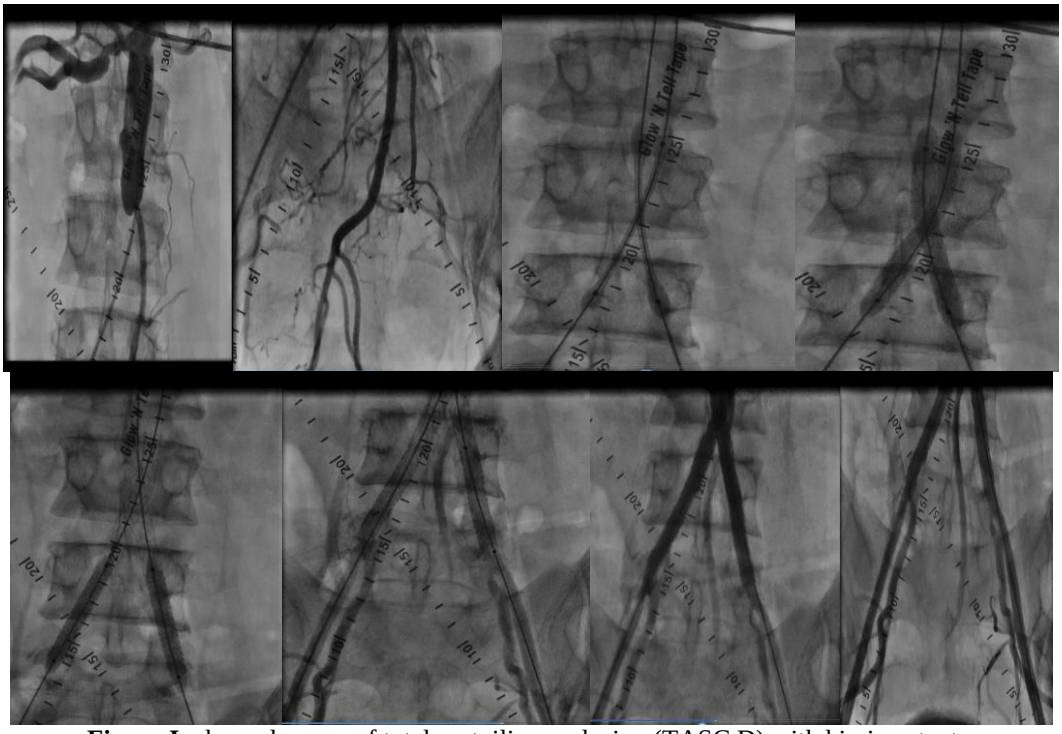


Figure I: showed a case of total aortoiliac occlusion (TASC D) with kissing stents.

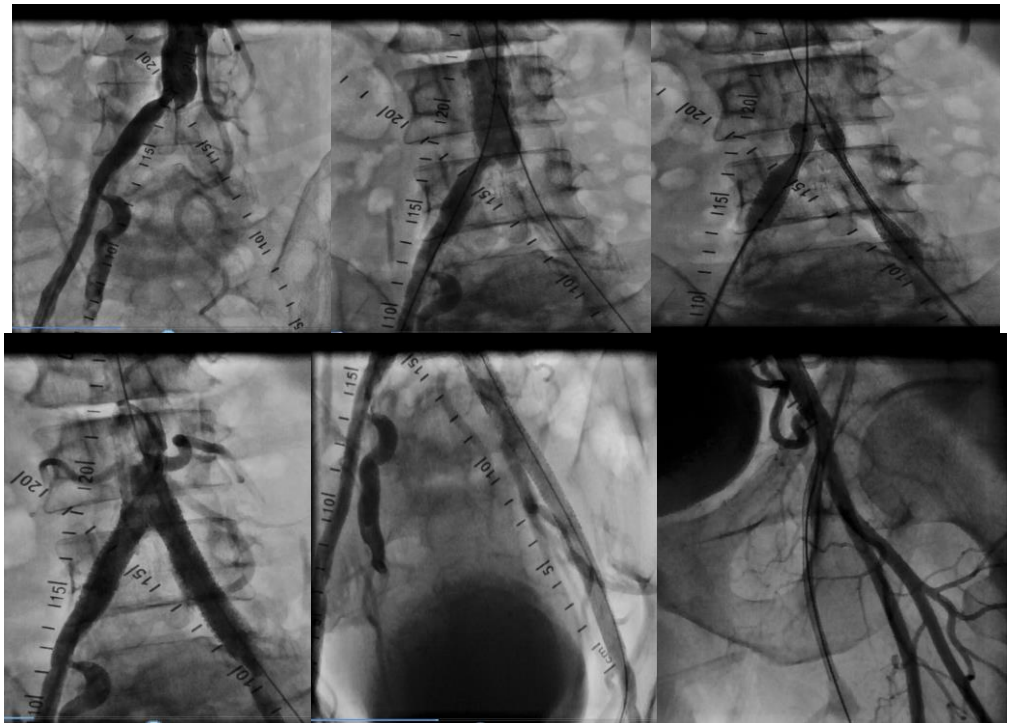


Figure II: Showed TASC D lesion of total CIA & EIA recanalization

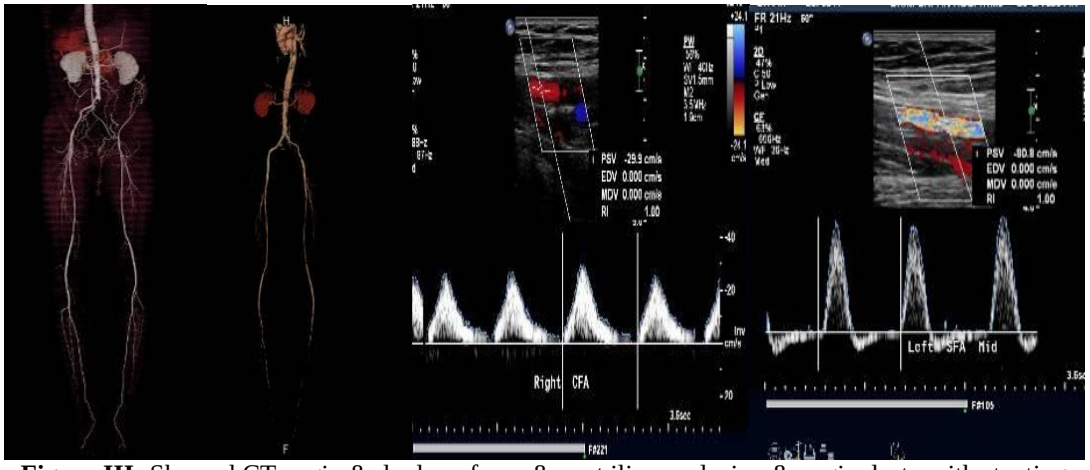


Figure III: Showed CT angio & duplex of pre & post iliac occlusion & angioplasty with stenting

Figure IV showed left total iliac occlusion with complete recanalization.

DISCUSSION

Despite the well-documented durability, effectiveness, and increasing safety of Aorto-Bifemoral bypass, which have justifiably established itself as the gold standard of revascularization for aortoiliac occlusive disease, it is noted that this procedure is being used less frequently in current practice.

Data from multiple sources clearly indicate that the percentage of patients with aortoiliac disease treated by direct aortic grafting is declining. Increasing use of alternative therapies, PTA, for treatment of symptomatic aortoiliac disease is attributable to several factors. The potential advantages of alternative therapies are indeed attractive: reduced risk of morbidity and mortality, reduced hospital stays, quicker recovery, and the perceived cost advantages stemming from these characteristics.

Nonetheless it is also important to recognize possible disadvantages of this method as well. They are almost certainly less durable than ABF, more often incomplete revascularization, and less applicable to patients with extensive patterns of disease. All of these potential deficiencies may blunt possible cost benefits [3, 9].

In a prospective study done in Toronto in late 90s, results of 667 iliac PTA procedures demonstrated that chances of long-term success can be accurately predicted depending on four key variables: indication, site, severity, and runoff. In the most favorable circumstance, that of a localized common iliac stenosis in a patient with claudication alone and good runoff, a 3-year patency rate of 68% was noted. Conversely, for common or external iliac occlusion in patients with limb-threatening ischemia and poor runoff, a successful result was noted in only 10% to 20% of patients in 3 years follow up. Overall, the 3-year success rate of iliac PTA determined in the Toronto experience was approximately 60%, certainly considerably inferior to that routinely achieved in all surgical series [4, 5].

A true comparison of iliac PTA with ABF is difficult, because the anatomy (distribution and extent) and severity of disease are usually quite different in patients selected for each method of treatment. Few randomized prospective data exist. In one study by Wilson et al comparing patients with limited disease suitable for treatment by either modality, the overall cumulative long-term success rate favored surgery (81% vs 62% success rate at 3 years). This statistically significant difference between surgery and PTA was due almost entirely to the initial failure rate of PTA (15.5%) rather than to late PTA failures **6**. In a similar randomized prospective trial from Holm et al in Sweden, immediate and 1-year results of PTA and surgery were equivalent, and patients who underwent PTA had a significantly shorter hospital stay. It is important to note, however, that only patients who could be treated by both methods were included, constituting only 5% of the total number of patients treated during the study period. It appears reasonable to conclude at

present that iliac PTA does have an established and valuable role in the treatment of selected patients with aortoiliac disease and should be considered as potential primary therapy, if the chances of long-term success are good. Proper criteria for its use have been fairly well established and consist principally of localized disease, ideally short stenotic lesions in the common iliac arteries [7, 10, 11].

One study compared early and midterm outcomes of polytetrafluoroethylene-covered stents (CSs) vs bare-metal stents (BMSs) in the primary treatment of severe TransAtlantic Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II) C and D iliac artery obstructive lesions. Overall, the use of CSs for severe iliac lesions has similar early and midterm outcomes compared with BMS. In a subcategory of TASC II D lesions with long-segment severe stenosis of both the common and external iliac arteries, CS should be considered as the primary line of treatment have reported preliminary results in several abstracts of a widely cited prospective randomized study comparing balloon angioplasty and stenting for iliac artery disease; however, a detailed publication is still not available nearly 4 years later despite widespread claims of superior results with stents. The interim data do suggest a clear advantage for the routine use of stents, with a 92.7% 5-year clinical success rate for iliac stenting compared with 69.7% for PTA alone [8].

REFERENCES

1. Norgren L, Hiatt WR, Dormandy JA, et al. Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II). J Vasc Surg 2007; 45 Suppl S:S5.
2. Jaff MR, White CJ, Hiatt WR, et al. An update on methods for revascularization and expansion of the TASC lesion classification to include below-the-knee arteries: A supplement to the inter-society consensus for the management of peripheral arterial disease (TASC II): The TASC steering committee. Catheter Cardiovasc Interv 2015; 86:611.
3. Rutherford RB, Baker JD, Ernst C, et al. Recommended standards for reports dealing with lower extremity ischemia: revised version. J Vasc Surg 1997; 26:517.
4. Bosch, J.L. and Hunink, M.G. Meta-analysis of the results of percutaneous transluminal angioplasty and stent placement for aortoiliac occlusive disease. Radiology. 1997; 204: 87–96
5. Hood, D.B. and Hodgson, K.J. Percutaneous transluminal angioplasty and stenting for iliac artery occlusive disease. Surg Clin North Am. 1999; 79: 575–596
6. Wilson, S.E., Wolf, G.L., Cross, A.P., and Veterans Administration Cooperative Study No 199. Percutaneous transluminal angioplasty versus operation for peripheral arteriosclerosis(report of a prospective randomized trial in a selected group of patients) . J Vasc Surg. 1989; 9: 1–9
7. Holm, J., Arfvidsson, B., Jivegard, L. et al. Chronic lower limb ischaemia(a prospective randomised controlled study comparing the 1-year results of vascular surgery and percutaneous transluminal angioplasty (PTA)) . Eur J Vasc Surg. 1991; 5: 517–522
8. Cull DL, Manos G, Hartley MC, et al. An early validation of the Society for Vascular Surgery lower e de Vries, S.O. and Hunink, M.G. Results of aortic bifurcation grafts for aortoiliac occlusive disease(a meta-analysis) . J Vasc Surg. 1997; 26: 558–569
9. Brewster, D.C., Perler, B.A., Robison, J.G., and Darling, R.C. Aortofemoral graft for multilevel occlusive disease(predictors of success and need for distal bypass) . Arch Surg. 1982; 117: 1593–1600
10. Ballard, J.L., Bergan, J.J., Singh, P., Yonemoto, H., and Killeen, J.D. Aortoiliac stent deployment versus surgical reconstruction (analysis of outcome and cost). J Vasc Surg. 1998; 28: 94–101
11. Sapoval, M.R., Chatellier, G., Long, A.L. et al. Self-expandable stents for the treatment of iliac artery obstructive lesions(long-term success and prognostic factors) . AJR. 1996; 166: 1173–1179