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Feasibility of endovascular treatment of TASC (C&D) aorto-iliac complex lesions

Ahmed Zaky Elsayed , Sherif Anwar Balbaa , Engy Tawfik Hefnawy, Hossam ELMahdy

Vascular Surgery Department, Faculty of Medicine, Cairo university, Egypt

Corresponding author: Ahmed Zaky Elsayed

Email: Zaki.kasr@gmail.com

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Abstract: **Background:** Open surgery is the traditional treatment of aortoiliac TASC type C and D lesions. However, as morbidity and mortality rates of open surgery are not negligible, endovascular treatment has emerged as a less invasive option over the last decade. **Objective:** TO report feasibility, Safety and effectiveness of endovascular treatment of TASC II type C&D aorto iliac complex lesions. **Methods:** This is a single -center, prospective, non-randomized, clinical trial that was conducted in Cairo university, vascular surgery unit. We performed a prospective and descriptive analysis of 60 endovascular interventions for TASC C-D lesions performed from June 2019 to December 2020, to evaluate technical success, perioperative mortality and patency. **Results:** Technical success was achieved in the 57 (95%) lesions treated. Primary patency was 89.3% after a mean follow-up of 12 months. Cumulative mortality was 0.02% (1 patients) during follow-up which was not procedure related. **Conclusion:** In our experience, endovascular treatment of aortoiliac TASC type C and D lesions is a feasible and safe procedure with a high recanalization rate. Endovascular treatment of this type of lesions could be considered a valid option if these findings are confirmed in large, randomized, controlled trials comparing this strategy with surgery.

Keywords: endovascular treatment; iliac occlusive disease;. angioplasty, aortoiliac disease

Introduction

Open surgery is the traditional treatment of aortoiliac TASC type C and D lesions. However, as morbidity and mortality rates of open surgery are not negligible, endovascular treatment has emerged as a less invasive option over the last decade **(1)**

However, with the rapid advancement of endovascular technology and equipment, the success rate of endovascular treatment has continuously increased, and the patency rate has also been significantly increased. Therefore, more clinicians and patients have chosen to first attempt endovascular intervention. **(2)**

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. **(3)**

Zhou et al. (4) noted that according to characteristics of the disease, endovascular treatment with an individualized, rational choice of approach and with fine-tuning of the operation is a safe and effective

treatment for long-term complex iliac artery occlusion, Customization of the treatment is also the key to a successful operation and to ensure good postoperative efficacy.

The aim of the study was to prospectively evaluate the technical success and patency rate over 12 months of endovascular intervention for TASC C&D aorto-iliac complex lesions.

Patients and Methods

This is a single -center, prospective, non-randomized, clinical trial that was conducted in Cairo university, vascular surgery unit over 60 patients who were recruited since June 2019 to December 2020.

Inclusion Criteria:

Patients with PAD affecting the aortoiliac segment, which could be classified anatomically into either TASC II class C or D aortoiliac lesions

Exclusion criteria:

- Patients with limbs requiring primary amputation
- Patients with TASC II A or B aortoiliac 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

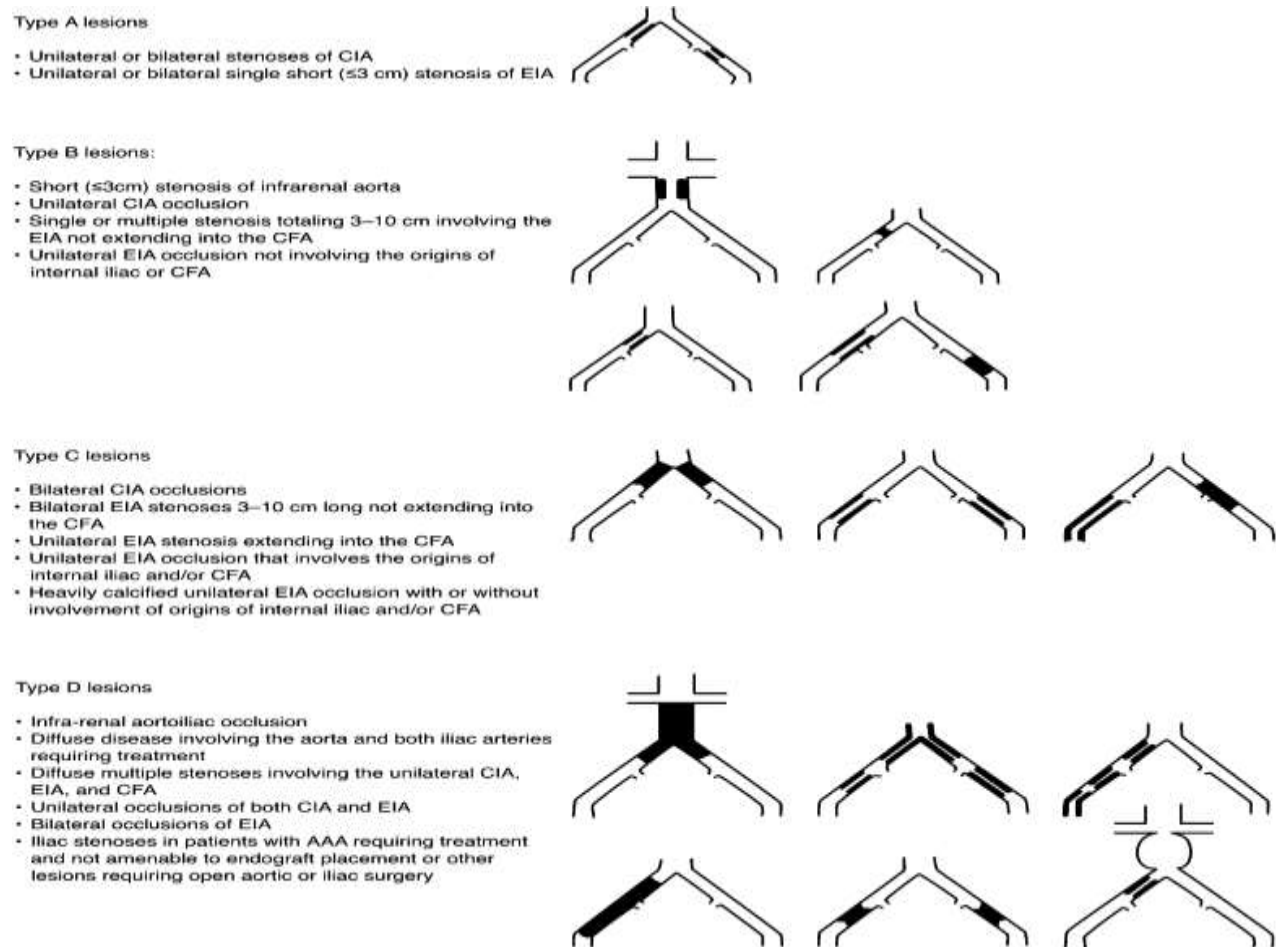


Figure (1) showing The TASC II classification of aortoiliac lesions (5).

Sixty patients with peripheral arterial disease affecting aortoiliac segments classified as TASC (C and D) lesions were recruited.

The recruited patients had incapacitating claudication in the buttock, thigh, and calf (Rutherford class III); ischemic rest pain (Rutherford class IV); tissue loss in the form of small ulcer (Rutherford class V); or gangrene (Rutherford class VI).

General measures were followed:

All patients were consented for the targeted treatment. Full vascular assessment was done for all patients, to assess the need for a revascularization procedure prior to the treatment. Laboratory investigations (complete blood picture, serum creatinine prothrombin activity) as well as arterial Duplex or CTA for all patients. All cases were instructed to visit our unit at scheduled session every week for a maximal follow up period of 12 weeks. All cases were reviewed concerning the demographic data and the associated comorbidities i.e.: age, sex, hypertension, IHD, previous stroke. All risk factors including smoking, diabetes, hypertension, ischemic heart disease, renal impairment, and cerebrovascular disease were controlled. Approval from ethical committee in Cairo university vascular surgery unit, general surgery department was taken prior to the beginning of the study.

Procedure:

The procedures were performed in the endovascular suite of vascular surgery unit ,Kasr EL-Ainy hospital , Cairo university . All the procedures were performed under local anesthesia supplemented with intravenous sedation and analgesia when required . General anesthesia was needed in non-cooperative patients and/or complex hybrid intervention .An intra-arterial bolus of heparin of 5,000 IU was given to every patient. All the arterial punctures were performed under U/S guidance. .Clinical success was defined as improvement in walking distance, absence of rest pain, and healing of trophic lesion changes after stent placement. Patency was defined as stenosis less than 50% by duplex ultrasound.

Follow up

Monthly follow up was performed up to 12 months by checking the femoral pulse bilaterally, measuring PSV at CFA by duplex, improvement of symptoms and comparing the results in an excel sheet for every patient. Minor and major complications were assessed during the follow up and recorded. Angiography was performed in the case of recurrence of symptoms, , or suspicion of restenosis in color-coded duplex scan because of an increase of peak systolic velocity ratio.

Statistical analysis

Data were coded and entered using the statistical package for the Social Sciences (SPSS) version 26 (IBM Corp., Armonk, NY, USA). Data were summarized using mean, standard deviation, minimum and maximum in quantitative data and using frequency (count) and relative frequency (percentage) for categorical data. Comparisons between quantitative variables were done using the non-parametric Mann-whitney test. For comparing categorical data, chi square (X^2) test were performed. Exact test was used instead when the expected frequency is less than 5. Survival curves were plotted by the Kaplan – Meier method and were compared using the long – rank test.P-values less than 0.05 were considered as statistically significant.

Results

This is a single –center, prospective, non-randomized, clinical trial that was conducted in Cairo university, vascular surgery unit over 60 patients complaining of PAD affecting the aortoiliac segment, which were classified anatomically into either TASC II class C or D aortoiliac complex lesions, and presented to us from June 2019 to December 2020. The recruited patients had incapacitating claudication in the buttock, thigh, and calf (Rutherford class III); ischemic rest pain (Rutherford class IV); tissue loss in the form of small ulcer (Rutherford class V); or gangrene (Rutherford class VI).

The study was ethically approved from the ethical committee of general surgery department prior to its conduct. Accurate assessment of the patients was done by history taking, meticulous vascular assessment for the need of vascular intervention, imaging I.e.: arterial duplex and /or CTA as well as routine blood investigations i.e., :(complete blood count, prothrombin activity, serum Creatinine, HBA1c). Monthly follow up was performed up to 12 months by checking the femoral pulse bilaterally, measuring PSV at CFA, improvement of symptoms and comparing the results in an excel sheet for every patient. Minor and major complications were assessed during the follow up and recorded.

Table 1: demographics of the included patients.

	Count	Column N %
Age in years (mean \pm SD) / Median (range)	53.8 \pm 8.4	53.5 (38-68)
Gender		
Male	54	90.0%
Female	6	10.0%
Smoking	52	86.7%
Hyperlipidemia	50	83%
Diabetes Mellitus	46	76.7%
Oral hypoglycemic drugs	8	13.3%
Insulin treatment	38	63.3%
Hypertension	26	43.3%
Ischemic heart disease	10	16.7%
Renal impairment	5	8.3%

Demographic data is demonstrated in table 1

Table 2: affected arterial segment among TASC D patients.

	TASC D (n=36)	
	Count	Percent
Aortoiliac	18	50.0%
Unilateral CIA, EIA, CFA stenosis	6	16.7%
Unilateral CIA, EIA block	11	33.6%
Bilateral EIA block	1	2.7%

Dissection was reported in 7(11.7) cases. Four cases were managed by hybrid intervention and the other three cases were converted to open procedure(axillofemoral or femoro femoral bypass). Iliac rupture occurred in one case which was managed by using a covered stent and contrast induced nephropathy was encountered in 3 cases (5%) and managed conservatively. One case presented after three weeks with acute thrombosis due to Covid 19 infection and this patient had above knee amputation. One case died after 10 days of intervention due to myocardial infarction. Failure of procedure occurred in 3 cases, all were TASC D

Table3: incidence of early complications, and Failure of procedure among the included patients.

Complications	Count	
Access (hematoma)	3(5%)	
Failure of the procedure	3(5%)	
Dissection	7(11.7%)	
Thrombosis	1(1.7%)	
Iliac rupture	1(1.7%)	
CIN	3(5%)	
Limb loss	1(1.7%)	
Death	1(1.7%)	

	Failure (n=3)		Cause of failure	Further intervention
	Count	%		
Infra renal aortoiliac occlusion	2	66.7%	Dissection of aorta near renal arteries	Converted to open Axillo-femoral bypass
Unilateral CIA and EIA block	1	33.3%	Dissection of aorta and failure of re-entry	Femro-femoral bypass

Table 4: cases with dissection:

Patient	Site of dissection	Management
Two cases with infra renal aortic block	Dissection of the aorta near renal arteries	Converted to open (axillo bifemoral bypass)
One case of unilateral CIA and EIA block	Dissection of aorta and failure of re-entry	Converted to open (femoro-femoral bypass)
One case of unilateral CIA,EIA and CFA stenosis	Dissection of the CFA	Hybrid (endovascular and surgical reconstruction) .Surgical reconstruction was in the form of common femoral endarterectomy and patch angioplasty using saphenous vein patch.
Two cases of EIA occlusion extends to the origin of CFA		
One case of EIA and CFA stenosis		

Assisted primary patency: After six months two patients presented with in-stent stenosis and were managed by balloon angioplasty, they were asymptomatic but there was a decrease in PSV in the CFA

secondary patency: After 12 months four patients presented with recurrence of symptoms and occluded stents, so another attempt of endovascular intervention was done to restore the patency. All had successful outcomes.

Table5 : showing Limb salvage rate.

	Count	%
Amputation free survival	55/57	96.5%
Freedom from amputation	55/56	98.2%
Life-long limb preservation	56/57	98.2%

Discussion

Open surgery is the traditional treatment of aortoiliac TASC type C and D lesions. However, as morbidity and mortality rates of open surgery are not negligible, endovascular treatment has emerged as a less invasive option over the last decade **(1)**.

Aorto-bifemoral and iliofemoral bypasses are the most common open surgical techniques for revascularization of these patients. Although the patency rate at 5 years is high (83.5%-88.3%), comorbidities are not negligible, ranging between 12.7% and 16% with mortality rate of 2.7% to 4.1% depending on the technique used. Therefore, endovascular treatment emerges as a valid strategy in these patients **(6)**.

It is worth noting that endovascular treatment of TASCII type C and D lesions has a low technical success rate and poor mid-to-long-term patency rates. Therefore, in 2007, TASC II recommended type D lesions to be principally treated with surgical bypass **(5)**.

However, with the rapid advancement of endovascular technology and equipment, the success rate of endovascular treatment has continuously increased, and the patency rate has also been significantly increased Therefore, more clinicians and patients have chosen to first attempt endovascular intervention **(2)**.

In 2020 a study which included 15 patients (11 males, 4 females) with aortoiliac occlusive disease had 100% technical success after being managed with endovascular technique, of which 25% of cases were achieved by using subintimal technique with no complications of renal artery emboli or massive retrograde dissection. Primary and secondary patency rates at 1, 3 and 5 years were 92.3% and 100%; 83.9% and 100%; and 83.9% and 100%, respectively **(7)**.

Ye et al. (8) had a meta-analysis which included sixteen articles between 2000 and 2010 consisting of 958 patients with TASC C&D complex aortoiliac lesions and they concluded that early and midterm outcomes of endovascular treatment for TASC C and D aorto-iliac lesions were acceptable, with a better patency for primary stenting than selective stenting as the technical success was 92.8% and Primary patency at 12 months was 88.7%.

Zhou et al. (4) noted that according to characteristics of the disease, endovascular treatment with an individualized, rational choice of approach and with fine-tuning of the operation is a safe and effective treatment for long-term complex iliac artery occlusion, Customization of the treatment is also the key to a successful operation and to ensure good postoperative efficacy.

It remains unclear whether EVT is appropriate in cases of aorto-iliac occlusive disease as opposed to bypass surgery. The patency rate in AIOD patients undergoing open bypass surgery has been reported to 80-86% at five years and 72- 79% at 10 years **(9)**

In contrast, **Zhou et al. (4)** reported a favorable primary patency rate at 6 months, 12 months, 24 months, and 36 months ($96.6 \pm 3.4\%$, $86.6 \pm 7.3\%$, $79.4 \pm 9.6\%$, and $66.20 \pm 14.5\%$).

Also as the society continues to age, more patients are not undergoing open surgery, but rather EVT, due to their high age and/or comorbidities, indeed, open bypass for AIOD carries a higher risk of perioperative complications and 30-day mortality than EVT **(10)**

Compared to this meta-analysis, this study had a better results as there was no complications occurred when brachial artery was used with no distal embolization, but three cases (0.05%) had access site hematoma (femoral access) which were managed conservatively with no need of surgical intervention. One case (0.017%) had iliac artery rupture which was managed by usage of covered stent, three cases had CIN (0.05%) and all of them had aortoiliac lesion which require a long intervention time and excessive use of contrast, none had developed end stage renal disease. One mortality (1.7%) was reported in this study and the cause of death was myocardial infarction after ten days of the procedure.

When comparing EVT with open surgery, mortality, and morbidity should also be considered. In this study, the operative mortality of EVT for TASC C and TASC D aorto-iliac lesions was 1.7%, and the complication rate was 23%. A prior meta-analysis of 25 articles showed a postoperative mortality rate of 4.4% and a complication

rate of 18.2% for ABF. Due to potential differences in patient selection when deciding on open or endovascular treatment and variations in type and severity of complications, a direct comparison of these results is not possible **(11)**.

Data of this study indicate that EVT may have the potential to achieve patency rates surpassing those of bypass surgery.

Also, this study demonstrates that outcomes of endovascular treatment for TASC C and TASC D aortoiliac lesions were acceptable with a high primary patency rate in the first year.

Endovascular treatment for iliac artery occlusive disease can be considered an alternative to open surgery for TASC-II C and D iliac lesions, especially in surgically unfit patients or those who refuse surgical intervention and kissing iliac stenting is a safe procedure. Although endovascular treatment is amenable to all patients, it is particularly beneficial for older patients with limited life expectancy and associated multiple comorbidities such as diabetes, hypertension and cardiac compromise owing to the less invasive nature of the endovascular procedure and its high patency rate.

Further accumulation of supporting medical evidence as well as technical standardization, device improvements and larger multicenter randomized controlled studies may make this procedure safer and more effective for use in patients with AIOD.

It is worth noting that despite the technical success rates of endovascular procedures, aortoiliac occlusive disease in young fit patients might benefit more from surgical revascularization procedure.

Conclusion

In our prospective, non-randomized study, endovascular treatment for iliac artery occlusions proved to be a safe and efficient approach with excellent primary and secondary patency rates regardless of the complexity of occlusions defined by TASC II classification. In well selected patients, endovascular therapy can be the treatment of choice even in complex iliac lesions if performed by experienced endovascular interventionists in high volume centers. 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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