

ROLE OF ENDOVASCULAR INTERVENTION IN ILIAC ARTERY DISEASE TASC C AND D CLASSIFICATION

By

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ABSTRACT

Background: For more than forty years, endarterectomy and bypass grafting have been the primary means of surgically revascularizing peripheral vessels threatened by atherosclerotic diseases. However, with today's endovascular technology, stenosis and occlusions in nearly every circulatory system can be approached intraluminally with balloon dilation and intravascular stents.

Objective: To evaluate the technical success rates, primary patency, limb salvage, patient survival and complications for TASC C, and D iliac lesions treated by endovascular procedure. Additionally, the influence of the access site and the clinical outcomes were analyzed.

Patients and Method: Between 2017 and 2019, data from 40 consecutive patients at Al-Zahra'a University Hospital and Damanhor Teaching Hospital with 47 chronic iliac artery stenosis, and/or occlusion who were treated with EVT were reviewed.

Results: The procedure time was longer for TASC D lesions than for TASC C lesions (180.43 ± 45.97 VS 131.69 ± 37.49 ; $p = 0.001$). There were two postoperative deaths in the TASC D lesion group, with the cause being one myocardial infarction, and one postoperative hospital acquired pneumonia. The total perioperative complication occurred in the TASC D lesions was [four (10%) vs. zero; $p = 0.011$] TASC C lesions. Corresponding 2-year primary patency rates were 100% in TASC C lesions, 71.4% in TASC D lesions, and for all cases were 87.5%.

Conclusion: The outcomes of EVT for TASC C and D aorto-iliac lesions were acceptable, with better technical success in TASC C lesions than in TASC D lesions. The 2-year patency rate for both TASC C and TASC D lesions was acceptable, and brachial access was useful for complex anatomy.

Keywords: Endovascular procedures, iliac artery, Trans-Atlantic Inter- Society Consensus (TASC), Patency, Peripheral artery disease.

INTRODUCTION

The long-term durability of open bypass is better than that of endovascular treatment (EVT) for Trans-Atlantic Inter-Society Consensus (TASC) C and D aorto-iliac lesions (Norgren *et al.*, 2017). However, an operative mortality rate of

2.9% and a complication rate of 15.3% make open surgery a less attractive option (Ahn *et al.*, 2017).

Major changes were made between the TASC I and TASC II classification, Satisfactory results were reported with EVT for TASC C and D aorto-iliac

lesions, and attempted to treat TASC C and TASC D lesions with EVT (*Gandini et al., 2018*). Moreover, technical and device improvements have encouraged vascular surgeons to perform EVT for TASC C or TASC D aorto-iliac lesions during the last 10 years (*Ahn et al., 2017*).

Primary stent placement for complex iliac artery occlusive disease provides acceptable long-term outcomes, but takes relatively longer and shows a higher incidence of complications compared with simple disease. Endovascular treatment for iliac artery occlusive disease is considered as an alternative to open surgery even for TASC-II C/D disease (*Ye et al., 2011*).

The present work aimed to evaluate the technical success rates, primary patency, Limb salvage, patient survival and complications for TASC C and D iliac lesions.

PATIENTS AND METHODS

Between 2017 and 2019, data from 40 consecutive patients at Al-Zahra'a University Hospital, and Damanhor Teaching Hospital with 47 chronic iliac artery stenosis and/or occlusion who were treated with EVT were retrospectively reviewed.

The TASC II classification of the disease severity for aorto-iliac lesions was used to define the lesion category. The number of patients with TASC C and D lesion morphology was 26 (28 limbs), and 14 (19 limbs) respectively. Endovascular first approach in all patients was the treatment of choice during our study period.

All patients were judged to be candidates for EVT if they reported disabling claudication, failed medical therapy, or rest pain or gangrene [Rutherford category (3, 4, 5 and 6) or Fontaine stage (IIb-IV)].

Electronic medical records and angiography images were reviewed for demographic data, anatomic lesion, procedural factors, complications, and other outcome variables. Patients with acute limb ischemia, restenotic lesions, diagnostic arteriography, or no intention to treat were excluded.

All patients underwent preoperative ankle-brachial indices (ABI), and duplex ultrasonography examinations to determine the need for EVT. Additionally, all patients had at least one radiological imaging including computed tomography angiography (CTA) or magnetic resonance angiography, before therapeutic angiography. The procedure was performed in a fully equipped endovascular suite. The procedure was performed under local infiltration anesthesia. The brachial approach was reserved for patients with difficulty in crossing proximal or ostial occlusion by a contralateral approach or in bilateral iliac lesions.

The length and diameter of the lesion was judged by intraoperative arteriograms. Routine stenting was performed in all patients. Predilatation of the occlusion before stent deployment was performed. Self-expandable stents for long-segment occlusions or balloon-expandable stents for short-segment occlusions (mostly at the common iliac artery orifice) were preferred.

All patients were given 325 mg of aspirin and 300 mg of clopidogrel immediately postoperatively, 75mg of clopidogrel for 6 weeks postoperatively, and 100 mg of aspirin indefinitely (lifelong enteric coated acetyl salicylic acid [ECASA]).

Technical success was defined as >30 % residual stenosis on angiography. Procedure-related morbidity and mortality rates within 30 days were determined.

Regular visits were attempted after 1month, 6 months, 1 year and 2 years. Restenosis was defined as >50% decrease in luminal diameter seen on non- invasive imaging or angiography.

The treated aorto-iliac lesions were assessed by duplex ultrasonography examination, and ABI was measured at 1 month and 6 months during the first postoperative year and annually thereafter. CTA was performed when there were recurrent symptoms, a decrease of ≥ 0.15

in ABI, and/or an increase of >300 cm/s in the peak systolic velocity.

Statistical analysis:

Data were fed to the computer and analyzed using IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp) Qualitative data were described using number and percent. The Kolmogorov-Smirnov test was used to verify the normality of distribution Quantitative data were described using range (minimum and maximum), mean, standard deviation and median. Significance of the obtained results was judged at the 5% level. Comparisons between patients with TASC C lesions and TASC D lesions were performed using the Student's t test. Primary patency of the percutaneous transluminal angioplasty site was analyzed using the Kaplan-Meier analysis with log-rank test applied.

RESULTS

The number of patients with TASC C and D lesion morphology was: 26 (65%) and 14 (35%), respectively. Demographic data were as following; Min. – Max WAS 50.0 – 75.0 which meant that aorto-iliac atherosclerosis is was disease of elderly. Sex distribution

showed a male preference of this disease. According to co-morbidities there were high incidences of DM, followed by HTN then IHD. Smoking prevalence was 62.5%. Showed high correlation between atherosclerosis of iliac arteries and both DM and smoking (**Table 1**).

Table (1): Demographic data and co-morbidities distribution of the study group

Parameters \ Groups	Total (n = 40)	TASC type		p
		TASC C (n = 26)	TASC D (n = 14)	
Sex				
Male	30 (75%)	19 (73.1)	11 (78.6%)	1.000
Female	10 (25%)	7 (26.9%)	3 (21.4%)	
Age (years)				
Min. – Max.	50 – 75	50 – 70	51 – 75	0.001
Mean ± SD.	65.5 ± 7.4	59.8 ± 6.3	67.6 ± 6.6	
Median (IQR)	63(56.3 – 69)	59(55 – 66)	68.5(66.5 – 72.3)	
Risk factors				
DM	31 (77.5%)	21 (80.8%)	10 (71.4%)	0.694
Smoking	25 (62.5%)	15 (57.7%)	10 (71.4%)	0.392
HTN	21 (52.5%)	9 (34.6%)	12 (85.7%)	0.002
IHD	18 (45%)	8 (30.8%)	10 (71.4%)	0.014
Dyslipidemia	16 (40%)	8 (30.8%)	8 (57.1%)	0.104
CVD	6 (15%)	0 (0%)	6 (42.9%)	0.001
Renal CR>1.2	5 (12.5%)	1 (3.8%)	4 (28.6%)	0.043
COPD	4 (10%)	1 (3.8%)	3 (21.4%)	0.115

p: p value for comparing between the two studied groups

A total of 47 limbs (40 patients) had been evaluated with anatomic variables, access site, and time of procedure. Most of the patients were treated for claudication (55%). Occlusion was higher in TASC D lesions than in TASC C lesions. Bilateral iliac artery occlusions were observed in seven patients, five of

which were in TASC D lesions. The procedure time was longer for TASC D lesions than for TASC C lesions (180.43 ± 45.97 VS 131.69 ± 37.49). Varieties of stents were used in 100% of TASC C lesions and in 85.7% of TASC D lesions (**Table 2**).

Table (2): Clinical presentation, completion angiography and procedure time distribution of the studied cases

Parameters \ Groups	Total (n = 40)	TASC type		P
		TASC C (n = 26)	TASC D (n = 14)	
Disable claudication	22 (55%)	11 (42.3%)	11 (78.6%)	0.028
Rest Pain	13 (32.5%)	7 (26.9%)	6 (42.9%)	0.480
Gangrene	21 (52.5%)	13 (50%)	8 (57.1%)	0.666
Completion angiography				
Passed	38 (95%)	26 (100%)	12 (85.7%)	0.117
Failed	2 (5%)	0 (0%)	2 (14.3%)	
Procedure time/min				
Min. – Max.	70 – 245	70 – 213	91 – 245	0.001
Mean ± SD.	148.75 ± 46.5	131.7 ± 37.5	180.4 ± 46	
Median (IQR)	137(121.3 – 180.8)	128(108.5 – 143.3)	178.5(137 – 217.8)	

p: p value for comparing between the two studied groups

There were two postoperative deaths in the TASC D lesion group, with the cause being one myocardial infarction and one postoperative hospital acquired pneumonia. The total postoperative complication occurred in the TASC D lesion group four cases. These

complications included one myocardial infarction, one hospital acquired pneumonia, one postoperative nephropathy, and one sheath site hematoma that resolved in two weeks without any surgical interference (Table3).

Table (3): Post-operative complications distribution of the studied cases

Post-operative complications	Groups	Total (n = 40)	TASC type		p
			TASC C (n = 26)	TASC D (n = 14)	
No		36 (90%)	26 (100%)	10 (71.4%)	0.011
Myocardial infarction		1 (2.5%)	0 (0%)	1 (7.1%)	
Post -operative pneumonia		1 (2.5%)	0 (0%)	1 (7.1%)	
Post-operative nephropathy		1 (2.5%)	0 (0%)	1 (7.1%)	
Sheath site hematoma		1 (2.5%)	0 (0%)	1 (7.1%)	

MC: Monte Carlo

p: p value for comparing between the two studied groups

The corresponding 2-year primary patency rates were 100% for TASC C lesions and 71.4% for TASC D lesions. Primary patency rate for all cases were

87.5% (Figure 1). However, there was no statistically significant difference between the groups considering the primary patency.

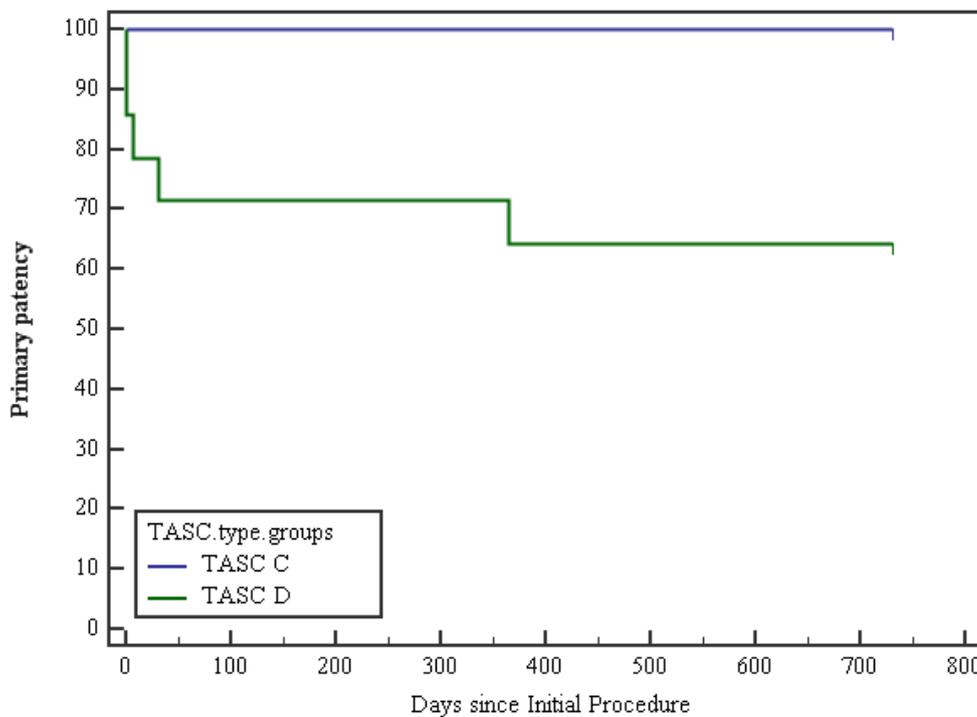


Figure (1): Kaplan-Meier curve for Primary patency rate

DISCUSSION

This study demonstrated a 100% technical success rate and a 100% primary patency at 2 years for TASC C lesions, and 85.7% technical success rate and 71.4% primary patency at 2 years for TASC D lesions. The complication rate was 0% for TASC C and 10% for TASC D lesions.

Considering the 95% technical success rate in this study, the results were high compared with those of TASC A and TASC B lesions treated by EVT that were 98% by *Galaria and Davies (2015)*. Additionally, easy-to-repeat procedures for re-stenosis constitute one reason for the increasing trend for EVT (*Galaria and Davis, 2015*).

Both intraluminal endovascular interventions and subintimal angioplasty can be applied to treat iliac chronic total occlusion lesions. There was no difference in the primary patency (74% for the intraluminal approach and 76% for subintimal angioplasty at the 3-year follow up) (*Chen et al, 2011*).

We preferred primary stenting in TASC C and D aorto-iliac lesions. *AbuRahma et al.* reported an overall early clinical success rate of 93% for primary stenting and 46% for selective stenting in TASC C and TASC D iliac lesions (*AbuRahma, 2007*). A 2- year primary patency rate of 100% in TASC C lesions and 71.4% in TASC D lesions in this study was comparable with previous reports.

Ahn et al. (2017) reported that puncture sites were 26.6 % Bifemoral, 20 % brachial, 33.3 % contralateral, 13.3% Ipsilateral, and 6.6% both brachial and

femoral. In our study, our results were not far away from *Ahn et al* results, access of puncture sites were 15% Bifemoral, 22.5% brachial, 35% contralateral, 15% Ipsilateral, and 12.5% both brachial and femoral. Brachial and femoral access were found in 5 cases of TASC D and 0 in TASC C, This means that tight iliac lesions may need 1st double access to be easily managed.

Brachial access is widely used in coronary interventions, but much less so in noncoronary interventions. The main reasons for reluctant use of brachial access are complications, such as hematoma and arterial thromboembolism. These complications were reported in 6% to 8% of cases (*Alvarez-Tostado et al., 2019*).

In our study, only left brachial artery accesses were performed in seven limbs (26.9%) in TASC C lesions and in two limbs (14.3%) in TASC D lesions. We performed brachial access using the Seldinger technique in all patients, and performed surgical closure after making a small incision. There were no complications related to the use of brachial access. The brachial approach offered a better pushability in complex endovascular procedures, while the surgical cut-down method can also be used safely (*Alvarez-Tostado et al., 2019*).

The technical success rate was higher in TASC C lesions than in TASC D lesions, and complications were fewer in TASC C lesions than in TASC D lesions. In a meta-analysis, comparing TASC C lesions and TASC D lesions, no significant difference was found between the two groups when considering technical success (*Ye et al., 2011*). Other factors may have played a role in the

patients as important as the length of the occlusion. Due to potential differences in patient selection, a direct comparison of these results is not possible (*Ozkan et al., 2010*).

When comparing EVT with open surgery, mortality and morbidity should also be considered. In this meta-analysis, the operative mortality of EVT for TASC C and TASC D aorto-iliac lesions was 2.9% (95% CI, 2.4%-3.4%), and the complication rate was 15.3% (95% CI, 11.5%-20%). A prior meta-analysis of 25 articles showed a postoperative mortality rate of 4.4% and a complication rate of 12.2% for ABF (*de Varies and Hunink, 2017*). 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 (*Ye et al., 2011*).

Five-year primary patency ranged from 60% to 86%, with secondary patency rates of 80% to 98%. In patients with chronic iliac occlusions, successful recanalization was accomplished in nearly 90% of patients, with marked clinical improvement in the vast majority (*Powell and Rzucidlo, 2018*). In another series of iliac artery CTOs, primary patency at 5 years in the CTO group was 82% versus 91% in patients treated for stenosis (*Pulli et al., 2011*).

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 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 compared with surgery.

Some analyzed data were retrospective, although it was a prospective data collection that originated from only two institutions. The techniques, equipment, and my experience also changed during data collecting. This may have resulted in an overestimation of the technical success rate.

Our study had some limitations. The estimated time was just 2 years, the number of patients was just forty, and the number of TASC C (65%) lesions is double the number of TASC D (35%) lesions, the technical success rate may have been overestimated.

We recommended also assessing the grade of calcifications at the level of the treated iliac lesion (Calcification score), axial CTA images may be used. Circumferential grade was measured by assessing the presence of calcium in one or more of the four 90 sectors: score 1 (0-90), score 2 (0-180), score 3 (0-270), and score 4 (0-360).

CONCLUSION

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 stenting is a safe procedure. Although endovascular treatment is amenable to all

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دور التدخل الوعائي للشريان الحرقي لمرضى قصور الدورة الدموية الطرفية تصنيف أطلسي ج و د

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خلفية البحث: على مدار أكثر من أربعين عامًا، كانت العمليات الجراحية للشرايين مثل إستئصال باطنة الشريان وتحويل المسار عن طريق إستخدام الوصلات الشريانية هي الوسيلة الأساسية لإعادة تنشيط الأوعية الدموية الطرفية المهتدة بمرض تصلب الشرايين، مع تكنولوجيا التدخل الوعائي بالقسطرة الطرفية اليوم، ضيق وإنسداد في كل نظام الدورة الدموية تقريبا يمكن الوصول له من داخل الوعاء الدموي وتوسيعه عن طريق البالونات ووضع دعامة شريانية.

الهدف من البحث: تقييم معدلات النجاح التقني، ومعدلات فتح الشريان الأولي، والمضاعفات لأمراض كلا من شريان الأورطي والحرقي تصنيف اطلسي ج و د التي تمت معالجتها بواسطة التدخل الوعائي للقسطرة الطرفية.

المرضى وطرق البحث: من 2017 الى 2019 تم تجميع بيانات 40 حالة من مستشفى الزهراء الجامعي ومستشفى دمنهور التعليمي. كان أعداد المرضى الذين يعانون من الانسداد تصنيف ج و د وهم 26 (28 أطرافه) و14 (19 أطرافه)، على التوالي. وكان التدخل الوعائي عن طريق القسطرة التداخية الطرفية هو النهج الأول المفضل في العلاج مع وضع إجباري للدعامة الأولية.

نتائج البحث: أظهرت هذه الدراسة علي مدار سنتين 100 % معدل نجاح تقني ومعدل فتح أولي لتصنيف أطلسي ج ومعدل نجاح تقني

بنسبة 85.7% ومعدل فتح أولي بنسبة 71.4% لتصنيف اطلسي د.
وكان معدل المضاعفات 0% لتصنيف اطلسي ج و 10% لتصنيف
اطلسي د.

الاستنتاج: تركيب الدعائم إجبارياً لكل مرضي انسداد الشريان
الحرقي المعقد يعطي نتائج مقبولة على المدى الطويل، ولكنه يستغرق
وقتاً أطول نسبياً ويظهر حدوث مضاعفات أعلى مقارنةً بانسداد
الشريان الحرقي البسيط. يمكن اعتبار علاج انسداد الأوعية الدموية
عن طريق التدخل الوعائي بالقسطرة الطرفية لمرض انسداد الشريان
الحرقي كبديل للجراحة التقليدية حتي في المرضي تصنيف اطلسي ج
و د.