

Role of Endovascular Intervention in Iliac Artery Disease TASC C and D Classification

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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 disease. However, with today's endovascular technology, stenosis and occlusions in nearly every circulatory system can be approached intraluminally with balloon dilatation and intravascular stents.

Aim of Study: Was 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 Methods: Between 2017 and 2019, data from 40 consecutive patients at Al-Zahraa 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 post-operative deaths in the TASC D lesion group, with the cause being one myocardial infarction and one post-operative hospital acquired pneumonia. The total perioperative complication rate was higher in the TASC D lesions than in TASC C lesions [four (10%) vs. zero; $p=0.011$]. 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: This study demonstrated that 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. Furthermore, the 2-year patency rate for both TASC C and TASC D lesions was acceptable, and brachial access was useful for complex anatomy.

Key Words: *Endovascular procedures – Iliac artery – Trans-Atlantic Inter – Society Consensus (TASC) – Patency – Peripheral artery disease.*

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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 [1]. However, an operative mortality rate of 2.9% and a complication rate of 15.3% make open surgery a less attractive option [2].

Major changes were made between the TASC I and TASC II classification, many centers have reported satisfactory results with EVT for TASC C and D aorto-iliac lesions [3], and more vascular surgeons are attempting to treat TASC C and TASC D lesions with EVT. 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 [2].

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 might be considered as an alternative to open surgery even for TASC-II C/D disease [4].

Patients and Methods

Between 2017 and 2019, data from 40 consecutive patients at Al-Zahraa 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, had failed medical therapy, or had 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.

Treatment procedure:

A- Pre-operative:

All patients underwent pre-operative Ankle-brachial Indexes (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.

All patients were adequately well hydrated before and after the procedure. All patients were given 325mg of oral aspirin prior to the procedure.

B- Intraoperative technique:

The procedure was performed in a fully equipped endovascular suite. The procedure was performed under local infiltration anesthesia.

After placing a 6-Fr introducer sheath into the ipsilateral and/or contralateral common femoral

artery (Crossover technique) or a 5-Fr introducer sheath into the left brachial artery, heparin was administered intravenously at a dose of 5000IU.

The brachial approach was reserved for patients with difficulty in crossing proximal or ostial occlusion by a contralateral approach or in bilateral iliac lesions.

After completing diagnostic angiography, in most cases, a hydrophilic stiff or a soft-tip 0.035-inch guide wire was used in combination with an angled catheter such as a Rim or Burn catheter to cross the lesion Figs. (1A,B, 2A).

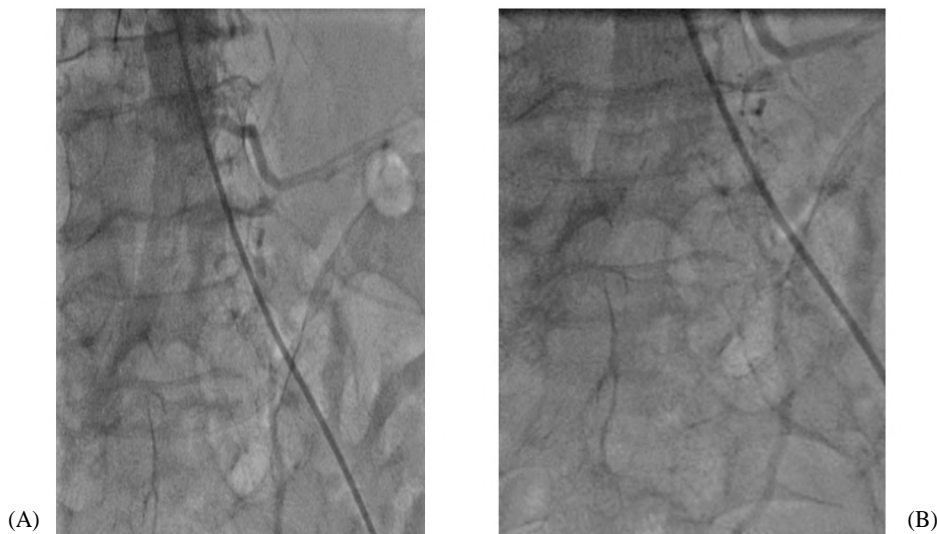
If the recanalization attempt failed via these approaches, antegrade recanalization was attempted via the brachial approach. Crossing the iliac lesion was achieved in a subintimal or intraluminal manner depending upon the character of the lesion.

The catheter was used to engage and direct the wire toward the lesion. Balloon angioplasty was performed in all cases for predilatation. The balloon diameter ranged between 6 and 8mm and balloon length ranged between 60 and 150mm Fig. (2C,D).

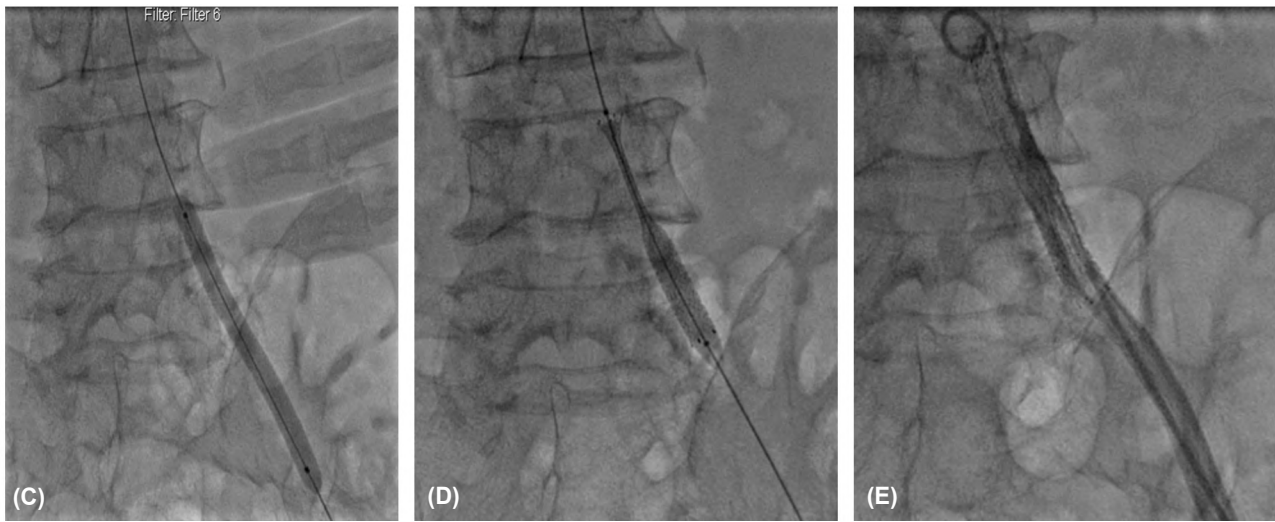
Inflation pressure ranged between 8 and 12 atm and inflation time ranged between 60 and 120s.

The length and diameter of the lesion was judged by intraoperative arteriograms Fig. (2B). 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 Fig. (2E,F) for short-segment occlusions (mostly at the common iliac artery orifice) were preferred.

C- Sample of cases:



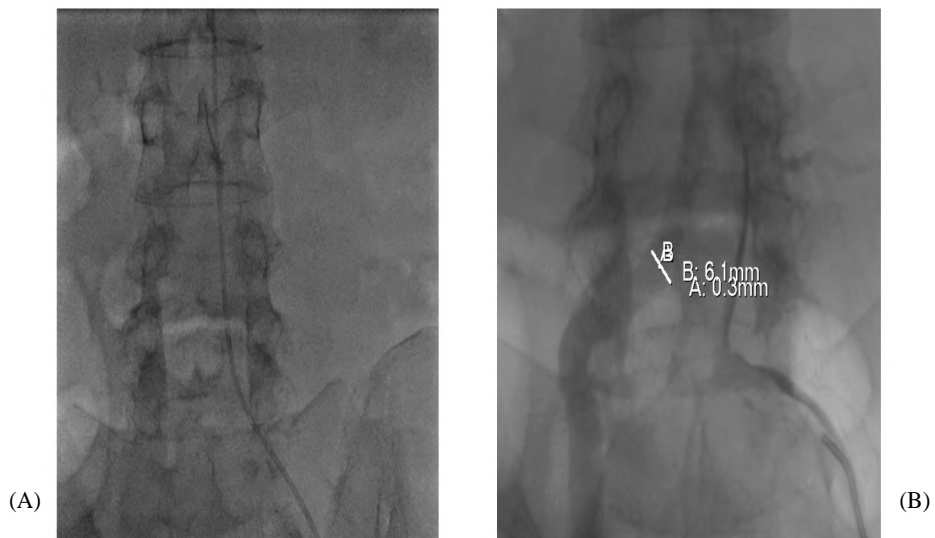
Passing of the lesion and balloon mounted stent of the LT EIA



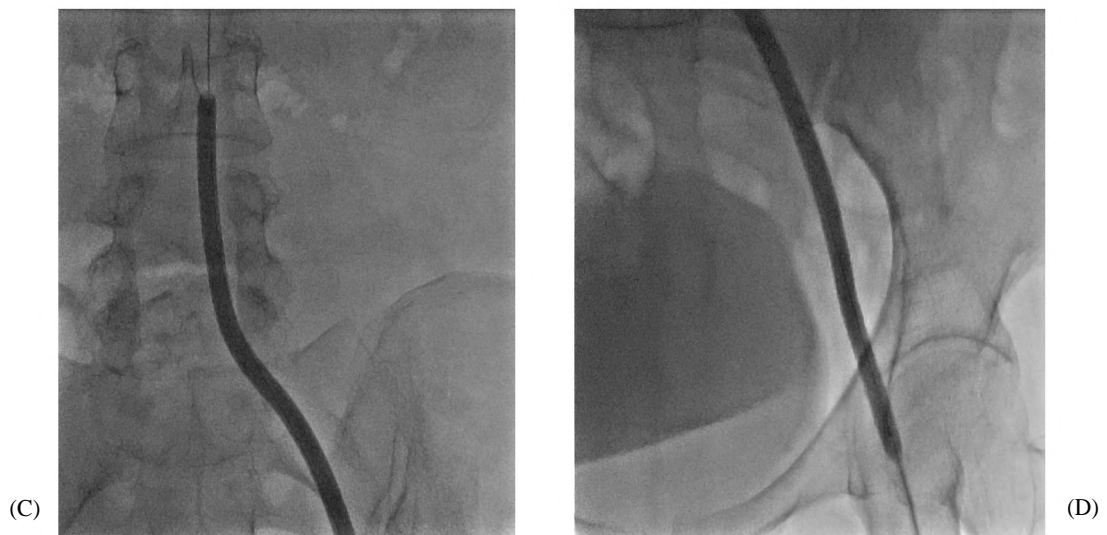
Passing of the lesion and balloon mounted stent of the LT EIA

Post conventional angiography

Fig. (1): Sample of cases for TASC C.



Intra-operative conventional angiography and passing of the lesion



Dilatation of the lesion by balloon

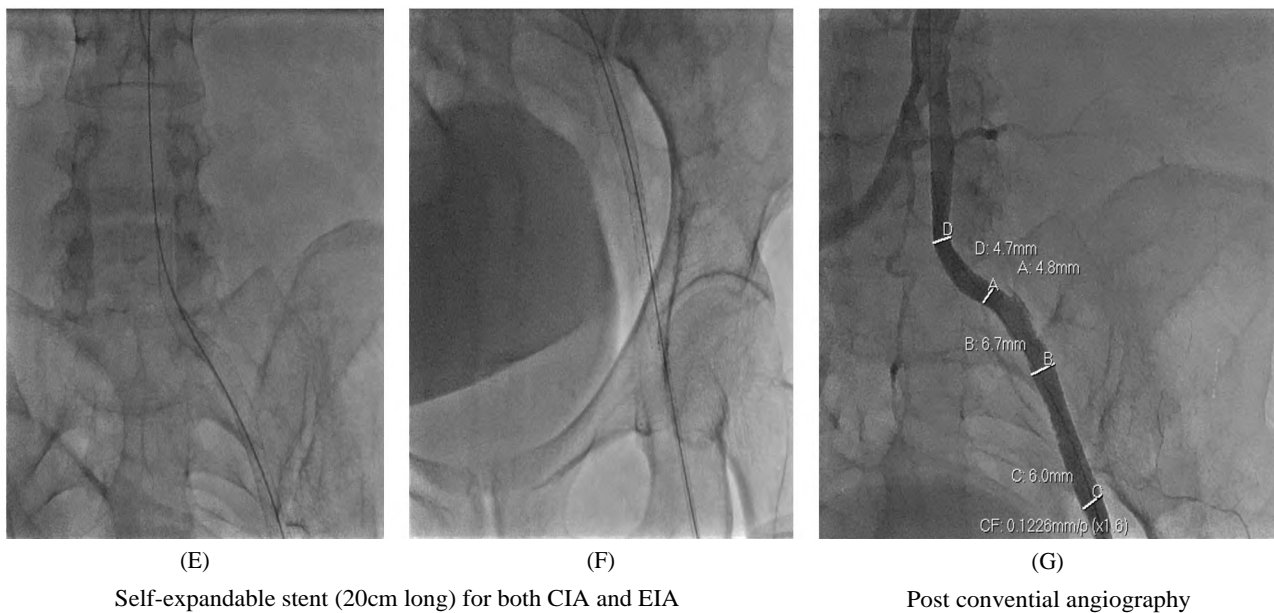


Fig. (2): Sample of cases for TASC D.

D- Post-operative:

All patients were given 325mg of aspirin and 300mg of clopidogrel immediately post-operatively, 75mg of clopidogrel for 6 weeks post-operatively, and 100mg of aspirin indefinitely (lifelong Enteric Coated Acetyl Salicylic Acid [ECASA]).

Sheaths will be removed using manual compression in the recovery room after activated clotting time is <180 seconds. Patients were generally discharged within 24-48h after the procedure.

Technical success:

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

Follow-up:

Regular visits were attempted in 1 month, 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 post-operative 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 analyses:

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 *t*-test. Primary patency of the percutaneous transluminal angioplasty site was analyzed using the Kaplan-Meier analysis with log-rank test applied.

Results

Patients:

The number of patients with TASC C and D lesion morphology was 26 (65%) and 14 (35%), respectively Fig. (3). Demographic data are as following; min.-max WAS 50.0-75.0 which means that aorto-iliac atherosclerosis is a disease of elderly. Sex distribution shows a male preference of this disease (Table 1). According to co-morbidities showed high incidence of DM followed by HTN then IHD. Also smoking prevalence is 62.5%. This shows high correlation between atherosclerosis of iliac arteries and both DM and smoking (Table 2).

Clinical outcome:

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%) (Table 3). 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 ; $p=0.001$) (Table 4). Varieties of stents (Table 5) were used in 100% of TASC C lesions and in 85.7% of TASC D lesions ($p=0.117$).

Complications:

There were two post-operative deaths in the TASC D lesion group, with the cause being one myocardial infarction and one post-operative hospital acquired pneumonia. The total post-operative complication rate was higher in the TASC D lesion group than in the TASC C lesion group [four (10%) vs. zero]. These complications included one myocardial infarction, one hospital acquired pneumonia, one post-operative nephropathy, and one sheath site hematoma that resolved in two weeks without any surgical interference (Table 6).

Patency:

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% Fig. (4); however, there was no statistically significant difference between the groups considering the primary patency.

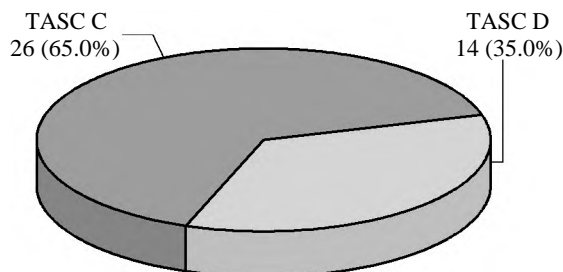


Fig. (3): Distribution of the studied cases according to TASC type (n=40).

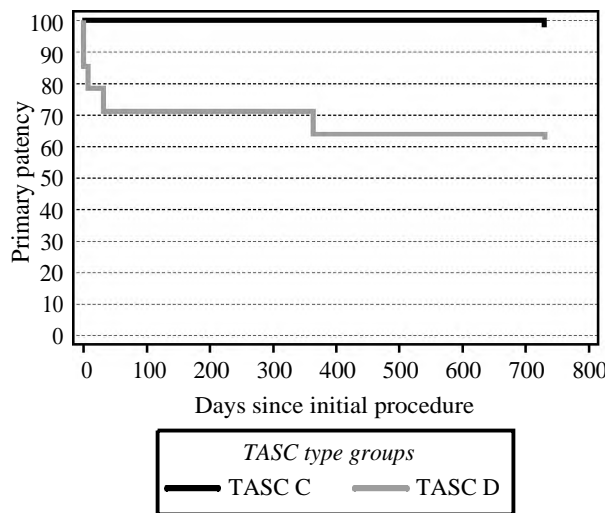


Fig. (4): Kaplan-Meier curve for primary patency rate.

Table (1): Demographic data distribution of the study group.

	Total (n=40)		TASC type				Test of sig.	p
			TASC C (n=26)		TASC D (n=14)			
	No.	%	No.	%	No.	%		
Sex:								
Male	30	75.0	19	73.1	11	78.6	$\chi^2 =$	$FE_p =$
Female	10	25.0	7	26.9	3	21.4	0.147	1.000
Age (years):								
Min.-max.	50.0-75.0		50.0-70.0		51.0-75.0		t=	0.001*
Mean \pm SD.	65.52 \pm 7.36		59.81 \pm 6.29		67.57 \pm 6.64		3.651*	
Median (IQR)	63.0 (56.25-69.0)		59.0 (55.0-66.0)		68.50 (66.50-72.25)			

Table (2): Distribution of the studied cases according to habits (co-morbidities).

Risk factors	Total (n=40)		TASC type				χ^2	p
			TASC C (n=26)		TASC D (n=14)			
	No.	%	No.	%	No.	%		
DM	31	77.5	10	71.4	21	80.8	0.455	$FE_p = 0.694$
Smoking	25	62.5	15	57.7	10	71.4	0.733	0.392
HTN	21	52.5	9	34.6	12	85.7	9.528*	0.002*
IHD	18	45.0	8	30.8	10	71.4	6.078*	0.014*
Dyslipidemia	16	40.0	8	30.8	8	57.1	2.637	0.104
CVD	6	15.0	0	0.0	6	42.9	13.109*	$FE_p = 0.001*$
Renal CR >1.2	5	12.5	1	3.8	4	28.6	5.086*	$FE_p = 0.043*$
COPD	4	10.0	1	3.8	3	21.4	3.126	$FE_p = 0.115$

Table (3): Clinical presentation distribution of the studied cases.

	Total (n=40)		TASC type				χ^2	P
			TASC C (n=26)		TASC D (n=14)			
	No.	%	No.	%	No.	%		
Disable claudication	22	55.0	11	42.3	11	78.6	4.835*	0.028 *
Rest pain	13	32.5	7	26.9	6	42.9	1.053	$F_{E_p}=0.480$
Gangrene	21	52.5	13	50.0	8	57.1	0.186	0.666

Table (4): Procedure time/min distribution of the studied cases.

Procedure time/min	Total (n=40)	TASC type				t	p
		TASC C (n=26)		TASC D (n=14)			
Min.-max.	70.0-245.0	70.0-213.0		91.0-245.0		3.622*	0.001 *
Mean \pm SD.	148.75 \pm 46.47	131.69 \pm 37.49		180.43 \pm 45.97			
Median (IQR)	137.0 (121.25-180.75)	128.0 (108.50-143.25)		178.50 (137.0-217.75)			

Table (5): Completion angiography distribution of the studied cases.

Completion angiography	Total (n=40)		TASC type				χ^2	P
			TASC C (n=26)		TASC D (n=14)			
	No.	%	No.	%	No.	%		
Passed	38	95.0	26	100.0	12	85.7	3.910	0.117
Failed	2	5.0	0	0.0	2	14.3		

Table (6): Post-op. complications distribution of the studied cases.

Post-op. complications	Total (n=40)		TASC type				χ^2	MC _p
			TASC C (n=26)		TASC D (n=14)			
	No.	%	No.	%	No.	%		
No	36	90.0	26	100.0	10	71.4	7.705*	0.011**
Myocardial infarction	1	2.5	0	0.0	1	7.1		
Post-operative pneumonia	1	2.5	0	0.0	1	7.1		
Post-operative nephropathy	1	2.5	0	0.0	1	7.1		
Sheath site hematoma	1	2.5	0	0.0	1	7.1		

Discussion

This study demonstrated a 100% technical success rate and a 100% primary patency at 2 years for TASC C lesions and an 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 are high compared with those of TASC A and TASC B lesions treated by EVT that were 98% by Galaria and Davies on 394 iliac artery primary intervention [5]. Additionally, easy-to-repeat procedures for re-stenosis constitute one reason for the increasing trend for EVT.

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) [6].

We prefer primary stenting in TASC C and D aorto-iliac lesions. Abu Rahma 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 [7]. 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., reported that puncture sites were 26.6% Bifemoral, 20% brachial, 33.3% contralateral, 13.3% Ipsilateral, and 6.6% both brachial and femoral [2].

In our study, our results was 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 management.

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 [8].

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 [8].

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 [4]. 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 was not possible [9].

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 [10]. 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 [4].

Five-year primary patency ranged from 60% to 86%, with secondary patency rates of 80% to 98%. In a series of 212 patients with chronic iliac occlusions, successful recanalization was accomplished in nearly 90% of patients, with marked clinical improvement in the vast majority [11]. In another series of 109 iliac artery CTOs, primary patency at 5 years in the CTO group was 82% versus 91% in patients treated for stenosis [12].

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 data analyzed 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 is just 2 years, the number of patents is just forty, and the number of TASC C (65%) lesions is double the number of TASC D (35%) lesions, this means that the technical success rate may have been overestimated. We recommend to increase the number of patients and to be equally distributed between the two groups TASC C and TASC D. We recommend also increasing the time for research to give us an exact primary patency rate and we can do also secondary patency rate.

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).

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

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

إن المزايا المحتملة للعلاج عن طريق التدخل الوعائي للشريان مقارنة بالعمليات الجراحية واضحة: لا يوجد أى تخدير كلى أو شق جراحى طويل، قصر مدة إقامة المريض بالمستشفى، إنخفاض معدلات المرض والوفيات، تدخل مبكر فى سياق المرض.

نحن نفضل زراعة الدعامة إجبارياً فى المرضى تصنيف أطلسي ج و د فى علاج إنسداد كلا من الشريان الأورطى والحرقي عن زراعة الدعامة إختيارياً. أظهرت العديد من التجارب العشوائية أن تركيب الدعامة إجبارياً أفضل بكثير عن التركيب الإختيارى للدعامة وذلك على مستوى كلاً من معدلات الدورة الدموية وتصنيف رانزفورد.

كان الهدف من هذه الدراسة هو تقييم معدلات النجاح التقنى، ومعدلات فتح الشريان الأولى، والمضاعفات لأمراض كلاً من شريان الأورطى والحرقي تصنيف أطلسي ج و د التى عولجت بواسطة التدخل الوعائي للقسطرة الطرفية. بالإضافة إلى ذلك، تم تحليل تأثير موقع الدخول والنتائج السريرية.

كانت التداخلات الوعائية بالقسطرة الطرفية التى تم إجراؤها تصنيف أطلسي ج و د ناجحة كما هو مبين فى هذه الدراسة التى تضم ٤٠ مريضاً: ٦٥٪ تصنيف ج و ٣٥٪ تصنيف د. فى هذه الدراسة، كان لجميع المرضى أعراض فى شكل تقلصات شديدة معيقة للحركة (٥٥٪)، غرغرينا بنسبة (٥٢.٥٪)، وآلم شديد مع الراحة بنسبة (١٣٪).

أظهرت هذه الدراسة على مدار سنتين معدل نجاح تقنى ١٠٠٪ و ١٠٠٪ معدل فتح أولى لتصنيف أطلسي ج ومعدل نجاح تقنى ٨٥.٧٪ ومعدل فتح أولى ٧١.٤٪ لتصنيف أطلسي د. وكان معدل المضاعفات ٠٪ لتصنيف أطلسي ج و ١٠٪ لتصنيف أطلسي د.