Covered Stents for Treating Aortoiliac Occlusive Disease: A single Center Experience

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Aim of work: To study the outcomes in patients with occlusive aortoiliac disease treated by covered stents.

Patients and methods: We performed retrospective analysis of prospectively collected data from 23 patients (28 limbs) with symptomatic aortoiliac disease during the period from January 2016 to October 2019. at Ain Shams University hospitals. We excluded patients with ulcer or gangrene; aortic lesions not extending to iliacs; previous aortoiliac interventions; acute ischemia of lower extremity, ectasia or aneurysm of iliacs and/or aorta, Extensive common femoral artery disease or need for concomitant groin procedures, contraindication to aspirin or clopidogrel usage, occluded superficial and profunda femoral arteries. We used the Rutherford categories to characterize the patients at time of treatment with stenting and to compare their clinical and functional outcome over the follow-up period.

Results: There were 13 males and 10 females, with ages ranging between 37-76 (mean= 59.1 ± 11.4) years. All patients had symptomatic aortoiliac arterial disease (Rutherford class 2,3,4). Patients were treated with balloon expandable covered stent and had a median follow-up of 32 months. The mean ABI was 0.52 (± 0.11) at the start of the study with a significant increase to 0.76 (± 0.12) at 3-year. At the 3-year follow-up, primary patency was 84.6%, assisted primary patency 92.3%, and secondary patency 96.2%. There were no instances of stent fracture.

Conclusions: Treating aortoiliac occlusive disease with a covered stent is an excellent choice. The technique has good patency rate and few complications. More randomized clinical trials are needed to enrich the guidelines.

Key words: Endovascular, covered stents, aortoiliac occlusion.

Introduction

In the management of lower limb arterial insufficiency, aortoiliac arterial occlusive disease is frequently faced. Initially, reconstruction was performed using thromboendarterectomy; however, graft technology advances have made bypass surgeries more commonly carried out with accepted durability, which has a reported surgical mortality of 4%, with major complications up to 21% of patients.[1]

Currently, the decision to perform an endovascular procedure or open surgical bypass depends on various factors, mainly the severity and anatomic distribution of disease based on the TransAtlantic Inter-Society Consensus (TASC) I and II working group.[1] For patients with TASC A and B lesions of iliac arteries, endovascular treatment is of low complication rates and high patency rates. On the other hand, lower patency rates with TASC C and D lesions render an open surgical approach recommendable, except in patients deemed to be high-risk.[2,3]

With advances in endovascular techniques and devices, the TASC classification was revised to TASC II, which allowed treatment of more extensive and multifocal iliac lesions using endovascular procedures.[4,5]

Traditionally, covered stents were used exclusively for iliac aneurysms, arteriovenous fistulas, iatrogenic perforations and ruptures. Recently, there are studies with promising results of covered stents compared with bare-metal stents for severe aortoiliac occlusive disease, that's why stent grafts became more routinely used in managing patients with TASC C and D lesions aortoiliac occlusive disease.[1,6] These devices are stainless steel, nickel-cobalt-titanium-steel alloy (Elgiloy), or nitinol stents covered with Dacron or polytetrafluoroethylene (PTFE).[7-9]

Theoretically, covered stent provides better patency and improved clinical outcome compared with bare metal stent by forming a mechanical barrier for intimal exclusion, thereby reducing intimal hyperplasia through preventing macrophage migration into endothelium with subsequent inflammatory process that contributes to initiating the process of neo-intimal hyperplasia and subsequent restenosis. In addition, there is decreased risk of iliac rupture with covered stents with possibility of use of higher inflation pressures.[10]

The Covered vs Balloon Expandable Stent Trial (COBEST), the first multicenter randomized controlled trial to compare the outcomes of bare metal stents and covered stents in the management of aortoiliac arterial occlusive lesions, reported an enduring patency advantage of covered stent over the bare metal stent in both the short (18 months) and long terms (5 years). Furthermore, in patients

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with TASC C and D lesions treated with a covered stent compared with bare metal stent treatment, the 5-year primary patency was significantly improved from 50% to 95% at 18 months, with fewer revascularization procedures required in patients treated with covered stents. However, the rate of major limb amputations was not affected with the choice of stent. But, TASC B lesions showed comparable results in both balloon-expandable covered stents and bare metal stents. The only predictors of patency were the use of stent graft and Rutherford class.[10]

In a recent meta-analysis comprising 10 studies, by Hu et al, the authors compared between covered and bare metal stents in treatment of AIOD, as regards efficacy and safety. They found no significant advantage in terms of primary patency of all patients (The total study population consisting of TASC A, B, C, and D). However, primary patency of patients with TASC D lesion was reported in only 3 studies covering 631 diseased arteries. Their analysis revealed that covered stents had a significant advantage in the treatment of patients with TASC D lesions.[11]

Apart from the COBEST trial, few studies have examined the long-term outcomes of primary stenting for iliac lesions based on the TASC II classification.

For this reason, the purpose of this study is to determine sustained benefits and outcomes of covered stents in aortoiliac lesions.

Patients and methods

We included patients with ischemic rest pain and claudication pain not responding to best medical treatment. Patients with tissue loss were excluded.

Our primary endpoints were 3-year primary, assisted primary and secondary patency. Secondary endpoints were procedure-related complications and procedure-related mortality.

Methodology

Retrospective analysis of prospectively collected data; of 23 patients (28 limbs) with symptomatic aortoiliac arterial disease (Rutherford class 2,3,4). The study period was from January 2017 to October 2020 in patients that had recanalization using balloon-expandable covered stent (Advanta V12; Atrium Medical Corporation, Hudson, NH) in Ain Shams University Hospitals.

We diagnosed Peripheral Arterial Disease by clinical examination as well as the presence of radiological evidence of arterial insufficiency. Lower limb arterial duplex and CT arteriography were pre-operative investigations for all patients.

Inclusion criteria: (1) Men and women aged ≥18 years; (2) Informed consent obtained; (3) Symptomatic aortoiliac arterial disease (Rutherford class 2,3,4) and (4) Radiological evidence of occlusion/stenosis at the Abdominal Aortic Bifurcation, Common Iliac arteries.

Exclusion criteria: Patients with ulcer or gangrene; aortic lesions not extending to iliacs; previous aortoiliac interventions; acute ischemia of lower extremity, juxtarenal aortic occlusion, hypoplastic aortic syndrome. Ectasia or Aneurysm of iliacs and/or aorta, Extensive common femoral artery disease or need for concomitant groin procedures, contraindication to aspirin or clopidogrel usage, occluded superficial and profunda femoral arteries.

Clinical records included patient demographics, etiology, and any previous vascular interventions. Procedural details included access site, equipment used, length and diameter of stents, procedural outcomes, and complications.

Patients were clinically classified at enrollment according to the Rutherford classification in consistency with the Reporting Standards of the International Society of Cardiovascular Surgery (ISCS)/Society for Vascular Surgery (SVS). We used the Rutherford categories to characterize the patients at time of treatment with stenting and to compare their clinical and functional outcome over the follow-up period.

Patients were followed clinically and by duplex, at 3, 6, 12, 24 and 36 months.

We performed Duplex ultrasound examination at each follow-up visit, looking for visible narrowing >50% of the flow lumen or localized increase in flow velocities along the stented segment (threefold increase in the flow velocity trans-lesion indicated more than 66 % reduction of the lumen). Patients underwent CT arteriography when there was a recurrence of symptoms or duplex findings suggested restenosis during the follow-up visits.

We repeated interventions in cases with recurrent symptoms with radiological evidence of restenosis more than 70%.

Definitions used:

- Rutherford classification of Peripheral Arterial Disease (PAD) refers to clinical signs of PAD (claudication, rest pain, minor or major tissue loss) associated with chronic obstruction of the arterial system and sustained peripheral hypoperfusion through collaterals.
- Hemodynamic success is defined as a rise in the ABI >0.15.
- Technical success is defined as <30% residual stenosis at the end of the procedure.

No embolic protection devices were used.

Results

We collected of data about 23 patients (28 limbs) who underwent graft-stenting for aortoiliac occlusive disease. The mean age was 59.1 years; 56.5% (n=13) of patients were males. Smoking, diabetes mellitus and hypertension were the dominant comorbidities (69.6%, 65.2% and 60.9% respectively). The baseline Rutherford's classification of Peripheral Arterial Disease of the 23 patients was as follows: 15 patients (53.6%) were class 2; 2 patients (7.1%) were class 3, and, 11 (39.3%) patients were class 4 **(Table 1).**

Mandatory clinical evaluations combined with measurement of ABIs were performed at pre-procedural and at each post-procedural follow-up intervals at 3, 6, 12, 24 and 36 months. ABI measurements during the follow-up period were not significantly different **(Table 2).** Median follow-up period was 32 months.

Procedural complications included hematoma (4 cases, 14.3%), non-flow limiting dissection (2 cases, 7.1%), micro-embolization (1 case, 3.6%) and pseudo-aneurysm (1 case, 3.6%), resolved without intervention. No conversions to open aortoiliac surgery during the perioperative period were reported. Technical success was achieved in 100% of cases **(Table 3).**

The primary patency rates at 3, 6, 12, 24 and 36 months were 100%, 96.4%, 92.9%, 88.9% and 84.6% respectively. The assisted primary patency rates at 3, 6, 12, 24 and 36 months were 100%, 96.4%, 96.4%, 96.3% and 92.3% respectively. The secondary patency shows a strong trend toward a significant difference as it was 96.2% at 36 months **(Table 4, Fig. 1).**

The subgroup analysis specifically looked at primary, assisted primary, and secondary patency according to the initially designated TASC lesions. The relation between TASC II Classification and 36- month patency in 21 patients (26 limbs) who completed the follow-up period showed no significant difference between different types of lesions **(Table 5).**

The subgroup analysis found no significant difference in primary, assisted primary, and secondary patency in relation to lesion length **(Table 6 a,b,c).**

At the end of the study, we lost one patient to follow-up, one patient died.

23 pts (28 limbs), 13 males, 10 females, age ranged 37-76 (mean= 59.1 years), 16 were smokers, 15 had DM, 14 had HTN, 4 pts had CKD (3 pts had GFR = 60-89%, 1 patient on regular dialysis), 15 had dyslipidemia, 9 had IHD, 14 had COPD.

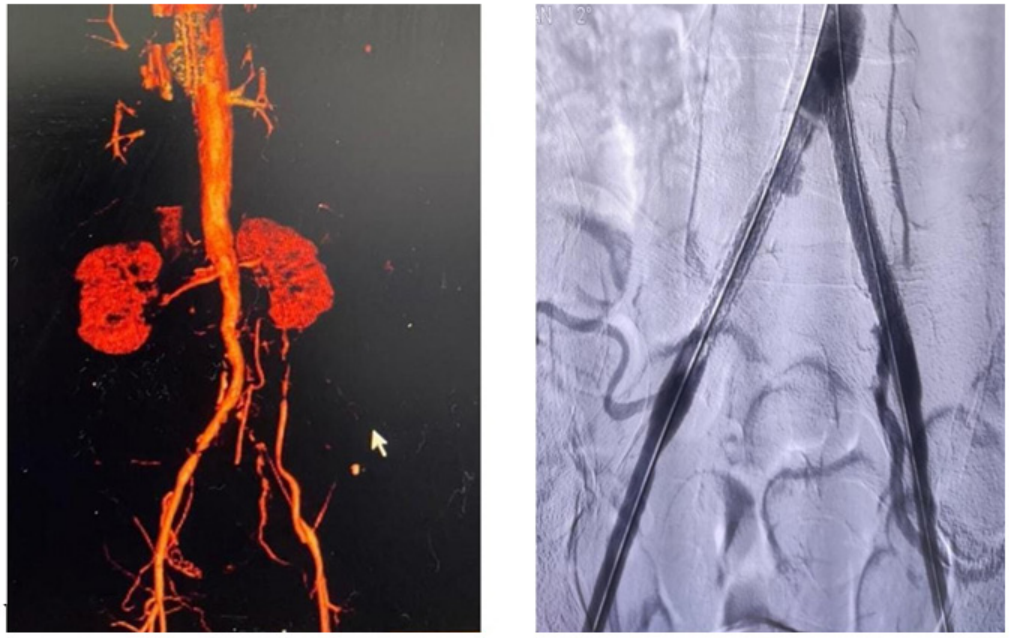

Fig 1: 60 years male patient, diabetic, hypertensive, known to have Crohn's disease (Not in activity at time of presentation). Patient presented with left lower limb rest pain. CTA showed occlusion of the left common iliac artery and stenosis in right common iliac artery. Femoral segment was not diseased. Bilateral iliac stenting was done.

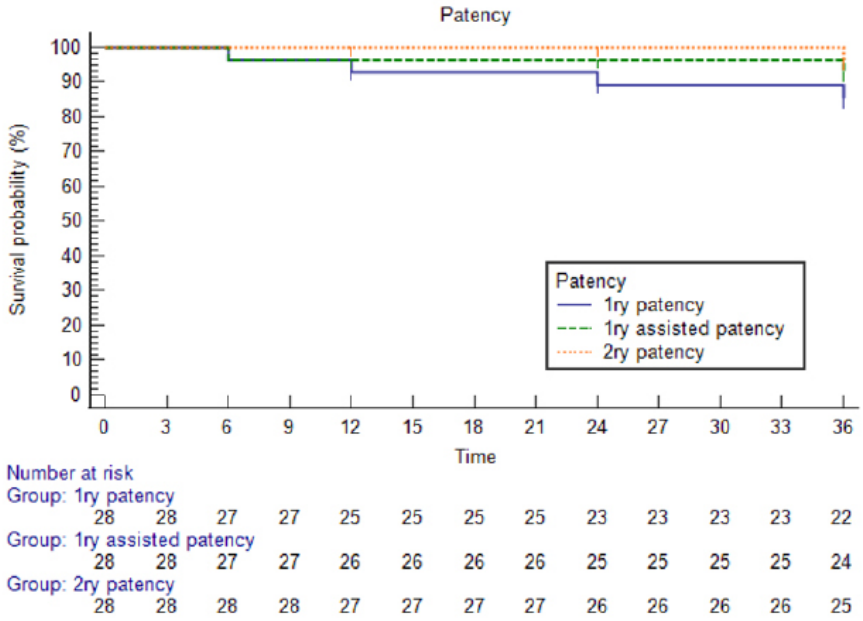

Fig 2: K-M curve for patency.

Table 1: Demographic data

Age	37-76 (mean= 59.1 ± 11.4) years
Gender	
Male	13 (56.5%)
Female	10 (43.5%)
Rutherford's classification	
2	15 (53.6%)
3	2 (7.1%)
4	11 (39.3%)
Risk Factors	
Smoking	16 (69.6%)
Diabetes	15 (65.2%)
Hypertension	14 (60.9%)
Chronic Kidney Disease	4 (17.4%)
Dyslipidemia	15 (65.2%)
Ischemic Heart Disease	9 (39.1%)
COPD	14 (60.9%)
Functional status	
No Impairment	9 (39.1%)
Impaired, but able to carry out ADL.	10 (43.5%)
Needs some assistance.	4 (17.4%)
Needs total assistance	0 (0.0%)

ADL: Activities of daily life, COPD: Chronic Obstructive Pulmonary Disease.

Table 2: Resting ABI pre-procedure and at follow up visits

ABI	Mean ± SD	Range
Preprocedural	0.52 ± 0.11	0.21 – 0.74
Postprocedural	0.79 ± 0.12	0.55 - 1.1
3M	0.79 ± 0.11	0.57 - 1
6M	0.79 ± 0.12	0.56 - 1.1
12M	0.78 ± 0.12	0.56 - 1.1
24M	0.77 ± 0.11	0.45 - 1
36M	0.76 ± 0.12	0.46 - 1.1

Table 3: Procedural complications

Thrombosis	0
Dissection	2 (7.1%), Didn't require treatment
Macroembolization	0
Microembolization	1 (3.6%), Resolved without intervention
Rupture	0
Device Malfunction	0
Hematoma	4 (14.3%), Resolved without intervention
Pseudoaneurysm	1 (3.6%), Resolved without intervention
Arteriovenous fistula	0
Infection	0

Table 4: Patency

Patency	Postprocedural	3 months	6 months	12 months	24 months	36 months
1ry	28 (100%)	28 (100%)	27 (96.4%)	26 (92.9%)	24 (88.9%)	22 (84.6%)
Assisted 1ry	28 (100%)	28 (100%)	27 (96.4%)	27 (96.4%)	26 (96.3%)	24 (92.3%)
Secondary	28 (100%)	28 (100%)	28 (100%)	28 (100%)	27 (100%)	25 (96.2)
Total	28	28	28	28	27 (1 patient lost follow up)	26 (1 patient died)

Table 5: Relation between TASC II classification and 36 months patency in 21 patients (26 limbs) who completed the follow up period

Lesion type	No. (%)	1ry	Assisted 1ry	2ry
A	10 (38.5%)	9 (90%)	9 (90%)	10 (100%)
B	1 (3.8%)	0 (0%)	0 (0%)	0 (0%)
C	13 (50%)	11 (84.6%)	13 (100%)	13 (100%)
D	2 (7.8%)	2 (100%)	2 (100%)	2 (100%)

Table 6: Relation between Length of lesion and 36 months patency in 21 patients (26 limbs) who completed the follow up period

Length of lesion	No. of patients	1ry	Assisted 1ry	2ry
≤6 cm	4 (14.3%)	4 (100%)	4 (100%)	4 (100%)
7-10 cm	18 (64.3%)	14 (77.8%)	16 (88.9%)	17 (94.4%)
>10 cm	4 (14.3%)	4 (100%)	4 (100%)	4 (100%)

Table 6a

		1ry				Fisher exact test		
		Not patent		Patent				
		N	%	N	%	value	p value	sig.
TASC II	A	1	10.0%	9	90.0%	4.21	0.287	NS
	B	1	100.0%	0	0.0%			
	C	2	15.4%	11	84.6%			
	D	0	0.0%	2	100.0%			
Lesion Length	≤6	0	0.0%	4	100.0%	1.17	0.563	NS
	7-10	4	22.2%	14	77.8%			
	>10	0	0.0%	4	100.0%			

Table 6b

		1ry assisted				Fisher exact test		
		Not patent		Patent				
		N	%	N	%	value	p value	sig.
TASC II	A	1	10.0%	9	90.0%	7.08	0.040	S
	B	1	100.0%	0	0.0%			
	C	0	0.0%	13	100.0%			
	D	0	0.0%	2	100.0%			
Lesion Length	≤6	0	0.0%	4	100.0%	0.72	1	NS
	7-10	2	11.1%	16	88.9%			
	>10	0	0.0%	4	100.0%			

Table 6c

		2ry				Fisher exact test		
		Not patent		Patent				
		N	%	N	%	value	p value	sig.
TASC II	A	0	0.0%	10	100.0%	8.59	0.038	S
	B	1	100.0%	0	0.0%			
	C	0	0.0%	13	100.0%			
	D	0	0.0%	2	100.0%			
Lesion Length	≤6	0	0.0%	4	100.0%	1.25	1	NS
	7-10	1	5.6%	17	94.4%			
	>10	0	0.0%	4	100.0%			

Discussion

Twenty-three patients were included in this study; all of them had symptomatic aortoiliac arterial disease (Rutherford class 2,3,4). Patients were treated with a balloon-expandable covered stent (Advanta V12) with the median follow-up of 32 months.

In our study, the post-procedural mean resting ABIs improved in comparison to pre-procedural mean resting ABIs with 0.24-0.27 increase throughout the follow-up intervals with no significant difference during such intervals. This finding is comparable to the results published by Mwipatayi et al., who found baseline, 12 months, 24 months, and 60 months mean resting ABI to be about 0.65, 0.94, 0.96 and 0.90 respectively.10 Rzucidlo et al. during his 12-month follow-up reported mean pre-intervention resting ABI was 0.30, which increased to 0.59 post-intervention.[7]

In our study, the overall procedural complications were low (1-4%) with no major events which necessitate intervention as well as 100% technical success. Rzucidlo et al. reported 3% overall complication rate with 100% technical success and no major amputations.[7]

In our study, 12-month primary, assisted primary, and secondary patency were 92.9%, 96.4%, and 100%, respectively. With no significant difference between different types of TASC lesions. Rzucidlo and colleagues reported stent-graft treatment of patients with severe aortoiliac occlusive disease (85% TASC types C and D lesions) which elevated the primary and assisted primary patency at 1 year to 70% and 88%, respectively, and led to 100% early hemodynamic and clinical success.[7,13]

In our study, 36-month primary, assisted primary, and secondary patency was 84.6%, 92.3%, and 96.2%, respectively. There was no significant difference between different types of TASC lesions regarding primary patency whereas there were significant differences in assisted primary and secondary patency between different types of TASC lesions.

Chang et al. reported long-term results of stent grafts for the treatment of complex aortoiliac occlusive disease at 3 and 5 years after intervention. The primary patency rates of the iliac segment were 80% and 80%, respectively; corresponding to assisted primary patency rates of 95% and 95%.[12]

Based on TASC classification, primary patency using stent grafts differed significantly. Rzucidlo and colleagues reported that TASC type B iliac lesions had a 100% 5-year patency rate while those with TASC type C iliac lesions had the lowest 5-year primary patency—significantly lower than TASC type D iliac lesions (61% vs. 85%; P = .04).[13]

E et al. conducted a multicenter study to compare the short and medium term outcomes of stent grafts and bare metal stents in treatment of AIOD. The study included 67 patients with different TASC II types and Rutherford classification 0, I, II, III, IV and IV. The authors reported the 2ry patency at 6, 12 and 24 months (92.19%, 96.08% and 95.74% respectively). They had 1 major complication (1.49%). There was distal arterial occlusion and led to major amputation. They also reported 1 case of aortoiliac artery bleeding leading to death of the patient (Mortality 1.49%).[14]

Nevelsteen and co-workers found that mean primary and secondary cumulative patency rates after 1 year were 85% and 95%, respectively. In this series, all patients underwent outflow procedures as, profundaplasty or femoral distal grafting.[15] Psacharopulo has demonstrated 91% 2-year primary patency in patients treated with self-expanding stent grafts for TASC D lesions. These patients also underwent concomitant femoral endarterectomy.[15]

Based on lesion length in our study, there was no statistically significant differences in relation to 36-month primary, assisted primary and secondary patencies. Unfortunately, there was no available data in other studies about the correlation between lesion length and patency.

Aortobifemoral bypass grafting remains the standard of care for diffuse aortoiliac disease. However, endovascular treatment with covered stents has comparable outcomes and is well tolerated. In addition, many of these patients would not be candidates for abdominal revascularization procedures and would benefit from the shortened hospital stay.[11]

Conclusion

Covered stents are excellent choice for treating aortoiliac lesions. It is safe and efficient with good patency rate. More studies and follow up time may prove its patency superiority over the bare metal stents. We recommend for multi-centric prospective clinical studies focusing on this issue to enrich the guidelines of treating aortoiliac occlusive disease.

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