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Different Methods of Endovascular Techniques in Management of Aorto-Iliac Occlusive Disease

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ABSTRACT

Background: AIOD (Aorto-Iliac Occlusive Disease) may affect any of the arteries from the distal aorta to the common femoral arteries. CERAB (Covered Endovascular Reconstruction of Aortic Bifurcation) is a minimally invasive method used to treat significant and/or recurring aortoiliac occlusive disease. Bare-Metal stents are both effective and safe for treating AIOD. Bare-Metal stents had a statistically substantial greater risk of primary patency in both the general cohort and more complicated TASC C/D lesions.

Methods: This was a comparative study done in Helwan University Hospital, Wadi Elnil Hospital, Shebin EL Kom teaching hospital and Aswan University Hospital from June 2020 to June 2022. The study was conducted on 45 subjects. Our study included 45 patients who were categorized into three groups in 1:1:1 ratio. Groups were covered stents, Endovascular Aneurysm Repair (EVAR), and Bare-Metal groups. Patients were followed clinically and by duplex US scan.

Results: There was no substantial variation among the three groups except in double barrel technique, Superficial Femoral Artery (SFA) angioplasty and complications occurrence. Double barrel was mostly used in Bare-Metal group, SFA angioplasty was significantly observed in Covered Stents group and complications frequently occurred in Bare-Metal group. Bare-Metal group re-intervention was significantly increased compared to other groups (Less patency).

Conclusion: A covered Stents and EVAR technique has proven to be optimal endovascular treatment options for aorto-iliac occlusive disease and is related to promising clinical outcomes. EVAR is more used with aneurysm occurrence. Through-out time Bare-Metal Stents have low patency rate compared to CERAB and EVAR techniques.

Keywords: AIOD, Covered Stents, CERAB, EVAR, Bare-Metal Stent.

INTRODUCTION

An inflow lesion known as AIOD may arise anywhere between the common femoral arteries and the distal aorta. Stenoses may impact either the aorta or the iliac arteries alone or both, and they can be short or long segmented, calcified or ulcerated, concentric or eccentric, numerous or few, unilateral or bilateral. Localized infrarenal aortic stenoses that do not affect the aortic bifurcation are infrequent. This is more common in young persons who have less atherosclerotic disease. The most frequent extension of distal aortic occlusive disease is into the common iliac arteries [(1)]. The atherosclerotic consequences of smoking constrict an already tiny aorta and iliac arteries, resulting in hypoplastic aortoiliac syndrome, which is more frequent in female smokers. Intervention should only be used for patients with limb-threatening claudication or claudication that restricts their lifestyle since patients with asymptomatic PAD are unlikely to benefit from endovascular or surgical therapies and may have difficulties connected to treatment. In addition, impotence is a common adverse effect among AIOD patients [(2)].

Risk considerations for the establishment of AIOD include non-white ethnicity, smoking, diabetes, dyslipidemia, high blood pressure, and age, and male sex, elevation of the C-reactive protein, hyper homocystinemia, hyperviscosity/hypercoagulability, and chronic renal impairment. Modifiable risk factor optimization is a critical component of effective AIOD management [(3)].

Aortoiliac endovascular intervention is recommended for patients with severe lifestyle-restricting claudication, rest pain, a non-healing ulcer, gangrene, or tissue loss, iliac system stenosis preventing other endovascular therapies, and reduced renal activity or hypertension in renal transplant recipients. In the case of complications, contraindications include a lack of symptoms, incorrect anticoagulation, and operator inexperience with insufficient surgical assistance [(4)]. Angioplasty and/or stenting are examples of endovascular treatments. The absence of further treatment following endovascular intervention is referred to as primary patency. When the treated segment is not occluded, primary assisted patency is defined; when the treated segment is occluded, secondary patency is produced [(5)].

Because of the high frequency of AIOD, as well as the possibility of severe lifestyle-limiting claudication, impotence, and/or tissue loss, proper diagnosis and therapy are required. The symptoms of aortoiliac illness are alleviated by a combination of medical management of modifiable risk factors for PAD, correct noninvasive and/or invasive diagnostic diagnosis for patients with claudication or CLI, and endovascular and/or surgical revascularization, as necessary [(6)].

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CERAB is a minimally invasive procedure utilized to treat severe and/or chronic aortoiliac occlusive disease. Stent-grafts are delivered remotely via the groin or arm arteries to reconstruct the wounded aortic bifurcation and iliac arteries. This innovative approach allows surgeons to treat severe aortoiliac disease, which would otherwise need significant vascular surgery [(7)].

In the treatment of AIOD, bare-metal stents are both safe and efficacious. In both the general cohort and the more severe TASC C/D lesions, bare-metal stents were linked with a statistically substantial enhance in the chance of primary patency [(8)].

During EVAR surgery, a stent graft is introduced into the afflicted area using tiny groin incisions. During EVAR, a stent-graft is utilised to replace the inner lining of the aorta. A stent-graft is a steel skeleton wrapped in impermeable fabric that is placed into the femoral arteries under fluoroscopic supervision [(9)].

The present study aimed to compare between CERAB, EVAR and Bare-Metal stent in management of Aorto-Iliac Occlusive disease.

MATERIAL AND METHODS

This was a comparative study from June 2020 to June 2022The study was conducted on 45 subjects. All were followed at the Vascular Surgery Department Units at the Faculty of Medicine of in Helwan University Hospital, Wadi Elnil Hospital, Shebin EL Kom Teaching Hospital and Aswan University Hospital. Our study included 45 patients who were categorized into three groups: Group A: 15 patients were treated with Covered Stents. Group B: 15 patients were treated with Bare-Metal stents. Group C: 15 patients were treated with EVAR.

Inclusion criteria: Aorto-Iliac Occlusion (Aorto-Iliac segment, Bilateral Iliac, Distal Aorta and Proximal Iliac), complex situations with blocked profunda and superficial femoral arteries.

Exclusion criteria: Life expectancy less than 12 months (Patients were to be followed up with for at least 18 months). Cases of acute complicated occlusion**,** uncontrolled hypertension**,** a mental illness that hinders the subject from appreciating the nature, scope, and possible ramifications of the study, or a language barrier that prohibits the person from providing informed permission, and participation in the study is rendered impossible due to an uncooperative attitude or suspected noncompliance with protocol standards.

Each patient was exposed to: Complete taking of history. Complete general, cardiological and vascular examination.

We used one left Trans-Brachial approach for passing the wire and maintaining single lumen and double Brachio-femoral approach.

For covered endovascular reconstruction of aortic bifurcation

employing crossing wires and catheters, the occlusive lesion was passed either subintimal or endoluminal for individuals having a subintimal route, angiography revealed correct placement after achieving re-entry into the aorta's lumen. Through the 9 Fr sheath, an 8-10 mm V12 LD balloon expandable ePTFE coated stent was inflated in the distal aorta 20 mm above the bifurcation. A bigger balloon, typically 16 mm, was used to flare the proximal 2/3 of the aortic stent to create a funnel-shaped covered stent. The new aortic bifurcation was then created by concurrently implanting two 8 mm V12 balloon expandable ePTFE coated stents in the common iliac arteries and the distal third of the aortic stent. This tight connection between the two stents created the new aortic bifurcation.

For CERAB Technique:

Complete CERAB with aortic stent with two bilateral ilia stent was performed with Bentley stent or double parrel cover stent using B12 stent (Figure 1).

For Bare-Metal stent (Double Parrel technique): Same technique was used. Stents were measured after surgery, with covered and BMS 1 mm larger than the measured diameter of the treated iliac artery.

For EVAR device technique: After deployment of the main stent-graft component with its contralateral iliac extension, device was on ultra-super stiff guide wire (260), then by canulation with 260 hydrophilic wires on the contralateral gate. EVAR technique was used in cases of thrombosed aneurysm, small aortic aneurysm or iliac occlusion due to extension of thrombus from ectatic aorta.

Follow up: Patients were followed clinically (with ABI and symptom relief) and by duplex US scan.

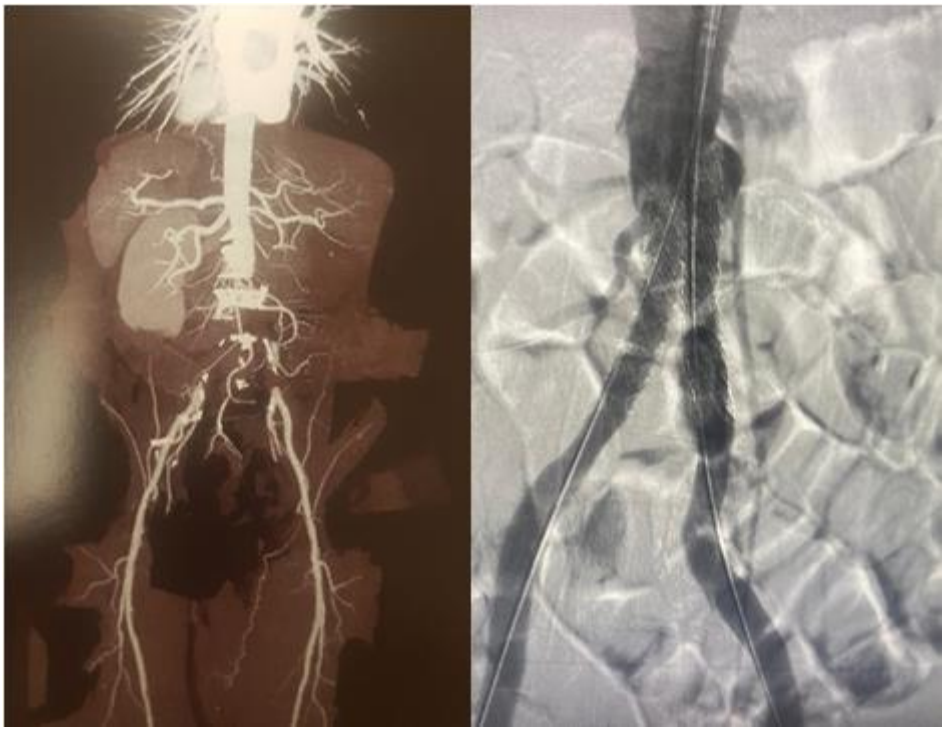

Figure (1): Double parrel covered stent for aorto-iliac occlusion

Ethical Approval:

The study was approved by the Ethics Board of the Helwan University. Participants were informed about surgery, its steps and its complications, and an informed written consent was taken from each participant in the study. This work has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

Statistical Analysis

Data analysis was carried out utilizing IBM-SPSS version 24. The statistical significance was assessed utilizing the Kruskal-Wallis. We used ANOVA for continuous data comparison and Chi square test for frequency comparison. If the P-values were less than 0.05, we regarded the findings as statistically substantial.

RESULTS

There was no substantial variation among the three groups except in Double barrel technique, SFA angioplasty and complications occurrence. Double barrel was mostly used in Bare-Metal group, SFA angioplasty was significantly observed in Covered Stents group and complications frequently occurred in Bare-Metal group. Bare-Metal group re-intervention was significantly increased compared to other groups (Less patency).

Table (1): Patients characteristics

Parameter	**Covered Stents Group** (N = 15)		**EVAR Group** (N = 15)		**Bare-Metal Group** (N = 15)		P. Value
	Number	Percent	Number	Percent	Number	Percent	
Age in years	63.13 ± 8.55		62.3 ± 6.15		64.3 ± 7.42		0.613
Sex (Male)	11	73.33	13	86.67	12	80	0.54
CAD	6	40	6	40	4	26.67	0.594
MI	2	13.33	1	6.67	2	13.33	0.332
Familial dyslipidemia	1	6.67	3	20	1	6.67	0.16
CABG/Bypass	2	13.33	4	26.67	4	26.67	0.54
Hypertension	13	86.67	12	80	11	73.33	0.54
Hypercholesterolemia	13	86.67	12	80	13	86.67	0.743
Smoker	11	73.33	14	93.33	11	73.33	0.174
Active smoking	11	73.33	13	86.67	12	80	0.54
COPD	5	33.33	2	13.33	4	26.67	0.236
Diabetes mellitus	13	86.67	14	93.33	13	86.67	0.321
Baseline creatinine	1.27 ± 1.45		1.17 ± 1.52		1.23 ± 1.36		0.132
EF	53.16 ± 3.43		54.62 ± 4.53		55.22 ± 5.11		0.163
TIA	2	13.33	7	46.67	4	26.67	0.0926
Aspirin	14	93.33	13	86.67	14	93.33	0.587
Plavix	7	46.67	6	40	9	60	0.675
Anticoagulant	1	6.67	1	6.67	4	26.67	0.071
Anticholesterol	8	53.33	8	53.33	7	46.67	0.807
Clinical presentation							
Claudication	4	26.67	7	46.67	6	40	0.203
Tissue loss	5	33.33	8	53.33	6	40	0.352
Impotence	4	26.67	4	26.67	6	40	0.442
Rest pain	10	66.67	5	33.33	7	46.67	0.125
CTA							
Arotoiliac	10	66.67	8	53.33	9	60	0.681
Arotoiliac and SFA	2	13.33	4	26.67	3	20	0.779
Arotoiliac and SFA and tibials	3	20	4	26.67	3	20	0.924
Any open Previous aortic surgery	4	26.67	5	33.33	7	46.67	0.327
Previous (aortoiliacal) endovascular intervention	2	13.33	2	13.33	2	13.33	1
Endovascular Total operated vessels	3.12 ± 0.98		3.32 ± 0.92		3.49 ± 1.02		0.77
SFA	4	26.67	3	20	4	26.67	0.927
Tibial	3	20	5	33.33	2	13.33	0.372
Transbrachial	13	86.67	10	66.67	12	80	0.119
Transfemoral (single)	14	93.33	11	73.33	10	66.67	0.108
Technical success	15	100	15	100	15	100	1
SFA angioplasty	4	26.67	5	33.33	1	6.67	0.019*
Tibial angioplasty	3	20	4	26.67	4	26.67	0.803
Total operation time in min	100 ± 49.8		105 ± 52.3		112 ± 44.8		0.853
Volume of Contrast in ml	107 ± 35.01		112 ± 32.15		102 ± 33.81		0.633
Number of stents	2.25 ± 0.74		2.13 ± 0.68		2.29 ± 0.86		0.435
ICU stay	2	13.33	2	13.33	2	13.33	1
Other complications	1	6.67	3	20	7	46.67	0.001*
Hematoma	1	6.67	2	13.33	3	20	0.446
Length of postop hospital Stay	3 ± 3.69		3.21 ± 3.68		3.46 ± 4.17		0.21
Discharge Status (intact femoral pulse)	11	73.33	13	86.67	14	93.33	0.171
Femoral pulse							
No	1	6.67	2	13.33	1	6.67	0.581
Intact	14	93.33	13	86.67	14	93.33	0.581
1st follow up intervention	1	6.67	2	13.33	5	33.33	0.139
2nd follow up intervention	1	6.67	1	6.67	6	40	0.022*

* Significant difference. CAD: Coronary artery disease, MI: Myocardial infarction, CABG: Coronary artery bypass graft, COPD: Chronic obstructive pulmonary disease, EF: Ejection Fraction, TIA: Transient ischemic attack, CTA: computed tomography angiography, SFA: Superficial Femoral Artery, ICU: Intensive care unit.

DISCUSSION

Traditional surgical reconstruction has traditionally been considered the gold standard for treating major aorto-iliac occlusions, with endovascular revascularization reserved for less problematic lesions [(10)].

Our study is the first to compare covered stents, Bare-Metal stents, and EVAR devices in the treatment of aortoiliac occlusive disease. Covered stents may limit vascular smooth muscle cell and inflammatory cell migration and proliferation through open stent struts, perhaps reducing late luminal loss. As a result, restenosis caused by luminal invasion from extracellular matrix deposition intimal hyperplasia may be decreased [(11)]. Bare-metal stents lack a barrier that inhibits the underlying plaque from entering the lumen, and stent oversizing in comparison to the reference lumen promotes neointimal development. Covered stents may also be less thrombogenic than Bare-Metal stents. Abdominal aortic aneurysms may be treated using endovascular aneurysm repair (EVAR), a minimally invasive technique; however, we utilised it to treat aorto-iliac occlusive diseases in our research [(12)].

Because it is less invasive and offers promising results, the CERAB technique is becoming increasingly popular as a viable alternative to traditional surgery [(10)].

The biggest cohort research on endovascular therapy for infrarenal aortic occlusive lesions was released [(13)]. In this investigation, bare metal balloon-expandable and self-expanding stents were used to treat 49 lesions. Distal embolization happened in 10.2% of the patients, while difficulties occurred in 16.3% of the patients. In comparison to earlier trial rates (0-28.5%), the 30-day total complication rate was 14.2% [(14)].

During endovascular intervention, eccentric and severely calcified lesions are more likely to rupture. One advantage of employing covered stents is that any rupture would be addressed as soon as possible. The use of covered stents may result in the exclusion of arterial collateral pathways, notably the inferior mesenteric artery (IMA). However, these arteries are often occluded in stenotic lesions [(8)].

Our patency rates were found to be almost identical to previous comparable study. **Goverde *et al.*** [(15)] used covered stents to treat 44 patients with acute, chronic, or recurrent aortoiliac occlusive disease. The technical success rate was 96% with follow-up ranging from 3 to 38 months. Four people died as a consequence of causes unrelated to the procedure. Ultrasound and CT-angiography were used as follow-up imaging. Four people were re-occluded as a consequence of distal peripheral vascular bed disease or hematological illnesses. Mechanical thrombectomy and outflow treatment were successful, with a patency rate of 90% at 6 months and 84.4% at 12 months.

Also, **El Samadoni & Eldmarany *et al.*** [(16)] published that Covered stent therapy for occlusive aortoiliac diseases is a technically feasible and potentially safe procedure that demonstrates very good early and mid-term patency.

Because of the rarity of single aortic lesions and the high expense of surgery, the small number of patients in our cohort restricted our results to early outcomes. Our first data showed that, regardless of the severity of the lesion, this method is both feasible and effective in achieving excellent morphological and hemodynamic improvement. In our study, there were no cases of visceral or spinal cord ischemia. Endovascular surgeries had a substantially lower complication rate with a shorter hospital stay, according to an old research by **Bosiers *et al.*** [(17)] which may compensate for the high cost of such therapies.

Mwipatayi *et al.* [(18)] state that a covered stent may be used to safely and efficiently treat patients with challenging aortoiliac lesions, such as persistent iliac artery occlusions and aortoiliac bifurcation occlusions, according to growing data from single-center clinical studies.

For patients with renal illness in particular, endovascular aneurysm repair (EVAR) has been shown to be a viable therapeutic alternative for abdominal aortic aneurysms. Its benefits over the conventional open approach include reduced morbidity, quicker operation, and a shorter hospital stay. We employed EVAR to treat aorto-iliac occlusive diseases in our study. Except for the majority of data, there was no substantial variation in the occurrence of difficulties between the EVAR group and the other groups.

In the **Tozzi *et al.*** [(19)] investigation, three EVAR surgeries were performed with no problems or changes in graft survival. During follow-up (4-30 months, mean 14 months), the only postoperative problems were two hematomas and one branch blockage, which is similar to the findings of **Galazka *et al.*** [(20)] in which no patients displayed symptoms of arterial graft infection following vascular reconstruction. There were no vascular graft-related problems throughout the healing process.

Re-intervention was much greater in the Bare-Metal group than in the CERAB and EVAR groups, suggesting decreased patency. Covered stents, as shown the findings of **Reijnen**[(21)], are the most suited endovascular treatment option for aorto-iliac occlusive disease in terms of form and flow, and are linked with favourable clinical outcomes.

CONCLUSION

Covered Stents and EVAR techniques have proven to be optimal endovascular treatment options for aorto-iliac occlusive disease and are related to promising clinical outcomes. EVAR is more used with aneurysm occurrence. Through-out time Bare-Metal Stents have low patency rate compared to Covered Stents and EVAR techniques.

DECLARATIONS

Consent for Publication: I confirm that all authors accept the manuscript for submission
Availability of data and material: Available
Competing interests: None
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Conflicts of Interest: The authors declare no conflicts of interest regarding the publication of this paper.

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