Endovascular Aortic Revascularization As A First Line of Treatment of Complex Aorto-Iliac Occlusive Disease in Patients with Co-Morbidities Precluding Open Surgery

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ABSTRACT

Introduction: *Complex infrarenal aortic disease is rare. Short focal lesions are best treated by endovascular means, while long lesions are better treated surgically. The aim of the study is to evaluate the feasibility, patency and complications of endovascular management of complex aorto-iliac occlusive disease (AIOD).* ***Patients and Methods:*** *This is a prospective study of patients with complex AIOD presenting to Kasr Al-Ainy hospital in the period from June 2013 to June 2015. CT Angiography was performed in all patients to plan the procedure access and tools. All lesions were pre-dilated with an undersized balloon, and then were stented either by self-expandable stents, Balloon-expandable stents or covered stents according to our pre-study selection criteria. Technical success, Clinical success, Complications and follow up were reported.* ***Results:*** *Thirteen patients were included in this study. Eight cases had total occlusions (3 of them were Juxtarenal extending into the iliac bifurcation and 5 were at the distal aorta extending into the commom iliac artery(CIA). The other five cases had tight and long stenoses of the distal aorta extending into CIAs. We used 35 stents: 22 self expandable stents, 7 balloon-expandable stents and 6 covered stents. Technical success was achieved initially in all patients. One limb was amputated due to extensive pre-procedural infrainguinal disease. one patient died in the first postoperative day and another patient died 3 months later. Clinical success was achieved in the remaining 11 patients.* ***Conclusion:*** *Endovascular aortic revascularization shows promising early and midterm results. Initial results justify its use as a first choice. Large scale studies with longer follow up are awaited for to establish its role in the management of complex aorto-iliac disease in comparison to open surgery.*
Keywords: *aortic occlusion - endovascular*

INTRODUCTION

Complex aortoiliac disease involving the infrarenal aorta is a rare disease. Total occlusion of the infrarenal aorta has been identified in3% to 8.5% of patients presenting with aortoiliac occlusive disease [1].

Current opinion suggests that short focal lesions of the aorta and iliac arteries are best treated by endovascular means, while longer diffuse iliac lesions, as well as those that extend into the infrarenal aorta, should be treated principally with surgical bypass. This opinion is underscored by fears of periprocedural safety and inferior long-term durability with endovascular methods. The Trans Atlantic Inter Society Consensus (TASC-II) guidelines define infrarenal aortic occlusion as a type D lesion and state definitively that ‘‘surgery is the treatment ofchoice,’’. But there is lack of good quality studies to base this recommendation. The surgical gold standard is aortobifemoral bypass, which has patency rates of 90% at 5 years and 75% at 10 years, but with significant major morbidity (9%–27%), impotence (11%–33%), and death (3.3%–5%). [2]

The relatively higher perioperative mortality and morbidity of surgery limit its use in some high-risk cases. During the past two decades, endovascular treatment has become the choice of management for localized aorto-iliac occlusive disease (AIOD), primarily because of the advent of balloon angioplasty and stent technology. Endovascular interventionalists have achieved technical success in the treatment of complex aortoiliac lesions, but it remains unclear whether the patency of endovascular reconstruction for type C and D lesions is comparable to that of traditional surgical revascularization. However, recent reports on the endovascular treatment of

more severe cases of AIOD have yielded results approximating those of open surgery. [3]

The aim of our study is to evaluate the feasibility, patency and complications of the endovascular management of complex AIOD, and define its role as a first line treatment in high risk patients.

PATIENTS AND METHODS

This is a prospective study of symptomatic patients with complex AIOD presenting to Kasr Al-Ainy hospital in the period from June 2013 to June 2015. Patients with acute embolic or recent thrombotic occlusion, fibromuscular dysplasia and hypolastic aorta syndrome were excluded. All patients had medical co-morbidities precluding a safe open vascular revascularization of their aorta. All patients fell into ASA grade 4 or more according to the American Society of Anaesthesiology grading system.

Demographics of the patients, detailed medical history, history of previous intervention and formal general and local examination were carried out followed by duplex ultrasound (DUS) and ankle brachial pressure index (ABPI) measurement. A CT angiography (CTA) was ordered as a routine investigation for all patients to evaluate lesion site, length, and distal runoff vessels. An informed consent was obtained and all procedures were explained to the patients.

According to the CTA findings the access, direction of crossing, and tools were planned. In patients with stenoses bilateral 6F femoral accesses were used under local anesthesia guided by a weakly palpable pulse, or under ultrasound guidance. Heparin (100 IU/kg) was administered. A hydrophilic angled or straight tip 0.035" guide wire (Terumo, Tokyo, Japan) is passed across the lesion in a transluminal plane in each iliac artery. If this failed a stiff hydrophilic 0.018" wire (V-18, Boston Scientific, USA) was used to negotiate the lesion.

In patients with occlusions a left brachial access was used under local anesthesia, where a 6F, 90 cm-long sheath (Cook, Bloomington, IN, USA) was utilized. the sheath was connected to a continuous infusion of heparinized saline to prevent development of pericatheter thrombus. A pigtail catheter (Cordis, Bridgewater, NJ, USA) was advanced into the suprarenal aorta to perform the initial arteriogram; 20ml of non-ionic contrast at a rate of 15ml/second and a pressure of 600mmHg. Crossing was attempted initially using a stiff 0.035- inch hydrophilic guidewire (angled or straight tip, Terumo, Tokyo, Japan) supported by a Multipurpose catheter (Cook, Bloomington, IN, USA). When the wire passes into one of the iliac arteries the catheter was replaced by a small-sized balloon (3-5mm diameter) as a straight support catheter for lesion negotiation till reaching the run off.

If the wire fails to cross by the antegrade approach, a retrograde approach through one or both femoral arteries was commenced under fluoroscopic or ultrasound guidance. Crossing of the lesion is attempted similarly by a a small-sized balloon.

After successful wire passage, the lesion was pre-dilated with an undersized balloon in all patients. According to lesion morphology the appropriate stent type and size is chosen. For stents with a large profile the 6F femoral sheaths were exchanged correspondingly to obtain an adequate access (7-9F). In all patients a minimum of two accesses were required to complete the procedure in the aorta and both iliac arteries.

Self-expandable bare stents were used in the aorta and both iliac arteries, except for severely calcific lesions, where balloon mounted stents were chosen. Aortic stents were deployed first followed by stents extending from the aorta to both iliac arteries in a kissing fashion. Covered stents were used in lesions with expected or suspected perforations, as well as high atherosclerotic/thrombotic burden.

Technical success was defined as restored vessel patency with a residual stenosis <30% and no evidence of embolizationto the renal arteries or distal runoff. Immediate hemodynamic success was determined by an increase in ABPI of >0.10 postoperatively. Clinical success was defined as a subjective perception of improved walking distance, absence of rest pain, and healing of trophic changes.

Complications were defined as any clinical or technical event that deviated from the expected. Major complications (requiring specific therapy to avert potential death or organ system dysfunction) were reported.

Patients were discharged on aspirin (100 mg/d), clopidogrel (75 mg/d), cilostazol (200 mg/d), and atorvastatin (40 mg/d) for at least 3 months followed by life-long aspirin, with general

recommendations regarding lifestyle changes and were strongly advised to exercise. Patients were followed up thereafter clinically and/or by duplex ultrasound every 3 months.

RESULTS

Thirteen patients (11 males and 2 females) presented to Kasr Al-Ainy hospital during the period from June 2013 and June 2015 with complex AIOD. Demographic data of the patients, and comorbidities are listed in table (1).

Table 1: Demographic of the patients, age and comorbidities

Parameter	No of patients
Sex	
Male	11
Female	2
Age	55-71 (mean 64.4)
Hypertension.	9
Diabetes	10
Renal insufficiency	3
Ishemic Heart Disease	7
Smoking	9
Dyslipidemia	8

The pathology of the lesion, presenting symptoms and Rutherford class(RC)are shown in table (2). The primary access, and type of stent used are shown in Table (3). Complications occurred are listed in table (4)

The brachial access was used as the initial access in 9 patients, followed by one or two femoral accesses to complete the procedure depending on the ease of crossing and the morphology of the lesion. Whereas in 4 patients an initial retrograde femoral access was commenced under ultrasound or fluoroscopic guidance, and the procedure was continued using another retrograde femoral access and/or a brachial access depending on the ease of crossing.

Table 3: Procedure details: The primary access, and type of stent used

Procedure details	No
Primary acces	
Brachial a	9
Femoral a	4
Type of used stent	
Self expandable bare metal stent	22
Balloon mounted bare metal stent	7
Covered stent	6

Table 4:Complications and mortality

Complications	
Perforation	1
Dissection	--
Distal thrombosis	--
Access site	
Hematoma	2
Thrombosis	--
Perioperative mortality	1

In two patients the juxtarenal aortic occlusion was considered to carry a great risk of embolisation to one of the renal arteries.

Table 2: pathology of the lesion, presenting symptoms / RC

The pathology of the lesion, symptoms presenting and Rhutherford class (RC)	NO. of patients/%	
Pathology of the lesion	Stenosis	Occlusion
Juxtarenal extending into the iliac bifurcation*	--	6
Lower Aorta and bifurcation	5	2
Symptoms presenting/ RC		
Intermittent Claudication	4 RCIII	
Rest pain	6 RC IV	
Ischemic ulcer	1 RC V	
Gangrene	2 RC V	
Impotence	1	

* Juxtarenal lesions(defined as a distance < 2 cm between the ostium of the more distal renal artery and the aortic lesion). All patients had an ASA score ≥4.

Figure 1: Juxtarenal aortic occlusion extending into the iliac arteries. a) preoperative angiogram, b) right renal artery protection duringpredilatation, c) kissing balloons at the bifurcation, d) Aortic self-expanding stent (14mmX60mm) and 2 iliac self-expanding stents (7mmX100mm and 7mmX150mm) deployed

In these patients the endangered renal artery was cannulated by a 0.035" guide wire from the brachial access and a 5 mm X 60mm Balloon was inflated at the ostium during the time of aortic dilatation to protect the renal artery (Figure 1). Pre-dilation was performed in all patients as the morphologic pattern of the lesion didn't allow a safe passage of the stents across the lesions, due to the higher profile of the delivery system.

Seven balloon expandable stents were used in 3 patients for a precise location and a great radial force against heavily calcific walls, while 22 self expanding stents where used as they conformed with vessel tortousity. According to the diameter of the aorta and the length of the infrarenal occlusion, the aorta was stented by a single 20mm balloon expandable stent (Bard) (n=1), a single 14mm self-expanding stent (EV3, Covidien) (n=3), two 8mm self-expanding side-by-side stents (n=5), two 9mm self expanding side-by-side covered stents (Wall graft, Boston scientific, USA) (n=1) or a single aortic covered stent (14mmx40mm, Wall graft, Boston scientific, USA).

Technical success was achieved initially for the management of the aorto-iliac segment in all cases. In patients with other distal lesions further intervention was not attempted due to the prolonged duration of the procedure and excessive contrast use. Moreover, the clinical

lesions were found to benefit from the proximal revascularization alone except for one patient with fixed colour changes in one of his limbs. For this patient a femoro-popliteal bypass was performed 2 weeks later with a successful uneventful course.

Three complications occurred. In one patient after right external iliac dilation a minor perforation with minimal extravasation of the dye was noticed , which was completely sealed after a prolonged inflation for 5 minutes. Then the vessel was stented by a balloon expandable stent and repeated angiograms showed no further dye extravasation. However, 10 hours later the patient developed a hypovolemic shock and was transferred to the operating room for exploration. Yet he succumbed immediately before starting the operation. The other complications were access hematomas. One of them was in the right groin and managed conservatively. The other hematoma was left brachial and was managed by exploration and primary repair.

Clinical improvement in the form of improvement of claudication distance, absence of rest pain and wound healing was achieved in 12 patients (after exclusion of the single postoperative mortality). However, one limb required an above knee amputation , due to extensive co-existing pre-procedural infrainguinal disease, which was not amenable for revascularization.

One patient died three months later due to myocardial infarction. The revascularization was patent with sustained clinical improvement and increase in ABPI in all remaining 11 patients after a mean follow up of 6 months (range: 3 to 12 months).

DISCUSSION

Bypass surgery is a well standardized revascularization procedure for aortoiliac disease for over 50 years with excellent long term patency and limb salvage rates but is associated with considerable morbidity in the form of cardiovascular system complications during and after the procedure, the need for blood transfusion, wound complications, long hospital stay, postoperative pain,sexual dysfunction, delayed recovery to work and mortality. All of these complications made surgeons search for other less invasive alternative[3]. And that is what established endovascular revascularization for aortoiliac disease as a competitor to bypass surgery even with its lower patency especially in the elderly moribund patients and even in the young patients who would like to avoid serious complications from bypass surgery. [3]

The aim of our study was to evaluate the feasibility, patency and complications of complex aorto-iliac disease and whether extending the endovascular option to treat the most complex lesions is well justified or not.

Our study population showed marked male over female predominance which is a common finding to atherosclerosis to all vascular territories , may be due to the protective role of estrogen and the higher incidence of smoking in males. [4]

Only one case in our series presented with tissue loss. Thisis related to the fact that most aortoiliac disease patients present with intermittent claudication or rest pain with tissue loss restricted to patientswith associated multilevel disease. [5]

All of our cases performed C.T angiography due to the limitations inherent to the duplex examination of this segment as inadequate visualization due to gases and obesity and calcification of the vessels. Moreover, CTA helps proper planning of the access and the required tools. Still duplex was done to tell if there is any suspicion that the occlusion is thromboembolic or not. Hossam Zaytounb et al has shown in his comparative study between CT angiography and color coded Doppler ultrasonography in aortoiliac occlusions that CT angiography was more sensitive. [6]

We used the brachial access in addition to one or two femoral accesses in 9 of our cases (in the 8 cases of occlusion and in 1 case of tight stenosis that failed crossing from the femoral access). We adopted this approach for the following reasons ; 1) the brachial access provides better in -line pushability to cross occlusions, Compared to the contralateral crossover approach ; 2) Compared to the ipsilateral femoral access , the reentry from the brachial access is much easier than reentry in the thick calcified aortic intima which may lead to aortic dissection or uncontrolled reentry site. [7]

Varcoe et al started with the femoral ipsilateral in all cases but they used reentry devices in case of failed reentry and thus they could avoid the use of a brachial access. [2]

The main disadvantage of the brachial access is the risk of developing hand ischemia or hematoma formation especially when using 7 Fr sheaths to deploy large-sized aortic and long iliac stents. In our series one case developed hematoma that needed surgical evacuation and surgical repair of the brachial artery. Alvarez et al have shown in a series of 323 brachial accesses that brachial access site–related complications occurred in 21 patients (6.5%). Thirteen of these 21 patients (62%) required a surgical correction , they have also shown that patients who had a long interventional sheath were more likely to develop complications. [8]

All of the lesions in our series were crossed with 0.035" guidewire (as these lesion are very tough and calcified) except one case with 95% stenosis which was crossed with 0.018" guidewire in which we feared that the 0.035" guidewire would cause a subintimal crossing and unpredictable reentry.

Diethrich started thrombolytic therapy in aortoiliac occlusions before angioplasty and stenting to facilitate wire passage and they report excellent results but also they reported thromboembolic complications.[9] In our series we did not use thrombolytic therapy as we excluded acute thrombotic cases.

Predilation was done in all cases without radiologically detectable gross distal embolization. Varcoe et al prefer primary stenting to trap possible thrombotic debris in the wall and eliminate the possibility of distal embolization [2], the main disadvantage of this approach is that there are some times difficulty of passing the stent through occlusions and the possibility of dislodgement of the stent from the balloon in balloon -mounted stents.another problem is when the self -expandable stent cannot open the lesion due to its low radial force with difficulty in putting the balloon in the stent to postdilate it. In our study we relied on the preoperative duplex and the wire traversal test to predict any soft plaque to avoid distal embolization but all of our lesions were tough and difficult to cross, so we performed predilatation to allow for smooth passage of the stents.

We used 22 self expandable stents out of 35 stents in our cases due to their longer length and thermal memory properties. Long stents provide a single conformable unit through the occlusion, while the thermal memory is useful in avoiding crush deformation. This was also the approach followed by Varcoe et al in his series of 8 infrarenal aortic occlusions extending to the iliac bifuraction [2]. We have not found the need for additional radial force in our cases. Threeballoon-expandable stents were used. One of them was juxtarenal and 2 in the CIA for precise location and better radial force . We used covered stent in 3 of our cases. We believe that the use of bare metal stents in preference to stent-grafts preserves aortic and iliac side branches as The lumbar, inferior mesenteric,and internal iliac arteries.in the case of future stent occlusion these branches prevent more severe ischemia by acting as natural mini- bypasses. [2]

However, a recent trial by Sabri et al retrospectively reviewed 54 consecutive patients with aortic bifurcation disease who were treated with bilateral common iliac artery kissing-balloon stenting.Twenty-six patients received stent grafts, and 28 patients received balloon-expandable bare-metal stents. Technical success was seen in 100% of patients in both groups. When compared to balloon-expandable bare-metal stents, covered stents were superior in regard to primary patency at a mean follow-up of 29.5 months (92% vs 62%; P = 0.02). Patients who received covered stents in this study had more TASC II C and D lesions.[10] The preliminary result in 2 randomized controlled trials , one from Australia called COBEST (Covered Versus Balloon Expandable Stent Trial) and one from the USA called iCARUS study, are in favour of viabahn covered stents. [11] [12] [13]

Perforation occurred in onecase that was managed by prolonged balloon dilatation followed by bare metal self expandable stent and the patient eventually collapsed and died and this justifies the policy of many interventionalists of not doing iliac angioplasty without backup of covered stents and their compatible sheaths. [14]

As regards other complications , there was one brachial hematoma that was surgically evacuated and brachial artery repairedand another small hematoma that was managed conservatively.

Technical success was achieved in all patients and clinical success was reached in 12 of the 13 patients, as only one case needed distal revascularization in another session due to inadequate healing of the foot after debridement (this was the only case presenting with tissue loss). This conformed with the 95-100% technical

success achieved by other studies like Zhang et al[3], Bruijnen et al [12] and Varcoe et al [2]

This study has demonstrated that endovascular management of complex juxtarenal and aortic bifurcation stenoses and occlusions is feasible, but it lacks long term follow up. Further studies with larger numbers of patients and randomization against the standard bypass surgery is needed before it can be considered a first line treatment for all patients including the young fit patient. At the moment the endovascular management of complex juxtarenal and aortic bifurcation is justified as a first line treatment for all patients with co-morbidities precluding open surgery.

CONCLUSION

Endovascular aortic revascularization shows promising early and midterm results. Initial results justify its use as a first choice. Large scale studies with long follow up are awaited to establish its role in the management of complex aorto-iliac disease in comparison to open surgery.

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