Endovascular aortic aneurysm repair with iliac branched device for treatment of aortoiliac aneurysms: short-term results

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Received: 8 November 2022
Revised: 30 November 2022
Accepted: 4 December 2022
Published: 28 April 2023

The Egyptian Journal of Surgery 2023, 41:1605–1610

Background
Abdominal aortic aneurysm (AAA) is a life-threatening disease, which may be discovered incidentally or upon its rupture. The endovascular AAA repair (EVAR) has become the treatment of choice owing to its minimal invasiveness. It is challenged by the presence of concomitant common iliac artery aneurysms as there is no proper sealing zone distal to the aneurysm. Currently, advances in graft technology yielded the iliac branch devices (IBDs) to be the solution to keep the internal iliac artery blood flow and preclude pelvic ischemic complications.
Aim
This study aimed to present our experience and the short-term outcome of using IBD during AAA repair.
Patients and methods
This is a retrospective study that included 20 patients with aortoiliac aneurysms indicating interventions. After proper selection, patients were treated with EVAR with Cook Zenith IBD implantation.
Results
Technical and clinical success was achieved in all cases. Primary patency was 100% at 1 year. No IBD-related complications were encountered. Type II endoleak was present in two cases with stable course and stationary sac size not requiring intervention.
Conclusion
The short-term patient follow-up in this study highlighted that when patients are properly selected and precise technical manipulation is secured, EVAR-IBD is a feasible, effective, and safe treatment of choice for patients with AAA and common iliac artery aneurysms. It offered substantial clinical and technical success, and iliac patency, with no procedure-related significant morbidity or mortality.

Keywords:
abdominal aortic aneurysm, concurrent common iliac aneurysms, endovascular aortic aneurysm repair, iliac branch device

Egyptian J Surgery 41:1605–1610

1110-1121

Introduction

Abdominal aortic aneurysm (AAA) is a permanent localized dilatation of the vessel that exceeds 50% of its normal diameter [1]. The pathogenesis of AAAs appears to be multifactorial, where risk factors predispose to the disease in genetically susceptible people [2].

AAA is a life-threatening disease that may be discovered incidentally or upon rupture. Ruptured AAAs are associated with an extremely high mortality rate, reaching up to 81% [3]. During the past three decades, there has been a significant reduction in the prevalence of AAA in developed countries. However, the AAA burden is still affecting low-income and middle-income countries with a rising prevalence [4].

AAA is one of the most challenging conditions encountered by vascular surgeons. Early diagnosis of AAAs before rupture is crucial for management. It is recommended to repair AAA in all patients with accepted perioperative risk if they have symptomatic or saccular AAA, or if they have an AAA of 5–5.5-cm diameter or more [5].

Open surgical repair was traditionally the only choice for patients with AAA. It was associated with high rates of perioperative morbidity and mortality [6]. The evolution of endovascular AAA repair (EVAR) has resulted in dramatic changes in the field of AAA repair. It has shown about half of the repair-associated mortality, and being minimally invasive, it has offered a treatment option for patients with high

perioperative risk who were previously considered unsuitable for repair [7].

It has been reported that ~20–40% of patients with AAA have common iliac artery (CIA) aneurysms [8]. This can be treated by extending the graft into the external iliac arteries (EIAs). However, this will be at the expense of the internal iliac arteries (IIAs), which will be excluded, with the consequent risk of pelvic ischemia [9]. It has recently been recommended to preserve at least one IIA to minimize the pelvic ischemia risk as far as possible. To achieve such a goal, branched devices with an IIA stent have been designated to be implanted during EVAR with adaption to potential anatomical variation [10].

Data about the implantation of iliac branch devices (IBD) are still scarce in the literature. This study aimed to present our experience and the short-term outcome of using IBD during AAA repair.

Patients and methods

This is a retrospective study that included 20 patients who were admitted to the Vascular Surgery Unit of Cairo University, Nasser Institute, and Damanhur Teaching Hospitals with aortoiliac aneurysms indicating interventions according to the institutes' guidelines during the period from June 2019 to June 2021. The study was conducted after approval by the institutional review board and per the Helsinki declaration.

Patients underwent full history taking, dedicated physical examination, and computed tomography angiographic or magnetic resonance arteriography examination to assess the aneurysm, the anatomical details of the aorta and iliac vessels, and any possible associated abdominal pathology. Patients with indications for open surgery, connective tissue disorders, pseudoaneurysm, aneurysm rupture, or infected aneurysm were excluded from the study. Patients with marked kinking or calcifications of the iliac vessels, or anatomical vascular measures not coinciding with the IBD system were also excluded. Informed written consent was obtained from the included patients.

Technique

All stent grafts were placed under general anesthesia in dedicated angiography suites. Patients were admitted 1 day before the procedure. In the current work, the Cook Zenith IBD (Cook Australia Pty Ltd, Brisbane, Queensland, Australia) was implanted. It is an endograft with a side branch that lands in the IIA. The introduction system of the IBD is preloaded with a catheter. The delivery system permits tailoring the final location before fully deploying and inserting the bridging stent graft (BSG).

All patients received prophylactic antibiotics and 5000 IU heparin. Arterial access was either percutaneously guided by duplex ultrasound with a ProGlide closure device or through open surgical exposure. From the contralateral femoral approach, a 7-Fr sheath was advanced inside a coaxial 12-Fr flexible sheath over a through-and-through wire, allowing both sheaths to be moved as one unit while maintaining position over the flow divider to avoid displacement of the preexisting endograft. Once the 12-Fr sheath was positioned in the iliac limb of the aortic stent graft and secured in place with the through-and-through wire, a separate new puncture of the 12-Fr sheath and cannulation of the IIA was done with 0.035 Terumo soft wire and Bern catheter, and then the repair was extended into the IIA using a BSG (Advanta V12 Maquet Cardio-vascular, Hudson, New Hampshire, USA) or BeGraft (Bentley Innomed, Hechingen, Germany). The surgeon was cautious not to extend the BSG above the gate of the device, to avoid occlusion of the IBD device.

Patients having contralateral IIA aneurysms underwent either simultaneous embolization or staged embolization in the form of coil embolization before EVAR-IBD was done. Coiling of contralateral IIA was performed using Tornado coils (Cook Medical, Bloomington, Indiana, USA).

Patients' follow-up

After patients' discharge, regular follow-up was done at 1, 6 months, and after 1 year. Follow-up included physical examination for any systemic or aneurysm-related complications or mortality, and a computed tomography scan to assess the aneurysm sac diameter, device integrity, or different types of endoleak. All patients received single-antiplatelet aspirin 81 mg once daily for at least 1 year.

Study outcomes

The primary outcomes of the study were clinical and technical success, patency rates, and reintervention rates. The secondary outcomes were the postoperative procedure-related adverse events or mortality.

Clinical success was defined as the absence of pelvic ischemia, and technical success was defined as the

complete exclusion of aortoiliac aneurysm with the absence of type I or III endoleak on completion angiogram. The reintervention rate was defined as the surgical correction of an EVAR-IBD-related complication after the discharge of the patient.

Statistical analysis

The patients' data were analyzed using the statistical package SPSS, version 26 (IBM, Armonk, New York, USA). After normality testing, expression of variables was made accordingly.

Results

This study included 20 patients. There was a male predominance, with males constituting 90% of the study patients (18 patients). The patients' ages ranged from 45 to 72 years, with a mean of 67±9.7 years. The patients' comorbidities were coronary artery disease (15 patients; 75%), hypertension (14 patients; 70%), hyperlipidemia (12 patients; 60%), diabetes mellitus (six patients; 30%), chronic pulmonary disease (four patients; 20%), renal insufficiency (two patients; 10%), and previous stroke (two patients; 10%). A total of 16 (80%) patients were smokers (Table 1).

Concerning clinical data, 11 (55%) patients had aortic and bilateral CIA aneurysms, eight (40%) patients had aortic and unilateral CIA aneurysms, and one (5%) patient had an isolated CIA aneurysm (Table 2).

Assessing the vessels' diameter revealed that the mean aortic aneurysm diameter was 55±5.3 mm, the mean aortic neck diameter was 27±4.6 mm, and length was 23±11 mm. The mean CIA diameter was 31±4.2, mean EIA diameter was 9±1.6 mm, and the mean IIA diameter was 8.5±1.1 mm (Table 2).

Table 1 Sociodemographic data of the study patients

	Study patients (*N*=20) Mean±SD (minimum–maximum)
Age (years)	â 67±9.7 (45–72)
	n (%)
Sex	
Female	2 (10)
Male	18 (90)
Comorbidities	
Diabetes mellitus	6 (30)
Hypertension	14 (70)
Dyslipidemia	12 (60)
CAD	15 (75)
COPD	4 (20)
Renal insufficiency	2 (10)
Smoking	16 (80)

Eight (40%) patients had contralateral IIA aneurysms, and six (30%) of them underwent simultaneous embolization. The remaining two (10%) patients underwent staged embolization 2 weeks before EVAR-IBD (Table 2).

The IBD was inserted in the right CIA in 12 (60%) patients and in the left in eight (40%) patients. Duplex-guided percutaneous access was achieved in 12 (60%) patients, and open access was performed in the remaining eight (40%) patients, with the right femoral artery accessed in five (25%) patients and the left femoral artery accessed in three (15%) patients. The mean procedure time was 150.7 ±36.3 min, and the mean fluoroscopy time was 30.9 ±16.5 min (Table 2).

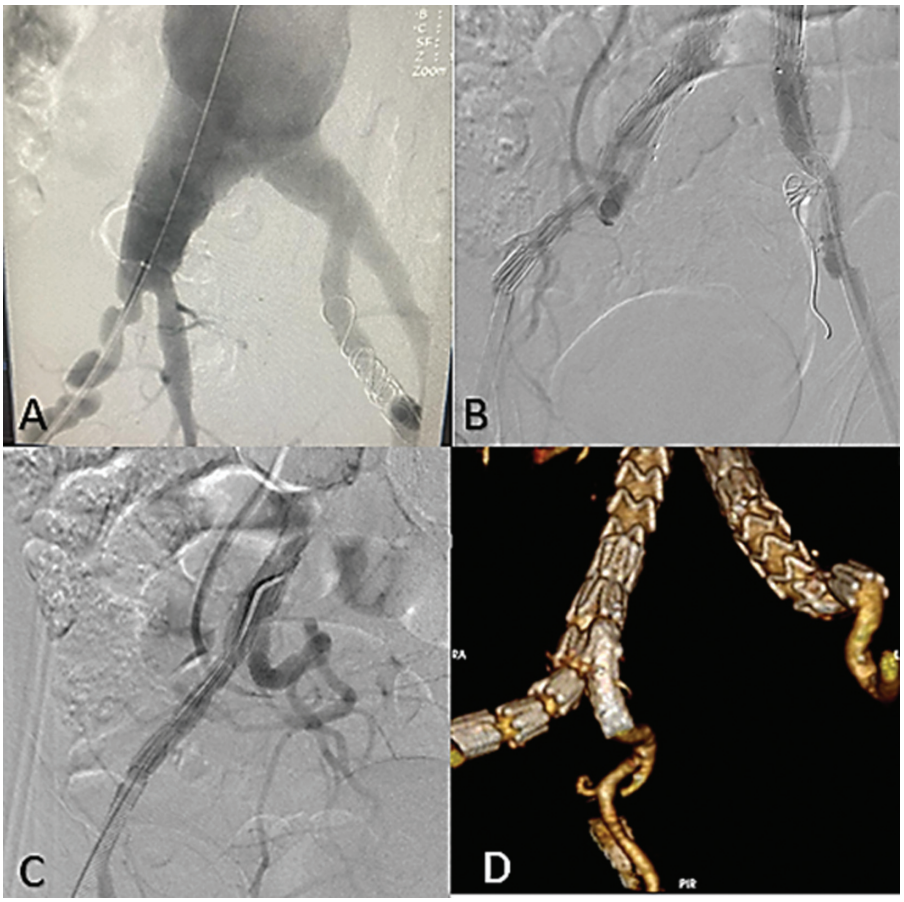
Regarding the patients' outcome, technical success was achieved in all cases with no type I or III endoleaks. Primary patency was 100% at 1 year, and all iliac side branches were patent at 1 year. Clinical success was achieved in all patients with no pelvic ischemia recorded, even in patients with simultaneous contralateral IIA embolization. No access site or other IBD-related complications were experienced. In two cases, type II endoleaks were present, with a stable course and stationary sac size not requiring intervention. There were no stent migration. No mortality cases were encountered during the first 30

Table 2 Clinical and surgical data of the study patients

	Study patients (*N*=20) Mean±SD
Aortic aneurysm diameter (mm)	â 55±5.3â
Aortic neck diameter (mm)	â 27±4.6
Aortic neck length (mm)	â 23±11
CIA diameter (mm)	â 31±4.2â
EIA diameter (mm)	â 9±1.6
IIA diameter (mm)	â 8.5±1.1
Procedure time (min)	â 150.7±36.3
Fluoroscopy time (min)	â 30.9±â â 16.5
	n (%)
Presentation	
Aortic and bilateral CIA aneurysms	11 (55)
Aortic and unilateral CIA aneurysm	8 (40)
Isolated CIA aneurysm	1 (5)
Contralateral IIA aneurysms	8 (40)
The IBD site	
Right CIA	12 (60)
Left CIA	8 (40)
Access	
Percutaneous	12 (60)
Open	8 (40)

CIA, common iliac artery; EIA, external iliac artery; IBD, iliac branch device; IIA, internal iliac artery.

Figure 1



(a) An angiography examination of a patient with aortoiliac aneurysm for right IBD; (b) EVAR-IBD of the right side with left IIA embolization; (c) patent right IIA with bridging stent graft; (d) follow-up CTA with patent IBD.â CTA, computed tomography angiographic; EVAR, endovascular AAA repair; IBD, iliac branch device; IIA, internal iliac artery.

days after the intervention. One case died from myocardial infarction 3 months after the procedure. Figure 1 shows examinations of a patient with aortic and right iliac aneurysm before and after intervention.

Discussion

The EVAR of AAA has become the treatment of choice in developed countries owing to its minimal invasiveness [6]. It is often challenged by the presence of concomitant CIA aneurysms as there is no proper sealing zone distal to the aneurysm [11]. Extending the graft into the EIA with a resultant occlusion of the IIA has been the strategy frequently adopted to treat these patients. However, sacrifice of the pelvic blood supply can lead to buttock claudication and erectile dysfunction, which will cause dramatic impairment of the patient's quality of life [12]. Currently, advances in graft technology have yielded IBD to be the solution to keep the IIA blood flow and preclude pelvic ischemic complications [10].

The current patient series is the first report from Egypt addressing the endovascular treatment of CIA aneurysms with an IBD.

This study showed outstanding technical and clinical success. This is comparable with other literature that reported the surgeons' experiences and demonstrated that IBD use was feasible in a selected group of patients. The technical success rates of EVAR-IBD ranged from 88.2 to 100% [13–17].

In the current work, we achieved a primary patency rate of 100%, which is consistent with other similar studies that found an iliac patency rate of 89.7–100% [13,18]. We had an endoleak rate of 10% (two cases). However, in the two patients, this was a type II endoleak and did not require reintervention. These findings are lower than those reported in the study of D'Oria *et al.* [19], who found 17 cases of type II endoleaks out of 96 studied patients, with a rate of 17.7%. We had no cases of reintervention, whereas other studies reported reintervention rates of 7.3–18.2% [17,20,21].

We believe that the excellent outcome achieved in the current study is multifactorial. First, we chose to use the Cook Zenith IBD. The graft is manufactured from full-thickness woven polyester fabric that is conjugated to self-expandable nitinol and stainless steel Cook Zenith stents. This offers stabilization and expandability during deployment to ensure patency of the lumen. Rings made of nitinol located proximally help to open the lumen during access. In addition, the essential seal between the vessel wall and the lumen could be achieved with the Cook Zenith stents. The side branch of the Cook Zenith stent is reinforced by a nitinol stent and two supporting rings. Its outer surface is marked by linear gold markers. Based on the computed tomography angiographic reconstruction, the device was justified for each patient's vascular anatomical variations in terms of the CIA aneurysm and the EIA length and diameter. We kept in mind that the side branch distal end should be positioned 10 mm superior to the iliac bifurcation, and the common iliac segment proximal end should be placed just adjacent to the aortic bifurcation. The devices were loaded into a sheath with an indwelling catheter and guide wire via the side branch to enable their cannulation through the contralateral side by trapping the wire [22]. Second, we properly selected the patients who would benefit from IBD. We diligently reviewed the suggested criteria required for patients to receive an IBD, including the sufficient diameter of CIA, length of EIA, and length and diameter of IIA to secure the proper landing of the branch device. Finally, patients with factors predisposing to technical or clinical failure, such as iliac tortuosity or calcification, CIA thrombus, ipsilateral IIA atherosclerosis, or IIA aneurysm, were excluded. Moreover, patients with aneurysmal rupture were not included in the study.Current evidence has revealed that the percutaneous technique is effective and provides a less-invasive approach than surgical cut down in patients undergoing EVAR [23,24]. We adopted the percutaneous approach unless the CFA was severely calcified, or very small in diameter.

Some publications have demonstrated that simple IIA coverage without previous embolization does not raise the probability of type II endoleak or reintervention. The evidence that is currently available, however, comes from limited retrospective series that are difficult to compare [25,26]. In the current work, IIA embolization did not result in poor outcomes.

The mean procedure time in this work was 150.7 ±36.3 min. This was in the range reported in the meta-analysis conducted by Karthikesalingam *et al.* [27] (101–290 min). This wide variation reflects the heterogeneity in the performed procedures, which ranged from solitary CIA aneurysm repair to bilateral IBD with simultaneous EVAR.

All patients in our study received single antiplatelet aspirin 81 mg once daily, as postprocedural antiplatelets might play a role in maintaining satisfactory long-term outcomes.

This work is limited by the small sample size, the short-term follow-up, and the absence of a group undergoing open surgery or another type of IBD for comparison. However, our study adds evidence to the few studies addressing the application of such a new device in the treatment of AAA accompanied by CIA aneurysms and is strengthened by being a retrospective multicentric study.

Conclusion

The short-term patient follow-up in this study highlighted that when patients are properly selected and precise technical manipulation is secured, EVAR-IBD is a feasible, effective, and safe treatment choice for patients with AAA and CIA aneurysms. It offered substantial clinical and technical success, and iliac patency, with no procedure-related significant morbidity or mortality.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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