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The Use of Iliac Branched Devices in the Acute Endovascular Repair of Ruptured Aortoiliac Aneurysms

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Background: The objective of this study was to evaluate the feasibility and midterm outcomes of iliac branch devices (IBDs) to preserve the internal iliac artery perfusion in emergent endovascular repair of ruptured aorto-iliac aneurysms.

Methods: Between December 2012 and July 2017, a total of 8 IBDs were implanted in 6 patients (the median age 65 years; all men) in a single tertiary referral center. The indication for IBD implantation was a ruptured abdominal aortic aneurysm with a concomitant common iliac artery aneurysm ($n = 4$) or isolated CIA aneurysms ($n = 2$). The main outcome measures were technical and clinical success. The secondary outcomes were primary and primary assisted patency, the occurrence of type I/III endoleaks, and reinterventions.

Results: All patients were hemodynamically stable during the procedures, which were performed under local anesthesia. Technical success was achieved in all cases (the median total procedure time of 188 min and the median IBD procedure time of 28 min). The median follow-up was 34 months (interquartile range 19−78). There were no deaths during the follow-up and no major complications unrelated to the IBD. Two (25%) secondary interventions were performed for IBD occlusion in patients with bilateral IBDs. The other reintervention was a type II endoleak embolization in 1 of these 2 patients. The freedom from reintervention estimate was 75% through 2 years. The overall primary assisted patency was 100% through 3 years.

Conclusions: The use of IBDs in the acute setting is feasible to exclude ruptured aortoiliac aneurysms while maintaining pelvic circulation. The secondary intervention rate is considerable; however, the midterm assisted primary patency rates are promising. Further studies are needed to guide patient selection and to evaluate longer term outcomes.

INTRODUCTION

The endovascular aortic aneurysm repair (EVAR) of ruptured abdominal aortic aneurysms has become the predominant treatment in developed countries, mainly because of the less invasive nature. This appears to provide favorable outcomes, mainly shown by the large registries[1] and midterm outcomes of randomized trials.[2]

Concomitant common iliac artery aneurysms (CIAs) or isolated and ruptured CIA aneurysms often preclude regular EVAR, if there is no suitable sealing zone distal to the aneurysm.

However, the current stent-graft technology allows treatment of iliac artery aneurysms with a distal sealing zone diameter of up to 25 mm because

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the largest commercially available iliac limb diameter is 28 mm (Endurant IIs, Medtronic Inc., Minneapolis, MN). These bell-bottom solutions have nevertheless been associated with a higher incidence of type Ib endoleaks and migration.[3–6] For this reason, the endograft can be extended into the external iliac artery, but the crossing of the internal iliac artery (IIA) needs to be dealt with. Initially, embolization with coils or plug occlusion of the proximal IIA to prevent a type II endoleak was the predominant alternative.[7] However, this compromises the pelvic circulation and may result in buttock claudication, erectile dysfunction, or even intestinal ischemia.[8,9] Patients with compromised collateral circulation because of contralateral IIA occlusion or bilateral common iliac artery aneurysms are especially at risk, and in these cases, the risk of ischemic complications (including spinal cord ischemia) is even higher.[7] The preservation of at least one IIA should therefore be pursued.[1] In these complex cases, open surgery remains an option but can be technically challenging and is associated with increased morbidity and mortality.[10–13] To prevent these complications, several less invasive endovascular and hybrid techniques have been developed to preserve flow to the IIA. A treatment option that has gained popularity in recent years in the elective setting because of its purely endovascular nature and good results is the so-called iliac branch device (IBD).[14,15] However, the application in the acute setting of ruptured aneurysms has not been reported.

The aim of this study is to evaluate the feasibility and midterm outcomes of the IBD in ruptured cases in a single tertiary center.

METHODS

All patients treated in a single tertiary referral center with an IBD between December 2012 and July 2017 in an emergent or acute setting for a ruptured aneurysm were included. The indication for IBD was rupture of a CIA aneurysm or rupture of an AAA with a concomitant CIA aneurysm. Data were collected retrospectively from electronic medical records and imaging was reviewed for the purpose of the study. The study was approved by the local ethical committee (Dnr 2014/732) and conducted in accordance with the declaration of Helsinki for medical research involving human patients.

All patients underwent preoperative and postoperative thin slice contrast-enhanced computed tomography angiography (CTA). CTA analysis and planning was performed in a dedicated 3-D workstation (iNtuition, TeraRecon, San Mateo, CA) by the attending surgeon. Aneurysm diameter was measured on axial imaging perpendicular to the flow line to the largest diameter of the vessel with three-dimensional reconstructed computed tomographic (CT) scan images.

The postoperative follow-up consisted of outpatient clinic visits and physical examination at one month and three-phase thin-slice CTA at 1 month, 1 year, and yearly thereafter.

IBD Procedure

All cases were performed by vascular surgeons with extensive experience on advanced endovascular procedures. All procedures were performed percutaneously via the bilateral common femoral arteries using the preclose technique for large bore sheaths (Perclose ProGlide, Abbott Vascular Inc., Santa Clara, CA). In 2 patients, concomitant upper extremity access was needed, one percutaneous brachial access and one percutaneous axillary access. The procedures were carried out in a hybrid room (Artis Zee, Siemens Healthineers, Forchheim, Germany) and started under local anesthesia converted to general in case of discomfort during the surgery.

The ZBIS IBD (Cook Medical, Bloomington, IN) was used in all cases. The anatomic criteria used for IBD suitability in this study were wider than the most flexible currently published[16] and included extension into the distal branches in case of the IIA main stem aneurysm. The graft was deployed as previously described.[17] In summary, after orientation of the IIA branch to match the target IIA, the IBD graft was advanced and partially deployed with the distal edge of the iliac branch about 1 cm above the orifice of the IIA. A femoro-femoral crossover or brachio-femoral body floss technique was used to advance a 12-F sheath into the branched graft. A second wire was then used to cannulate the IIA through a separate puncture of the 12-F sheath valve. A balloon- or self-expandable covered stent was used to bridge from the IBD to the IIA (Atrium Advanta V12, Atrium Maquet, Getinge Group, Mijdrecht, the Netherlands; Fluency or COVERA, Bard, Tempe, AZ). Self-expanding stents were placed bare back and, if they were 10 mm or larger in diameter, were reinforced with a short balloon-expandable uncovered stent in the IBD gate to avoid stenosis caused by infolding. The placement of balloon-expandable covered stents was preceded by the placement of a 7 Fr in the IIA. The overlap and landing zones were then routinely balloon dilated before and after retrieval of the body floss wire. The

Table I. Patient's demographical and anatomical characteristics

Patient characteristics	Median (IQR)	*N*
Age, y	65 (42−80)	
Male		6
Diabetes mellitus		0
Hypertension		4
Hyperlipidemia		2
Cardiac disease [a]		2
Renal failure [b]		0
GFR (mL/min/1.73 m^2)	68 (43−118)	
COPD		1
Smoking, current		1
Buttock claudication		0
BMI	27 (22−30)	
Circulatory stable		6
ASA classification 4		6
AAA (mm)	48 (22−104)	
CIAA (mm)	51 (25−65)	

Circulatory stability was assumed as systolic blood pressure >90 mm Hg and conscious patient.
COPD, chronic obstructive pulmonary disease; BMI, body mass index.
[a]Defined as current angina pectoris, previous myocardial infarction, CABG operation or PCI, current or previous arrhythmia, or heart failure.
[b]Defined as a serum creatinine level >130 μmol/L.

duration of IBD placement was assumed from the angiography to identify the IIA origin to the completion angiography of the IIA on the respective side. A cone-beam CT was performed in all cases as a completion control.

Outcomes

The main outcome measure was technical success, defined as successful exclusion of the aneurysm with the patent external and internal iliac arteries at completion angiography.

The secondary outcomes were primary and assisted patency of the IBD and its branches, assisted primary success, reintervention-free survival, incidence of type Ib or III endoleaks, and all-cause mortality. Morbidity was defined as any adverse event within 90 days after the operation. Major complications were events requiring surgical intervention or causing prolonged hospitalization, irreversible disability, or death.[18]

IIA patency was defined as uninterrupted contrast enhancement on CTA without significant stenosis.[19] Aneurysm sac enlargement referred to diameter changes >5 mm as measured on CTA. Preoperative and postoperative CTAs were assessed by 2 observers (A.K. and N.D.).

Table II. Procedural details

	Median (IQR)
Total procedure time, min	188 (114−350)
Procedure time per IBD, min	28 (14−55)
Contrast volume, ml	139 (57−260)
Procedural radiation, Gy.cm^2	87.1 (67.9−181)
Fluoroscopy time, min	33 (20−76)

Statistical Analysis

The continuous data were presented as the median and interquartile range in case of skewed data within parenthesis when not stated otherwise. The categorical data are presented as the absolute number and as count (percentage). Analyses were performed using SPSS software (version 25; IBM Corporation, Somers, NY).

RESULTS

Patient Characteristics

Six patients who had CIA aneurysms >25 mm and 4 patients who had an AAA with concomitant unilateral ($n = 2$) or bilateral ($n = 2$) CIA aneurysms were included. All patients were male, and the median age was 65 (42−80) years. Indications for use of IBD in the current series was rupture of the abdominal aortic aneurysm with concomitant CIA aneurysm ($n = 3$) and rupture of iliac artery aneurysms ($n = 3$). Two bilateral IBD implantations were performed. In all patients, the IBD was combined with an aortic stent graft. One patient had previous aortic surgery for a rupture, which was treated with a straight synthetic graft open. One patient with a juxtarenal aneurysm that was initially planned to be treated with a triple fenestrated EVAR and IBD ruptured during the waiting period and was treated with emergent EVAR plus IBD implantation. This was followed by a proximal extension with FEVAR after one month. None of the patients had a history of buttock claudication. All patients were prescribed a single antiplatelet and statin therapy postoperatively, unless they were already on oral anticoagulation therapy. Full patient demographics and anatomical characteristics are presented in Table I.

Intraoperative and Perioperative Results

A total of 6 (75%) IBDs were implanted in the left CIA and 2 in the right CIA. The median total procedure time was 188 (114−350) min and the median procedure time per IBD was 28 (14−55) min. All the procedures were performed under local

Table III. All components per case likewise the age, diagnosis, and iliac tortuosity index calculated as per SVS/AAVS reporting standards

Age, years	Diagnosis	Type aortic SG	Type of IBD SG	IAA branch SG	Iliac tortuosity index
65	rCIA aneurysm eft	Zenith Flex, Cook	ZBIS, Cook	Fluency + Visipro	1.13
42	rCIA aneurysm right	Zenith Alpha, Cook	ZBIS, Cook bilateral	Advanta (right), Advanta + Fluency (left)	1.35 right 1.38 left
72	rCIA aneurysm left	Zenith Alpha, Cook	ZBIS, Cook	Covera + Visipro	1.32
64	rAAA	Zenith Flex, Cook	ZBIS, Cook	Fluency + Visipro	1.16
65	rAAA	Zenith Flex, Cook	ZBIS, Cook bilateral	Advanta + Fluency + Protege (right), Fluency + Vispiro (left)	1.61 right 1.68 left
80	rAAA	Endurand IIs, Medtronic	ZBIS, Cook	Fluency	1.17

SG, stent graft.

anesthesia; however, in two cases, this was converted to general anesthesia for surgical exposure of access sites in the axillary and brachial artery, and it was used in one case to perform bilateral fascia sutures. The remaining 5 patients had percutaneous femoral accesses with closure devices bilaterally under local anesthesia, as described in the Methods section. There were no access-related complications. No patient became circulatory unstable under the procedure, and technical success was obtained in all 8 IBDs. Additional procedural details are shown in Table II.

The IBDs were bridged into main branch of the IIA ($n = 6$), the superior gluteal artery ($n = 1$), or the anterior division of the IIA ($n = 1$). Distal extensions were performed because of aneurysmal degeneration of the IIA in patients with bilateral iliac aneurysms. The nonbridged branches were embolized before the placement of the bridging covered stent into the preserved one. All components that were used per case likewise the iliac tortuosity index, which was calculated as the ratio between the distance along the central lumen line from the aortic bifurcation and the CFA and the shortest distance between the same anatomical landmarks[20] as per SVS/AAVS reporting standards[18,21] for every iliac artery which received the IBD, are shown in Table III. One patient had severe tortuosity in the iliac arteries (x: 1.61 on the right and x: 1.68 on the left) and needed an adjunctive procedure during primary IBD placement, requiring a brachial access for relining a disconnection of the bridging grafts in the IIA with a type III endoleak. The main aortic endografts used were the Zenith Flex stent graft (Cook Medical, Bloomington, Ind) in 3 cases, Zenith LP stent graft (Cook Medical) in two other cases, and Endurant IIs (Medtronic) in one case.

One patient underwent an adjunctive procedure during primary IBD placement. This occurred in a patient, receiving bilateral IBDs with very tortuous iliac arteries and where the completion angiography showed an unclear leak at the IIA, which was ascertained with the cone-beam CT to a disconnection of the 2 bridging stents used bridging to the superior gluteal artery (Fig. 1). This is assumed to have occurred during the removal of the stiff wire (Supra-Core, Abbott Vascular Inc., Santa Clara, CA) where the graft conformed to the tortuous anatomy leading to an extension of the lengths and gliding of the overlapping segment. A brachial access was established to successfully perform a relining of the IIA branch.

There were no cases of gluteal claudication after IBD implantation.

Postoperative Follow-up

The median follow-up time was 34 months (range 19–78 months). During surveillance, 4 secondary interventions were performed in 2 patients, both who had bilateral IBDs. One patient presented with new onset buttock claudication 10 months postoperatively and CTA showed occlusion of the whole IBD. This was subsequently treated through endovascular means by pharmacomechanical thrombectomy (AngioJet, Boston Scientific, Marlborough, MA) and catheter-directed thrombolysis of the occluded branch, and they helped in

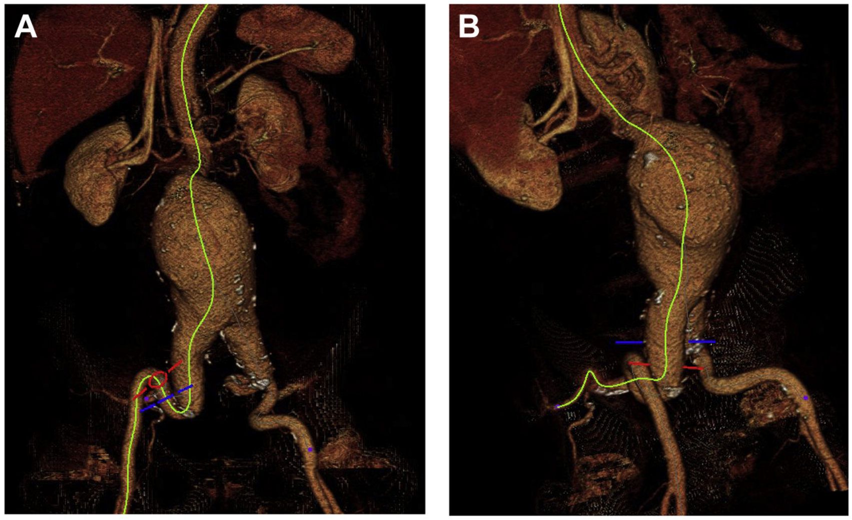

Fig. 1. The patient with a ruptured abdominal aortic aneurysm and bilateral common iliac aneurysms with severe tortuosity in 3-D volume rendering reconstruction from the preoperative CTA. This reconstruction includes a centerline of flow to the external iliac **(A)** and internal iliac **(B)** artery.

restoration of the flow in the external and internal iliac artery. Additional placement of the stent for the external iliac and internal iliac artery needed to ensure the patency of the iliac bifurcation. The same patient underwent one more reintervention 16 months postoperatively because of a type II endoleak from the lumbar arteries with aneurysm expansion. An elective embolization via a translumbal aortic puncture and injection of 18 ml Onyx 34 (Medtronic Inc., Minneapolis, MN) was successfully performed. The second patient was the one requiring an intraoperative adjunctive procedure on the IBD. The first reintervention was a balloon-expandable stent reinforcement of for a kink of the stent graft on the right external iliac component discovered 5 months postoperatively. Subsequently, this patient presented with buttock claudication due to occlusion of the IIA branch after 15 months. This was also treated by endovascular means from the ipsilateral femoral artery with pharmacomechanical thrombectomy and additional placement of balloon-expandable covered stents in the external iliac and IIA. This last patient was given clopidogrel therapy besides ASA, whereas the former was placed on non-vitamin K antagonist oral anticoagulant because of a deep vein thrombosis history.

Primary clinical success was achieved in 6 (75%) of the 8 IBDs (2 patients with bilateral aneurysms). The overall primary and primary assisted clinical success rates at 24 months postoperatively were 75% and 100%, respectively. The primary and assisted IIA patency at the same time point were 75% and 100%, respectively, whereas the secondary intervention-free survival estimate was 75%. No other major complications occurred during the follow-up, and there were no deaths.

DISCUSSION

The present study shows that the acute endovascular treatment of ruptured aorto-iliac aneurysms using IBDs is feasible with promising midterm outcomes. This offers a valuable treatment option for patients without a suitable CIA, landing zone eliminating the need to sacrifice the artery in the acute setting.

There are some issues that need consideration in repair of ruptured aortoiliac aneurysms with IBD. Broad anatomical criteria had to be used to achieve the preservation of the IIA. A widening of the anatomic criteria may potentially lead to an increased risk of failure as seen in infrarenal EVAR. This was likely to have also occurred in these patients because reinterventions were needed in the ones receiving bilateral IBDs where the anatomic inclusion criteria had been broadest because it was considered very important to preserve the pelvic circulation. Another important factor that should be taken into consideration under the selection of patients is the heavily calcified, and tortuous iliac arteries account for most of access complications, such as iliac artery injuries and misalignment of the stent graft at the deployment site, which can affect the outcomes and increase the reintervention rate.[22] In the specific case of IBD, extreme tortuosity can lead to significant changes when the stiff wires and devices are in place and subsequently removed, which challenges the conformability to the anatomy. This was illustrated in 1 patient with severe tortuous iliac arteries where an adjunctive procedure during primary IBD placement was needed from a brachial access to reline the matting grafts. These grafts in the IIA had disconnected upon removal of the stiff wires with a type III endoleak at the completion angiography.

Most importantly, the secondary clinical success could be achieved in all cases, which reinforces the potential long-term benefit of the initial procedure, which was performed to save the life in the emergency setting. However, this also needs to be balanced with feasibility of the procedure. On the one hand, the appropriateness of the procedure in the acute setting may be considered to be adding complexity to the EVAR. However, the IBD did not add a significant amount of time to the procedure (median 28 min), even if the anatomy was challenging as mentioned previously. It is, nevertheless, important to underline that this additional time was the reason for selecting only patients who were hemodynamically stable. Instability mandates the immediate exclusion of the aneurysm with subsequent embolization of the IIA. This can be preferably performed with liquid embolic agents because it allows the IIA embolization as the last step.[23] The embolization of the IIA in ruptured aneurysms may be associated with an increased risk of ischemic complications, especially colonic ischemia, compared with the elective setting because of the hypoperfusion related to hypotension and the risk of increased abdominal pressure.[24]

The need for reinterventions mentioned previously is most likely related to the conformability in very tortuous anatomies. The IBD device has designed based on Z-stents, which have limited conformability in those anatomies. Until further developments to improve this limitation occur, similarly to what has happened to the iliac extensions of the same device,[25] a liberal relining of the device with self-expanding stents and reinforcement of kinks with balloon expandable should be carried out. Moreover, cone-beam CT should also be liberally used and centered on the pelvic area to identify and allow the intraoperative correction of any conformability issues mentioned previously.

The present study has limitations. The study design was retrospective with a small cohort patient to a considerable selection bias. Moreover, all procedures were performed in a tertiary referral center by vascular surgeons with extensive endovascular experience in IBDs. These results may therefore not be readily achievable in real-world practice and need to be confirmed on a larger basis. Although follow-up duration is reasonable, it is unclear how IBDs will be performed in the longer term because these data are lacking.

CONCLUSION

The IBDs are a feasible option to exclude ruptured aortoiliac aneurysms while maintaining the pelvic circulation. The reintervention rate is considerable, especially for the bilateral procedures, but the midterm primary assisted patency rates are very good. Further studies are needed to guide patient selection and to evaluate longer term outcomes.

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