Outcomes of a novel technique of endovascular repair of aneurysmal internal iliac arteries using iliac branch devices

Martin Austermann, MD,[a] **Theodosios Bisdas, MD,**[a] **Giovanni Torsello, MD,**[a] **Michel J. Bosiers, MD,**[a] **Konstantinos Lazaridis, PhD,**[b] and **Konstantinos P. Donas, MD, PhD,**[a] *Münster, Germany; and Athens, Greece*

Objective: **To present midterm outcomes of a novel technique of endovascular repair of aneurysmal internal iliac arteries (AIIAs) using iliac branch devices (IBDs).**

Methods: **Between January 2005 and August 2012, 129 patients with aneurysms involving the iliac bifurcation underwent placement of IBDs. In particular, between April 2010 and August 2012, 16 consecutive patients with aortoiliac or solitary iliac aneurysms and coexisting AIIAs were treated with the novel suggested strategy. The follow-up included physical examination and computed tomography (CT) angiography postoperatively, duplex scan at 3 months, CT scan at 6 months, and then CT scan annually.**

Results: **The technical success rate was 100%. The primary patency rate for the overall 21 internal iliac branches (five patients with bilateral aneurysms) was 95.3%. The overall assisted patency was 100%. No patient had evidence of type I/III endoleak during the follow-up of 2 years. Two patients showed type II endoleaks originating from the abdominal aneurysm sac and are under radiological surveillance.**

Conclusions: **Our 2-year experience with the described novel approach showed its safety and feasibility, expanding the applicability of IBDs also in case of coexisting AIIAs. Long-term results and an increased number of treated patients with this technique are needed. (J Vasc Surg 2013;58:1186-91.)**

Use of iliac branch devices (IBDs; Cook Inc, Bloomington, Ind) is gaining ever greater acceptance in the treatment of aortoiliac aneurysms.[1,2] However, one important issue is that coexisting internal iliac aneurysm (AIIA) increases the technical difficulty, representing exclusion criterion for some authors.[3] Tielliu et al[3] reported that only 52% of patients with aortoiliac or solitary iliac aneurysms were morphologically suitable for IBD.

In our previously published experience with the use of IBD in 64 patients,[4] coexisting AIIA was noted as an adverse feature for IBD deployment. The main technical difficulty is the absence of a sufficient distal landing zone. Placement of bridging stents in AIIA are linked to higher risk for dislocation and rupture of the aneurysm due to persistent perfusion.[4] Use of the rigid balloon-expandable covered stents (BECSs) shows a limited conformability in such anatomical conditions. We reported recently on dislocation of the previously deployed BECSs in a hugh AIIA with consecutive rupture of the aneurysm.[4]

From the Department of Vascular Surgery, St Franziskus Hospital Münster, and Clinic for Vascular and Endovascular Surgery, Münster University Hospital, Münster[a]; and the Hellenic Institute Pasteur, Athens.[b]

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Reprint requests: Konstantinos P. Donas, MD, PhD, Department of Vascular Surgery, St Franziskus Hospital Münster, and Clinic for Vascular and Endovascular Surgery, Münster University Hospital, Hohenzollernring 72, 48145 Münster, Germany (e-mail: k.donas@gmx.at).

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Over 2 years ago, we introduced a novel therapeutic approach to overcome the anatomical limitation of a coexisting AIIA. The aim of the present study was to report the 2-year results of this therapeutic strategy in patients with aortoiliac or solitary iliac aneurysms and coexisting AIIAs who had undergone placement of IBD.

METHODS

Prospectively collected data were retrospectively analyzed. Between January 2005 and August 2012, 129 patients with aneurysms involving the iliac bifurcation underwent placement of IBDs. Forty-six patients (35.7%) had an internal iliac artery diameter of more than 11 mm or common iliac artery length of less than 45 mm, which are clear anatomical conditions of an off-label use. During the first period (January 2005 to March 2010) patients with coexisting AIIA underwent placement of one or more BECSs, such as the V12 i-Cast/Advanta (Atrium, Hudson, NH). In the second period (April 2010 to August 2012), 16 consecutive patients with coexisting AIIAs were treated by a novel approach. Table I shows the demographics and Table II the aneurysm characteristics and periprocedural data of the 16 patients. Fifteen of them were male (93.8%). The mean age was 69.2 ± 4.4 years. All patients had a diameter of the internal iliac artery of more than 11 mm. Five of them (31.2%) had a bilateral AIIA.

Procedure. The first step is the deployment of the IBD. We prefer the percutaneous transfemoral approach using the Prostar XL 10F system (Abbott Laboratories, Abbott Park, Ill).[4] The indwelling wire will be changed with a Terumo stiff wire. After snaring of the wire and

Table I. Patient demographics

Comorbidities	*No.*	*%*
Arterial hypertension	16	100
Diabetes mellitus	2	12.5
Hyperlipidemia	8	50
Previous myocardial infarction/ coronary artery disease	3	18.7
Chronic obstructive lung disease	8	50
Renal insufficiency	3	18.7
Nicotine abuse	14	87.5

removal through the contralateral groin, the 12 F flexor sheath (Cook) will be advanced from the contralateral side up to the end of the side branch. The internal branch will be cannulated with the standard Terumo wire 0.035' and a vertebral catheter. After insertion of the vertebral catheter in the internal iliac artery, removal of the Terumo wire and application of contrast agent confirms intraluminal position of the catheter and orientation of the origin of the two main branches such as the posterior and the anterior trunk/division. Our goal is to catheterize the posterior trunk via the atraumatic Rosen wire with the J-tip (Fig 1, *A*). The first used bridging covered stent for the internal branch is the balloon-expandable V12 iCast/ Advanta. The BECS will be preloaded in the 7F shuttle sheath extracorporeally. Fig 2 shows the preloaded V12 iCast/Advanta covered stent into the 7F sheath.

The BECS will be deployed in the internal branch. The proximal part of the stent graft gives stability at the origin of the internal branch, and the distal part is normally in the middle of the AIIA. We are mostly using the 8-mm × 59-mm V12 iCast/Advanta covered stent (Fig 1, *B*). The next step is the advance of the 12F sheath at the distal edge of the first bridging covered stent with synchronous deflation of the balloon of the covered stent (Fig 1, *C*). This allows a safe advance of the 12F sheath without risk for dislocation and crushing of the already deployed BECS. In case of other coexisting relevant branches (>6 mm diameter) originating from the AIIA, previous coiling by Tornado coils (Cook) or Amplatzer plug was performed (Fig 1, *D*). After positioning of the 12F sheath at the distal edge of the V12 (Fig 1, *D*) the self-expanding covered stent (SECS; Viabahn; Gore, Flagstaff, Ariz, or Fluency; Bard, Covington, Ga) will be deployed in the posterior trunk (Fig 1, *E*). We used mostly the 10 mm × 100 mm Viabahn. In all cases, at least 50% overlapping with the previous deployed BECS is warranted (Fig 1, *E*). The recommended distal landing zone is at least 2 cm. Finally, additional placement of a self-expanding bare metal stent (SMART; Cordis, Bridgewater, NJ, Zilver; Cook, or Complete; Medtronic, Santa Rosa, Calif) into the covered stents (Fig 1, *F*) aims to achieve a smooth transition of the stent grafts to the posterior trunk, simultaneously improving the fixation of the covered stents. The V12 i-Cast/Advanta is a BECS available in diameters of 6, 7, and 8 mm and length up to 59 mm, and is characterized by radial force, excellent fluoroscopic visibility, and precise placement. The Viabahn is a flexible SECS, also available in lengths up to 150 mm. The Fluency is also a SECS, which is available in lengths up to 130 mm. We recommend an oversizing of the covered stents of 15% to 20% (range, 13%-22%), related to the diameter of the treated vessels.

Exclusion criteria for use of IBD and the suggested technique for AIIAs were severe kinking of the external iliac artery and insufficient outflow of the posterior trunk of the hypogastric artery.

We accepted the suggested oversizing for the SECS (Viabahn and Fluency) from the manufacturer's instructions for use.

Follow-up consisted of physical examination and computed tomography (CT) scan at discharge, duplex scan at 3 months, CT scan at 6 months, and annual CT scans thereafter. Fig 3, *A-F* shows pre- (Fig 3, *A* and *B*) and post-CT angiographies (Fig 3, *D-F*) of a patient with bilateral common and internal iliac aneurysms treated by the suggested technique. Fig 3, *C* demonstrates the intraoperative angiography with the final result after placement of the BECS and SECS.

Statistics. We performed a descriptive statistical analysis using the MedCalc software (version 12.4.0.0; Mariakerke, Belgium). Categoric variables were presented as percentages, where continuous variables as mean ± standard deviation (standard deviation) or median (range). Cumulative patency rate of combined branched stent grafts was calculated using the Kaplan-Meier method.

RESULTS

The technical success rate was 100%. The average diameter of the posterior trunk was 7.2 mm ± 1.8. In all cases, the V12 iCast/Advanta was deployed first. Additionally, 15 patients underwent placement of a Viabahn and one patient a Fluency SECS. Table II highlights aneurysm characteristics and procedural details for each case. One patient suffered from acute limb ischemia due to total occlusion of the entire iliac segment on the left side, 6 months postoperatively. The patient underwent urgent thrombectomy of the occluded external branch and restoration of the flow in the external and internal iliac artery. Additional placement of an 8-mm × 39-mm Genesis Palmaz and 5-mm × 18-mm Genesis blue stent for the external iliac and internal iliac artery, respectively, via brachial approach, ensured the patency of the iliac bifurcation. The covered stents used in this particular case were the V12 iCast/Advanta and Fluency, respectively.

The primary patency rate for the overall 21 internal iliac branches (five patients with bilateral aneurysms) was 95.3% (Fig 4). At 6 months, the standard error was 0.05 in 95% survival proportion. The overall assisted patency was 100%. No patient suffered from buttock claudication or had evidence of type I/III endoleak during the follow-up of 2 years. Two patients showed type II endoleaks originating from the abdominal aortic aneurysm sac and are under radiological surveillance. The mean postoperative internal iliac aneurysm sac diameter was not

Table II. Aneurysm characteristics, patient demographics, and procedural data per each treated case

Patient	*Aneurysm*	*Internal artery diameter, mm*	*V12 length and diameter, mm*	*Viabahn length and diameter, mm*	*Fluency length and diameter, mm*
1	IA	24	8 × 59	10 × 100	–
2	AIA	25	8 × 59	10 × 100	–
3	IA	23	8 × 59	10 × 50	–
4	IA	17	8 × 59	10 × 50	–
5	AIA	22	8 × 59	10 × 50	–
			8 × 59		
6	IA	21	8 × 59	10 × 50	–
7	AIA	51	8 × 59	10 × 100	–
8	AIA	33	8 × 59	10 × 100	–
9	AIA	18	8 × 59	10 × 50	–
10	AIA	22	8 × 59	10 × 100	–
11	AIA	15	8 × 59	10 × 50	–
12	AIA	31	8 × 59	10 × 100	–
13	IA	24	8 × 59	10 × 100	–
14	AIA	20	8 × 59	10 × 100	–
15	AIA	29	8 × 59	–	10 × 80
16	IA	31	8 × 59	10 × 100	–

AIA, Aortoiliac aneurysm; *IA,* iliac artery aneurysm.

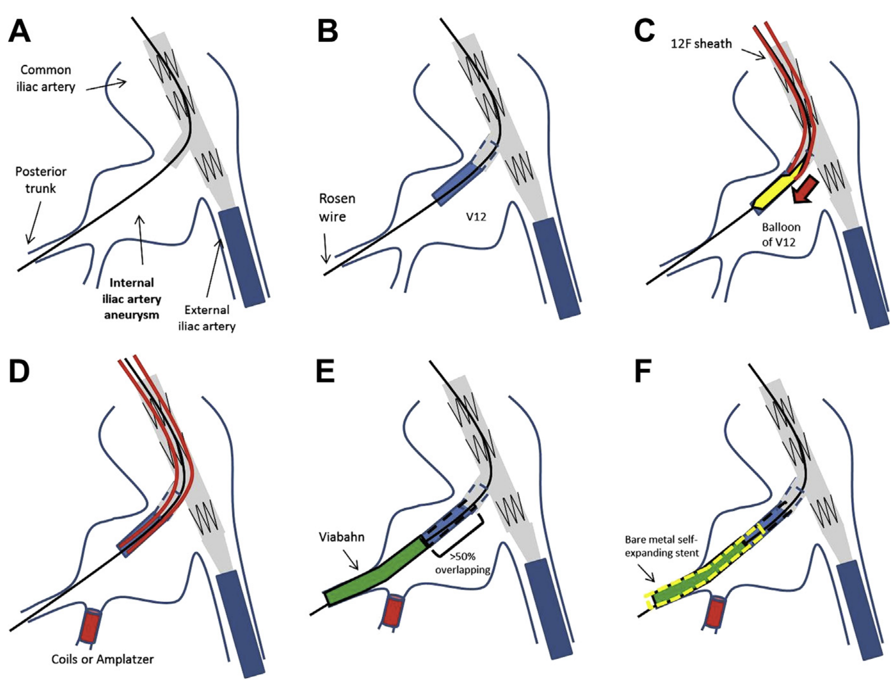

Fig 1. Sketch showing the technique of endovascular repair of aneurysmal internal iliac arteries (AIIAs) using iliac branch devices (IBDs). **A,** Placement of the IBD and catheterization of the posterior trunk of the internal iliac artery with the 0.035' Terumo wire via a vertebral catheter (Terumo Medical Corporation). **B,** Advance and placement of the V12 iCast/Advanta (Atrium) balloon-expandable covered stent (BECS) in the proximal part of the internal iliac artery after "preload" in a 7F shuttle sheath (Cook). Please note that now the guide wire is the Rosen wire (Cook), which is less traumatic due to the J-tip. **C** and **D,** Advance of the 12F flexor sheath (Cook) at the edge of the V12 covered stent with synchronous deflation of the balloon of the V12. This allows a safe and cautious advance of the 12F sheath into the V12. In case of relevant (>6 mm) coexisting relevant branches, such as those from the anterior trunk that may lead to endoleak type II, embolization by coils (Tornado; Cook) or Amplatzer vascular plug (St. Jude Medical) was performed. **E,** Advance and deployment of the self-expanding covered stent (SECS) (Viabahn; Gore, or Fluency; Bard) after retraction of the 12F sheath. Please note that at least 50% overlapping with the previous deployed V12 covered stent is needed. The distal landing zone should be at least 2 cm. **F,** Additional lining of the deployed covered stents by a self-expanding bare metal stent (SMART; Cordis, Complete; Medtronic, or Zilver; Cook) improves the fixation of the covered stents and leads to a smooth transition of the distal end of the SECS to the hypogastric branch.

Table II. Continued.

Lining bare metal stent length and diameter, mm	*Embolization (coils, Amplatzer)*	*Occlusion of internal branch*	*Postoperative buttock claudication*	*Landing zone, cm*	*Follow-up aneurysm sac size, mm*
10 × 80	10-mm Amplatzer	No	No	2.2	24
10 × 80	No	No	No	2.4	25
10 × 80	No	No	No	3.3	23
10 × 80	No	No	No	2.9	17
10 × 120	6-mm coils	No	No	3.3	18
10 × 80	6-mm coils/10-mm Amplatzer	No	No	2.8	21
10 × 80	No	No	No	2.8	34
10 × 80	6-mm coils/10-mm Amplatzer	No	No	2.2	33
10 × 80	No	No	No	2.5	18
10 × 80	No	No	No	3.3	22
10 × 80	No	No	No	2.6	15
10 × 80	6-mm coils	No	No	2.2	22
10 × 80	No	No	No	2.8	24
10 × 80	No	No	No	3.1	20
10 × 80	No	Yes	No	2.2	26
10 × 80	No	No	No	2.8	31

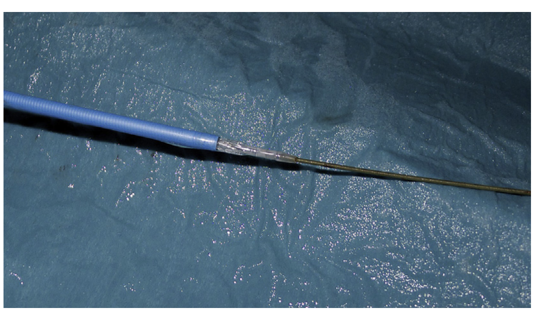

Fig 2. The "preloaded" technique. The balloon-expandable covered stent (BECS) (V12; Atrium) was inserted into the 7F shuttle sheath (Cook) extracorporeally in order into improve the system's ability to track severe angulations of the entire aorta and the safety of the V12's deployment.

changed significantly ($P = .23$). One patient reported mild erectile dysfunction postoperatively, probably caused by intraoperative coil embolization of a branch of the internal iliac artery in order to avoid type II endoleak. Two patients postoperatively developed postimplantation syndrome with elevation of C-reactive protein and leucocytes. The patients underwent administration of Cortisone 200 mg for 24 hours intravenously, and after 3 days were symptom-free. The early (30-day) and procedure-related mortality during the follow up was 0%.

DISCUSSION

The present article describes for the first time in the literature an endovascular technique to treat patients with aortoiliac aneurysms and coexisting AIIAs by IBD placement. Use of BECS first stabilizes the origin of the IIA due to the high radial force and precise placement of BECS and additionally the placement of SECS distally improves the adaptability and conformability of the covered stents in tortous and kinked branches of the hypogastric artery. Our intention is always to create a landing zone of at least 2 cm in the posterior division of the internal iliac artery. Table II summarizes the achieved landing zones. Additionally, placement of bare metal self-expanding stent into the covered stents provides better fixation and smooth transition of the distal end of the covered stent, leading to successful exclusion of the aneurysms. The flexible and long 150-mm SECS (Viabahn) showed excellent patency of 100% One occlusion of the internal branch was recorded in the one patient who underwent deployment of V12 iCast/Advanta and Fluency. The overall primary patency of the internal branch was 95.3%, and assisted patency was 100%. Compromising the hypogastric circulation during endovascular aneurysm repair may be associated with several risks. Generally, lifestyle-limiting buttock claudication and sexual dysfunction occurs in 30% and 15%, respectively. Use of IBD aims to preserve the hypogastric artery perfusion. In 2010, Karthikesalignam et al[5] conducted the first systematic review analysis on IBDs including 196 patients. In the same year, the same group[6] published a morphological score to identify patients with aortoiliac aneurysms suitable for endovascular treatment with IBDs. The score was based on the recommendations of device manufacture instruction for use and the publications by expert vascular surgeons through 2010. The most common limitation for IBD use was a coexisting AIIA.

In our previous published work about the first 64 patients with aortoiliac aneurysms who were treated by IBDs, the issue and technically demanding treatment of coexistence of an AIIA has been described extensively.[4] One patient presented with a ruptured 6-cm IIA, 2 years after the first placement of IBD. The cause for the ruptured IIA was dislocation of the two BECSs, leading to endoleak type III and consecutive rupture. The patient was treated in the urgent setting with placement of an endurant limb

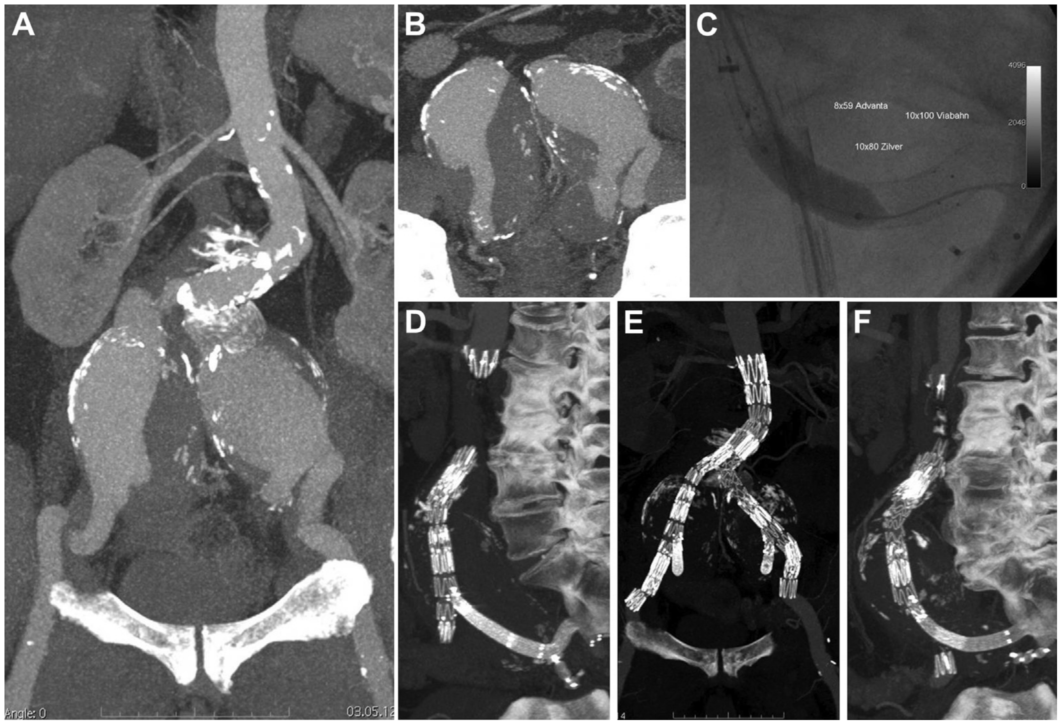

Fig 3. Pre-, intra-, and postoperative demonstration of the technique of endovascular repair of aneurysmal internal iliac arteries (AIIAs) using iliac branch devices (IBDs). **A** and **B,** Preoperative computed tomography (CT) angiographic reconstruction of a patient with bilateral iliac and internal iliac aneurysms of more than 5 cm. **C,** Intraoperative angiography of the technique of endovascular repair AIIAs using IBDs. Please note the sequence of the deployed stents. First, deployment of the V12 iCast/Advanta (Atrium) balloon-expandable covered stent (BECS) in the proximal part of the internal iliac artery. Second, deployment of the self-expanding covered stent (SECS) (Viabahn; Gore). Finally, deployment of the self expanding bare metal stent (Zilver; Cook). **D**-**F,** Postoperative CT angiography with a coronary, axial, and sagital view.

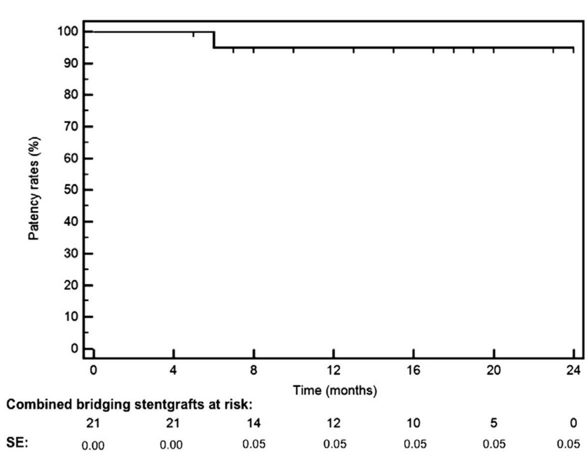

Fig 4. Kaplan-Meier curve analysis of the patency of the internal iliac artery branch. At 6 months, the standard error was 0.05 in 95% survival proportion.

at the origin of the internal iliac artery. A recannulation of the dislocated covered stents was not possible. Disconnection of a BECS with SECS in the internal iliac artery has been also described in the literature.[2]

Recently, we published a pooled analysis of the current published experience, regarding patency of the internal branch.[7] No clear evidence exists in the literature. It seems that, especially in the first 30 days, BECSs have better patency than SECSs. During the follow-up, the results are equal between the two subgroups. Use of the flexible Viabahn SECS in the internal branch as bridging covered stent in combination with BECS reflects the largest experience in the literature with this covered stent. The midterm patency of 100% is a strong argument for its use as a bridging covered stent. Our experience with the less flexible and likely to kink Fluency, which is the most commonly deployed bridging covered stent in the literature,[7] was disappointing. We recorded one occlusion of the one case in which we used it. However, other authors may have better experience with this specific SECS.[2,3]

One other important issue in the treatment with IBDs is the fact that the distal part of IBD in the external iliac artery is rigid, and this may lead to stenosis or occlusion of the IBD especially in case of tortuous iliac arteries. The new Zenith flex with spiral-z technology iliac leg graft was designed to increase the system's ability to track kinked anatomies. We observed one acute limb ischemia due to occlusion of the external iliac artery in a patient with angulated and calcified iliac arteries. The patient underwent successful hybrid surgical endovascular repair. A new low-profile design with an inner diameter of <22F IBD should most likely overcome heavily calcified and stenosed iliac arteries, increasing the applicability of IBD.

In summary, after a 7-year experience with the use of IBDs in more than 120 cases, combined placement of BECSs and SECSs, such as the Viabahn, in the internal iliac artery with additional lining with a bare metal self-expanding stent leads to successful exclusion of coexisting AIIAs. Long-term results and a larger number of treated patients are necessary to establish the suggested approach as a durable therapeutic option in these complex anatomical conditions.

AUTHOR CONTRIBUTIONS

Conception and design: MA, KPD
Analysis and interpretation: MA, KPD, GT
Data collection: MA, KPD, TB, MB
Writing the article: KPD, KL
Critical revision of the article: MA, TB, GT, MB, KPD
Final approval of the article: MA, TB, GT, MB, KL, KPD
Statistical analysis: TB
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MA and TB contributed equally to this article.

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