Endovascular repair of aorto-iliac aneurysmal disease with the Gore IBE device: midterm outcomes of a single center experience

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Abstract:

Introduction: Preservation of the internal iliac artery (IIA) perfusion during endovascular repair of isolated iliac or aorto-iliac aneurysms is important in order to avoid significant ischemic complications. The aim of the study is to evaluate the early results of endovascular treatment of patients with either single or bilateral iliac and aorto-iliac aneurysmal disease preserving the IIA blood flow with the use of the Gore IBE device.

Methods: A single center retrospective study including patients with unilateral or bilateral common iliac and/or aorto-iliac aneurysmal disease treated by endovascular means was undertaken. All patients were treated with IIA flow preservation with the Gore IBE device during the 2017-2019 period. Primary outcomes included technical success rate, mortality and 30 days target vessel patency, while secondary outcomes were procedure related morbidities, freedom from re-intervention and freedom from aneurysm exclusion events.

Results: From 2017 to 2019, 8 patients with aorto-iliac aneurysmatic disease (88.8%; 8/9 patients) and 1 with bilateral isolated iliac aneurysms (11.1%; 1/9) underwent endovascular repair. Technical success rate was 88.8%. One IIA branch thrombosis was detected at the completion angiography due to adverse artery angulation. Mortality rate was 0% and 30-days patency rate was 88.8%. The mean follow up period was 9,6 ± 8.1 months (range 1-24 months). Overall patency remained at 88.8%. No other thrombosis events occurred. Re-intervention rate was 0%. No procedure related complications such as buttock, bowel or spinal ischemia events occurred in any patient. The patient with the iliac branch intraoperative thrombosis was also asymptomatic. Freedom from endoleak type I/III IBE related was 100%.

Conclusion: The GORE EXCLUDER IBE device achieved good early and midterm results with high technical success and patency rates, along with low complication and reintervention rates.

Keywords: Iliac branch device, IBE, Aneurysm, Iliac, Endovascular

INTRODUCTION

Common iliac artery aneurysms (CIAAs) are defined as an artery of diameter > 18mm. As an isolated pathological vascular entity, CIAAs are quite rare with a prevalence of 0.03% of the general population and 3% of all kinds of aneurysms. Up to 40% of the patients with an abdominal aortic aneurysms (AAAs), present a concomitant CIAA.[1,2]

CIAAs may extend to the iliac bifurcation without an adequate proximal or distal neck, thus making their treatment quite challenging. Open surgical repair includes internal iliac artery (IIA) transposition, bypass or ligation, but exposes these patients to increased risk for postoperative morbidity.[3] On the other hand, endovascular approach has been adopted during the last decade showing good outcomes. Endovascular approach includes two main techniques: i. coverage/embolism of IIA ii. Preservation of IIA. Patients undergoing coverage or embolism of the IIA using coils or vascular plugs have been at higher risk of gluteal ischemia (16%-55%) and erectile dysfunction (10%-46%), or even worse complications such as bowel or spinal cord ischemia, especially when bilateral.[4,5] In a systematic review of the literature, Kouvelos et al.[6] reported that unilateral or bilateral IIA occlusion during EVAR seems to carry a substantial risk of significant ischemic complications in nearly one quarter of patients. Bilateral IIA occlusion was related to a significantly higher rate of buttock claudication.[6]

Preservation of the IIA perfusion by endovascular means included primarily the bell-bottom technique, the double-barrel "sandwich" technique, or surgeon modified devices through the off-label use of endografts. From 2006 the first dedicated devices for the treatment of CIAAs were introduced in the market. The *Iliac Branched Devices* consisting of one branched component, positioned in the CIA and extended

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with a covered stent in the IIA, thus achieving preservation of the antegrade blood flow in the IIA. Since then, several companies launched their devices to the market.

The aim of the study is to evaluate the early results of endovascular treatment of patients with both single or bilateral iliac and aorto-iliac aneurysmal disease preserving the IIA blood flow with the use of the IBE device.

METHODOLOGY

A single center retrospective study including patients with unilateral or bilateral common iliac and/or aorto-iliac aneurysmal disease treated by endovascular means was undertaken. All patients were treated with IIA flow preservation with the Gore (W.L. Gore & Associates, Flagstaff, AZ, USA) IBE device during the 2017-2019 period. This device has been introduced in the EU market in 2013 and in the US market in 2016. The IBE device consists of two dedicated components, both specifically designed for the iliac treatment: the Iliac Branch Component (IBC) and the Internal Iliac Component (IIC). The IBE device is designed to be used in conjunction with the Gore Excluder AAA Endoprosthesis and is composed of an expanded polytetrafluoroethylene (ePTFE) graft and a nitinol stent. Bilateral femoral access is required in most of the cases, while in some cases, brachial access can be of use. The details of the intervention have been previously described. [10,12]

Indications for the treatment of CIAA was a diameter of >20 mm isolated or associated with an AAA and anatomical characteristics that allowed the deployment of the device such as:

-CIA diameter > 17 mm in the proximal zone

-Non-aneurysmal length of the external iliac artery (EIA) > 10 mm with a diameter of 6.5 to 13.5 mm or with a diameter range of 6.5 to 25 mm in case an extension is used.

-Diameter of the IIA should be 6.5 to 13.5 mm with a distal sealing zone length of at least 10 mm.

-There is no limitation regarding the length of the CIA.

-A minimal distance of 165 mm between the lowest renal artery and the iliac bifurcation is required.

Sizing and planning were performed based on the pre-operative computed tomography angiography (CTA) using a 3Mensio workstation (Medical Imaging B.V., Bilthoven, the Netherlands) with dedicated reconstruction software. All of the procedures were performed in an adequately equipped operating room, using a moveable radiolucent surgical table and a mobile digital angiographic system (Ziehm Vision RFD 3D, Ziehm Imaging GmbH, Nuremberg, Germany).

Baseline and procedural characteristics

Demographic data, like age and pre-operative comorbidities [coronary artery disease CAD), chronic obstructive pulmonary disease (COPD), hypertension (HT), hypelipidemia (HL) and diabetes mellitus (DM)] were recorded. Anatomical details the aneurysmal disease was recorded. Procedural characteristics as the type of endograft used in combination with the IBE device, the type of the iliac stent graft, access site and eventual relining were captured. Other procedural details like the operation time, the radiation time and the amount of contrast used, were reported.

All patients underwent a follow up protocol including ultrasonographic examination before discharge and at 6 months and a CTA at 1 month, 12 months and yearly thereafter.

Outcomes and definitions

Primary outcomes constituted of technical success rate, mortality and 30 days target vessel patency, while secondary outcomes were procedure related morbidities as well as freedom from re-intervention and freedom from aneurysm exclusion events occurred during the study period.

Technical success was defined as successful implantation of the IBE in the target iliac vessels with preservation of antegrade flow into the IIA with aneurysm exclusion (no type Ib or III endoleak on the completion angiogram). Morbidities related to the procedure include buttock claudication, ischemic colitis and spinal cord ischemia. Aneurysm exclusion outcome events include rupture, endoleaks type I or III of the target vessels detected on completion angiography and subsequent imaging exams (Computed Tomography Angiography) during the follow up period.

Statistical analysis

Continuous data were expressed as mean ± standard deviation. Categorical data were expressed as absolute numbers and percentage of prevalence (%) in the study cohort. Statistical analysis was carried out using SPSS 19 (IBM, Armonk, NY).

RESULTS

Baseline and anatomic characteristics

From 2017 to 2019, 8 patients with aorto-iliac aneurysmatic disease (88.8%; 8/9 patients) and 1 with bilateral isolated iliac aneurysms (11.1%; 1/9) were treated electively by endovascular means (Table 1). All patients were males with a mean age of 70.2 ± 8 years. The most common comorbidities included HL (100%; 9/9 patients), HT (88.8%; 8/9 patients) and CAD (55.5%; 5/9 patients),

Seven patients had bilateral iliac aneurysms (77.7%; 7/9 patients), including the one with isolated iliac aneurysmal disease. In the group of patients with aortoiliac aneurysms, the mean maximum aortic aneurysm diameter was 61.3±2mm. The mean maximum right iliac aneurysm diameter was 33±10mm and the left 38.3±19mm.

Peri-operative and procedural details

All of the patients were treated under general anesthesia. In eight of them, a bifurcated GORE EXCLUDER (W. L. Gore and Associates, Flagstaff, Ariz) aortic endograft was combined to the IBE device; in one patient there was an infrarenal aortic aneurysm treated with the “chimney technique” (Table 2). A tubular thoracic endoprosthesis BOLTON-RELAY (Bolton Medical, Sunrise, Fla) was placed in a patient with a previous standard endovascular aortic repair (EVAR) and endoleak type Ia that required

a tubular graft to extend the proximal sealing at the level of the celiac artery and to establish splancic perfusion through the placement of three covered stents to the renals and superior mesenteric artery with the chimney technique. Moreover, an IBE device was placed to his left iliac, in order to treat his common iliac aneurysm and maintain flow in the IIA.

In 7/9 interventions, the IBE was introduced through femoral access (figure 1), while in two cases a brachial access was used due to internal iliac catheterization issues (adverse IIA angulation) (figure 2).

Patients	Gender	Age	Commorbodities	Aortoiliac Disease	Isolated CIAAs	Unilateral CIAAs	Bilateral CIAAs	AAA Dmax	RCIAA Dmax	LCIAA Dmax
1	MALE	55	DLP, HT, CAD, COPD	YES	NO	NO	YES	90	29,9	58,3
2	MALE	66	DLP, HT	YES	NO	NO	YES	69,7	38,3	35,6
3	MALE	66	DLP, HT, COPD	YES	NO	YES (L)	NO	60,8	19	40,4
4	MALE	73	DLP, COPD, LUNG Ca	YES	NO	YES (R)	NO	56	56	18,4
5	MALE	65	DLP, HT, CAD	YES	NO	NO	YES	50,1	33,9	20,8
6	MALE	76	DLP, HT, DM, CAD	YES	NO	NO	YES	52,8	27,4	29,1
7	MALE	82	DLP, HT, CAD	YES	NO	NO	YES	95,2	35,9	35,1
8	MALE	69	DLP, HT, CAD, DM, COPD	YES	NO	NO	YES	53,7	34,3	27,2
9	MALE	80	DLP, HT, DM, COPD	NO	YES	NO	YES	23,7	22,3	80,3
AVG (Std Dev)		70,2±8,45						61,3±21,6	33±10,7	38,3±19,6

AVG (Std Dev): Average (Standard Deviation), DLP: Dyslipidemia, HT: Hypertension, CAD: Coronary Artery Disease, COPD: Chronic obstructive pulmonary disease, DM: Diabetes Mellitus, Lung Ca: Lung Carcinoma, CIAA: Common Iliac Artery Aneurysm, Dmax: Maximum Diameter, RCIAA: Right CIAA, LCIAA: Left CIAA

Table 1. Demographics of the patients included in the study and morphological characteristics of the aorto-iliac and isolated iliac aneurysms

Patients	Graft	Access	Iliac Stent	Relining	Anesthesia	Operation Time (mins)	Radiation Time (mins)	Contrast	LOS	Complications	FU
1	EXCLUDER, IBE	Brachial	Viabahn, 13x5	NO	GENERAL	220	40	200	4	NO	24
2	EXCLUDER, IBE	Femoral	GORE IBC, 16x10	NO	GENERAL	200	45,38	130	4	NO	12
3	EXCLUDER, IBE	Femoral	Viabahn 13x5	NO	GENERAL	420	137,30	300	6	NO	18
4	EXCLUDER, IBE	Femoral	GORE IBC, 16x10	NO	GENERAL	145	30	100	4	NO	6
5	EXCLUDER, IBE	Femoral	GORE IBC, 16x12	NO	GENERAL	120	29,16	80	3	NO	1
6	EXCLUDER, IBE	Femoral	GORE IBC, 16x12	NO	GENERAL	180	45	150	4	NO	12
7	RELAY, IBE	Brachial	Viabahn 13x5	YES	GENERAL	360	102	180	10	NO	12
8	EXCLUDER, IBE	Femoral	GORE IBC, 16x14	NO	GENERAL	240	9,32	170	4	NO	1
9	EXCLUDER, IBE	Femoral	GORE IBC, 16x14	NO	GENERAL	180	7,02	120	7	NO	1
AVG (Std Dev)						229,4±99	54,25±32,43	158,8±65,4	5,1±2,2		9,6±8,1

AVG (Std Dev): Average (Standard Deviation), IBE: Internal Iliac extension, IBC: Iliac Branch Component, LOS: Length of Stay, FU: Follow Up

Table 2. Procedural details

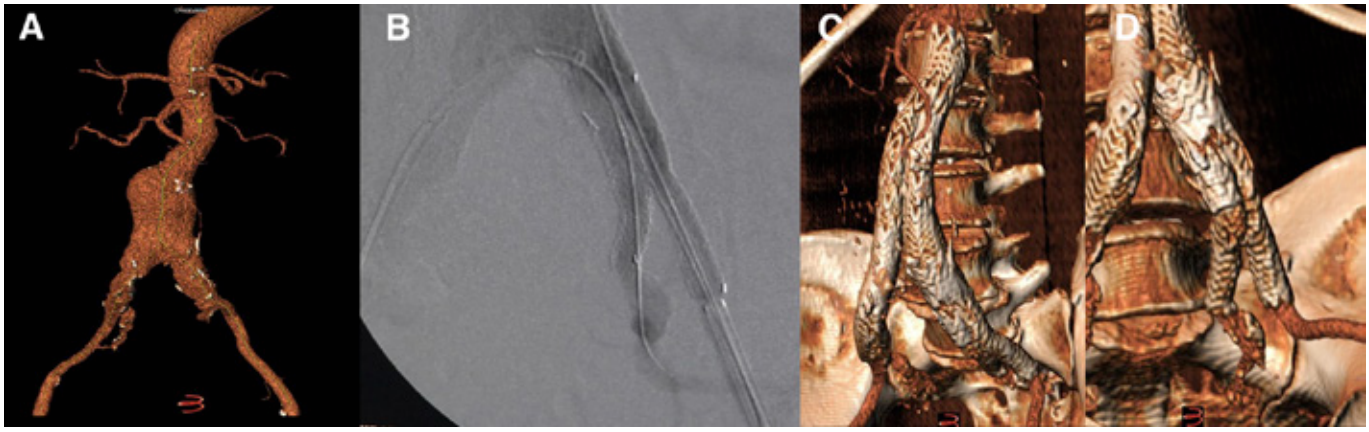

Figure 1. Bilateral aorto-iliac aneurysm. A: Pre-operative 3D reconstruction and center lumen line of the aneurysm, B: Deployment of the Internal Iliac Component through contralateral femoral access, C: Post-operative image of the bifurcated aortic endograft combined with the IBE device on the left ilac, D: Anteroposterior view of the IBE device

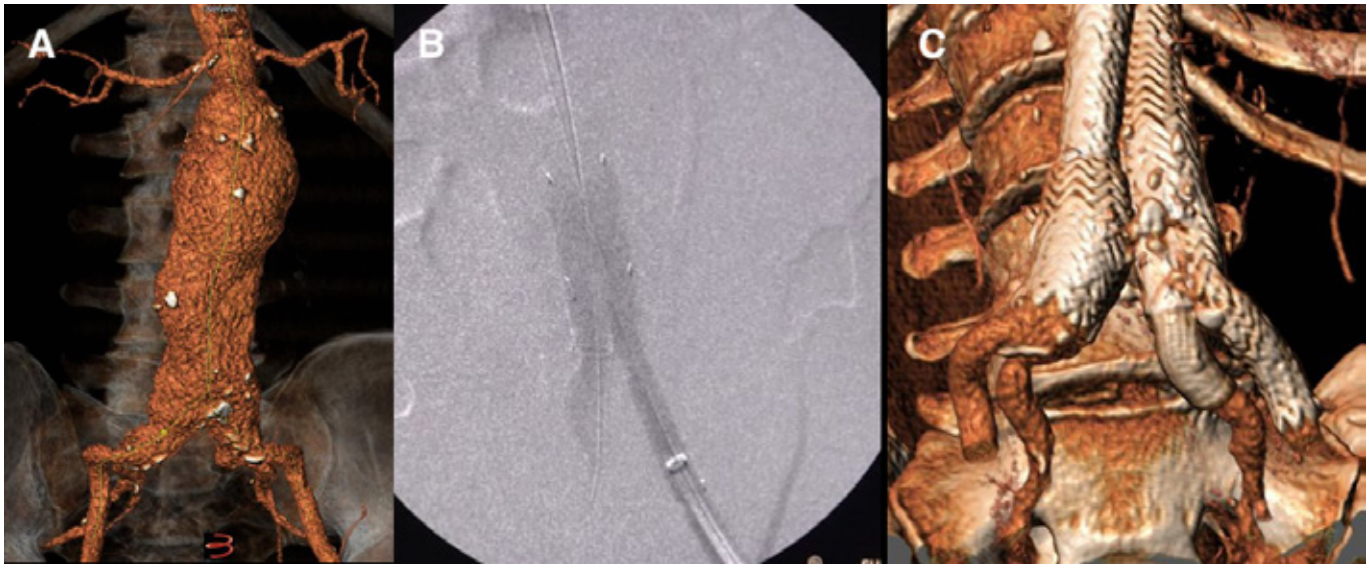

Figure 2. Bilateral aorto-iliac aneurysm treated with "Bell bottom" technique on the right side and an IBE device on the left side. B: Cannulation of the left internal iliac artery through left brachial access, C: Post-operative image of the bifurcated aortic endograft combined with the IBE device on the left ilac

In most cases (6/9; 67%) the GORE IIC available diameter of 16mm) was used to establish blood flow in the IIA. In 3 cases, a Viabahn self-expandable covered stent was combined to the IBE device. The choice of the stent graft was based on the access site in two cases, since a longer shaft is needed when brachial access is used (available Viabahn shaft of 120mm, instead of the IBC shaft of 63mm) and the smaller IIA diameter in the third one. (available diameter of 13mm).

Relining with an additional balloon expandable bare metal stent was undertaken only in one patient due to severe angulation of the IIA treated.

The median procedure time was calculated at 229 minutes (range 120-420 minutes) while the median radiation exposure time was 54 minutes (range 7-137.3 minutes). The median contrast volume used was 158ml (range 80-300ml). Patients were discharged after a median hospitalization time of 5 days (range 3-10 days).

The technical success rate was 88.8% (8/9 successful stent placements). One IIA branch thrombosis was detected at the completion angiography. It concerned a Viabahn self-expanding stent occluded due to adverse IIA angulation. Mortality rate was 0%. The 30-days patency rate was 88.8% as no other target arteries occluded and antegrade flow was preserved (Table 3).

Technical Success	88,8%
30days Patency	88,8%
Morbidity	0
Mortality Aneurysm Exclusion Events	11,2%
Reintervention Rate	0

Table 3: Primary and secondary outcomes

The mean follow up period was 9,6 ± 8.1 months (range 1-24 months). Overall patency during the follow up period remained at 88.8% as no other thrombosis events occurred. The re-intervention rate was 0% during follow up period. No procedure related complications such as buttock, bowel or spinal ischemia events occurred in any patient. The patient with the iliac branch intraoperative thrombosis did also show no clinical symptoms. Freedom from endoleak type I/III IBE related was 100%. There was only one endoleak type Ib, but on the contralateral side of a patient that was treated with the "bell-bottom" technique. The 30 days follow up examination revealed a patent IBE on one side and the endoleak Ib on the contralateral side. The patient with this endoleak was treated with the "coil and cover" technique, by occluding the internal iliac artery with coils and extending further to the external iliac artery. After 6 months, the iliac extension was occluded (the patient presented with acute limb ischemia) due to adverse limb tortuosity and a femoral-femoral by pass re-established blood flow among the patient's lower limbs. No other events were recorded during the follow up period.

DISCUSSION

The occlusion or preservation of IIA blood flow during an EVAR has been in the center of interest during last years. Major complications from the occlusion of IIA are buttock claudication, bowel and spinal cord ischemia. The main IIA occlusion techniques are IIA coverage with stenting with or without coiling. Those interventions were correlated to a significant percentage of ischemic complications. Verzini et al.[7] reported a morbidity up to 22% after IIA occlusion. In a recent systematic review of the literature, Kouvelos et al.[6] demonstrated that pooled 30-day buttock claudication rate was 29.2% in patients undergoing IIA occlusion (uni- or bilateral), compared to patients with IIA preservation (4.1%).

Both the American and European Vascular Societies' most recent guidelines, strongly recommend the preservation of blood flow to at least one internal iliac artery [(Society of

Vascular Surgery, Level 1A) and (European Society of Vascular Surgery, Class I, Level B)].[14,15] The bell-bottom technique is a treatment option for common iliac arteries with up to 24 mm of diameter. Although apparently effective in the short-term, long-term durability has been questionable with reported type 1b endoleak rates varying from 3.4-7.8% and high reintervention rates.[8] Other techniques, like parallel graft "sandwich" technique and IBD have been proven to be safe and valid approaches, with less anatomical restrictions. Nevertheless, while there is scarce data on ST's outcomes and durability, IBD placement has been established as an effective and durable procedure.[9] Our experience, even if preliminary, has shown that implantation of an IBD such as the GORE EXCLUDER IBE device, leads to high procedural success, low re-intervention rates, and high short and mid-term patency. The technical success rate was 88.8% and overall patency rate remained excellent during the follow up period. Along this line, a Dutch retrospective cohort analysis of IBE implantation in 46 patients with iliac aneurysmal disease, presented a procedural success rate of 93.4% and early patency rates (after 6 months of follow up period) of 94%. Similar results were reported by Maldonado et al.[11], with successful placement of IBE in 97,9% of the patients showing patency rates of 97.5% at 6 months. In a multicenter study in the United States, Schneider et al.[12], showed a procedural success rate of 95.2% and patency rate of 95.1%. Midterm outcomes of this study reported also high patency rate (93.6%) up to 24 months of follow up.[13]

In the present series, no ischemic complications occurred (buttock claudication, ischemic colitis or spinal cord ischemic). The patient with the IIA branch occluded was completely asymptomatic. Reintervention rate in the target arteries treated was null. There was one intentional IIA occlusion in a patient with bilateral CIA aneurysms, but on the contralateral side from the IBE. The aneurysm initially treated with the "Bell bottom" technique, required IIA coiling and overstenting, due to an endoleak type Ib found at 30 days CTA. In this case there were no clinical ischemic symptoms after the re-intervention. In a multicenter study in the United States, reintervention rate was 2.1% at the IDE group for thrombotic events and 5% for non-thrombotic events at 6 months, while 3.4% and 4.1% of patients treated of type II endoleaks at 12 months and 24 months, respectively.[13] The Dutch large series published by van Sterkenburg et al,[10] reported a new-onset buttock claudication ipsilateral to the IBE device in 4.6% of the patients postoperatively, that disappeared during follow up. Schneider et al, reported loss of patency of the IIA of 4.9%.[12] Similarly, based on data from a large European registry, the PELVIS registry, Donas et al showed that midterm experience with placement of IBDs is associated with a low incidence of secondary procedures (overall postoperative reintervention rate of 8.9%)[16] and even in more complex treatment options (f/bEVAR) the use of IBDs can achieve equally good results and have become the standard of care.[17]

In the present study, most of the iliac branch devices were delivered through femoral access. In two of the patients, brachial access was used, because of adverse iliac anatomy with severe tortuosity and kinking of the common iliac arteries. Brachial access can become an alternative access in the patients with relative contra-indication due to anatomy. However, an alternative covered stent may be required in such cases, with a longer shaft than the dedicated IBE's IIC. In the present series a 13mmx5mm Viabahn (W. L. Gore & Associates, Flagstaff, Ariz) stent graft was used in both cases.

The Gore (W.L. Gore & Associates, Flagstaff, AZ, USA) IBE device, is not the only iliac branched device exists in the market. Another FDA-approved iliac branched device is Cook (Cook, Bloomington, IN, USA) IBD, with slightly different characteristics between the two. Gore IBE is a lower profile endoprosthesis with a 16 Fr introducer sheath suitable for narrower common femoral arteries than the Cook IBD that requires a 20 Fr sheath. The use of Cook IBD is limited by the need for a smaller internal iliac diameter (6-11 mm) and a narrower external iliac artery (EIA: 8-11mm), compared to the IBE (IIA diameter: 6.5-13.5 and EIA: 6.5-25mm). In case of patients with severe iliac tortuosity, the Gore IBE branched iliac stent graft is more conformable than the Cook IBD as it does not modify with the indices of tortuosity nor the post-endovascular aneurysm repair lengths of the iliac axes, as Della Schiava et al.[18] have shown in their recent study. The key for a successful iliac branched device implantation is the proper device selection that best suits the patients' anatomical criteria.

The main limitation of the study is its retrospective nature, the small number of patients and the relatively short follow up period. No data on erectile dysfunction were recorded.

CONCLUSION

The GORE EXCLUDER IBE device achieved good early and midterm results with high technical success and patency rates, along with low complication and re-intervention rates.

Conflict of interest: None

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