Solitary iliac branch endoprosthesis placement for iliac artery aneurysms

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ABSTRACT

Background: Isolated iliac artery aneurysms (IAAs), accounting for 2% to 7% of all abdominal aneurysms, are often treated with the use of iliac branched endografts. Although outside the manufacturer's instructions for use, iliac branched devices can be used solely, without the adjunctive placement of an endovascular aneurysm repair device, for the treatment of an isolated IAA. In the present study, we have described the outcomes of the use of the Gore iliac branched endoprosthesis (IBE; W.L. Gore & Associates, Flagstaff, Ariz), without the support of an infrarenal endovascular aneurysm repair device, for the exclusion of an isolated IAA. The present study was an international multicenter retrospective cohort analysis.

Methods: All the patients who had undergone treatment with a solitary IBE for IAA exclusion from January 11, 2013 to December 31, 2018 were retrospectively reviewed. The primary outcome was technical success. The secondary outcomes included mortality, intraoperative and postoperative complications, and reintervention.

Results: A total of 18 European and American centers participated, with a total of 51 patients in whom 54 IAAs were excluded. The technical success rate was 94.1%, with an assisted technical success rate of 96.1%. No 30-day mortality occurred, with 98.1% patency of the internal and external iliac artery found at 24 months of follow-up. At 24 months of follow-up, 81.5% of the patients were free of complications and 90% were free of a secondary intervention.

Conclusions: Treatment with a solitary IBE is a safe and, at midterm, an effective treatment strategy for selected patients with a solitary IAA. (J Vasc Surg 2022;75:1268-75.)

Keywords: Aneurysm; Endovascular; EVAR; Iliac artery aneurysm

In 10% to 40% of infrarenal abdominal aortic aneurysms (AAAs), the pathology will coincide with aneurysmal dilatation of the iliac artery.[1,2] Only 2% to 7% of all AAAs will be isolated iliac artery aneurysms (IAAs; ie, without involvement of the infrarenal abdominal aorta).[2] When ruptured, isolated IAAs result in high mortality. The historically reported mortality rates have ranged from 13% to 50%.[3,4] Therefore, preventive surgery could be indicated. Similar to AAAs, the risk of rupture increases with an increasing aneurysm diameter.[3,5] However, the incidence of rupture and its relationship to the size and growth rate in IAAs has remained unclear owing to the limited research. The growth rate appears to be similar to that of AAAs, at ~1 to 4 mm annually, depending on the aneurysm size.[6-8] Laine et al[5] reported a rupture rate of 6.3% for IAAs with a diameter of ≤40 mm.

The latest guidelines from the European Society for Vascular Surgery, reported in 2018, have recommended elective repair of isolated IAAs, including the common iliac artery (CIA), internal iliac artery (IIA), and external iliac artery (EIA), or combinations, should be considered at a threshold diameter of 3.5 cm.[6] No recommendations have been reported regarding an expansion rate threshold.[7]

Endovascular aneurysm repair (EVAR) has become the preferred treatment modality for most abdominal aneurysms.[6] Also, for patients with IAAs, EVAR might be considered for first-line therapy. Compared with the traditional open approach of IAAs, the use of EVAR has resulted in a significant decrease in mortality, a shorter length of hospital stay, and fewer short-term complications.[9] Before the development of iliac branched endoprosthesis (IBE) devices, the endovascular approach to IAAs entailed embolization of the IIA with stent placement into the EIA and overstenting the orifice of the IIA. The European Society for Vascular Surgery guidelines have recommended preservation of blood flow to at

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*A complete list of the SIBES Study Group can be found in the Appendix (online only).

Author conflict of interest: T.S.M., M.M.P.J.R., and J.M.M.H. are consultants for W. L. Gore & Associates. F.K.O. has no conflicts of interest.

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The editors and reviewers of this article have no relevant financial relationships to disclose per the JVS policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.

0741-5214

https://doi.org/10.1016/j.jvs.2021.10.005

least one IIA to minimize the risk of gluteal claudication, erectile dysfunction, pelvic necrosis, and colon ischemia.[6] In addition, the 2018 Society for Vascular Surgery guidelines stated that the Food and Drug Administration–approved iliac branch grafts had shown satisfactory outcomes and should be considered as first-line therapy for aortoiliac aneurysmal disease.[10]

For most patients, the IBE will be used in combination with an infrarenal aortic device, as intended. Although outside the manufacturer's instructions for use (IFU), iliac branched devices can also be used for treatment of isolated IAAs without the support of an EVAR device on top of the iliac component. This potentially decreases the risk of occluding the lumbar arteries or inferior mesenteric artery and also reduces the procedural time and costs.[6] The reported data, although scarcely available and consisting of small study populations, described favorable outcomes after the solitary exclusion of IAAs using iliac branched technology. Only one study compared solitary iliac branched device placement with the combined use of an iliac branched device and an infrarenal component and found no differences in technical success, mortality, or morbidity among the two groups.[11] In their retrospective multicenter study, the implanted iliac branched devices had mostly been manufactured by Cook Medical (Bloomington, Ind) and had been implanted in only three European countries.[11]

In the present study, we aimed to describe the outcomes of the use of the Gore IBE device (W.L. Gore & Associates, Flagstaff, Ariz), without the support of an infrarenal EVAR device, for exclusion of isolated IAAs in a global multicenter setting.

METHODS

The present study was designed as an international, multicenter, retrospective, observational cohort study. A request for participation in our study was sent to centers with experience in the use of solitary endovascular exclusion of an IAA using the Gore IBE from January 11, 2013 to December 31, 2018. Each participating center completed a case record form for each patient from the hospital records and imaging studies. Each research site provided local medical ethical approval in accordance with the national guidelines before data collection. The patients' personal data were anonymized and managed in compliance with the Dutch personal data protection act (in Dutch: Wet Bescherming Persoonsgegevens). The study was conducted in accordance with the principles of the Declaration of Helsinki (64th World Medical Association General Assembly, Fortaleza, Brazil, 2013) and the applicable guidelines, regulations, and acts.

Patients with a ruptured aneurysm, previous endovascular intervention of an infrarenal aortic aneurysm, or scheduled concomitant EVAR placement were excluded. The demographics, medical history, aneurysm morphology, procedural details, device specifics, follow-up data, morbidity, and mortality through the latest follow-up examination were recorded and analyzed.

ARTICLE HIGHLIGHTS

- **Type of Research:** A multicenter, retrospective cohort study
- **Key Findings:** Endovascular exclusion of isolated iliac artery aneurysms with an iliac branched endoprosthesis in 51 patients resulted in a 94.1% technical success rate and no 30-day mortality. At 24 months of follow-up, the patency of the external and internal iliac arteries was 98.1% for both, freedom from complications was 81.5%, and 90.0% of cases were free of a secondary intervention.
- **Take Home Message:** Solitary iliac branched endoprosthesis use, without an endovascular aortic repair device on top, is a safe and effective treatment strategy for isolated iliac aneurysms.

Outcomes and definitions. The endpoints were defined using the reporting standards of the Society for Vascular Surgery.[10,12] The primary outcome measure was technical success. Technical success was defined as the introduction and deployment of the device in the absence of surgical conversion or mortality, type I or III endoleaks, and graft limb obstruction. The use of unplanned endovascular procedures during the index procedure, but with successful deployment, was defined as assisted primary success. The intraoperative secondary outcomes were the procedure time, fluoroscopy time, presence of a type I or III endoleak, and occurrence of intraoperative limb obstruction (ie, loss of device patency at the IIA or loss of device patency at EIA). The secondary outcomes also included procedural and short-term (30-day) mortality and the incidence of endoleaks, aneurysm rupture, postoperative endograft limb obstruction, and reinterventions throughout follow-up. The frequency of follow-up visits was not standardized nor was the use of diagnostic testing. Iliac limb patency was determined using either computed tomography angiography or duplex ultrasound, or both. Maldonado et al[13] provided a thorough description of the Gore IBE device, technique of deployment, and possibilities for graft extension. Oderich et al[14] described the anatomic considerations for proper IBE placement and provided suggestions for technique optimization.

We retrospectively included all the patients who had received an IBE for an isolated IAA without any anatomic restrictions.

Statistical analysis. Continuous variables are presented as the mean ± standard deviation or median and interquartile range, depending on the data distribution. The data distribution was determined using Kolmogorov-Smirnov tests and observation of histograms. Categorical

Table I. Patients per contributing site

Collaborating site	Patients,[a] No.	Country
University of Texas Health Science Center	11	USA
University Hospital of Catania	9	Italy
Elisabeth TweeSteden Hospital	5	The Netherlands
Rijnstate Hospital	4	The Netherlands
Dijklander Hospital	3	The Netherlands
Gelderse Vallei Hospital	3	The Netherlands
Poliambulanza Foundation Hospital	3	Italy
Erasmus Medical Center	2	The Netherlands
Reinier de Graaf Gasthuis	2	The Netherlands
Vanderbilt University Medical Centre	2	USA
Albert Schweitzer Hospital	1	The Netherlands
Alreine Hospital	1	The Netherlands
Haga Teaching Hospital	1	The Netherlands
IRCCS Policlinico San Donato	1	Italy
Maasstad Hospital	1	The Netherlands
Medical Center Leeuwarden	1	The Netherlands
New York University Langone Health	1	USA

IRCCS, Scientific Institute of Recovery and Care.
[a]The patients were contributed by 21 physicians in total.

Table II. Baseline characteristics (N = 51)

Characteristic	No. (%) or mean ± SD
Gender	
Female	4 (7.5)
Male	46 (90.1)
Missing	1 (1.9)
Age, years	72 ± 8
CAD	
Yes	14 (27.5)
No	35 (68.6)
Missing	2 (3.9)
Smoking	
Yes	14 (27.5)
No	33 (64.7)
Missing	4 (7.8)
Diabetes mellitus	
Yes	5 (9.8)
No	43 (84.3)
Missing	3 (5.9)
History of buttock claudication	
Yes	0 (0.0)
No	45 (88.2)
Missing	6 (11.8)
History of erectile dysfunction[a]	
Yes	0 (0.0)
No	39 (83.0)
Missing	8 (17.0)

CAD, Coronary artery disease; *SD*, standard deviation.
[a]Total number of patients at risk for history of erectile dysfunction was 47, with women excluded from analysis.

variables are presented as frequencies and percentages. All statistical analyses were performed using IBM SPSS Statistics, version 24.0 (IBM Corp, Armonk, NY). Kaplan-Meier survival analysis was performed, with censoring for patients lost to follow-up. The graph was truncated when the standard error was >10%.

RESULTS

A total of 21 European and American physicians had participated in the present study and had enrolled 51 patients who had undergone solitary IBE placement. An overview of the number of patients contributed at each site is presented in Table I. A total of 54 IBEs were implanted because three patients had had bilateral IAAs that had been treated at a single session. The IIA was aneurysmatic in 15 cases (27.8%), and in 8 (54%), the aneurysm only comprised the IIA. The baseline characteristics are listed in Table II. All 51 patients, except for one, were treated in an elective setting. The remaining patient had undergone treatment of a symptomatic, nonruptured, aneurysm. The vascular characteristics are presented in Table III.

Technical success. Most patients were treated under general anesthesia, with a mean duration of 131 ± 56 minutes. The procedural characteristics are presented in Table IV. For most patients, the IBE placed consisted of three components: one iliac branch component, one internal iliac component, and an accessory piece (Table IV). Of the 54 procedures, 17 had required placement of a balloon-expandable stent to achieve an adequate seal of the IIA graft limb, and 2 had required kissing balloon angioplasty to achieve a proper proximal seal in the CIA. In eight cases, the graft was extended into a branch vessel of the IIA. In four patients, the IIA or one of its branches had required coil embolization, and in six patients, the IIA was covered by a graft extension with a Viabahn stent (Gore Medical) or was occluded using an Amplatzer plug (Abbott Laboratories, Chicago, Ill). This mainly involved the anterior side branch (data missing for 11 patients).

Endovascular access was successfully obtained in all 51 patients. For one patient, deployment of the device failed, although the anatomic requirements of a sufficient sealing zone were met. After deployment of the IBE graft in the CIA and advancing the sheath via the contralateral side over the body floss wire, the graft

Table III. Vascular characteristics of 55 iliac artery aneurysms (*IAAs*)[a]

Variable	Value	Missing
Location		1
Right IAA	27 (50)	
Left IAA	26 (48.1)	
CIA aneurysm, mm		
CIA length	69.0 (25-115)	4
CIA maximum diameter	41.5 (30-68)	0
CIA minimum diameter	17.6 (11-31)	6
IIA length	32.4 (19-69)	9
IIA maximum diameter	9.7 (5-15)	8
IIA minimum diameter	8.6 (5-13)	18
Proximal seal length	33.4 (11-78)	11
Proximal seal diameter	17.3 (11-26)	5
Distal seal length	28.0 (11-40)	11
Distal seal diameter	10.7 (5-15)	10
Distal IIA diameter	8.8 (6-11)	12
CIA and IIA aneurysm, mm		
CIA length	60.4 (47-91)	2
CIA maximum diameter	32.2 (25-44)	0
CIA minimum diameter	15.0 (11-20)	1
IIA length	45.7 (25-65)	1
IIA maximum diameter	28.5 (18-36)	0
IIA minimum diameter	15.9 (9-27.2)	1
Proximal seal length	39.7 (21-62)	4
Proximal seal diameter	15.2 (12-19)	1
Distal seal length	44.3 (33-65)	4
Distal seal diameter	9.7 (7-12)	4
Distal IIA diameter	14.2 (7-27)	1
IIA aneurysm, mm		
CIA length	71.0 (58-98)	4
CIA maximum diameter	19.9 (18-21)	4
CIA minimum diameter	16.4 (14-21)	4
IIA length	38.5 (26-60)	3
IIA maximum diameter	37.3 (27-50)	0
IIA minimum diameter	8.4 (6-10)	4
Proximal seal length	36.2 (18-63)	3
Proximal seal diameter	14.7 (13-16)	1
Distal seal length	58.3 (28-80)	4
Distal seal diameter	11.3 (7-13)	4
IIA diameter	7.0 (6-10)	2

CIA, Common iliac artery; *IIA*, internal iliac artery.
Data presented as number (%) or mean (range).
[a]The mean diameter was calculated for three groups of aneurysms: those involving only the CIA, those involving both the CIA and the IIA, and those involving only the IIA.

Table IV. Procedural characteristics (N = 51 patients)

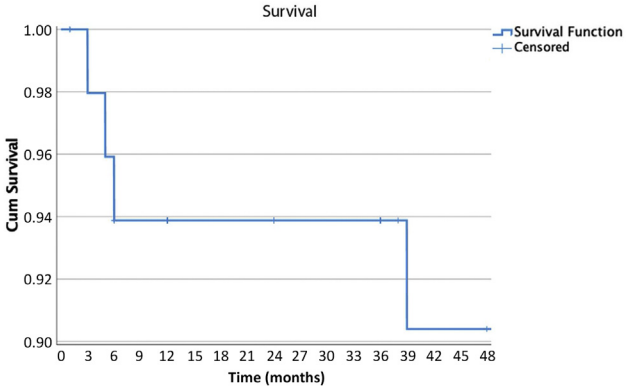
Characteristic	No. (%), mean ± SD, or median (IQR)	Missing
Type of anesthesia		1
General	35 (70.0)	
Local	10 (20.0)	
Spinal	5 (10.0)	
Type of access		15
Bilateral percutaneous	21 (56.8)	
Unilateral percutaneous	3 (8.1)	
Bilateral open	13 (35.1)	
Procedural time, min	124 ± 43	1
Contrast used, mL	94 ± 39	9
Fluoroscopy time, min	31 ± 15	15
Graft components placed	3 (2-5)	11

IQR, Interquartile range; *SD*, standard deviation.

came down and advancement was no longer possible, hampering achievement of the proximal seal. Therefore, after completion of the IBE procedure, a bifurcated Gore Excluder AAA endoprosthesis was placed in the nonaneurysmatic aorta. In another patient, technical success was not achieved because of a procedural type Ib endoleak that was not corrected until 31 days postoperatively. Another patient had received an extension of the external component to treat a type Ib endoleak. The technical success and assisted technical success rates were 94.1% and 96.1%, respectively. In three cases, bilateral IAAs were treated in one procedure; hence, we calculated the technical success rated per individual. The 30-day reintervention rate was 2.0%, with no early mortality.

Survival rate. The median follow-up was 36 months (interquartile range, 48 months). During the follow-up period, five patients had died (9.8%). Of these five patients, one had died after 3 months, one after 5 months, one after 7 months, and two at 3 years. All the deaths, but one, had resulted from a severe pulmonary or neurologic comorbidity. For one patient, the cause of death was unclear because the patient was lost to follow-up. No aneurysm-related mortality was reported throughout the follow-up period. None of the cases had developed aneurysm rupture or the loss of device integrity. The Kaplan-Meier curve (Fig 1) showed a 94.0% survival rate after 12 months.

Patency. The 2-year patency for both the internal iliac branch and the external iliac branch was 98.1% (Fig 2). Only one case experienced loss of IIA patency. The hypogastric side branch had become occluded at 1 month of follow-up. The occlusion had likely developed from a severely calcified aorta, with subsequent thrombus formation and occlusion of the graft. The patient remained asymptomatic and did not require a secondary procedure. One patient had presented with an occlusion of the left common femoral artery 1 day postoperatively and underwent thrombendarterectomy. During this procedure, a dissection occurred, which had been caused by the ProGlide vascular closure device (Abbott



Time (months)	0	3	6	12	24	48
Number at risk	51	49	47	44	37	26
Cumulative Survival	.	0.980	0.939	0.939	0.939	0.904
SE	.	0.020	0.034	0.034	0.034	0.047

Fig 1. Kaplan-Meier survival curve after iliac branched endoprosthesis (IBE) placement. The cumulative (*Cum*) survival, number at risk, and standard error (*SE*) at 0, 3, 6, 12, 24, and 48 months are shown.

Cardiovascular, Plymouth, Minn). The dissection was patched and patency restored. This patient later developed an endoleak on the right side but did not require treatment. Two patients were diagnosed with an inner wall floating thrombus in the EIA. For one patient, the anticoagulant therapy was switched to an oral warfarin derivative with complete resolution of the thrombus revealed at the final follow-up. For the second patient, the thrombus had dissolved without intervention. In both patients, thrombus formation had occurred without an anatomic justification such as a tortuous or small EIA. During follow-up, none of the patients had developed buttock claudication, colonic ischemia, gluteal or perineal necrosis, or medullar ischemia (data were missing for 10 patients).

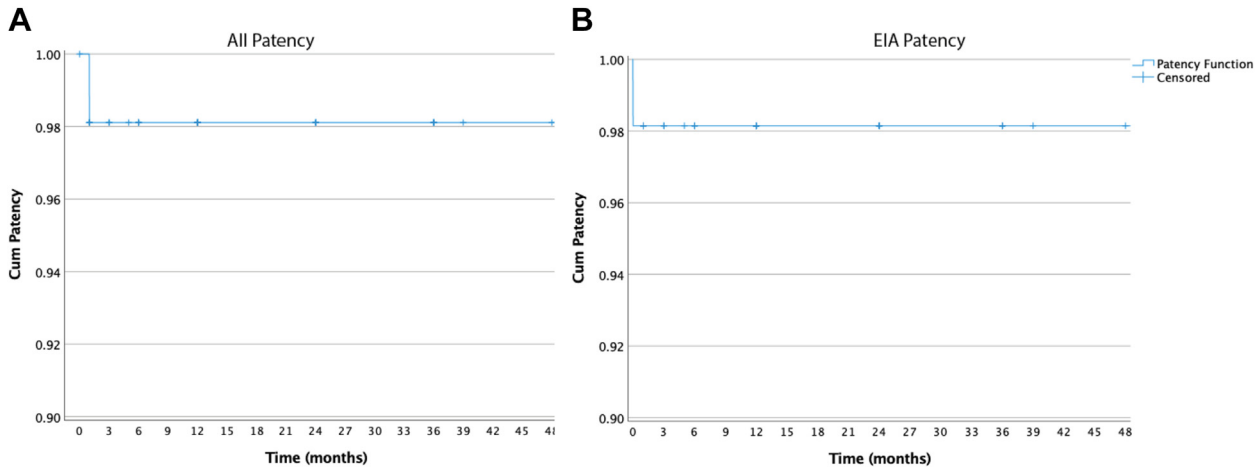
Endoleaks. Overall, six endoleaks had developed in five patients. These included one type Ia endoleak, two type Ib endoleaks, two type II endoleaks, and one type III endoleak. One type Ib endoleak had been diagnosed and treated during the index procedure, as described. Three endoleaks eventually required reintervention. The second procedural Ib endoleak was treated at 1 month of follow-up with a distal extension. The same patient had also developed a type II endoleak at 6 months. One patient with a type III endoleak was treated with a bridging stent in the internal iliac component at 7 months postoperatively. During this procedure, a side branch of the IIA was embolized using an Amplatzer plug (Abbott Laboratories). The third reintervention was for a type Ia endoleak, which was treated by proximal extension with an Excluder cuff (W. L. Gore & Associates) at 3 months of follow-up. All treatments were considered successful with confirmation by follow-up imaging studies without an endoleak present and with patent outflow visualized through the internal component. The two type II endoleaks had not required treatment at the latest follow-up examination. The freedom from type I and III endoleaks at 1 and 2 years of follow-up was 92.2% (Fig 3, *A*). Aneurysm growth was not observed in any patient. Shrinkage had occurred in 29 patients, with an average decrease of 8.7 mm (data missing for 15 patients).

Secondary procedures. During follow-up, five secondary procedures were required for five patients, for a freedom from secondary intervention rate of 90.0% at 2 years of follow-up. Three secondary procedures were performed to treat endoleaks and one to restore patency. The remaining secondary procedure entailed treatment of an intraoperatively formed access site arterial dissection at the CIA at 3 months postoperatively using the sandwich technique. However, the procedure was performed elsewhere; thus, no operation or follow-up data were available for investigation. All other patients had been followed up at the same hospital where they had received their IBE. The freedom from a secondary procedure or reintervention is displayed in Fig 3, *B*.

DISCUSSION

In the present international, multicenter, retrospective cohort study, focusing on the performance of the Gore IBE device, we have shown that this treatment is a safe and effective strategy for selected patients with a solitary IAA. We found no intraoperative mortality and a patency of the IIA of 98.1% at 24 months of follow-up. In addition, 81.5% of the patients were free of complications at 24 months postoperatively, and 90.0% were free of a secondary procedure, with most secondary procedures performed to treat endoleaks. The low morbidity, no aneurysm-related mortality, low reintervention rate, high IIA and EIA patency rates, and low procedural and fluoroscopy times are all in favor of successful exclusion of an IAA with solitary IBE placement, without manipulating an otherwise healthy aorta and maintaining an adequate proximal and distal sealing.

Giaquinta et al,[15] in 2018, were the first to report on solitary iliac branched graft use in an all-Italian collaboration. In their cohort of 41 patients, the Zenith bifurcated iliac side branch device (Cook Medical) was used in 78% of cases, with the IBE used in the remaining patients. They reported a 30-day mortality of 2.4% and an IBD patency of 95.2% at 1 and 5 years.[15] At 1 year of follow-up, the freedom from reintervention rate was 95.7%. The use of different types of devices did not result in significant differences in the primary or secondary



Time (months)	0	3	6	12	24	48		0	3	6	12	24	48
Number at risk	54	49	46	43	36	27		54	49	46	43	36	27
Cum freedom of loss of patency	.	0.981	0.981	0.981	0.981	0.981		.	0.981	0.981	0.981	0.981	0.981
SE	.	0.019	0.019	0.019	0.019	0.019		.	0.019	0.019	0.019	0.019	0.019

Fig 2. A, Kaplan-Meier curve showing internal iliac artery (IIA) patency. **B,** Kaplan-Meier curve showing external iliac artery (EIA) patency. The cumulative (*Cum*) patency of the IIA and EIA, number at risk, and standard error (*SE*) at 0, 3, 6, 12, 24, and 48 months are shown.

outcomes. With comparable mortality and freedom from reintervention, the findings from the Italian collaboration and the present study research are comparable, with both favoring the sole use of an iliac branched device to treat IAAs. However, some overlay was present in the data because Veroux had contributed the data from 10 patients to both the Italian collaboration and our international study. D'Oria et al.[16] and Fargion et al[11] reported satisfactory results with solitary IBE placement for isolated IAAs. However, these were small, single-center cohorts of only 11 and 28 patients, respectively.[11]

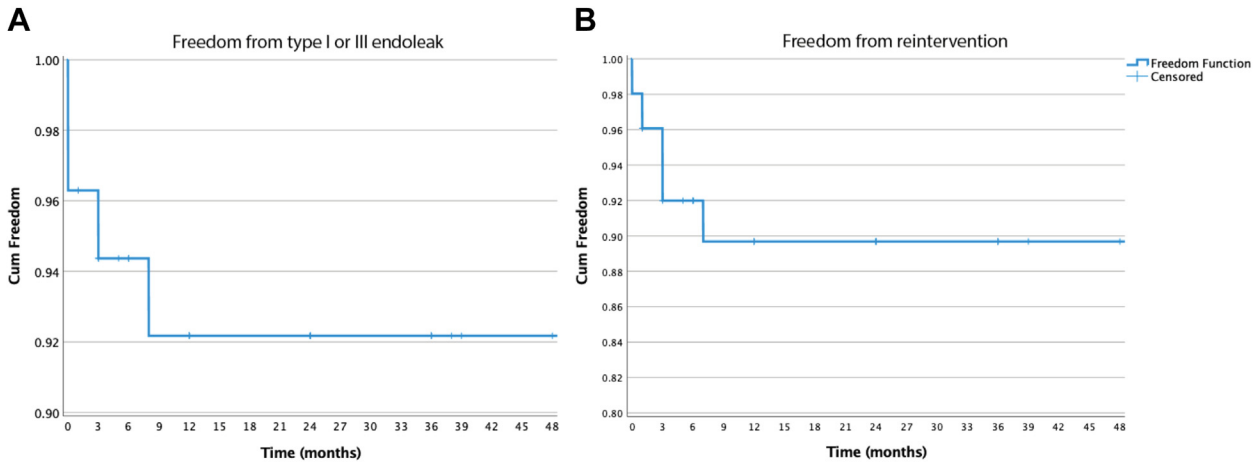
It must be emphasized that the solitary use of an IBE device is outside the IFU for the device. The IFUs for the Gore, Cook and CryoLife/Jotec (Jotec GmbH, Hechingen, Baden-Wurttenberg, Germany) state that their iliac branched device should be connected to an aortic component to improve stability and reduce risk of endoleaks and device migration.

The GREAT (global registry for endovascular aortic treatment) registry, investigational device exemption (IDE) trial, Dutch IBE collaboration, and the IceBERG (iliac branch excluder registry) registry are recent research collaborations focusing on the IBE device combined with an EVAR device on top.[17-19] These studies showed high technical success rates (100%, 93.5%, 97.9%, and 97.0% for the GREAT registry, IDE trial, Dutch IBE collaboration, and IceBERG registry, respectively).[17-19] After 6 months, reintervention was required for 3.0% to 8.7% of cases, mostly to treat endoleaks, similar to our study. We found an 8.0% reintervention rate at 6 months and only two type Ib endoleaks had developed that were easily resolved by endovascular extension, one of which had been diagnosed and treated during the index procedure.

During follow-up, no stent migration or kinking occurred. Of the 54 implants, only 1 IIA (1.9%) had become occluded without clinical effects. In the Italian collaboration also, only one IIA (2.4%) had become occluded.[15] These proportions differ considerably from the IIA patency reported with concomitant EVAR use, with occlusion of ~6% to 7%.[17,18] Solitary IBE placement seems to reduce the IIA occlusion rate compared with the concurrent use of EVAR and IBE.

Moreover, the placement of an infrarenal aortic component on top can result in longer procedural times, longer fluoroscopy times, greater contrast administration, and increased costs.[11] Comparing our results to previously reported data for IAA exclusion, we found a more favorable procedural time of 124 ± 43 minutes, fluoroscopy time of 31 ± 15 minutes, and required contrast use of 94 ± 39 mL.[17-19]

The only study to date that has compared solitary IBE placement with the combined use of an infrarenal aortic bifurcation device is the pELVIS (performance of iliac branch devices for aneurysms involving the iliac



Time (months)	0	3	6	12	24	48		0	3	6.	12	24	48
Number at risk	54	50	46	42	37	25		51	47	43	39	35	25
Cum freedom	0.964	0.944	0.944	0.922	0.922	0.922		.	0.961	0.920	0.897	0.897	0.897
SE	0.025	0.032	0.032	0.038	0.038	0.038		.	0.027	0.038	0.044	0.044	0.044

Fig 3. A, Kaplan-Meier curve showing freedom from type I and III endoleaks. **B,** Kaplan-Meier curve showing freedom from reintervention. The cumulative (*Cum*) freedom from endoleaks and reintervention, number at risk, and standard error (*SE*) at 0, 3, 6, 12, 24, and 48 months are shown. Any additional procedure performed during the index procedure was not considered a reintervention but was considered assisted technical success.

bifurcation) registry.[11] Technical success did not differ between the two study arms (solitary IBE placement, 98.9%; and concomitant EVAR use, 97.8%). A slight difference, although not statistically significant, was found in IIA patency in favor of solitary IBE placement (98.3% vs 91.3%) at 60 months of follow-up.[11] They also demonstrated a significant reduction in radiation exposure, overall procedural time, and the use of contrast medium with solitary IBE use.[11] Their study had mainly used Cook devices, with only seven Gore IBEs included.[11] Because our technical success and IIA patency rates were comparable to those from the pELVIS registry, it is reasonable to suspect that no IBE from a single manufacturer is inferior to another.

However, not all IAAs will be fit for solitary IBE placement. The development of IIA ostial stenosis is a significant risk factor for IIA thrombosis. A straight aortic bifurcation, tortuous or calcified iliac axes, the presence of thrombus in the CIA lumen, and a calcified IIA are additional anatomic factors increasing the difficulty of IBE placement.[20-22] This might differ between different ethnic groups, as was demonstrated in the GREAT registry and IDE trial.[18] In their series, the investigators did not have access to the preoperative and postoperative imaging studies and, therefore, were unable to assess these risk factors and their relationship to the surgical outcomes.[18]

IIA embolization or coverage by a stent graft results in a risk of gluteal claudication, ischemic colitis, gluteal or perineal necrosis, and medullar ischemia.[20] In our series, 10 branches of the IIA were embolized or covered, mainly the anterior branch. These patients remained asymptomatic, suggesting sufficient collateral flow into the distal IIA branches.

Another important factor in the outcomes of endovascular exclusion of aneurysms is the presence of a suitable sealing zone. Other than an advised minimal aneurysmal diameter of 35 mm, no guidelines are available regarding the anatomic criteria for IBD placement in IAAs, let alone for isolated IAAs.[6] The commonly accepted criteria for isolated CIA aneurysm exclusion are as follows: (1) a proximal nonaneurysmal sealing zone length of ≥10 mm; (2) an EIA with a diameter of 6.5 to 25 mm, with a recommended length of ≥30 mm and a nonaneurysmal seal zone of ≥10 mm; and (3) an IIA with a diameter of 6.5 to 13.5 mm and ≥30 mm in length, with a nonaneurysmal seal zone of ≥10 mm.[14,23,24] All reported cases had a proximal sealing zone length at the CIA of ≥10 mm. In a few cases, the graft had landed distally in an IIA side branch; however, this had not resulted in occlusion or thrombosis of the IIA. This should only be considered for patients with suitable anatomy, because small, tortuous, or calcified branches are

likely to result in kinking of the device or thrombus formation and occlusion of the IIA branch component.[14,20]

The present study had some limitations. These were mainly unavoidable and a consequence of the study design. For some variables, the proportion of missing data was significant. We have reported the numbers of missing data to provide a clear overview and place the outcomes in perspective. In addition, we were unable to compare the preoperative and postoperative imaging findings. Therefore, we could not evaluate any possible differences in anatomy. Also, the imaging studies were examined by different physicians in different countries, which could have resulted in an examiner bias. However, legislation and differences in software kept us from centralizing the examinations. Also, our sample size did not permit a subanalysis of the role of the IAA location or whether the IIA is involved. IAA location has been suggested as a potential factor influencing successful distal sealing.[25] Additional, preferably prospective, analyses are required for this particular group of aneurysms.

CONCLUSIONS

The SIBES data have shown that a solitary IBE implant from Gore without an EVAR device on top can be safely used in the treatment of IAAs with a low complication and reintervention risk. Further research should focus on the anatomy of the IAAs and conjunctive vasculature and its role in surgical outcomes to provide anatomic requirements for IBE use.

AUTHOR CONTRIBUTIONS

Conception and design: TM, MR, JH
Analysis and interpretation: FO
Data collection: FO, TM, MR
Writing the article: FO, MR, JH
Critical revision of the article: FO, TM, MR, JH
Final approval of the article: FO, TM, MR, JH
Statistical analysis: FO
Obtained funding: Not applicable
Overall responsibility: FO

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Submitted May 6, 2021; accepted Oct 5, 2021.

Additional material for this article may be found online at www.jvascsurg.org.

APPENDIX (online only).

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