

One Year Experience of Iliac Bifurcated Device for Aortoiliac Aneurysm in a Korean Single Center

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One of the predominant methods for preserving the internal iliac artery (IIA) in aortoiliac aneurysms is to use an iliac bifurcated device (IBD). However, there are a few limitations to the use of IBD in Korea. Our study aims to present the technical aspects of these devices, and to provide a mid-term analysis of IBD. Since 2013, 4 IBDs were used in 4 patients, with a mean follow-up of 14 months (range, 6-22 months). A 100% technical success rate was achieved without mortality and morbidity in our cases. The mean procedural time was 176 min (range, 145-240 min), and the mean contrast dose used was 184 mL (range, 135-220 mL). Type I or III endoleaks and postoperative expansion of the aneurysms weren't observed. Our cases demonstrates that IBD is a relatively safe repair method of aortoiliac aneurysms with preservation of the IIAs. However, a longer follow-up is needed to review the midterm results.

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INTRODUCTION

Endovascular aneurysm repair (EVAR) has become the standard treatment option for abdominal aortic aneurysms (AAA) owing to its enhanced efficacy, lower invasiveness, and lower mortality and morbidity rate, as compared to open surgery [1,2]. However, in aneurysms involving the common iliac artery (CIA) or the internal iliac artery (IIA), deployment of a stent-graft is performed at the external iliac artery (EIA) with embolization of the IIA to avoid type II endoleaks.

The embolization of the IIA can result in serious complications [3,4]. To reduce such complications of IIA embolization, various methods have been described to preserve pelvic perfusion [5-8].

The iliac bifurcated device (IBD) is a branch of EVAR that is beneficial for the preservation of internal and external iliac flow, and it is a good alternative treatment option to

avoid IIA embolization [6]. However, in Korea, the sole IBD available is the SEAL IBD (S&G Biotech., Seongnam, Korea), with the exception of hand-made IBDs [6]. As a result, in Korea, there are only few studies of IBDs being used for treating CIA aneurysms and AAA involving the CIA, with follow-up. In this study, we have described the technical results of EVAR using IBDs and the early results obtained during follow-up.

CASE

We performed a retrospective study using a database of patients who had undergone EVAR with IBDs between 2013 and 2014. We reviewed preoperative, perioperative, and postoperative follow-up data from hospital records and radiology studies. Follow-up for all patients undergoing EVAR consisted of an office visit with the operating surgeon.

We performed 4 EVARs with IBDs between 2013 and

2014, which were indicated according to the instructions for use (IFU) by the company. The recommended IFU was that the CIA should have a diameter of more than 20 mm and a length of more than 45 mm. For the distal landing zone, the EIA diameter was to be less than 12 mm and have a length of more than 15 mm. It is further recommended that the length of the IIA trunk should be more than 10 mm. Prior to surgery, the vascular surgeon and intervention radiologist discussed these cases thoroughly to check for aneurysm location, size and length of the infra-renal artery, and diameter and length of both CIAs.

Three patients underwent surgery via a percutaneous approach, while the fourth patient was operated via a cutdown approach. After insertion of a sheath access, we inserted a pigtail catheter to the abdominal aorta, and obtained an aortogram. Embolization of the IIA was performed with interlock coils (Boston Scientific, Marlborough, MA, USA) or Amplatzer plugs (St. Jude Medical, Saint Paul, MN, USA) prior to insertion of the stent-graft.

The SEAL stent-graft (S&tG Biotech.) consisted of self-expanding nitinol stents, along with a lining of polyester fabric and a 15-Fr delivery system (Fig. 1). The IBDs were inserted into the ipsilateral femoral artery by using a stiff wire, and deployed via the contralateral femoral artery after selection of the IIA. After inserting the IBD and deploying the internal iliac limbs, the main EVAR body was placed below the renal artery. Following this, the contralateral limb and the ipsilateral limb were inserted. Furthermore, an extension limb was also deployed. Balloon dilatation was carried out to ensure efficient placement of stents, and a final aortogram was obtained to check for any endoleaks or complications (Fig. 2).

All patients had a technically successful EVAR. The technical success of such a procedure was primarily dependent upon perioperative events occurring from the initiation of the procedure and extending through the first 24-h postoperative period. Primary technical success was defined by an intention-to-treat basis and required the successful introduction and deployment of the device in the absence of any surgical conversion, type I or type III endoleaks, graft limb obstruction, or death.

Contrast-enhanced ultrasonography or computed tomography (CT) was scheduled at 1, 6, and 12 months post-surgery, and annually thereafter. Primary endpoints of our study were perioperative morbidity and mortality, while the secondary endpoints were patency of IBDs and aneurysmal expansion.

Since 2013, 4 IBDs were inserted in 4 patients who were previously diagnosed with CIA aneurysms. All the patients were men, with a mean age of 67.5 years (range, 58-74 years). One of the patients had an abdominal aortic



Fig. 1. Photograph shows SEAL stent-graft (S&tG Biotech., Seongnam, Korea) with both iliac bifurcated devices consisted of self-expanding nitinol stents, along with a lining of polyester fabric.

aneurysm with aneurysms in both CIAs, while the other 3 patients had aneurysms in only both CIAs (Table 1). The mean procedural time was 176 min (range, 145–240 min), and the mean contrast dose used was 184 mL (range, 135–220 mL) (Table 1). Iliac embolization was performed in 3 patients (interlock coils were used in 2 patients and an Amplatzer plug in 1 patient). In 2 cases, IBDs were inserted in the left IIAs, and in the other 2 cases, IBDs were inserted in the right IIAs. A 100% technical success rate was achieved. There was a single endoleak (type II), as observed on a postprocedural angiogram. However, no acute complications related to IBD grafts developed, such as graft occlusion or limb occlusion. Moreover, no perioperative or postoperative morbidity or mortality was observed in any of the cases. The median duration of follow-up was 14 months (range, 6–22 months). During follow-up, there was no morbidity or mortality, nor any pelvic ischemic symptoms such as buttock claudication, erectile dysfunction, or colon ischemia. Follow-up CT-angiography failed to reveal any aneurysmal expansion of more than 5 mm. However, contralateral limb stenosis was detected in 1 case for which angioplasty was performed (Table 2).

DISCUSSION

EVAR has become the standard treatment option for abdominal aortic aneurysm owing to its enhanced efficacy, lower invasiveness, and lower mortality and morbidity rate, as compared to open surgical repair [2,5]. However, in aneurysms involving the CIA, deployment of EVAR grafts is

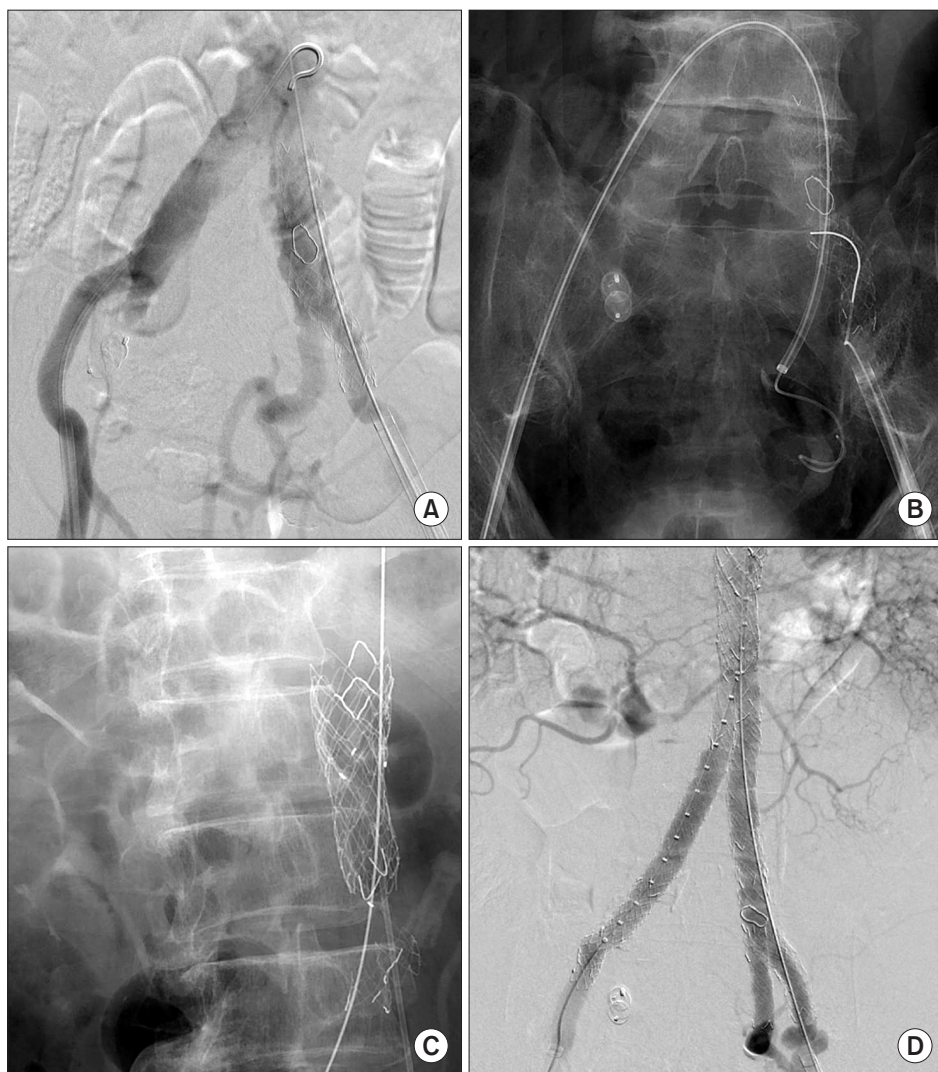


Fig. 2. Figures show our procedure of iliac bifurcated devices (IBDs). Ipsilateral limb was deployed in iliac artery (A). The IBD was inserted into contralateral femoral artery over a stiff wire and deployed after selection of internal iliac artery (B). After inserting IBD, main body was placed below renal artery (C). Final aortogram was done for checking any endoleaks or complications (D).

Table 1. Characteristics and procedural detail

No.	Age (y)	Sex	Aorta diameter (mm)	Rt. CIA diameter (mm)	Lt. CIA diameter (mm)	IBD location	IIA Embo-lization	Procedure time (min)
1	69	Male	35	36	52	Lt.	Coil	240
2	74	Male	25	37	21	Rt.	N/A ^a	145
3	58	Male	20	35	37	Rt.	Coil	175
4	66	Male	55	27	32	Lt.	Plug	135

Rt., right; CIA, common iliac artery; Lt., left; IBD, iliac bifurcated device; IIA, internal iliac artery; N/A, not available.

^aPrevious left IIA occlusion.

performed at the EIA with embolization of the IIA in order to avoid type II endoleaks. The embolization of the IIA, particularly on both sides, can result in serious complications, such as buttock claudication, erectile dysfunction, and in rare cases, life-threatening complications including colon ischemia, perineal necrosis, non-healing pressure sores, paraesthesia, incontinence, and acute limb ischemia.

Various methods are known for the preservation of IIA flow, such as the hybrid method [3], the bell-bottom technique [7], sandwich-graft technique [8], crossover chimney technique [9] and IBDs [4].

The IBD is a branched endovascular graft that can be inserted easily in the area of vessel bifurcation, especially in CIA aneurysms. Many types of IBDs are used for treating

Table 2. Results of iliac bifurcated device insertion

No.	Duration of F/U (mo)	Endoleak	IBD patency	Rt. CIA diameter change ^a (mm)	Lt. CIA diameter change ^o (mm)	Other complications
1	22	Type II	Patent	-3	-4	No
2	18	No	Patent	-1	-2	No
3	10	No	Patent	-1	-2	Contralateral limb stenosis ^b
4	6	No	Patent	-2	-	No

F/U, follow-up; IBD, iliac bifurcated device; Rt., right; CIA, common iliac artery; Lt., left; CT, computed tomography; EVAR, endovascular aneurysm repair.

^aDiameter of last CT–diameter of initial CT. ^bAngioplasty was done at 4 moths after EVAR.

CIA aneurysms, such as helical IBDs and bifurcated-bifurcated IBDs [10]. These devices are the best choice of grafts for the endovascular treatment of CIA aneurysms or AAAs involving the CIA, as shown in some large-scale studies with long-term follow-ups [8,11]. Unfortunately, in Korea, IBDs are not easily accessible, and are difficult to use owing to insurance policies. Hence, there are many constraints regarding the use of IBDs for treating CIA aneurysms or AAAs involving the CIA [12]. Furthermore, CIA aneurysms also occur in 15%–30% of AAAs, and hence, the potential requirement of IBDs is much higher than that of other techniques.

The results obtained in our study using IBDs were similar to those obtained in other western studies [6,8]. A technical success rate of 100% was achieved in all cases in our study, without any pelvic ischemic symptoms such as buttock claudication, and erectile dysfunction. This was in agreement with previous reports, where the technical success rate achieved was 85%–100% [6,8]. Early success of EVAR with IBD was plagued by deployment failure and stent-graft dislocation or kinking, leading to thrombosis and endoleaks at the junction of the IBDs and bridging stent-grafts. A previous study reported the patency of IBDs to be 90% at 1 year, and 81% at 5 years [6]. In our study, the mean operating time (176 min) and the contrast dose (184

mL) used were similar to that of a previous western study [6]. In addition, no last-minute IBD-related complications arose in our study, such as IIA occlusion, stent-graft fracture, or type III endoleaks. However, the limitations of our study were the short follow-up period and the small sample size. We conclude that a large study with long-term follow-up data is required to further delineate the safety and efficacy of IBDs.

CONCLUSION

Our study of IBDs demonstrates high technical success rates and good mid-term patency of IBDs, which is in agreement with the results of previous studies. However, occlusions of IBDs, requiring re-intervention, were reported in a previous study. A risk stratification system and morphological data are required to identify the group of patients who will benefit the most from EVAR using IBDs. Further studies will be necessary for careful selection of patients with favorable anatomy (for example, the presence of iliac tortuosity, thrombus formation, and calcification of the iliac artery). In the future, highly favorable outcomes may be expected in further studies, with meticulous planning, expert endovascular skills, and delicate selection of devices from the variety of IBDs available in Korea.

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