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The Use of an Iliac Branch Device: Single-Center Study of Endovascular Preservation of Internal Iliac Artery Flow

장골 분지 장치 사용: 내장골동맥 흐름의 혈관내 보존에 대한 단일 기관의 경험

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Purpose To determine the efficacy and safety of iliac branch device (IBD) implantation and to evaluate its limitations based on 7 years of experience in a single center.

Materials and Methods This single-center study included patients with bilateral common iliac artery aneurysms (CIAAs). We investigated follow-up CT and reviewed the internal iliac artery (IIA) patency and complications related to IBD. A retrospective analysis was performed and the overall survival rate and freedom from reintervention rate were reported according to the Kaplan–Meier method.

Results Of the 38 patients with CIAAs, only 10 (12 CIAAs) were suitable for IBD treatment. Five patients underwent unilateral IBD insertion with contralateral IIA embolization, and three (60%) showed claudication; however, symptoms resolved within 6 months. The 7-year freedom from IBD-related reintervention rate was 77.8%. No procedure-related deaths occurred.

Conclusion IBD has good technical success and long-term patency rates; however, anatomical factors frequently limit its application, particularly in Asians. Additionally, unilateral IIA embolization showed relatively mild complications and a good prognosis; therefore, it can be performed safely for anatomically complex aortoiliac aneurysms.

Index terms Iliac Aneurysm; Endovascular Procedure; Therapeutic Embolization; Endovascular Aneurysm Repair

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INTRODUCTION

Of all cases of abdominal aortic aneurysm (AAA), 16%–43% are concomitant with unilateral common iliac artery aneurysms (CIAAs) and 11%–12% are concomitant with bilateral CIAAs, complicating endovascular aneurysm repair (EVAR) (1).

Conventional CIAA repair with standard EVAR uses a distal landing zone in the external iliac artery (EIA) and embolization of the ipsilateral internal iliac artery (IIA) using a vascular plug or coil. However, this can cause complications such as buttock claudication, impotence, ischemic colitis, spinal cord ischemia, and gluteal necrosis. Occlusion of the unilateral IIA results in buttock claudication in approximately 25%–50% of patients (2-4).

To preserve the IIA, an iliac branch device (IBD) has been introduced and is increasingly used to avoid ischemic complications. Recent studies have reported that IBD could be easily and efficiently used to treat aortoiliac aneurysms, resulting in high technical success rates. Therefore, IBD has become the first-line treatment option whenever anatomically feasible (5-7).

The use of IBDs has limitations depending on the vascular anatomy of the patient. However, Gray et al. (5) recommended expanding the usage criteria of the manufacturers. In their study, only 40.9% (36/88) of the iliac arteries met the criteria of the manufacturer's instruction (CIA length ≥ 50 mm in instructions for the use of Cook Zenith, Cook Medical; Bloomington, IN, USA); however, 58% (51/88) of the patients could have been treated with IBD by applying the expanded criteria, including a shorter CIA length (> 40 mm) and adequate distal landing in distal IIA or main branch (5).

When considering the use of IBD, the possibility of intervention is determined based on the anatomy of the patient. However, IBDs are rarely used in Asian patients due to their short CIA. This study aimed to investigate IBD use over 7 years in a single center and evaluate its long-term efficacy, clinical outcomes, and suitability.

MATERIALS AND METHODS

We retrospectively analyzed medical records of patients with bilateral or unilateral CIAAs, with or without AAAs, between January 2013 and December 2020. This study was approved by the Institutional Review Board of our hospital (IRB No. 2021-08-035).

At our facility, indications for endovascular repair are a diameter of ≥ 30 mm for isolated CIAA and a diameter of ≥ 20 mm when combined with an aortic aneurysm (diameter ≥ 50 mm) (Table 1).

Table 1. Practical Indications for Intervention

Aneurysmal Size	Number of Patients
CIA aneurysm > 20 mm with AAA (> 50 mm)	4
CIA aneurysm > 30 mm	
Combined with AAA (< 50 mm)	1
Isolated	5
Bilateral	10

AAA = abdominal aortic aneurysm, CIA = common iliac artery

Preoperative CT images of eligible patients were analyzed. Those with a short CIA length (< 50 mm), severe EIA kinking, a wide iliac bifurcation angle (not compatible with the iliac side branch), or IIA that was not suitable for stent-graft sealing were excluded. A total of 38 patients had aneurysms involving the iliac arteries during the study period, and 12 IBDs were used in 10 patients.

Information on sex, age, underlying disease (hypertension, chronic obstructive pulmonary disease [COPD], ischemic heart disease, diabetes mellitus, and chronic renal failure), the aneurysmal diameter of vessels, and procedure time was collected for all patients who met these criteria. The procedure time was calculated from the time of the initial abdominal aortic angiography to the final angiography. We analyzed the procedure time using a simple linear regression analysis with SPSS Statistics (version 21, IBM Corp., Armonk, NY, USA).

All procedures were performed with access to the femoral artery under general anesthesia. Until 2016, the EXCLUDER® Iliac Branch Endoprosthesis (W. L. Gore & Associates, Flagstaff, AZ, USA) was used (seven procedures including one technical failure), and, after 2018, the Zenith Branch Endovascular Graft-Iliac Bifurcation (Cook Medical) was used (five procedures) as graft. The instructions for these two devices are listed in Tables 2 and 3.

We checked the follow-up CT scans of the patients and reviewed IIA patency, clinical symptoms related to IBD, and complications, such as endoleak or claudication. The period of freedom from reintervention, perioperative death, and overall survival rates during the 7-year study period were evaluated.

Statistical analyses were performed using IBM SPSS Statistics for Windows version 21. Freedom from reintervention and overall survival rates were reported using the Kaplan–Meier method.

RESULTS

In our study, 38 patients (bilateral CIAAs in 13 patients) and a total of 51 CIAAs were included from 2013 to 2020. Only 10 patients (12 CIAAs) were suitable for IBD treatment, all of

Table 2. Instructions for the Use of GORE-TEX® Vascular Graft (W. L. Gore & Associates)

CIA	IIA	EIA	Additional Detail
No limitation in length	Length ≥ 10 mm	Length ≥ 10 mm	A minimal distance of 165 mm between the lowest renal artery and iliac bifurcation is required
Diameter ≥ 17 mm	Diameter = 6.5–13.5 mm Diameter = 6.5–25 mm (using extension)	Diameter = 6.5–25 mm	

CIA = common iliac artery, EIA = external iliac artery, IIA = internal iliac artery

Table 3. Instructions for the Use of Cook Zenith (Cook Medical)

CIA	IIA	EIA	Difficulty With
Length ≥ 50 mm	Length ≥ 10 mm (20–30 mm being preferred)	Length ≥ 20 mm	Aortic bifurcation angle < 40°
Diameter ≥ 18 mm	Diameter = adequate for distal sealing	Diameter = 8–11 mm	CIA patent lumen ≤ 16 mm

CIA = common iliac artery, EIA = external iliac artery, IIA = internal iliac artery

whom had bilateral CIAAs. Two of these 10 patients were treated simultaneously with bilateral IBDs (Fig. 1), while the others were treated with unilateral IBDs.

The factors that made the cases unsuitable for IBD were short CIA length, large iliac bifurcation angle, IIA unsuitable for stent-graft sealing, severe EIA kinking, and IIA occlusion.

Of the 10 patients suitable for IBD treatment, nine were male and one was female. The mean age (mean ± standard deviation [SD]) was 70.8 ± 8 years. Four patients had ischemic heart disease, three had hypertension, two had diabetes mellitus, one had COPD, and none had chronic renal failure (Table 4).

Technical failure due to the inability to introduce a side branch into the IIA occurred in one case (Fig. 2). The overall technical success rate per vessel was 91.6%. In all technically success-

Fig. 1. Case successfully treated with bilateral IBDs.
A. Three-dimensional volume rendering CT scan shows bilateral common iliac artery aneurysms and a left internal iliac artery aneurysm.
B. Aortogram shows bilateral common iliac artery aneurysms and a left internal iliac artery aneurysm.
C. After placing the left IBD with stent graft sealing, a guiding sheath is inserted into the right IBD, and the right internal iliac artery is selected with a 5 Fr catheter.
D. The final angiogram shows good flow of the graft and bilateral IBD without evidence of endoleak.
IBD = iliac branch device

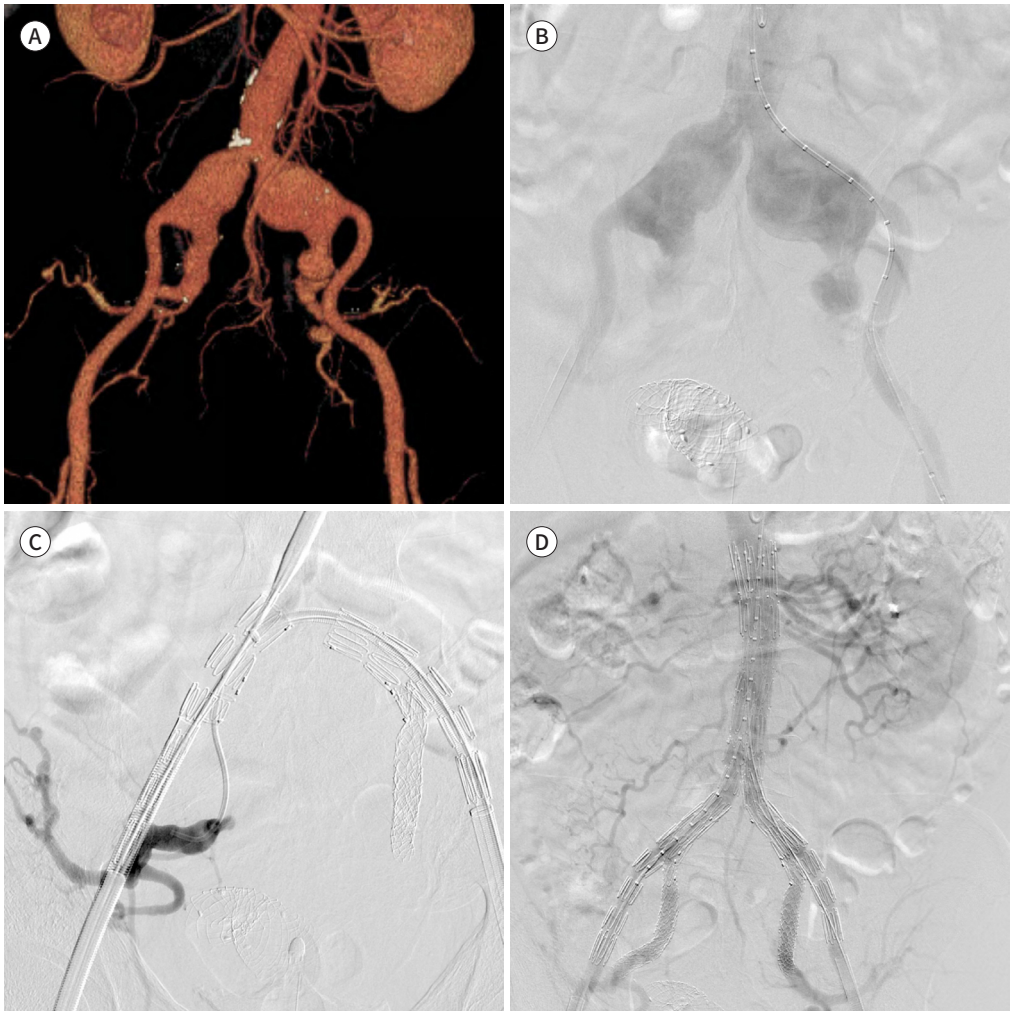

Table 4. Characteristics of IBD Cases in Ten Patients

Characteristics of Patient Information	Number of Patients
Sex	
Male	9
Female	1
Mean age ± SD (years)	70.8 ± 8.0
Underlying disease	
Ischemic heart disease	4
Hypertension	3
Diabetes mellitus	2
COPD	1
Chronic renal failure	0

COPD = chronic obstructive pulmonary disease, IBD = iliac branch device, SD = standard deviation

Fig. 2. Case of technical failure in IBD use.
A. The aortogram shows an infrarenal abdominal aortic aneurysm and bilateral common iliac artery aneurysms.
B. Embolization of the right IIA was performed, and the angiogram shows the absence of contrast flow in the left IIA due to a failure of selection.
C. The final angiogram shows endovascular aneurysm repair with bilateral IIA embolization due to technical failure in left IBD placement.
IBD = iliac branch device, IIA = internal iliac artery

ful procedures, IBD insertion was performed with EVAR. The characteristics of the procedures are reported in Table 5. The mean procedure time (mean ± SD) for one-sided IBD implantation was 43.1 ± 14.6 min. One case of one-sided IBD implantation required an unusually long procedural time (75 min) because selection took a long time due to the tortuous iliac artery. The procedure times for the two patients with bilateral IBD were 104 and 92 min, respectively.

A simple linear regression analysis of seven cases involving one-sided IBD implantation was performed to evaluate the statistical significance of the procedure time according to experience. This analysis did not show significant differences in procedure time according to experience (p = 0.909).

We followed patients who underwent IBD implantation and the mean follow-up period (mean ± SD) was 32.1 ± 28.6 months (range, 1–86 months). The IIA flow patency was investi-

Table 5. Characteristics of the Procedure

Information Related to the Procedure	Number of Patients	Number of IBDs Used
IBE Gore	5*	6
ZBIS COOK	4*	5
Technical failure (IBE Gore)	1	1
Total number of patients/IBDs used	10	12
Contralateral IIA embolization	5	
Mean procedure time ± SD (min) of one-sided IBD	43.1 ± 14.6	
Type I endoleak	1	
Type II endoleak	4	

*One patient had IBD procedures on both side.
IBD = iliac branch device, IIA = internal iliac artery, SD = standard deviation

Fig. 3. Case requiring IBD-related reintervention for pseudoaneurysm.
A. The final angiogram shows good flow in bilateral IBD.
B. Follow-up angiogram shows the pseudoaneurysm formation in the left superior gluteal artery.
C. After embolization of the superior gluteal artery, the pseudoaneurysm on the angiogram disappears.
IBD = iliac branch device

gated using CT images obtained during follow-up, which showed that it was maintained at 100% during the study period. Of the seven patients who underwent unilateral IBD treatment, five underwent contralateral IIA embolization. Among them, three (60%) patients showed claudication with or without leg swelling on the ipsilateral side of the embolization. These claudication symptoms occurred 1, 4, and 6 months after the procedure, and the symptoms improved in all cases after 5–6 months. No pelvic blood flow-related morbidity, such as claudication, erectile dysfunction, or colon ischemia, was observed in other patients without embolization (bilateral IBD in two patients and unilateral IBD without embolization in two patients) during the follow-up period.

The follow-up imaging study recorded one type Ib endoleak and four type II endoleaks. The type Ib endoleak of IIA occurred due to a mismatch between the IIA and IBD diameters. However, no further intervention was performed because the size of the aneurysm decreased during follow-up.

Two IBD-related reinterventions were performed. One patient required embolization owing to a pseudoaneurysm in the gluteal artery branch, which was performed 1 week after the pro-

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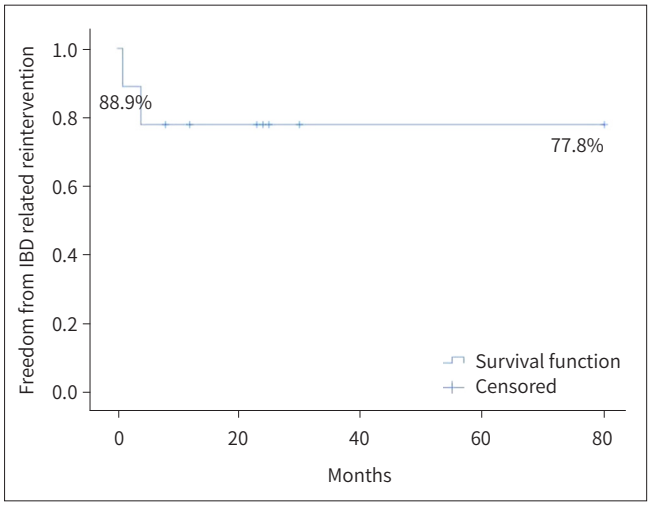

Fig. 4. The 7-year freedom from reintervention rate is calculated using the Kaplan–Meier method.
IBD = iliac branch device

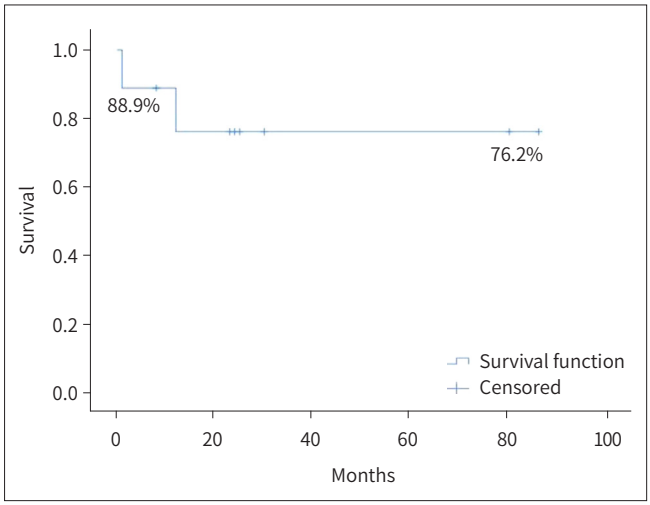

Fig. 5. The 7-year survival rate is calculated using the Kaplan–Meier method.

cedure (Fig. 3). In the retrospectively reviewed initial procedural images, a pseudoaneurysm of the IIA branch was observed on the final angiogram due to careless wire advancement. The other patient required reintervention owing to focal stenosis in the limb graft, 4 months after the procedure. Stenosis was caused by compression of the contralateral limb and a self-expandable stent was inserted. Therefore, the freedom from IBD-related reintervention rates were 77.8%, 77.8%, and 77.8% at 1, 3, and 7 years, respectively (Fig. 4).

Two of the nine patients died during the follow-up period due to underlying diseases (lung cancer and colon cancer, respectively). These deaths were not attributable to aneurysms or endovascular aortoiliac repair. Periprocedural deaths were not recorded and overall survival rates were 88.9%, 76.2%, and 76.2% at 1, 3, and 7 years, respectively (Fig. 5).

DISCUSSION

In the past, EVAR for AAA with concomitant CIAA repair was reported to interrupt the flow in the ipsilateral IIA owing to the distal landing zone of the EIA. As a result, it caused compli-

cations, including buttock claudication, impotence, ischemic colitis, spinal cord ischemia, and gluteal necrosis. The rate of buttock claudication is reportedly 25%–50% when unilateral IIA is embolized (2-4).

Although unilateral occlusion can be asymptomatic in many patients, mild symptoms, such as buttock claudication, and severe symptoms, such as pelvic or spinal cord ischemia, can occur as sequelae of IIA occlusion. Furthermore, the bilateral occlusion was frequently symptomatic. Thus, the operator tries to maintain IIA blood flow using an IBD to prevent these complications. Since the introduction of IBDs, several studies have shown their safety and effectiveness.

In a meta-analysis of 22 studies with 1064 patients, the pooled technical success rate of IBD was 93% (91%–95%), and the follow-up patency rate was 86% (84%–88%). Regarding complications, the buttock claudication rate was 6% (5%–8%), and the endoleak rate was 12% (8%–17%). The IBD-associated reintervention rate was 11% (8%–14%), and the 30-day mortality rate was 2% (1%–4%) (8).

Verzini et al. (9) reported the late outcomes of IBD in aortoiliac endografting, recorded in the pErformance of iLiac branch deVIces for aneurysmS involving the iliac bifurcation (pELVIS) Registry in nine European centers. The overall primary patency rates were 99.2%, 97.9%, and 95.1% at 1, 12, and 72 months, respectively. During the follow-up period, the IBD-related reintervention rate was 13.5%. Overall, the freedom from reintervention and conversion rates were 90.4% and 71.0% at 12 and 72 months, respectively.

Recent prospective studies have reported low rates of IBD-related reintervention with high IBD patency and overall survival rates. Parlani et al. (10) reported the results of 100 consecutive patients enrolled in a prospective database. The procedural success rate was 95%, and the IBD patency rate of the internal iliac branch was 91.4% at 5 years. Four patients developed buttock claudication during follow-up (three with IIA branch occlusion and one with IBD on one side and contralateral IIA embolization). The freedom from reintervention rates were 90% at 1 year and 81.3% at 5 years, and most reinterventions were due to EIA occlusion or endoleaks. The all-cause survival rate at 5 years was 70.4%.

Similarly, our data show a high technical success rate of 91.6%. The IIA flow patency rate was 100% for all procedures and no complications occurred in patients treated for bilateral or unilateral IBDs without embolization. Furthermore, the freedom from IBD-related reintervention rates were 77.8%, 77.8%, and 77.8% at 1, 3, and 7 years, respectively, comparable to the results of other studies (6, 10, 11). During the follow-up period, two patients died from their underlying disease and the overall survival rates were 88.9%, 76.2%, and 76.2% at 1, 3, and 7 years, respectively.

Despite the effectiveness and good prognosis of IBD, its application in Asia is limited. An international multicenter study with two institutions from Europe and one from China showed differences in aortoiliac anatomy between Caucasian and Asian patients (12). Caucasian patients had longer CIA, larger CIA and EIA diameters, and a greater aneurysm-to-aortic axis angle. Another retrospective study conducted in two institutions in Hawaii evaluated the association between the outcomes of aortoiliac stent insertion in Asian and non-Asian patients (13). In this study, Asians had a higher risk of device-related complications after aortoiliac stent grafting than non-Asians and had limitations in using IBD. These findings can be attributed to

the smaller and more tortuous anatomy of the iliac arteries in Asian patients. Therefore, IBDs may not be ideally suitable for Asians, and there may be fewer cases of IBD use in Asians than in non-Asians. It is necessary to discuss whether the use of IBDs in Asia is as effective and meaningful as in non-Asian countries.

A study published by Karthikesalingam et al. (14) showed that among a population of patients with aortoiliac aneurysms, the morphological applicability of a commercially available IBD was less than 40% and that patients commonly had adverse anatomical characteristics. In our study, among the 38 patients with aortoiliac aneurysms, IBD treatment was anatomically possible in only 10 (26.3%) patients. Among the nine patients with bilateral CIAA, only two could be treated bilaterally with IBD. The number of patients suitable for the indication is believed to be insufficient; therefore, the number of patients enrolled in the study was inevitably small.

Gray et al. (5) recommended the following expanded criteria for IBD: shorter CIA length (> 40 mm) and adequate distal landing in the distal IIA or main branch. In their study, only 40.9% (36/88) of the iliac arteries met the criteria of the manufacturer's instruction (CIA length $\geq$ 50 mm in instructions for the use of Cook Zenith); however, 58% (51/88) of the patients could have been treated with IBD by applying the expanded criteria (5).

Several studies have reported buttock claudication in up to 60% of cases of bilateral obstruction; however, serious complications, such as buttock necrosis or ischemic colitis, are rare when single IIAs are interrupted. In addition, symptoms of buttock claudication caused by unilateral IIA occlusion resolve spontaneously in approximately 48%–78% of cases (4, 15, 16). Similarly, in our study, claudication occurred in three of the five patients who underwent unilateral IBD implantation with contralateral embolization, and symptoms improved within 6 months for all patients. This finding can be attributed to the development and preservation of the branch vessels.

Therefore, CIAAs are rarely suitable for bilateral IBDs, especially in Asians, and complications caused by unilateral embolization are not serious and patients have recovered well. When the application of IBD is anatomically unsuitable, unilateral IBD implantation with contralateral embolization can result in a good prognosis.

Our study had a few limitations. The main limitations are the small amount of data and the fact that the study was conducted in a single center. Errors in the incidence of claudication cannot be excluded and the recovery rate from embolization may have been exaggerated. Furthermore, the technical success rate cannot be standardized because the patients were selected according to single-center criteria. In addition, we used two different endograft models of IBDs, and only one device was available for each period. Differences in procedural outcomes may depend on the instruments used. It is difficult to accurately compare procedure times or prognosis because we cannot control for variables such as anatomical diversity and individual clinical conditions. Finally, data may have been missed due to limitations in the retrospective data collection of the study.

In conclusion, IBD is considered the first-choice treatment for CIAA; however, its application is frequently limited because of unsuitable anatomical factors. Fortunately, serious complications, such as buttock necrosis or ischemic colitis, are rare with the interruption of a single IIA. Moreover, symptoms of claudication due to unilateral IIA occlusion resolved spontaneously at a high frequency. Therefore, selective interruption of IIAs can usually be performed safely in

patients with anatomically complex aortoiliac aneurysms, instead of using IBD bilaterally.

Author Contributions

Conceptualization, L.H., L.J.; data curation, L.H., L.J.; formal analysis, L.H., L.J.; supervision, L.J., C.S., H.J.; writing—original draft, L.H., L.J.; and writing—review & editing, L.H., H.J.

Conflicts of Interest

The authors have no potential conflicts of interest to disclose.

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장골 분지 장치 사용: 내장골동맥 흐름의 혈관내 보존에 대한 단일 기관의 경험

이혜승 · 이정민* · 조순구 · 홍정의

목적 단일 기관에서 7년간의 장골 분지 장치 사용 경험을 바탕으로 그 효과와 안전성을 확인하고 효용성 및 한계를 고찰하고자 하였다.

대상과 방법 이 연구는 단일 기관에서 총장골동맥류에 장골 분지 장치 삽입술을 받은 환자들을 대상으로 시행했다. 추적 컴퓨터단층촬영 스캔을 분석하고, 내장골동맥의 개방성 및 장골 분지 장치 사용과 관련된 합병증을 검토했다. 후향적 분석을 시행하였으며 전체 생존율과 재시술이 필요 없는 환자의 비율을 Kaplan–Meier method에 따라 분석했다.

결과 38명의 총장골동맥류가 있는 환자들 중에서 10명의 환자(12개의 총장골동맥류)만이 해부학적으로 장골 분지 장치 사용에 적합했다. 5명의 환자는 반대측 내장골동맥 색전술과 함께 장골 분지 장치 삽입술을 받았으며, 이 중 3명의 환자(60%)는 합병증으로 파행을 보였으나 모두 6개월 만에 증상이 호전되었다. 또한 7년 후 장골 분지 장치 사용 관련 재시술이 필요 없는 환자의 비율은 77.8%였으며 시술과 관련된 사망은 없었다.

결론 장골 분지 장치는 높은 기술적 성공률과 장기 개통률을 보이지만, 아시아인의 경우 해부학적 요인으로 인해 적용이 제한되는 경우가 많다. 또한 단측 내장골동맥 색전술을 시행한 경우에도 경미한 합병증과 좋은 예후를 보였으므로, 해부학적으로 복잡한 총장골동맥류에서 단측 장골 분지 장치 삽입술 및 반대측 내장골동맥 색전술을 선택하여 시행할 수 있다.

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