ORIGINAL ARTICLES

Evaluation Of Prophylactic Internal Iliac Artery Embolization for Endovascular Aortic Aneurysm Repair Using Amplatzer Vascular Plug

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Purpose: *To assess the efficacy of Amplatzer vascular plug (AVP) for prophylactic internal iliac artery embolization during endovascular aortic aneurysm repair (EVAR) by comparing the cases with and without using AVP.*

Subjects: *A total of 147 embolization's were performed at our hospital from September 2009 to January 2024 during EVAR procedures with preventive internal iliac artery embolization. There were 100 male and 23 female patients. Among the embolization's, 125 were simultaneous and 22 were staged. Bilateral embolization's were performed in 24 cases.*

Methods: *We evaluated the success rate and details of embolization in all cases, changes in procedures before and after the introduction of AVP, comparison between the coil group and the AVP group, retrospective evaluation of adverse events, time and costs required for embolization.*

Results: *The success rate of embolization procedures was 100%. Before the introduction of AVP, all 46 embolization procedures were performed using metal coils, but after the introduction of AVP, embolization with AVP was possible in 92 of 101 embolization procedures (91%). There was no significant difference between the two groups in terms of type 2 endoleaks and intraoperative vascular injuries. The AVP group showed significantly lower rates of buttock claudication (P=0.028), higher cumulative improvement rates in buttock claudication (P=0.0385), shorter procedural times (coil 105.1 ± 13.5 minutes vs AVP 50.4 ± 4.9 minutes P=0.003), and lower costs for embolization procedures (coil ¥309,445 ± ¥51,240 vs AVP ¥189,131 ± ¥13,476 P=0.000).*

Conclusion: *Embolization using AVP has a high success rate, and may reduce the frequency of buttock claudication, improve the cumulative improvement rate, shorten procedure times, and reduce the costs of embolization.*

BACKGROUND

Endovascular abdominal aortic repair (EVAR) for abdominal aortic aneurysms (AAA) is commonly accepted as a safe alternative to open surgery. Cases involving aneurysmal dilatation of at least one of the left and right common iliac arteries, which account for 20% of AAAs,[1] or cases with the characteristic of thick and short common iliac arteries common in Asians, may require extending the iliac branch of the stent graft to the external iliac artery, posing a risk of type 2 endoleak due to retrograde flow from the occluded internal iliac artery. To prevent such type 2 endoleaks, it is known as the standard treatment to embolize the internal iliac artery with metal coils simultaneously or staged with EVAR.[2] Recently, a new technique called iliac branch stent grafting has made it possible to perform EVAR with external iliac artery landing while maintaining blood flow in the internal iliac artery. However, this device has various anatomical requirements, making generalized use unfeasible. Therefore, highlighting the continued importance of prophylactic internal iliac artery embolization.

The Amplatzer Vascular Plug (Abbott Vascular,

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Redwood City, California, USA) is a self-expanding cylindrical occlusion device based on nitinol, known as a suitable alternative to coil embolization.[3,4,5] Our institution has been using AVP primarily for preventive internal iliac artery embolization since 2014. The purpose of this study is to assess the efficacy of Amplatzer vascular plug (AVP) for prophylactic internal iliac artery embolization during EVAR by comparing the cases with and without using AVP.

MATERIALS AND METHODS

This was a retrospective single-center study.

Patient Characteristics: The study included 147 embolizations performed at Nagaoka Red Cross Hospital from September 2009 to January 2024, where prophylactic embolization of the internal iliac artery was carried out before or simultaneously with EVAR procedures. The male- to-female ratio was 100:23, with ages ranging from 41 to 90 years and an average age of 76.1 years. Lesion sites were abdominal aortic aneurysm + common iliac artery aneurysm in 68 embolizations, localized iliac artery aneurysm in 44 embolizations, and localized abdominal aortic aneurysm (with inadequate distal landing zone) in 35 embolizations. Additionally, 57 embolizations involved aneurysmal dilatation of the internal iliac artery.At our institution, in cases requiring bilateral embolization, a staged embolization targeting one side was performed first, followed by simultaneous embolization during EVAR surgery on the remaining side.

For cases with unilateral embolization only, simultaneous embolization was generally performed. Therefore, there were 103 cases of unilateral embolization and 44 cases of bilateral embolization. Regarding the timing of embolization, 125 embolizations were performed simultaneously with EVAR surgery, while 22 embolizations were staged (Table 1).

Table 1. Summary of Clinical Characteristics for All Patients & procedures.

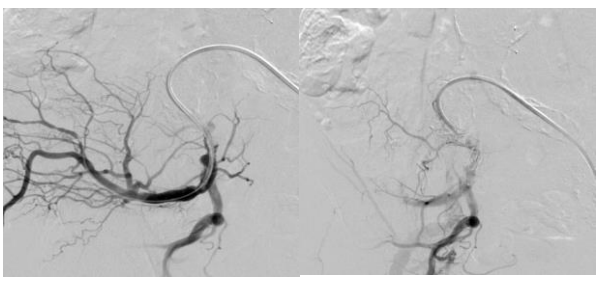
Characteristic	No. of Patients / procedures
Total no. of patients / procedures	123 / 147
Sex	
Male	100
Female	23
Age, y	
Mean	76.1
Range	41 - 90
Indication for IIA embolization	
AAA with iliac artery aneurysm	68 proc
Common Iliac artery aneurysm only	44 proc
Although AAA only forperipheral landing reservation	35 proc
Accompanied by aneurysm of the internal iliac artery	57 proc
Embolization side	
Unilateral	103 proc
Bilateral	44 proc
Embolization timing	
Simultaneous	125 proc
Metachronous	22 proc
Access route	
Contralateral	115 proc
Ipsilateral	31 proc
Brachial	1 proc

AAA, abdominal aortic aneurysm; IIA, internal iliac artery; proc, procedure

For insertion into the internal iliac artery, the standard procedure was to approach from the contralateral femoral artery across the aortic bifurcation, insert a stiff guidewire (diameter: 0.035 in, length: 180-300 cm) into the periphery of the superior or inferior gluteal artery, guide a 6Fr long sheath (Destination Terumo, Tokyo, Japan) to the periphery of the internal iliac artery trunk, and place the AVP using the pullback technique described in the instruction manual from the internal iliac artery trunk to the level of its origin proximal to the superior gluteal/inferior gluteal artery bifurcation. If necessary, an approach from the ipsilateral femoral artery was also used Figure 1. The breakdown of approaches included 115 embolizations (78%) with a contralateral approach, 31 embolizations (21%) with an ipsilateral approach, and 1 embolization (1%) with a brachial approach. The brachial approach was used only once in the early stages, but due to a lack of appropriate devices and concerns about the risk of stroke, it has not been chosen as an access route for prophylactic internal iliac artery embolization thereafter.

Figure 1: (a) Approach from the contralateral femoral artery across the aortic bifurcation, insert a stiff wire at the periphery of the SGA or IGA, and guide the 6Fr long sheath (arrow head) distal to the main trunk of the IIA.
(b) AVP (arrow) is placed in the main trunk of the IIA, proximal to the SGA or IGA bifurcation.

A B



A snare-assisted pull-through technique was used in 3 embolizations (1 in the coil group and 2 in the AVP group). Patient information, radiological data, and surgical data were obtained from the paper and electronic medical records of our institution. All patient names and other Health Insurance Portability and Accountability Act (HIPAA) identifiers have been removed from all sections of the manuscript, including supplementary information, and no other information that could potentially identify subjects (such as clinical images or videos) was included in the study. Due to the retrospective nature of the study, Nagaoka Red Cross Hospital ethics committee waived the need of obtaining ethical approval and informed consent. All methods were performed in accordance with relevant guidelines and regulations.

Investigated Items

(1) Overall embolization success rate and breakdown of procedures and embolization content for all cases/all procedures
(2) Changes in procedures before and after the introduction of AVP
(3) Comparison between the coil group and AVP group for adverse events (type 2 endoleak, intraoperative vascular injury, frequency and cumulative improvement rate of buttock claudication), procedural time, and cost incurred for the procedures

The evaluation of type 2 endoleaks was conducted using contrast-enhanced CT scans targeting the internal iliac artery and the common iliac artery where preventive embolization was performed.

Regarding the cumulative improvement rate of buttock claudication, cases that did not report symptoms of buttock claudication were treated as having symptom improvement on postoperative day 0.

At our institution, during EVAR surgery, the anesthesia department administers systemic heparinization at the time of inserting short sheaths into both groins. Therefore, regarding the procedure time of embolization, in the case of simultaneous embolization with EVAR, the start time was defined as the time of systemic heparinization in the anesthesiology records. If preceding interventional radiology (IVR) procedures (17 procedures, including 1 renal artery stenting, 14 preventive IMA embolizations, and 2 type 1b interventions immediately after EVAR placement) were performed, the start time was defined as the time of confirmation imaging of the preceding IVR. In the case of staged embolization, the start time was defined as the time of arterial

puncture. In all cases, the end time was defined as the time of confirmation contrast imaging at the end of embolization. Furthermore, after the introduction of AVP, our institution has adopted a policy of first attempting embolization with AVP in all cases and procedures, and if that proves difficult, transitioning to other devices such as coils. Therefore, cases in which coil embolization was performed after the introduction of AVP were excluded from the analysis of procedural time. Additionally, for the 7 embolization procedures in the coil group and 2 in the AVP group performed in the operating room, the confirmation imaging time at the end of the embolization could not be identified from the imaging equipment records, and these cases were also excluded from the analysis of procedural time.

Regarding the costs associated with the procedure, we referred to the documentation from the radiology department and the details of the surgical procedures, as well as our institution's medical billing claims. We accounted for the costs of items used solely for internal iliac artery embolization.

The analysis was performed using Dr. SPSS-II. The frequency of type 2 endoleak and buttock claudication at 6 months postoperatively were analyzed using the chi-square test, the frequency of intraoperative vascular injury using Fisher's exact test, and the cumulative improvement rate of buttock claudication was analyzed using the Kaplan-Meier method to plot cumulative improvement rate curves, with significant differences between the groups determined by the log-rank test. The procedure time and cost were analyzed using the t-test. In all analyses, a P-value of less than 0.05 was considered statistically significant.

Regarding gonadal dysfunction, which is generally considered one of the adverse events associated with internal iliac artery embolization, it was not considered in this study due to the high proportion of elderly patients in the target group and the absence of postoperative complaints from the patients. Similarly, severe pelvic ischemia, such as bowel ischemia, which is also considered a common adverse event, was not observed in any cases.

RESULTS

(1) Success Rate of Embolization and Breakdown of Embolization Content in All Cases/Procedures

The success rate of embolization was 100%, with no perioperative deaths or non-target embolizations observed. However, during one EVAR procedure, a thrombotic occlusion of the common iliac artery occurred unrelated to embolization, and F-F bypass surgery was performed. Another embolization procedure required conservative treatment due to the formation of a femoral artery pseudoaneurysm, and one thrombectomy procedure was performed due to lower extremity arterial thrombosis unrelated to the embolization procedure.

The breakdown of the embolization content was as follows: 42 procedures using metallic coils alone, 11 procedures using a combination of metallic coils and NBCA, 86 procedures using AVP alone, 4 procedures using a combination of AVP and metal coils, 2 procedures using a combination of AVP and NBCA, and 2 procedures using NBCA alone.

In the metallic coil embolization group, an average of 18.4 ± 2.5 coils were used, consisting of 10.2 ± 2.4 pushable coils (0.035), 7.5 ± 3.0 pushable coils (0.018), 0.06 ± 0.1 detachable coils (0.035), and 0.7 ± 0.6 detachable coils (0.018). In the AVP embolization group, an average of 1.3 ± 0.1 AVPs and 0.1 ± 0.1 coils were used. The breakdown of the coils used was 0.08 ± 0.1 pushable coils (0.018) and 0.07 ± 0.08 detachable coils (0.035).

The devices used included 8 embolization procedures with the Cook Zenith (Medtronic Cardiovascular, Santa Rosa, California), 120 embolization procedures with the Gore Excluder (W. L. Gore & Associates, Inc., Newark, Delaware), 10 embolization procedures with the ENDURANT (Medtronic Cardiovascular, Santa Rosa, California), 7 embolization procedures with the Endologix Powerlink/AFX/AFX2 (Endologix Inc., Irvine, California), and 2 embolization procedures with the Aorfix stent graft (Lombard Medical Technologies Inc., Tempe, Arizona) Table 2.

Changes in Procedures Before and After the Introduction of AVP

Regarding patient background factors before and

Table 2: Results of procedures for all patients

Items	results
Success rate	100%
Contents of embolization	Metallic coils alone: 42 proc Metallic coils with NBCA: 11 proc AVP alone: 86 proc AVP with metallic coils: 4proc AVP with NBCA: 2proc NBCA alone: 2proc
Numbers of embolic material	
Coil group (mean ± SD)	Average: 18.4 ± 2.5 35P: 10.2 ± 2.4 35D: 0.06 ± 0.1 18P: 7.5 ± 3.0 18D: 0.7 ± 0.6
AVP group (mean ± SD)	Average: AVP 1.3 & coils 0.1 AVP: 1.3 ± 0.1 35D: 0.07 ± 0.08 18P: 0.08 ± 0.1
Used Endografts	Cook Zenith: 8 proc Gore Excluder: 120 proc ENDURANT: 10 proc Endologic Powerlink / AFX / AFX2: 7 proc Aorfix stentgraft: 2proc
Preceding IVR procedures	Renal artery stent insertion: 1 proc Prophylactic IMA embolization: 14 proc EVAR (treatment for type 1b EL): 2 proc

Pts, patients; proc, procedure; NBCA, n-butyl-2-cyanoacrylate; AVP, amplatzer vascular plug; SD, standard deviation; 35P, 0.035-inch push able coil; 35D, 0.035-inch detachable coil; 18P, 0.018-inch push able coil; 18D, 0.018-inch detachable coil; IVR, interventional radiology; IMA, inferior mesenteric artery; EVAR, endovascular arterial repair; EL, endoleak.

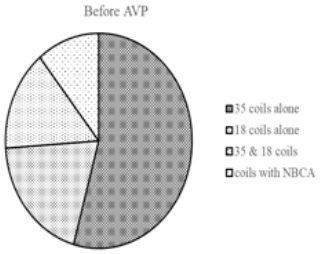
after the introduction of AVP, the frequency of bilateral embolization was significantly higher after the introduction of AVP. However, no significant differences were observed in other factors (Table 3). Additionally, regarding the access route, the brachial approach was only performed in the initial embolization procedure as mentioned above, and has not been chosen since, so it was excluded from the analysis of patient background factors.

Before the introduction of AVP, there were 25 embolization procedures using 0.035-inch coils alone, 9 procedures using 0.018-inch coils alone, 7 procedures using a combination of 0.035-inch coils and 0.018-inch coils, and 5 procedures using a combination of metallic coils and NBCA.

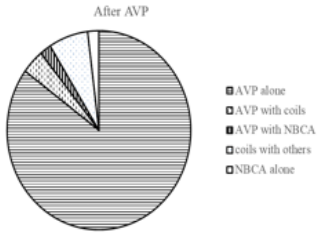
On the other hand, after the introduction of AVP, there were 86 embolization procedures using AVP alone, 4 procedures using a combination of AVP and metallic coils, 2 procedures using a combination of AVP and NBCA, 1 procedure using metallic coils alone, 6 procedures using a combination of metallic coils and NBCA, and 2 procedures using NBCA alone Figure. 2.

After the introduction of AVP, embolization using AVP was performed in all procedures, and was possible in more than 90% of cases. The reasons for abandoning AVP embolization were as follows:

Figure 2, Changes in embolization procedures before and after the introduction of AVP



variable	number
35 coils alone	25 proc
18 coils alone	9 proc
35 & 18 coils	7 proc
Coils with NBCA	5 proc



variable	number
AVP alone	86 proc
AVP with coils	4 proc
AVP with NBCA	2 proc
Coils with others	7 proc
NBCA alone	2 proc

1. In 5 procedures using a combination of metal coils and NBCA, severe tortuosity and aneurysmal changes in the iliac artery made it impossible to insert a 6Fr long sheath.
2. In 2 procedures using NBCA alone, catheter insertion was difficult due to severe calcification at the origin of the internal iliac artery.
3. In 1 procedure using a combination of metal coils and NBCA, it was performed immediately after EVAR to address a type 1b endoleak.
4. In 1 procedure using metal coils alone, embolization was necessary after penetrating the stent mesh, following the placement of a metal stent in the common and external iliac arteries for ASO.

As described above, embolization using AVP can be performed with a high success rate.

Comparison of Coil Group and AVP Group

Adverse Events (Type 2 Endoleak, Intraoperative Vascular Injury, Frequency of Buttock Claudication, and Cumulative Improvement Rate of Buttock Claudication), Procedure Time, and Procedure Cost Regarding patient background factors in the coil group and AVP group, the frequency of bilateral embolization was significantly higher in the AVP group. However, no significant differences were observed in other factors (Table 4). Additionally, the brachial approach was excluded from the analysis of patient background factors, as previously mentioned.

Regarding type 2 endoleak, the frequency was 2 cases (3.8%) in the coil group and 4 cases (4.6%) in the AVP group, with no significant difference between the two groups (P = 0.833). Furthermore, there were no type 2 endoleaks requiring additional treatment. It should be noted that in 1 procedure in the coil group and 5 procedures in the AVP group, postoperative contrast-enhanced CT imaging could not be performed due to renal function decline, making it impossible to evaluate type 2 endoleak in these cases.

Regarding intraoperative vascular injury, there were no cases (0%) in the coil group, whereas the AVP group had 3 cases (3.3%) of vascular injury caused by migration of stiff guidewire tip, which were managed with intraoperative TAE. There was no significant difference in the frequency of vascular injury between the two groups (P = 0.299).

Regarding the frequency of buttock claudication, at the 6-month postoperative evaluation, the rate was 12 cases (24%) in the coil group versus 9 cases (10%) in the AVP group. The AVP group had a significantly lower frequency of buttock claudication (P = 0.028) (Table 5). Additionally, evaluations of buttock claudication could not be performed for 3 cases in the coil group and 1 case in the AVP group due to the destruction of medical records, and for 2 cases in the AVP group due to early postoperative discharge.

Using the Kaplan-Meier method to analyze the cumulative improvement rate of buttock claudication, the results were as follows:

6-month Cumulative Improvement Rate: 68% in the coil group vs. 81% in the AVP group.

1-year Cumulative Improvement Rate: 82% in the coil group vs. 92% in the AVP group.

Average Improvement Period: 224 days (95% confidence interval: 61 to 387 days) in the coil group vs. 76 days (95% confidence interval: 39 to 114 days) in the AVP group.

The AVP group showed a significantly better improvement rate (P = 0.0385) (Fig. 3).

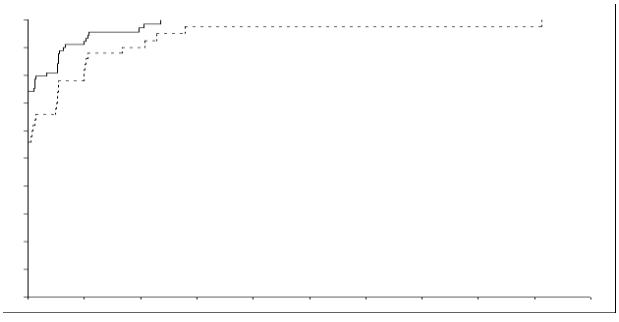
In the analysis of procedure time, the average time was 105.1 ± 13.5 minutes in the coil group vs 50.4 ± 4.9 minutes in the AVP group. The AVP group had

Table 3: Patients Characteristics for before and after AVP introduction.

variable	Before AVP	after AVP	P value
Age (mean ± SD)	77 ± 2.3	75 ± 1.6	.320
Gender	M 38 / F 5	M 63 / F 18	.149
Indication of embolization			
AAA with CIAA	23	41	.526
CIAA only	13	31	
Peripheral landing	10	29	
With IIA aneurysm	Yes 17 / No 29	Yes 41 / No 60	.676
Embolization side			
Unilateral	41	62	.001
Bilateral	5	39	
Embolization timing			
Simultaneous	41	84	.347
Metachronous	5	17	
Access route			
Contralateral	35	80	.845
Ipsilateral	10	21	
Used Endografts			
Cook Zenith	8	0	N/A
Gore Excluder	30	90	
ENDURANT	6	4	
Endologic Powerlink / AFX / AFX2	2	5	
Aorfix stentgraft	0	2	
Preceding IVR procedures			
Renal artery stent insertion	1	0	N/A
Prophylactic IMA embolization	1	13	
EVAR (treatment for type 1b EL)	0	2	

AVP, amplatzer vascular plug; SD, standard deviation; M, male; F, female; EVAR, endovascular arterial repair; AAA, abdominal aortic aneurysm; CIAA, common iliac artery aneurysm; IIA, internal iliac artery; IVR, interventional radiology; IMA, inferior mesenteric artery; EL, endoleak.

Figure 3:



Comparison of the cumulative improvement rate of buttock claudication between coils group vs AVP group.

The improvement rates on 6 months, and 1 years of coils group were 68%,82% respectively and mean was 224days (95% confidence interval:61-387 days) and those of AVP group were 81%, 92% respectively and mean was 76 days (95%confidence interval: 39-144 days.)

The improvement rates of AVP group were more both groups. better than those of coils group, and there was the significant difference (P = 0.0385) between both groups.

Table 4. Patients Characteristics for coil group vs AVP group

Age (mean ± SD)	**77 ± 2.2**	**76 ± 1.6**	**.813**
Gender	**M 41 / F 8**	**M 59 / F 16**	**.490**
Indication of embolization AAA with CIAA	25	38	.790
CIAA only	15	29	
Peripheral landing	13	25	
With IIA aneurysm	Yes 22 / No 31	Yes 35 / No 57	.681
Embolization side			
Unilateral	45	56	.002
Bilateral	8	36	
Embolization timing			
Simultaneous	47	76	.326
Metachronous	6	16	
Access route			
Contralateral	38	76	.176
Ipsilateral	14	16	
Used Endografts			
Cook Zenith	8	0	N/A
Gore Excluder	37	81	
ENDURANT	6	4	
Endologic Powerlink / AFX / AFX2	2	5	
Aorfix stentgraft	0	2	
Preceding IVR procedures Renal artery stent insertion	1	0	N/A
Prophylactic IMA embolization	1	13	
EVAR (treatment for type 1b EL)	1	1	

AVP, amplatzer vascular plug; SD, standard deviation; M, male; F, female; EVAR, endovascular arterial repair; AAA, abdominal aortic aneurysm; CIAA, common iliac artery aneurysm; IIA, internal iliac artery; IVR, interventional radiology; IMA, inferior mesenteric artery; EL, endoleak.

Table 5: Adverse event between coil group vs AVP group.

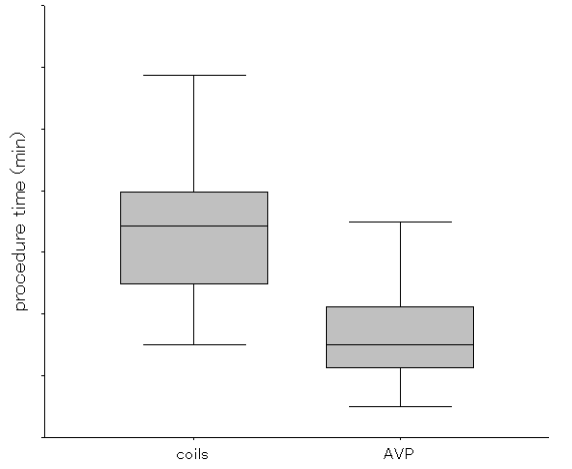
variable	Coil group	AVP group	P value
Type 2 EL	2 proc (3.8%)	4 proc (4.6%)	0.813
Vascular damage during EVAR	0 proc (0%)	3 proc (3.3%)	0.299
Buttock claudication 6M after procedure	12 proc (24%)	9 proc (10%)	0.028

The buttock claudication 6 months after procedure of coils group were 12 procedure (24%), and those of AVP group were 9procedure (10%).

There was the significant difference (P = 0.028) between both groups.

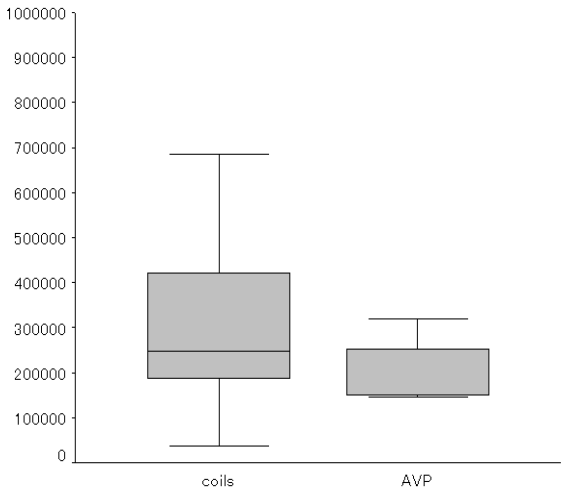
AVP, amplatzer vascular plug; EL, endoleak; proc, procedure; EVAR, endovascular arterial repair.

a significantly shorter procedure time (P = 0.003)
Figure. 4: Comparison of the required procedure time between coils group vs AVP group.



The procedure time of AVP group were shorter than those of coils group, and there was the significant difference (P = 0.003) between both groups.

Regarding the cost of the procedure, the average cost was ¥309,445 ± 51,240 in the coil group vs ¥189,131 ± 13,476 in the AVP group. The AVP group had a significantly lower cost (P = 0.000)
Figure 5: Comparison of the cost of embolization between coils group vs AVP group.



The AVP group had lower costs than the coils group, and there was the significant difference (P = 0.000) between both groups.

DISCUSSION

Buttock claudication is one of the important adverse events in prophylactic internal iliac artery embolization, with reported frequencies ranging from 19% to 55%.[6,7,8,9,11,12] On the other hand, there are reports indicating that the frequency of buttock claudication decreases with embolization at the proximal internal iliac artery or with the use of AVP.[6,10,12,13,14,15] This study also observed a reduction in the frequency of hip claudication and a higher cumulative improvement rate in the AVP group. AVP embolization appears to be one of the important factors in reducing the frequency of buttock claudication and enhancing the improvement rate.

It has already been reported that using AVP in prophylactic internal iliac artery embolization leads to a reduction in procedure time.[9,10,12]. This study similarly demonstrates a reduction in procedure time with AVP, suggesting that AVP embolization contributes to shortening the procedure time in prophylactic internal iliac artery embolization.

Both.[13,16]. reported that the cost of prophylactic internal iliac artery embolization using AVP was significantly lower than that of coil embolization. They reported the cost of the AVP group to be in the $300 range, but in Japan the cost of one AVP is 131,000 yen (approximately $879 at the average dollar-yen rate in March 2025), so this does not reflect the correct procurement cost of AVP.[9] reported in a similar study that the cost of the AVP group tended to be lower, but there was no significant difference between the AVP group and the coil group.[17] reported that a special technique called coil-in-plug (CIP), in which a coil is inserted into the AVP, reduced costs compared to conventional coil embolization, but their report was not a simple comparison between AVP embolization and coil embolization.

In this study, it was shown that the cost of the AVP embolization group was lower than that of the coil embolization group with a clear statistically significant difference. Similar results have not been reported in reliable studies of prophylactic internal iliac artery embolization based on a certain number of cases and reflecting the formal procurement costs of AVP, so this study is the first of its kind in

the world.
The impact of AVP embolization on the overall cost of EVAR surgery is an interesting factor, but.[9] reported that there was no significant difference in this regard. On the other hand, it is well known that the cost of EVAR surgery varies greatly depending on the plan. Therefore, it is difficult to imagine that meaningful results would be obtained by simply calculating the average of cases collected retrospectively without paying attention to the plan, such as the case group in this study. In the future, we await the results of a prospective comparative study that standardizes EVAR plans and randomizes the embolic material.

CONCLUSION

The active use of AVP in prophylactic internal iliac artery embolization for EVAR offers benefits such as a reduced incidence of buttock claudication, an increased rate of improvement in buttock claudication, a shorter procedure time, and reduced embolization costs, without any significant adverse events.

LIMITATIONS

The limitations of this study include the following:

The study is a single-center retrospective analysis.
Since the study involves a single operator, there is an element of learning curve that may influence the results.
The study spans a long patient enrollment period, which introduces potential bias due to advancements in device technology over time.

DECLARATIONS

Ethics approval and consent to participate

Due to the retrospective nature of the study, Nagaoka Red Cross Hospital ethics committee waived the need of obtaining ethical approval and informed consent. All methods were performed in accordance with relevant guidelines and regulations.

consent for publication

Not applicable

Availability of data and materials

The data that support the findings of this study are available from Nagaoka Red Cross Hospital ethics committee but restrictions apply to the availability of these data, which were used under license for the current study, and so are not publicly available. Data are however available from the authors upon reasonable request and with permission of Nagaoka Red Cross Hospital ethics committee. If you would like to share our raw data, please contact Satoshi Takaki.

Competing interests

The authors have no competing interests to declare that are relevant to the content of this article.

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Authors' contributions

S. Takaki contributed to the research, development and approval of the manuscript, agreement to be accountable, and statistical analysis.
Y. Tani contributed to design of the research, critical revision and approval of the manuscript, agreement to be accountable.
H. Hirahara and M. Sugawara contributed to data collection of the research, critical revision and approval of the manuscript, agreement to be accountable.

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