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Assessing Radiation Exposure and Contrast Agent Utilization: A Comparative Analysis of the Woven EndoBridge Device and Stent-Assisted Coil Embolization for Managing Unruptured Wide-Neck Bifurcation Aneurysms

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Purpose: In this study, we determined whether there were significant differences in procedure time, radiation dose, fluoroscopy time, and total contrast media dose when unruptured wide-neck bifurcation aneurysms (WNBAs) were treated with the Woven EndoBridge (WEB) device and stent-assisted coil (SAC) embolization.

Materials and Methods: The WEB device and SAC embolization (14:17) were used to treat 31 cases of internal carotid artery bifurcation, anterior communicating artery, middle cerebral artery bifurcation, and basilar bifurcation aneurysms between August 2021 and December 2022. The procedure time, radiation dose, fluoroscopy time, and total contrast medium dose between the 2 treatment groups were compared and analyzed. In the WEB device group, the results between operators were compared, and the follow-up radiologic outcomes were investigated.

Results: The procedure and fluoroscopy times were significantly shorter in the WEB device group. Radiation and total contrast media dose were also significantly smaller in the WEB device, but there was no significant difference in results between operators. The follow-up radiological outcome showed adequate occlusion in 83.3% (10/12) of cases.

Conclusion: The WEB device can be used as an alternative treatment method among the available endovascular treatment methods for WNBAs to reduce radiation exposure and the dose of contrast media when used adequately with appropriate indications.

Key Words: Intracranial aneurysm; Endovascular procedures; Contrast media; Fluoroscopy

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INTRODUCTION

Intracranial wide-neck bifurcation aneurysms (WNBAs) can be treated using various methods, including simple coil embolization, stent-assisted coil (SAC) embolization, and clip ligation.[1] However, treating WNBAs is technically difficult, and the results are not guaranteed.[2]

The Woven EndoBridge (WEB; MicroVention/Terumo) device, unlike the previously mentioned treatment methods, was specially designed to treat WNBAs and has been available for clinical use in Europe since 2011.[3] Furthermore, the United States Food and Drug Adminis-

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tration recently approved the WEB device for treating both ruptured and unruptured wide-neck aneurysms of the anterior communicating artery (AcomA), middle cerebral artery (MCA) bifurcation, internal carotid artery (ICA) bifurcation, and basilar artery bifurcation.[4] In Korea, it was approved for use in 2021 only for aneurysms in locations identical to those approved in the United States.

The WEB device is a self-expandable braided mesh made of a platinum core and nitinol wire. When placed inside the aneurysm, the blood supply into the aneurysm is dramatically decreased because of the device's high metal coverage rate, which begins, and neo-endothelization proceeds along the interface between the parent artery and the neck of the aneurysm. The aneurysm is then separated from the parent artery and treated.[5,6] The WEB device is called a "flow disruptor" because of this treatment principle.

A number of clinical studies on the results of using the WEB device have already been published, clearly illustrating that the WEB device shows favorable treatment outcomes.[7-11] However, other advantages of using the WEB device compared to existing treatment methods such as SAC, are not well known, and few studies have been conducted to clarify these aspects.[12] Therefore, we aimed to explore whether there is a difference in the radiation and contrast media dose exposure, outcomes that have rarely been reported, between the WEB and SAC.

MATERIALS AND METHODS

This study was a single center, retrospective study. The Institutional Review Board waived the requirement for informed consent (Inje University Busan Paik Hospital, approval number: 2022-08-039). All intracranial aneurysms treated with endovascular methods were enrolled from August 2021, when the WEB device was first used in our hospital, to December 2022. Ruptured aneurysms were excluded from the study. Aneurysms other than the AcomA, MCA bifurcation, ICA bifurcation, and basilar artery bifurcation, as well as aneurysms treated with methods other than SAC or the WEB were excluded. The operators chose which of the methods, WEB or SAC, to use according to their own discretion.

Three neurointerventionists, with between 8 to over 20 years of experience, performed the endovascular procedures. A biplane angiographic unit (Atris Z; Siemens Healthineers) was used. All patients underwent their procedure under general anesthesia. The procedure time was defined as the time from arterial puncture to arterial closure. The radiation dose and fluoroscopy time, which are radiation exposure variables, depended on the information provided by the angiographic system used in the procedure. The total volume of contrast medium used during the procedure was also recorded.

Patients treated with the WEB device were scheduled to undergo follow-up with computed tomography angiography (CTA) and digital subtraction angiography (DSA) at 3 and 6 months after the procedure, respectively. The radiologic outcome of the WEB device was judged as 4 grades using the WEB occlusion scale (WOS): WOS A, B, and C were evaluated as adequate occlusion, and D as inadequate occlusion.[4] Patients treated with SAC were routinely followed up with magnetic resonance angiography (MRA) or DSA at 6 months after the procedure. The radiologic outcome of SAC was evaluated according to the modified Raymond–Roy classification.[13]

Statistical analysis was performed to identify differences in baseline characteristics, procedure time, radiation dose, fluoroscopy time, and total contrast media dose between the 2 treatment groups. For descriptive statistics, continuous variables without normal distribution were reported as the median with 25th–75th percentiles, and categorical variables were calculated as numbers and percentages. The Kolmogorov–Smirnov test was used to evaluate the normality of variable distribution. In the comparison between the 2 groups, after the normality test was performed, the Student t-test was used if the distribution was normal, and the Mann–Whitney U-test if not. Statistical analysis was conducted to find out whether there was a statistically significant difference in procedure time, radiation dose, fluoroscopy time, and total contrast media dose according to the operator in the treatment group using the WEB device. In the comparison between 3 or more multiple groups, a normality test was performed, and the analysis of variance or Kruskal–Wallis test was used according to the result. Statistical significance was set at $P<0.05$. Statistical Package for Social Sciences (SPSS) software version 27 (IBM Co.) was used for all data analysis.

RESULTS

Patient Characteristics

Patient characteristics are presented in Table 1. Endovascular treatment was performed on 316 aneurysms in 313 patients during the study period and, of these aneurysms, 75 ruptured aneurysms were excluded from the study. In addition, 184 aneurysms where the WEB device was not approved for use—i.e., AcomA, MCA bifurcation, ICA bifurcation, and basilar artery bifurcation—and 26 aneurysms treated with methods other than the WEB device or SAC were excluded. Ultimately, 31 aneurysms were included in this study. Among these aneurysms, WEB and SAC were performed in 14 and 17 aneurysms, respectively.

The mean age of the patients treated using the WEB device was 63.50 years old, and there were 3 males and 11 females.

Table 1. **Characteristics of the patients and 31 aneurysms included in the study**

	WEB group (n=14)	SAC group (n=17)	P-value
Age (mean age, y)	63.50	67.18	
Sex			
Male	3	4	
Female	11	13	
Aneurysm character, median (range)			
Volume (mm^3)	0.03 (0.02–0.46)	0.03 (0.01–0.50)	0.597
Size (mm)	4.79 (3.48–9.70)	4.84 (2.59–12.46)	0.710
Neck diameter (mm)	3.77 (2.70–6.89)	4.00 (2.27–9.37)	0.468
Dome/neck ratio	1.28 (1.19–1.41)	1.14 (1.03–1.50)	0.173
Location			
AcomA	3	4	
ICA bifurcation	1	0	
MCA bifurcation	6	6	
Basilar bifurcation	4	7	

Shown as median (25–75% percentile).
WEB, Woven EndoBridge; SAC, stent-assisted coil; AcomA, anterior communicating artery; ICA, internal carotid artery; MCA, middle cerebral artery.
Median values were calculated using the Mann–Whitney U-test.

Table 2. **Procedure time, radiation dose, fluoroscopy time, and total used contrast dose according to different treatment methods**

	WEB group	SAC group	P-value
Procedure time (min)			
Mean	88.07±24.60	115.12±30.29	0.014
Median	82 (57–141)	110 (80–193)	0.012
Radiation dose (mGy)			
Mean	1,559.82±605.99	2,821.68±1,249.96	0.002
Median	1,414.5 (906.9–3,115)	2,685 (781.6–4,896)	0.004
Fluoroscopy time (min)			
Mean	36.45±17.97	73.96±34.31	0.001
Median	32 (14.8–76.6)	67.2 (18.6–157.4)	0.001
Contrast media dose (mL)			
Mean	102.14±14.83	138.41±34.40	0.001
Median	99 (80–137)	126 (101–238)	<0.001

Shown as mean±standard deviation (95% confidence interval) or median (25–75% percentile).
WEB, Woven EndoBridge; SAC, stent-assisted coil.
Mean values were calculated using the Student's t-test. The Mann–Whitney U-test was used to calculate the median values.

The mean age of the patients treated with SAC was 67.18 years, and there were 4 males and 13 females.

The characteristics of aneurysms included in each group were as follows.

In the WEB group, the median volume was 0.03 mm^3 (range: 0.02–0.46), the size was 4.79 mm (range: 3.48–9.70), the neck diameter was 3.77 mm (range: 2.70–6.89), and the dome/neck ratio was 1.28 (range: 1.19–1.41). Three of the 14 aneurysms were located in the AcomA, 1 in the ICA bifurcation, 6 in the MCA bifurcation, and 4 in the basilar artery bifurcation.

In the SAC group, the median volume was also 0.03 mm^3 (range: 0.01–0.50), the size was 4.84 mm (range: 2.59–12.46),

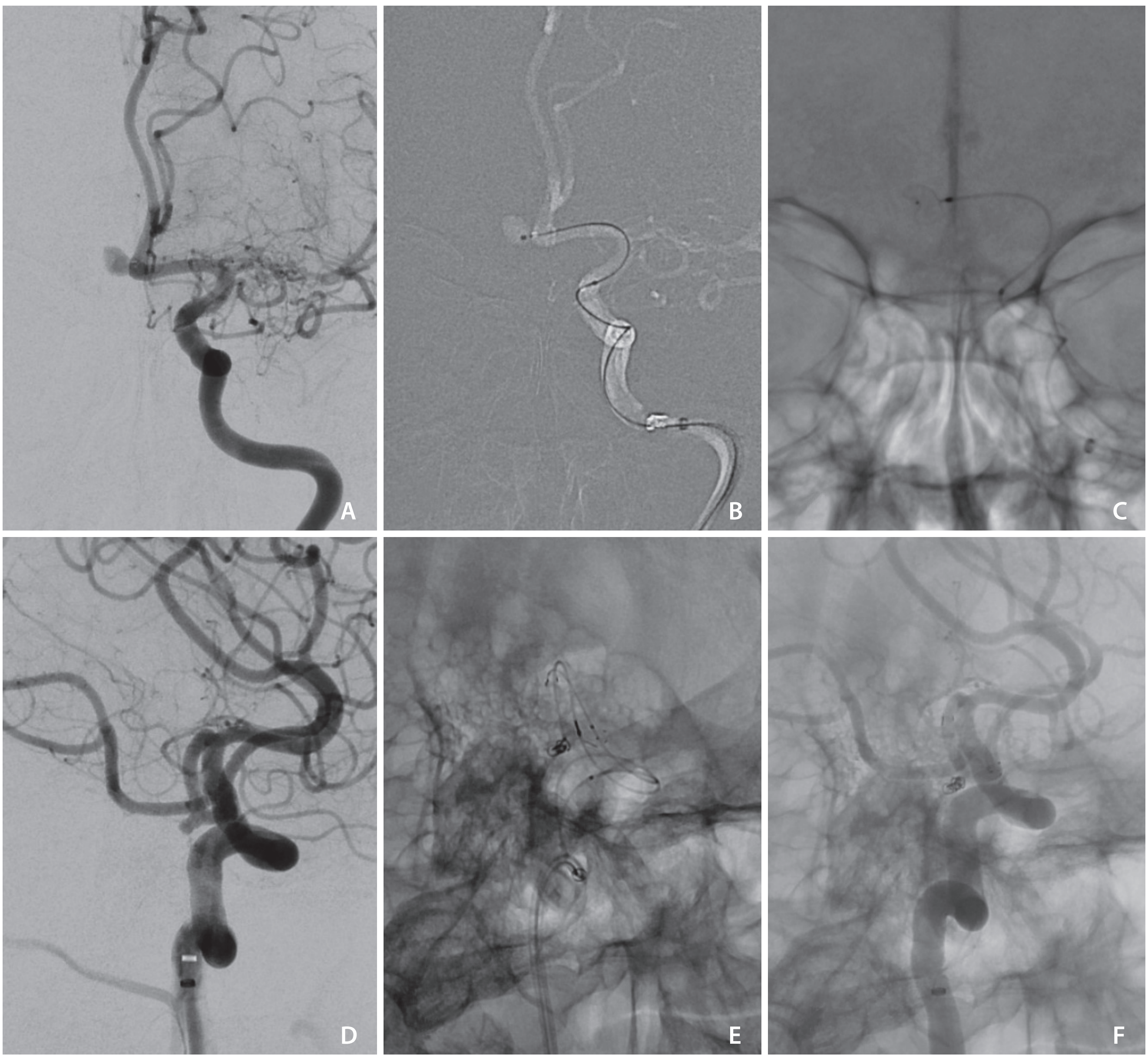

Fig. 1. (**A–C**) A patient in their 60s patient with an anterior communicating artery (AcomA) aneurysm treated using the Woven EndoBridge (WEB; MicroVention/Terumo) device. (**A**) Anteroposterior view of the working projection. (**B**) Superselected state of the WEB device delivery microcatheter. (**C**) Final anteroposterior working projection after the procedure. Radiation dose, fluoroscopy time, procedural time, and amount of contrast agent used are as follows. 907 mGy, 20.9 minutes, 84 minutes, 86 mL. (**D–F**) A patient in their 70s with an AcomA aneurysm treated with stent-assisted coil embolization. (**D**) Anteroposterior view showing the working projection. (**E**) Placement of coil and stent delivery microcatheter at the appropriate location. (**F**) Final anteroposterior working projection after the procedure. Radiation dose, fluoroscopy time, procedural time, and amount of contrast agent used are as follows. 4,151 mGy, 110.1 minutes, 141 minutes, 151 mL.

the neck diameter was 4.00 mm (range: 2.27–9.37), and the dome/neck ratio was 1.14 (range: 1.03–1.50). Four of the 17 aneurysms were located in the AcomA, 6 in the MCA bifurcation, and 7 in the basilar artery bifurcation.

There were no significant differences between the WEB and SAC groups in terms of aneurysm volume, size, neck diameter, or dome/neck ratio.

Procedure Time, Radiation Dose, Fluoroscopy Time, and Total Used Contrast Media Dose

The procedure time, radiation dose, fluoroscopy time, and total contrast media dose are summarized in Table 2.

In the WEB group, the mean and median procedure time (minutes) was 88.07±24.60 and 82 (57–141), respectively, the radiation dose (mGy) was 1,559.82±605.99 and 1,414.5 (906.9–3,115), respectively, the fluoroscopy time (minutes) was 36.45±17.97 and 32 (14.8–76.6), respectively, and the contrast media dose (mL) was 102.14±14.83 and 99 (80–137), respectively.

In the SAC group, the mean and median procedure time (minutes) was 115.12±30.29 and 110 (80–193), respectively, the radiation dose (mGy) was 2,821.68±1,249.96 and 2,685 (781.6–4,896), respectively, the fluoroscopy time (minutes) was 73.96±34.31 and 67.2 (18.6–157.4), respectively, and the contrast media dose (mL) was 138.41±34.40 and 126 (101–238), respectively.

In the statistical analysis, there was a significant difference in procedure time, radiation dose, fluoroscopy time, and total contrast media dose between the WEB and SAC groups ($P<0.05$). This suggests that the WEB group received a smaller radiation and contrast dose during a significantly shorter procedure and fluoroscopy time. Through the cases of 2 patients with aneurysms located in the AcomA, treated with WEB and SAC, respectively, differences between the 2 procedures can be clearly observed (Fig. 1).

Additionally, the WEB device has been used relatively recently, and statistical analysis was performed considering that the results may differ depending on the operator's proficiency. However, no significant differences were observed in procedure time, radiation dose, fluoroscopy time, or total contrast dose used according to the operator (Table 3).

In this study, no unusual complications related to contrast agents or radiation were observed in any of the included patients.

Radiologic Outcome

Follow-up angiographic images for the WEB device were performed in 12 of 14 patients (85.7%), 7 DSA and 5 CTA. The mean follow-up interval was 4.83±1.99 months, and adequate occlusion between WOS A and C was observed in 10 cases (10/12, 83.3%).

Follow-up angiographic images for SAC were taken in 7 of the 17 patients (41.2%), 1 DSA and 6 MRA. The mean follow-up interval was 8.42±2.84 months. Four cases showed complete occlusion and 2 cases showed a residual neck, according to the modified Raymond–Roy classification. One case showed minor recanalization at the neck portion on DSA. However, there was no need for retreatment. Finally, 6 out of 7 cases showed adequate occlusion in follow-up images (85.7%).

DISCUSSION

According to a 2003 International Study of Unruptured Intracranial Aneurysms (ISUIA) study, most cerebral aneurysms are bifurcation aneurysms,[14] with the MCA bifurcation and AcomA being the most common locations.[15] Moreover, more than half of the aneurysms treated surgically were in the MCA bifurcation and AcomA, and only 21% of the an-

Table 3. Radiation dose, fluoroscopy time, procedure time, and contrast dose according to different operators using the Woven EndoBridge device

	Operator 1 (n=10)	Operator 2 (n=2)	Operator 3 (n=2)	P-value
Radiation dose (mGy)	1, 348 (906.9–1,922)	2,012.8 (910.6–3,115)	2,100 (1,631–2,569)	0.535
Fluoroscopy time (min)	27.85 (14.8–76.6)	45.95 (22.4–69.5)	44.4 (42.8–46)	0.294
Procedure time (min)	82 (57–141)	105 (90–120)	70 (69–71)	0.772
Contrast dose (mL)	99 (86–137)	100 (80–120)	104 (95–113)	0.875

Shown as median (25–75% percentile).
The Kruskal–Wallis test was used to calculate the median values.

eurysms at these locations were treated with endovascular treatment.[14] However, since the publication of the ISUIA study, the locations of aneurysms treated with endovascular therapy have become more diverse, and the number of aneurysms is much greater.[16] In addition, several studies have shown that the treatment results of several newly developed endovascular treatment devices are as good as the existing treatment methods, further fueling this trend.[9,17,18]

In this study, we aimed to confirm whether there was a difference in radiation exposure, total contrast media dose, and treatment results when WNBA was treated using the WEB device compared to SAC.

The WEB device is a treatment method in which the procedure is completed when a single device is placed inside the aneurysm, unlike conventional endovascular treatment. The greatest advantage arising from the difference in this treatment method is that the procedure time can be reduced markedly, which allows the amount of radiation exposure to be reduced accordingly. As the procedure becomes simpler and the time decreases, the total amount of contrast media dose also decreases. This reduction in radiation exposure and total contrast media dose can reduce radiation- and contrast-related side effects that possibly occur in endovascular treatment. Several studies have clarified that the smaller the amount of radiation and contrast media dose in endovascular treatment, the better.[19-22] Currently, most of the studies related to the WEB device were focused on the treatment results of the WEB device itself.[7-11] Contrastingly, we have only found 1 study that focused on the advantages of other aspects that the WEB device can have over conventional treatment.[12] However, although the previous study contains information about radiation doses, the main subject is the reduction of treatment cost due to the reduction of operation time. In this study, we focused on the previously unexplored merits of the WEB device and investigated whether there was a real difference compared to the conventional treatment methods, such as SAC. Our results confirmed that, similar to a previous study,[12] a shorter fluoroscopy time could be obtained through the shorter procedure time obtained by using the WEB device and, accordingly, the radiation dose was small. In addition, as the procedure became simpler, the total amount of contrast medium used was also confirmed to be less. Furthermore, as the procedure time was shortened, the time under general anesthesia was also shortened. This is considered to be another advantage of the WEB device, as it can be good option for patients for whom time under general anesthesia is a concern.

We confirmed that there were significant differences in procedure time, radiation dose, fluoroscopy time, and contrast media dose between the WEB device and SAC (Table 2). Consequently, in the statistical analysis, the procedure and fluoroscopy time and the radiation and total used contrast dose were significantly reduced in the WEB group (Table 2).

Of course, these results can be influenced not only by the treatment method used but also by several other variables. However, efforts were made to reduce selection bias by confirming that there was no significant difference between the 2 treatment groups in the aneurysm characteristics that could directly affect the procedure time (Table 1). Additionally, we used statistical analysis to determine whether the operator affected the results of the WEB procedure. However, it was confirmed that there was no significant difference in the radiation dose, fluoroscopy time, procedure time, and contrast dose according to operators (Table 3). There was no statistically significant difference in procedural time depending on the operator. However, there were small variations in actual procedural time. Generally, this is believed to be due to differences in operator proficiency to some extent. While these factors may have some influence, our experience suggests that the selection of the incorrect size of the WEB device selected for the procedure had a greater impact on increasing procedural time. There were instances where procedures had to be restarted with a new device due to inappropriate sizing, which contributed more to the increase in procedural time. Considering these factors, careful selection of the size of the WEB device is deemed crucial not only for smoother procedures but also for the overall success of the procedure itself.

Many previous studies reported that a relatively high degree of occlusion was obtained when WNBA was treated using the WEB device.[7,8,10,11,23] In our study, we found an adequate occlusion rate (83.3%) for the WEB device, which was in line with the occlusion rate confirmed in previous studies.[8,10,11] In addition, when compared with the follow-up results of the SAC treatment group included in this study, we confirmed that there was no significant difference. Therefore, in this study, as in previous studies, it can be confirmed that the treatment performance of the WEB device itself is not significantly different compared to conventional treatment.

To summarize, treating WNBA using the WEB device clearly showed several advantages over SAC. However, because the data reported in this study and the results were collected retrospectively from a single center, these results must be evaluated against several study limitations. First, all procedures were performed using only 1 specific angiography system from a single vendor (Atris Z). Depending on the manufacturer, the grade of the equipment, and even the inevitable performance differences in the same equipment from the same company, different radiation doses may be provided according to the environment or setting in which the system is used. In this respect, using a single device to conduct the study could be a limitation, but it may also act as a control for other variables. If further studies are to be conducted, using a variety of equipment will be an opportunity to identify other factors that can affect the results. Second, several variables that could have affected the outcomes were not included in the evaluation; for example, the type of aortic arch, which can affect procedure time. Third, the number of cases was small; therefore, representativeness is limited. Fourth, although efforts have been made to control all variables, it is difficult to assert that appropriate controls have been made for all variables that can affect the results. In addition, for WEB devices, although we found no operator difference in this study, this may be because it is a device that has recently been used relatively consistently; however, the accessibility of new users is not high, so this result may differ depending on the operator in other situations. Specifically, in Korea, WEB use is still restricted because the patient's cost burden is higher than that of conventional treatments due to the specific circumstances related to the Korean national medical insurance system. In these respects, it is clear that this study has limitations. Therefore, when more advanced studies are conducted in the future, it is necessary to consider these limitations and reflect them in the research design.

CONCLUSION

According to our study, in the endovascular treatment of WNBA, the WEB device is expected to reduce radiation exposure and contrast use, with a shorter procedure time, than SAC with comparable outcomes. Therefore, when treating WNBA of selected patients with appropriate indications, the use of the WEB device has several expected advantages compared with SAC.

Fund

None.

Ethics Statement

The Institutional Review Board waived the requirement for informed consent (Inje University Busan Paik Hospital, approval number: 2022-08-039). We anonymized the patient information such as age and sex in the figure legend.

Conflicts of Interest

The authors have no conflicts to disclose.

Author Contributions

Concept and design: JB. Analysis and interpretation: JB, JYH, YJH, and SY. Data collection: JB and STK. Writing the article: JB. Critical revision of the article: WHL and HWJ. Final approval of the article: JB and HWJ. Statistical analysis: JB. Overall responsibility: JB and HWJ.

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