

 **Original Article** 

Usefulness of Abdominal Duplex Ultrasound for Detecting Endoleaks after Endovascular Aneurysm Repair

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Objective: The usefulness of abdominal duplex ultrasound (DUS) for the detection of endoleaks after endovascular aneurysm repair (EVAR) was evaluated.

Materials and Methods: Among 286 patients who underwent EVAR between September 2007 and July 2017, 241 patients were followed up using abdominal DUS. Endoleaks were detected in 74 patients (31%), who were divided into enlarged and nonenlarged sac groups. Endoleak velocities and widths were measured using abdominal DUS every 6 months after EVAR and were compared between the 2 groups.

Results: The aneurysm diameter in the nonenlarged sac group was 54.4 ± 8.7 mm in the final follow-up. None of the patients in the nonenlarged sac group were subjected to reintervention, whereas all patients in the enlarged sac group were subjected to reintervention. The aneurysm diameter in the enlarged sac group was 62.8 ± 8.8 mm at the time of reintervention, and the maximum endoleak flow velocities and endoleak widths were significantly higher in the enlarged sac group than in the nonenlarged sac group ($p < 0.05$). The cutoff values on receiver operating characteristics curves for endoleak velocity and width were 83.4 cm/s and 4.0 mm, respectively.

Conclusion: Follow-ups using abdominal DUS are useful after EVAR. Endoleak velocity and width measurements are important, and reintervention may be needed when these measurements exceed their cutoff values.


Keywords: EVAR, endoleaks, abdominal duplex ultrasound

Introduction

Endovascular aneurysm repair (EVAR) for abdominal aortic aneurysms is a widely performed treatment method, and this method has high efficacy in the elderly and in patients with other morbidities because it is less invasive than surgical blood vessel prosthesis implantation.^{1,2)} However, complications, such as endoleaks and rupture, may occur after treatment; therefore, long-term follow-ups are necessary. Aneurysms were previously reported to be 5 mm wider or more 5 years after EVAR in 23.3% of patients than before EVAR,³⁾ thus demonstrating that the dilation of aneurysm diameters during follow-ups is a matter of concern. Periodic contrast-enhanced computed tomography (CT) is generally used in follow-ups because evaluations are unlikely to vary significantly, and there are few concerns regarding the difficulties associated with performing an examination due to a patient's physique (e.g., obesity). Not only the presence of endoleaks but also the three dimensional (3D) structure of stent grafts, such as migration and breakage, may be easily evaluated using contrast-enhanced CT.⁴⁾ However, given that renal function is compromised in many elderly patients and patients with other morbidities, CT using a contrast medium needs to be avoided. Image interpretation requires skill, whereas abdominal duplex ultrasound (DUS) may be easily performed on patients with renal hypofunction for whom the use of contrast-enhanced CT needs to be avoided. The information acquired by the color Doppler method also includes information that cannot be obtained using contrast-enhanced CT. Therefore, abdominal DUS is a minimally invasive, simple, and useful examination.⁵⁾ In the present study, we evaluated the usefulness of follow-ups using abdominal DUS in detecting endoleaks after EVAR.

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Materials and Methods

Our hospital introduced in September 2007, and abdominal DUS and plain CT are currently performed every 3 or 6 months during postoperative follow-ups. Our hospital policy on follow-ups is as follows: when no increase in the aneurysm diameter is detected after EVAR on plain CT in patients with endoleaks, follow-ups are conducted every 6 months in the outpatient clinic; when the aneurysm diameter increases, the patient is followed up every 3 months. An aneurysm with a rapid increase in diameter of 5 mm or more within 6 months or has continuous dilatation exceeding 60 mm in diameter is considered an enlarged sac. All patients who meet these judgment criteria are subjected to reintervention. Endovascular repair, including proximal extension, distal extension, and coil embolization, is performed for the reintervention. When the endoleak remains and the lesion continues to expand, open repair is performed. Our department has strictly applied these criteria, and no judgment is made on the basis of any other factor as a rule.

Abdominal DUS was performed during follow-ups by using Aplio 500 (TUS-A500, Canon Medical Systems, Ohtawara, Japan) on 241 out of the 286 patients who underwent EVAR at our hospital between September 2007 and July 2017, and endoleaks were detected in 74 patients. These patients were selected as subjects and divided as follows: 59 patients without enlargement and reintervention (the nonenlarged sac group) and 15 patients with enlargement and reintervention (the enlarged sac group) for comparison. Only patients in whom endoleak flow was detected in the aneurysm were analyzed in this study, and no patient who was receiving reintervention for endotension without endoleak flow in the aneurysm, graft infection, or limb occlusion was included in the analysis.

The following items were investigated: age, sex, postoperative follow-up duration (months), time to reintervention after the first surgery (months), aneurysm diameter (mm) at the time of the first surgery and reintervention, and device model (Zenith: Cook Medical Inc., Bloomington, IN, USA; Excluder: W.L. Gore and Associates Inc., Flagstaff, AZ, USA; Endurant: Medtronic Vascular, Santa Rosa, CA, USA; Powerlink/AFX: Endologix, Irvine, CA, USA; AORFIX: Lombard Medical, Didcot, UK). Endoleak flow velocity (cm/s) and maximum endoleak width (mm) were measured using abdominal DUS and were retrospectively compared between the two groups.

In the endoleaks detected by abdominal DUS after EVAR, the maximum width (mm) of blood flow intersecting the endoleak flow was measured using the color Doppler method, and the maximum endoleak velocity (cm/s) was assessed at a site at which the maximum flow velocity of blood entering the aneurysm was measurable using the

pulse Doppler method. Both parameters were evaluated to assess the 3D distribution of endoleak flow in the long and short axial views of the aneurysm to confirm reproducibility in the same examination. The maximum values measured for velocity and width during the follow-up period were adopted in subsequent analyses. Furthermore, the receiver operating characteristics (ROC) curves for endoleak velocity and width were prepared to investigate their relationship with additional treatments, and the cut-off value for each parameter was evaluated.

Statistical analysis

The means \pm standard deviations of endoleak velocity and width on abdominal DUS were calculated. Student's t-test (for continuous variables with a normal distribution), Mann-Whitney U-test (for continuous variables with a non-normal distribution), χ^2 test, or Fisher's exact test (nominal scale) was used for comparisons between the two groups. ROC curves were prepared to obtain cutoff values for velocity and width. Statistical analyses were performed using JMP 12.2.0 (SAS Institute Japan, Tokyo, Japan), and a p value <0.05 was considered significant.

This study was approved by the ethics committee of our institution (Approval No. 201805-014).

Results

Table 1 shows the patient backgrounds. No significant differences were observed in age, sex, postoperative follow-up duration (months), or aneurysm diameter (mm) at the time of the first surgery between the two groups. Among the devices examined in this study, only Zenith was used significantly in the enlarged sac group. None of the patients in the nonenlarged sac group were subjected to reintervention, whereas all patients in the enlarged sac group were subjected to reintervention. In the enlarged sac group, the mean time to reintervention after the first surgery was 36.5 ± 18.4 months. The aneurysm diameter at the time of reintervention was 62.8 ± 8.8 mm, and no ruptures or complications occurred after reintervention. The aneurysm diameter at the time of the final follow-up (mean follow-up duration: 60.1 ± 31.8 months) was 54.4 ± 8.7 mm in the nonenlarged sac group. The aneurysm dilatation rates were $7.5 \pm 18.7\%$ and $15.3 \pm 10.9\%$ in the nonenlarged sac group and enlarged sac group, respectively; these results showed that no significant difference existed between the two groups ($p=0.08$). Type II endoleaks were found in all 59 patients in the nonenlarged sac group. **Table 2** shows the final diagnoses of endoleak types in the enlarged sac group and the corresponding reintervention. Type IA endoleaks were detected in 2 patients in the enlarged sac group, and both of whom were treated by proximal extension. Type IB endoleaks were

Table 1 Patient characteristics

	Nonenlarged sac group (n=59)	Enlarged sac group (n=15)	p value
Age (years old)	76.9±8.6	77.4±4.3	0.816
Sex (male/female)	43/16	10/5	0.637
Postoperative follow-up period (months)	60.1±31.8	51.9±24.9	0.354
Period from EVAR to reintervention (months)		36.5±18.4	
Aneurysm diameter at the time of EVAR (mm)	51.8±11.5	53.1±10.5	0.702
Aneurysm diameter at the time of reintervention (mm)		62.8±8.8	
Devices used			
Zenith	5/59 (8.5)	5/15 (33.4)	0.021
Excluder	30/59 (50.8)	6/15 (40.0)	0.451
Endurant	19/59 (32.2)	2/15 (13.3)	0.125
Powerlink	3/59 (5.1)	2/15 (13.3)	0.265
AORFIX	2/59 (3.4)	0/15 (0)	0.337

Mean±standard deviation

EVAR: endovascular aneurysm repair

Table 2 Types of endoleaks and reintervention performed in the enlarged sac group

Type of endoleak (n=15)	Reintervention (n)
IA (2)	Proximal extension (2)
IB (3)	Distal extension (2) Open graft replacement* (1)
II (9)	Coil embolization (6) Surgical ligation of lumbar arteries (3)
III (1)	Distal extension** (1)

*The postoperative diagnosis was changed from preoperative type II to type IB endoleak.

**The postoperative diagnosis was changed from preoperative type IB to type III endoleak.

detected in 3 patients: 2 patients were treated by distal extension, and the other patient was treated by open graft replacement. The endoleak type was type II in the preoperative diagnosis of the patient treated by open graft replacement; however, this diagnosis was changed to type IB on the basis of intraoperative findings. Type II endoleaks were detected in 9 patients, 6 of whom were treated by coil embolization and 3 by surgical ligation of the lumbar arteries. A type III endoleak was detected in 1 patient and was treated by distal extension. The preoperative diagnosis was type IB in this patient but was changed to type III on the basis of intraoperative findings.

A representative image of an endoleak and its scheme are shown in Figs. 1A and 1B, respectively. A similar image was acquired in most patients, and endoleak width was measured on the basis of this image. Velocity was evaluated as described above, and the image shown in Fig. 1C was consistently acquired in all patients. Furthermore, there was no difference in the visual performance of DUS among the devices. Moreover, no marked difference due to fabrics or metal parts was noted during visualization on ultrasound (US) among the devices.

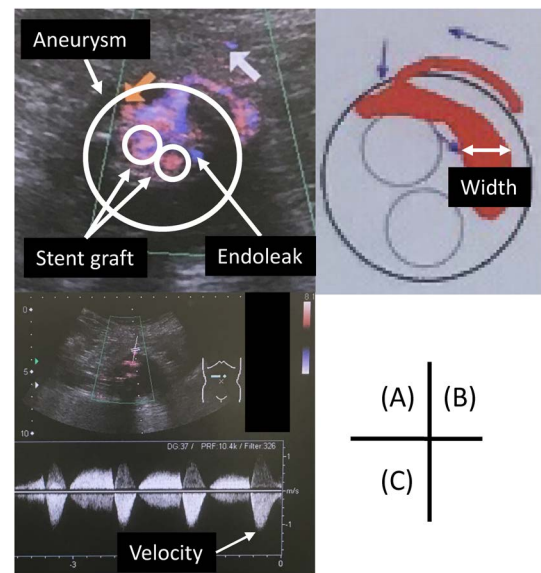


Fig. 1 (A) Typical image of an endoleak on abdominal echo (arrow). (B) Scheme of Fig. 1A and endoleak width (mm). (C) Image of endoleak velocity and the maximum endoleak velocity (arrow).

The endoleak velocities on abdominal DUS were 41.0 ± 31.8 and 107.0 ± 101.0 cm/s in the nonenlarged sac group and enlarged sac group, respectively, and were significantly higher in the enlarged sac group ($p = 0.003$) (Fig. 2A). Furthermore, the endoleak widths were 3.4 ± 1.5 and 5.79 ± 2.6 mm in the nonenlarged sac group and enlarged sac group, respectively, and were significantly higher in the enlarged sac group ($p = 0.001$) (Fig. 2B). In the ROC curve analysis, the cutoff value for endoleak velocity was 83.4 cm/s, with a sensitivity and specificity of 0.6 and 0.89, respectively, and the area under the ROC curve was 0.75 (Fig. 3A). The cutoff value for endoleak width was 4.0 mm, with a sensitivity and specificity of 0.73 and 0.78,

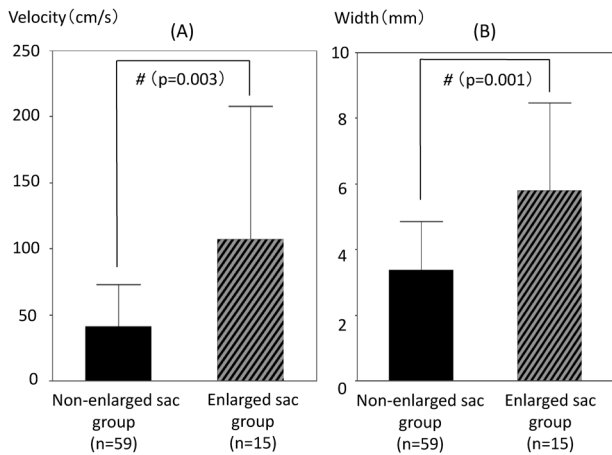


Fig. 2 (A) Comparison of endoleak velocities between groups. The endoleak velocities were 41.0 ± 31.8 and 107.0 ± 101.0 cm/s in the nonenlarged sac group and enlarged sac group, respectively; these values showed that a significant difference existed between the groups. (B) Comparison of endoleak widths between groups. The endoleak widths were 3.4 ± 1.5 and 5.79 ± 2.6 mm in the nonenlarged sac group and enlarged sac group, respectively; these values showed that a significant difference existed between the groups.

#: significant ($p < 0.05$) difference between groups.

The values are expressed as means \pm standard deviation.

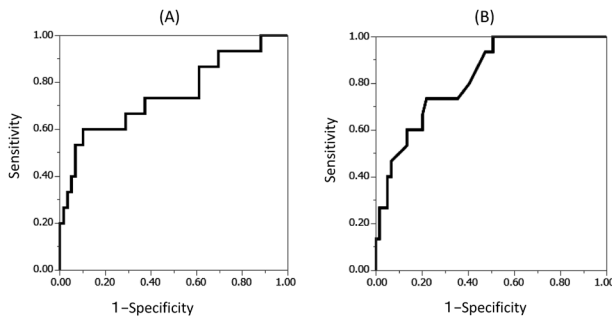


Fig. 3 (A) The results of the receiver operating characteristics (ROC) curve analysis of endoleak flow velocity are shown. At the point nearest the left upper corner (cutoff value of 83.4 cm/s), the sensitivity and specificity were 60.0% and 89.0%, respectively. The area under the ROC curve for endoleak flow velocity was 0.75. (B) The results of the ROC curve analysis of endoleak flow width are shown. At the point nearest the left upper corner (cutoff value of 4.0 mm), the sensitivity and specificity were 73.0% and 78.0%, respectively. The area under the ROC curve for endoleak flow width was 0.83.

respectively, and the area under the ROC curve was 0.83 (Fig. 3B). The areas under the curves for endoleak velocity and width were high, and the accuracy of this test was judged high according to this result. These results indicate that an aneurysm with a rapidly or continuously increasing diameter will likely require reintervention in the future

in patients with an endoleak velocity and width exceeding 83.4 cm/s and 4.0 mm, respectively.

Discussion

EVAR is less invasive⁶⁾ than conventional laparotomic blood vessel prosthesis implantation and is widely recognized as an effective treatment method.^{1,2,7-9)} On the contrary, endoleaks are the major disadvantage of EVAR and are detected in 10%–45% of treated patients.^{5,10)} The follow-up methods for patients with endoleaks include contrast-enhanced CT or plain CT in combination with abdominal US at 1, 6, and 12 months after treatment and every 6 months thereafter.^{4,10)} Laparotomic surgery, such as blood vessel prosthesis implantation, lumbar artery ligation, inferior mesenteric artery ligation, and aneurysmorrhaphy, and endovascular treatments, including additional stent-graft placement on the central and peripheral sides and coil embolization, are performed as additional treatments for endoleaks; however, there is currently no established treatment.¹⁰⁻¹³⁾

Contrast-enhanced CT is generally used during follow-ups after EVAR because evaluations are unlikely to vary significantly, and there are few concerns regarding the difficulties associated with performing an examination due to a patient's physique (e.g., obesity). Furthermore, not only the presence of endoleaks but also the 3D structure of a stent-graft, such as migration and breakage, may be easily evaluated using contrast-enhanced CT.⁴⁾ However, given that imaging induced by exposure and contrast medium is difficult in patients with renal disorders, other examinations, including echo, are needed. Reproducibility may be reduced depending on the skill of the technologists and the resolution of the echo device. However, trained technologists who are skilled at identifying aneurysms by abdominal echo and visualizing aneurysms in the long and short axial directions by using US devices compatible with color and pulse Doppler US may accurately detect endoleaks and measure different parameters. Moreover, the appropriate timing and frequency of examinations by CT remain controversial: 2 or more times per year, reexamination within 6 months, and reexamination only at 6 months have been reported.^{11,14)}

In a previous study in which CT was not used as a basic examination, patients were followed up by abdominal plain radiography and abdominal DUS only, with contrast-enhanced CT being performed only when needed. Contrast-enhanced CT was required for 30 of the 194 patients, and 11 patients needed retreatment.¹⁵⁾ Given that no complications associated with aneurysms, such as ruptures, developed in any patient treated with their protocol, they concluded that the efficacy of a follow-up using abdominal DUS was similar to that with contrast-enhanced

CT as a standard procedure and that the follow-up was satisfactory.

The characteristics of a US examination include real-time detection, identification of the direction of blood flow not evaluable by CT, and the acquisition of information on blood flow velocity and width. According to a previous study that compared contrast-enhanced CT and US by using the color Doppler method in examinations after EVAR, 89% of endoleaks that required treatment were detected by the US examination, whereas only 58% of endoleaks were identified by contrast-enhanced CT; therefore, the US examination was more useful than contrast-enhanced CT.¹⁶⁾ In another study on velocity waveform, waveforms were classified into 3 types: monophasic, biphasic, and bidirectional. The bidirectional type was a risk factor for an increase in the aneurysm diameter.¹⁷⁾ Furthermore, a previous study on the predictors for additional treatments identified the high-flow pattern or to-and-fro flow pattern of endoleak flow as a high-risk factor.¹⁸⁾ Furthermore, the identification of the endoleak flow direction is important for measuring the flow velocity. In a recent study, the identification of the endoleak flow direction using four dimensional magnetic resonance (4D MR) was investigated, and 4D MR was found to be superior to contrast-enhanced CT for detecting endoleaks. Moreover, 4D MR enabled the subclassification of type II endoleaks and distinguished the differences among simultaneously occurring types of endoleaks.¹⁹⁾ The usefulness of 4D MR needs to be investigated in the future, including comparisons with DUS. Furthermore, a study that is limited to type II endoleaks reported that the risk was low when the endoleak velocity was less than 80 cm/s and was high when it exceeded 100 cm/s, with additional treatments to expand aneurysms potentially being necessary.⁶⁾ This study also identified the diameter of the inferior mesenteric artery and number of patent lumbar arteries as risk factors. In the present study, we focused on the velocity and width of endoleak flow as parameters that may be predictors for additional treatments. Our result shows that endoleaks with a velocity exceeding 83.4 cm/s were likely to require additional treatments, and this finding was consistent with previous findings.⁶⁾ Regarding the value for velocity, we consider 80 cm/s to be valid as a practical standard value after considering reproducibility and errors of echo. When the velocity exceeds 80 cm/s, it is likely to be an endoleak indicated for additional treatment. Width may be a useful parameter because it is simple to measure, and the influence of errors associated with its measurement in a US examination is small; however, this has not yet been investigated. The present result shows that endoleaks with a width exceeding 4.0 mm are likely to require additional treatment, and this result is a novel result. A number of studies have been performed on abdominal DUS exami-

nations, endoleaks, and additional treatments, and they demonstrated that more errors were generated on these methods due to the artifacts of intestinal gas and contents and the patient's physique than on contrast-enhanced CT; however, no clearly specified predictor or quantitative criteria are currently available. Contrast-enhanced CT was performed before reintervention only for patients who meet the criteria for reintervention but not until the condition progressed to this state. Considering that endoleak flow velocity was high and its width was large on DUS in patients who subsequently required reintervention, its usefulness was retrospectively investigated. Patients who are at high risk and require reintervention in the future may be distinguished on the basis of DUS findings, which may help in investigating the necessity of additional examinations (contrast-enhanced CT and angiography), thereby demonstrating the usefulness of DUS.

Regarding device models, a significant difference was noted only for Zenith (Cook Medical Inc., Bloomington, IN, USA). This device was used soon after the introduction of US examinations at our hospital; therefore, the significant difference observed may be attributed to the long postoperative follow-up increasing the possibility of endoleaks compared with other models.

Regarding the diagnosis of the endoleak type using abdominal DUS, it is very useful if the conditions of the examinees and the issues associated with the techniques used by technologists may be solved. The sensitivity and specificity of the examination were 0.62–0.83 and 0.90–0.97 for all types, respectively, and 0.40–0.97 and 0.97–1.00 for types I and III, respectively, thus demonstrating that the examination is very accurate and effective.^{20–23)} In the present study, the final diagnosis was the same as the preoperative diagnosis based on abdominal DUS in 13 (87%) of the 15 patients in the enlarged sac group, thus suggesting that the accuracy of the diagnosis of the endoleak type using abdominal DUS was high, whereas the final diagnosis differed from the preoperative diagnosis in 2 (13%) of the 15 patients. Although the direction of endoleak flow may be identified, making a differential diagnosis of each endoleak type is difficult in some patients. Further investigations are needed to clarify the usefulness of abdominal DUS for diagnosing endoleak types.

Conclusion

Follow-ups after EVAR using abdominal DUS are simple and useful, and endoleak velocity and width measurements are important. Aneurysm diameters may increase in patients with a leak velocity >80.0 cm/s (cutoff value: 83.4 cm/s) and leak width >4.0 mm during follow-ups. These values indicate that reintervention is necessary. Therefore, comprehensive follow-ups should be per-

formed.

Disclosure Statement

Conflict of interest and source of funding statement: nothing to declare.

Author Contributions

Study conception: HU, HT, YM

Data collection: HU, HT

Analysis: HU, HT

Investigation: HU, HT

Writing: HU, HT, YM

Critical review and revision: all authors

Final approval of the article: all authors

Accountability for all aspects of the work: all authors

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