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A Logical Method of Selecting an Approach for Amplatzer Septal Occluder Implantation: Using Transesophageal Echocardiography to Reduce Procedure Durations and Avoid Complications

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ABSTRACT

Percutaneous closure of atrial septal defects using an Amplatzer Septal Occluder (ASO) has recently become the procedure of first choice. However, when ASO deployment is difficult, procedures may be prolonged and complications may occur. We investigated a method for identifying cases in which ASO deployment would be difficult. After retrospectively identifying 70 patients (age: 4.1-70.4 years; body weight: 15.6-77.3 kg) who underwent atrial septal defect closure using an ASO in 2007 or later, we classified them into three groups: Group A, implantation by a conventional approach; Group B, implantation by a right upper pulmonary vein approach, and Group C, change from a conventional to a right upper pulmonary vein approach. Characteristics of the groups were compared. Individually, none of the investigated characteristics was suitable for identifying difficult cases. Furthermore, we observed no consistent trends between aortic rim deficiency and ASO diameter, or between SG/IAS angle, which is the angle formed by the super stiff guidewire (SG) and the intra-atrial septum (IAS). However, the ASO diameter divided by the diameter of the left atrium (ASO/LA) correlated with the SG/IAS angle in Group C. Using this correlation, ASO implantation is predicted to be difficult in patients with an ASO/LA (%) ratio exceeding the (SG/IAS angle) × 1.44 + 48.1, which represents the 95th percentile of Group C. Graphing the SG/IAS angle and the ASO/LA ratio can identify cases in which ASO implantation may be difficult. We consider this method of selecting an approach to be extremely useful for avoiding various risks.

Key words: *Amplatzer Septal Occluder, Transesophageal echocardiography, Atrial septal defect, Congenital heart disease*

Percutaneous closure using an Amplatzer Septal Occluder (ASO) has been established as the universal technique for ostium secundum atrial septal defects (ASD), in place of surgical procedures[2,7]. Usually, the recommended approach is to insert a guidewire into the left upper pulmonary vein (LUPV), perform balloon sizing, and advance a delivery sheath over the guidewire[1,9,11,13]. Various other methods have been discussed for cases in which an ASO cannot be implanted by this procedure. These other methods include the use of a Hausdorf sheath and a Mullin's sheath[10]; a right upper pulmonary vein (RUPV) approach, in which a left atrium (LA) disk is deployed at the mouth of the RUPV[7,16]; opening an LA disk with the appearance of an American football in the pulmonary vein[16]; the use of a dilator[17], and a balloon-assisted technique[6]. However, for cases in which an ASO cannot be implanted by the usual approach, switching to one of the alternative approaches requires a long period of fluoroscopy[1]. In addition, switching to other procedures results in a risk of the device unscrewing in the course of multiple removals and insertions[9,16], as well as a risk of thrombus formation in the sheath[1,4,18].

To avoid these risks, it is desirable to identify cases in which ASO implantation by means of the usual approach is expected to be difficult. If such cases can be identified in advance, an alternative method can be introduced from the beginning. Various reasons for difficulty in implantation have been proposed, such as the large size of the ASD (≥25 mm); defects of the rim, particularly the aortic rim (<3 mm)[1,9,12], and the orientation of the device

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in a nearly perpendicular position relative to the intra-atrial septum (IAS)[5,6,9,10,15,16]. However, there are no clearly quantified reference values. Further, difficulty in implantation cannot be determined solely from any one of these independent factors. Therefore, in the present study, we used transesophageal echocardiography (TEE) to assess these factors quantitatively and succeeded in identifying cases in which ASO implantation was difficult by means of the usual approach.

PATIENTS AND METHODS

Patients: The subjects were 70 consecutive patients (33 men and 37 women; age: 4.1-70.4 years [median: 10.8 ± 14.8]; body weight: 15.6-77.3 kg [median: 31.2 ± 16.9]) who underwent atrial septal defect closure using an ASO (AGA Medical Corporation, Golden Valley, MN, USA) in 2007 or later. The present study was approved by the Internal Institutional Review Board of the Hiroshima Citizens' Hospital (Approval No. 24-20).

Group definitions: The medical records of the 70 patients were reviewed retrospectively. In the first half of the study period, implantation was begun by the usual approach (LUPV approach). If this approach was found to be unsuitable, it was changed to an RUPV approach. In the latter half of the study period, a proactive RUPV approach was selected from the start for patients with features such as aortic rim deficiencies and large ASD, which are known to make ASO implantation difficult. Based on this sorting, we classified the patients into three groups. Group A comprised patients for whom implantation was begun with the usual approach and was successful. Group B comprised patients for whom implantation was begun with an RUPV approach and was successful. Group C comprised patients who required a change from the usual approach to an RUPV approach.

Procedure: All procedures were performed under general anesthesia. As is standard practice, the morphologic characteristics of the defect and size of the rim were evaluated with TEE before the deployment of ASO. TEE was performed with an SSD-2200 (Aloka, Tokyo, Japan) or a SONOS 5500 (The Philips Company, Amsterdam, The Netherlands). The size of the ASD was measured using the stop-flow technique. A cylindrical Amplatzer sizing balloon (AGA Medical Corporation, Golden Valley, MN, USA) was inflated. Once the shunt flow had ceased (as evaluated by TEE), the balloon

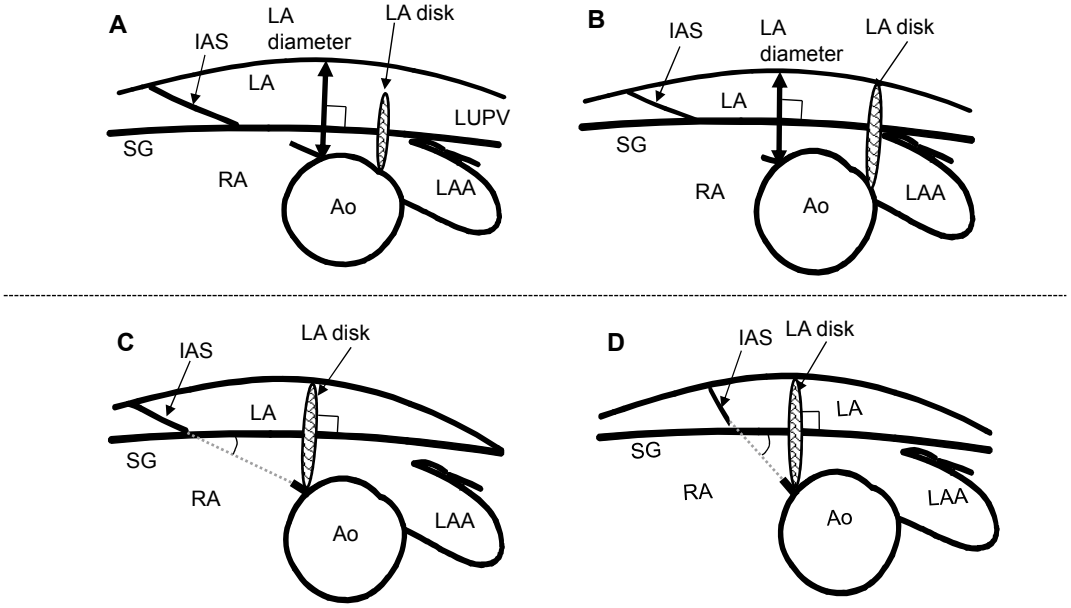


Fig. 1. Method of measurement of the LA diameter and the SG/IAS angle.
The SG was visualized using cross-sections that depict its maximum length. The distance from the base of the aortic rim to the LA wall was measured at an angle of 90° compared with the SG, and was considered the LA diameter (A, B). When the LA disk diameter is smaller than the LA diameter (A), the deployment of an ASO is easy to achieve (usually the LA disk diameter is 14 mm larger than ASO diameter); however, if it is larger, deployment can be expected to be difficult (B). The angle formed by the SG and IAS was also measured in the same cross-sections (C, D). When this angle is small, the angle between the LA disk and the IAS will be larger, and the LA disk on the side of the anterosuperior margin is likely to drop easily towards the side of the RA (C). On the other hand, if this angle is large, the LA disk and the IAS will become nearly parallel to each other. As a result, the LA disk on the side of the anterosuperior margin is unlikely to drop (D).
Ao = aorta; IAS = intra-atrial septum; LA = left atrium; LAA = left atrial appendage; LUPV = left upper pulmonary vein; RA = right atrium; SG = super stiff guidewire.

size was measured as the diameter of the defect. The ASO diameter was decided as the same size as this diameter or 1-2 mm larger than this diameter.

Cross-sections that show the greatest possible length of the super stiff guidewire (SG) were visualized with TEE. The LA diameter and SG/IAS angle were assessed from these cross-sections (Fig. 1). The form of the SG was observed on the fluoroscopic image. When the SG was strongly curved, it was withdrawn a little to straighten the part of the SG passing through the ASD. The distance from the base of the aortic rim to the LA wall was measured at an angle of 90° relative to the SG, and was considered as the LA diameter. The angle formed by the SG and the IAS was also measured in the same cross-sections. This corresponded to the supplement of the angle formed by the LA disk and the IAS.

Instruments: During the procedures, we emphasized the merit of not using more instruments than those necessary. Thus, the method we adopted for cases of difficult ASO implantation entailed deploying the ASO after advancing the delivery sheath in the right pulmonary vein. This method employed an RUPV approach in which the delivery sheath was withdrawn and the LA disk was opened while the tip of the disk was in the right pulmonary vein. These actions were taken to prevent the direction of the delivery sheath from changing. In the patients included in this study, ASO implantation only involved basic instruments, no other special instruments were used for any patient, such as a Hausdorf sheath, a Mullin's sheath, a long sheath, or a balloon.

Investigated characteristics and measurements: In each group, we determined the ratio of pulmonary flow to systemic flow (Qp/Qs), the presence or absence of aortic rim, the ASO diameter, the ratio of the ASO diameter to the LA diameter (ASO/LA ratio [%]), and the angle formed by the SG and the IAS (SG/IAS angle). Subsequently, we examined whether characteristics could be used to predict difficulty in ASO implantation. We also investigated the procedure duration in each group; procedure duration was defined as the time elapsed from the insertion of the delivery cable into the delivery sheath to the release of the ASO.

STATISTICAL ANALYSIS

Measurements and continuous characteristics of the enrolled subjects (such as age, body weight, ASO/LA ratios, and ASO/LA diameter) were summarized by their means and standard deviations. Student's t-test was used for statistical comparisons of group-specific distributions of the continuous variables. Non-parametric methods, such as Spearman's rank-correlation coefficient, the chi-square test, and the Kruskal-Wallis H-test, were also used for statistical tests of correlations or independence between the continuous variables or the ordered categorical variables. Results were considered to be statistically significant if $p < 0.05$.

RESULTS

Group A consisted of 44 patients (21 men and 23 women) with an age range of 4.7-45.8 years (mean: 14.3 ± 10.0) and a body weight range of 12.0-77.3 kg (mean: 38.4 ± 17.0). Group B consisted of 19

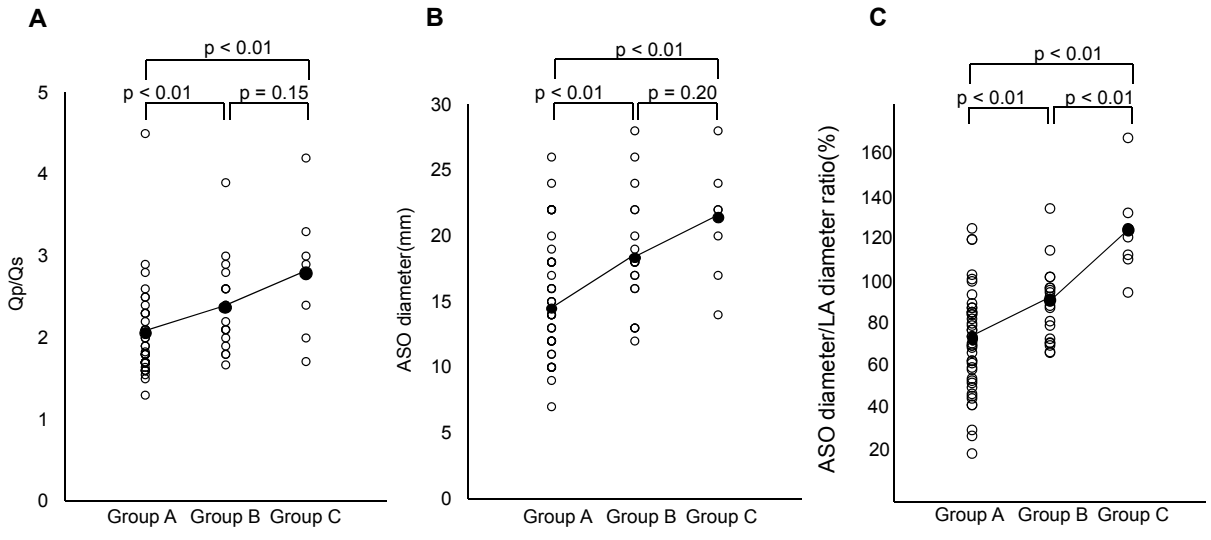


Fig. 2. Qp/Qs (A), ASO diameter (B), and ASO diameter/LA diameter ratio (%) (C).
Many patients in Groups B and C had a high shunt flow rate (Fig. 2-A). In Group C (in which a change of procedure was needed), many patients needed the deployed ASOs to have larger diameters than the LAs (Fig. 2-B, C).

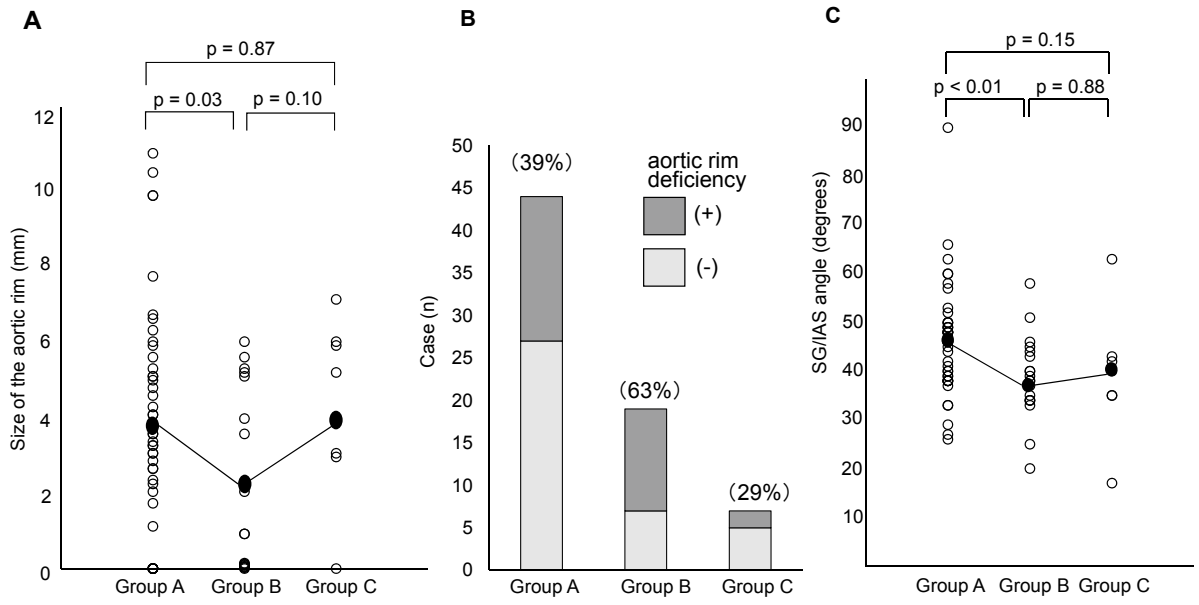
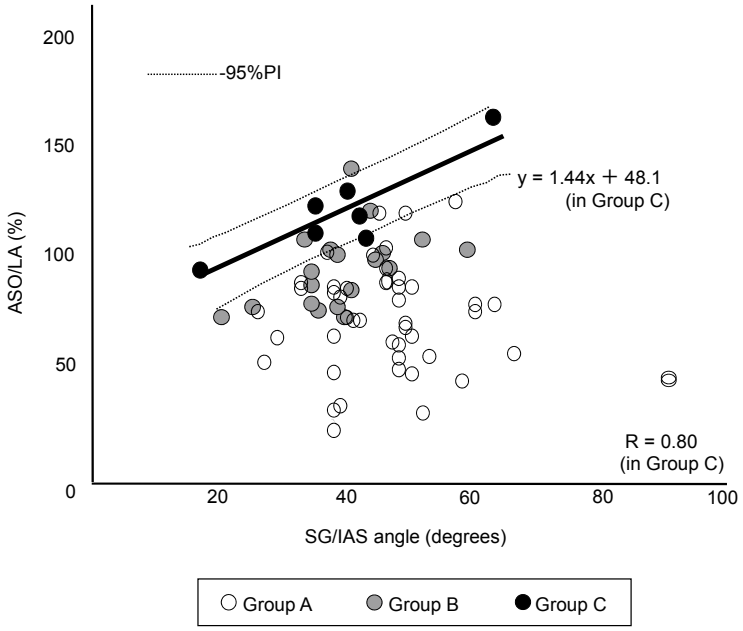


Fig. 3. Size of the aortic rim (A), percentage of patients with aortic rim deficiency (B), and SG/IAS angle (C). A high percentage of patients had aortic rim deficiency in Group B, but this percentage was not high in Group C. The SG/IAS angle showed no significant difference between group C and the other groups, and the distributions nearly overlapped.



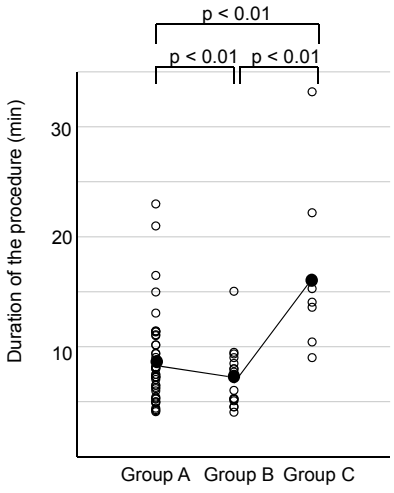


Fig. 4. Correlation between the SG/IAS angle and the ASO/LA diameter. No correlation was found between Groups A and B. A correlation following the linear relationship y = 1.44x + 65.75 was found in Group C. Most patients in Group A were distributed under ASO/LA = 1.44 (SG/IAS angle), which represented the 95th percentile of Group C. Accordingly, the deployment of an ASO using the LUPV approach can be predicted to be difficult in patients with an ASO/LA exceeding {ASO/LA (%) = 1.44 (SG/IAS angle) + 48.1}.

Fig. 5. The duration of the procedure in Group B was markedly shorter than that in Group A.
The RUPV approach did not require a longer procedure time than the conventional approach.

patients (7 men and 12 women) with an age range of 4.1-70.4 years (mean: 17.6 ± 17.7) and a body weight range of 15.6-65.9 kg (mean: 39.7 ± 18.5). Group C consisted of seven patients (four men, three women) with an age range of 6.4-56.9 years (mean: 23.5 ± 23.2) and a body weight range of 16.3-72.5 kg (mean: 38.5 ± 20.1). There were no significant differences of age and body weight among these 3 groups.

In Groups A, B, and C, the Qp/Qs values were 2.00 ± 0.53, 2.38 ± 0.53, and 2.79 ± 0.84, respectively; shunt flow was higher in Group B and Group C than in Group A (Fig. 2-A). The ASO diameter ranges in Groups A, B, and C were 7-26 mm (15.4 ± 4.6 mm), 12-28 mm (18.4 ± 4.4 mm), and 14-28 mm (21.0 ± 4.6 mm), respectively. As with the Qp/Qs, the ASO diameter was larger in Group B and Group C than in Group A (Fig. 2-B).

The ASO/LA ratios (%) in Groups A, B, and C were 72.7 ± 23.2, 89.1 ± 17.11, and 122.4 ± 22.0, respectively. The ASO/LA diameter was significantly larger in Group C than in the other two groups (Fig. 2-C). However, the distributions of these factors also overlapped considerably.

Although there was a significant difference in aortic rim size between Group A and Group B, there were no significant differences between Group A and Group C. Additionally, Group C did not demonstrate a high percentage of patients with aortic rim deficiencies (<3 mm) (Fig. 3-A, B).

We observed a significant difference in SG/IAS angle between Group A and Group B. However, we observed no significant difference between Group C and either of the other two groups. (Fig. 3-C).

We then examined the association between SG/IAS angle and ASO/LA ratio (Fig. 4). Groups A and B did not demonstrate a correlation. Group C, however, demonstrated a correlation ($y = 1.44x + 65.75$).

The procedure durations in Groups A, B, and C were 8.8 ± 4.1 min, 7.2 ± 2.6 min, and 16.8 ± 8.4 min, respectively. Accordingly, the shortest duration was observed in Group B (Fig. 5).

DISCUSSION

Percutaneous closure of secundum ASDs using an ASO is less invasive than surgical treatment, and has therefore been established as the universal procedure[2,7]. Although an ASO cannot be implanted in patients with characteristics such as an extremely large ASD or multiple rim deficiencies, various alternative implantation methods having been developed, allowing ASO implantation in more patients and catheterization for a wider range of targets.

In the present study, we demonstrated a method of identifying cases in which ASO implantation was difficult by means of the usual approach. The ability to identify these cases allowed us to introduce an alternative approach from the beginning, instead of starting with the conventional LUPV approach. Such identification would shorten the fluoroscopy time, eliminate the possibility of the device unscrewing, and avoid the risk of thrombus formation in the sheath.

Various explanations have been proposed for the difficulties that are encountered in implantation, such as large ASD sizes (≥25 mm) and defects of the rim (particularly the aortic rim; <3 mm)[1,9,12]. The results of this study showed larger mean ASO diameters in Group B and Group C than in Group A; however, the distributions of the sizes in each group overlapped greatly. In regard to aortic rim size, although there was a significant difference between Group A and Group B, there were no significant differences between Group A and Group C. In addition, Group C did not demonstrate a high percentage of patients with aortic rim deficiencies. Therefore, by themselves, these factors could not be used to predict cases in which ASO implantation would be difficult.

The other explanation for the difficulty of implanting an ASO with a conventional LUPV approach is that withdrawal of the disk requires rotation of the disk inside the LA. In cases in which the LA disk has a large diameter, this rotation places the disk at nearly a right angle relative to the IAS, thus causing it to be easily dislodged into the RA side[1,5,6,8-10,14]. Even if the size of the LA disk is the same, a smaller LA results in greater restriction on the movement of the disk, thus causing it to be dislodged more easily[6,15,16]. Therefore, it is not the absolute size of the ASO, but rather its size relative to the LA diameter that appears to reflect the difficulty of implanting an ASO. However, we observed a large overlap in the distributions of the ASO/LA ratio in the three groups in this study. Thus, this value alone could not predict difficulty in ASO implantation.

Next, to discuss the angle formed by the LA disk and the IAS, if the LA disk is opened so that it is parallel to the IAS, then, theoretically, it will not prolapse. However, in reality, the delivery sheath inserted from the inferior vena cava and the IAS are diagonal to each other, making it impossible for the LA disk and the IAS to be parallel. As the LA disk more closely approaches a perpendicular position relative to the IAS, the anterosuperior rim of the LA disk will be more easily dislodged into the RA side. Previous ASO implantation methods for cases in which implantation was difficult have included the use of a Hausdorf sheath or Mullin's sheath[10], deployment of an LA disk in the opening of the RUPV[7,16], opening an LA disk with the appearance of an American football in the pulmonary vein[16], the use of a dilator[17], and a balloon-assisted technique[6]. Thus, the angle formed by the IAS and the LA disk is a major factor that affects the difficulty of ASO implantation[16]. Therefore, we

assessed the angle formed by the IAS and the LA disk. The SG/IAS angle is supplementary to the angle formed by the IAS and the LA disk, and we predicted that, as this angle decreased, ASO implantation would become more difficult. However, in reality, Group A included multiple patients in whom this angle was small. In contrast, Group C included patients in which this angle was large. Distributions of the SG/IAS angle were widely scattered in all groups; thus, SG/IAS angle alone could not predict difficulty in ASO implantation.

Although each of these factors is independent of the others, they are actually intertwined in a complex fashion. It is this complex intertwining that determines whether ASO implantation is possible.

Next, we examined the association between SG/IAS angle and ASO/LA ratio. The distributions diverged between Group A and Group C. Based on this finding, we obtained the criterion that patients with an ASO/LA ratio (%) greater than (SG/IAS angle) × 1.44 + 48.1 would experience difficulty in ASO implantation (Fig 4).

Procedure duration was actually shorter in Group B than in Group A (Fig. 5). On the other hand, the procedure duration was naturally longer in Group C. These results indicated that procedure durations could be shortened by identifying cases in which ASO implantation would be difficult and thereby choosing an alternative approach from the beginning.

Balloon sizing is usually performed with a guidewire inserted into the LUPV. Therefore, changing to an RUPV approach requires the inserted delivery sheath to be withdrawn from the LUPV and oriented towards the RUPV. At this point, caution is necessary due to the possibility of the tip of the sheath being dislodged into the RA side[1)]. When ASO implantation is deemed possible by means of the usual approach, based on the results of the present analysis, it is safer to proceed with implantation from the LUPV side. In addition, if a patient is considered to possess factors that make ASO implantation difficult based on the present analysis, the procedure duration can be shortened by changing to an RUPV approach from the beginning. This change in approach is directly linked to avoiding the risks of prolonged fluoroscopy time[1)], unscrewing of the device[9,16)], and thrombus formation in the sheath[1,4,18)]. In addition, measurements and calculations of the SG/IAS angle and the ASO/LA ratio are completed during preparation (while connecting the ASO to the delivery cable); thus, these measurements and calculations themselves do not affect procedure duration in any way. Therefore, this method can accurately identify the cases in which ASO implantation would be difficult. Accordingly, we consider it extremely useful for avoiding various risks.

CONCLUSIONS

We investigated several factors quantitatively and succeeded in identifying cases in which ASO implantation was difficult by the usual approach. We can avoid complications when we use this method because an alternative procedure can be introduced from the beginning for these cases. We believe these methods to be extremely useful.

LIMITATIONS

The present study was a retrospective study. Furthermore, the operator classified the target group subjectively, and decisions regarding the preferred approach changed during this study. Therefore, a prospective study is necessary to prove that the present method is suitable for predicting cases in which ASO implantation is difficult, and thereby demonstrating that the present method can serve as a basis for changing the approach. We are currently proceeding with a study in which we are actually applying the formula determined in the present study and sorting patients into different groups.

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