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Device Size for Transcatheter Closure of Ovoid Interatrial Septal Defect

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ABSTRACT

Background: For successful transcatheter closure of an atrial septal defect with the Amplatzer septal occluder, the shape of the defect should be considered before selecting the device size. The purpose of this study was to evaluate the results of transcatheter closure of an ovoid atrial septal defect.

Methods: Between January 2010 and February 2012, cardiac computer tomography examinations were performed in 78 patients who subsequently underwent transcatheter closure of an atrial septal defect. In this retrospective study, we reviewed these patients' medical records. We defined an ovoid atrial septal defect as a value of 0.75 for the ratio of the shortest diameter of the defect to the longest diameter, as measured in a computed tomography image. Transthoracic echocardiography examinations were made at 1 day and 6 months after the procedure.

Results: Transcatheter closure of an atrial septal defect was successful in 26 patients in the ovoid-defect group and in 52 patients in the round-defect group. There were no serious complications in either group, and the rate of complete closure at 6 months was 92.3% in the ovoid-defect group and 93.1% in the round-defect group ($P > .05$). The mean (SD) difference between the device size and the defect's longest diameter, and the mean ratio of the device size to the longest diameter were significantly smaller in the ovoid-defect group (1.7 ± 2.9 versus 3.8 ± 2.5 and 1.1 ± 0.1 versus 1.3 ± 0.2, respectively).

Conclusions: Transcatheter closure of an atrial septal defect is indicated even for an ovoid atrial septal defect. Ovoid atrial septal defects can be closed successfully with smaller sizes of the Amplatzer septal occluder than for round atrial septal defects.

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INTRODUCTION

Atrial septal defect is one of the most common congenital heart diseases, with an incidence of approximately 1 per 100 live births [Hoffman 2002]. Surgical closure was once considered the best treatment; however, closure with the Amplatzer septal occluder device (AGA Medical, Golden Valley, MN, USA) has gradually become a competitive alternative [Masura 2005; Yew 2005]. For closure of an atrial septal defect to be successful, an accurate evaluation of defect size and a detailed morphologic description of the defect are essential. In general, atrial septal defects can have various shapes, including round, ovoid, and a complex morphology [Johri 2011; Roberson 2011]. Even though good long-term results have been reported for transcatheter closure of atrial septal defects with the Amplatzer septal occluder [Acar 2000; Knepp 2010], it is difficult to find a report that specifically discusses transcatheter closure of atrial septal defects of different morphologies. Therefore, the purpose of the present study was to evaluate the outcomes of transcatheter closure of ovoid atrial septal defects.

MATERIALS AND METHODS

This study is a retrospective chart review of patients who underwent transcatheter closure of an atrial septal defect. Between January 2010 and February 2012, 78 patients who were appropriate for transcatheter closure of a secundum atrial septal defect with the Amplatzer septal occluder, underwent a cardiac computed tomography evaluation and then transcatheter closure of the defect. We excluded patients who had >2 atrial septal defects or had defects with complex shapes that appeared neither elliptical nor round on computed tomography images. The decision for transcatheter closure of an atrial septal defect with the Amplatzer septal occluder was based on the results of a transthoracic echocardiography examination. If the nature of the defect was not apparent because of a poor window in the transthoracic echocardiogram, a transesophageal echocardiography evaluation was performed for selected patients. The inclusion criteria for transcatheter closure of an atrial septal defect with the Amplatzer septal occluder were as follows: secundum atrial septal defect with evidence of right ventricular volume overload; no significant

Table 1. There Were no Significant Differences in the Characteristics of Patients with an Ovoid Atrial Septal Defect and Patients with a Round Atrial Septal Defect, except for Age*

	Ovoid-Defect Group	Round-Defect Group	*P*
Patients, n (male/female)	26 (7/19)	52 (18/34)	
Ratio of shortest to longest defect diameter (b/a)	0.66 ± 0.05	0.83 ± 0.04	
Age, y	36.2 ± 16.5	43.2 ± 12.5	.045
Body weight, kg	59.2 ± 13.6	62.1 ± 12.1	.365
Longest diameter, mm	23.8 ± 8.5	21.2 ± 6.6	.082
Qp/Qs	3.0 ± 1.5	2.5 ± 1.3	.452

*Data are expressed as the mean ± SD where indicated. Qp/Qs indicates shunt ratio.

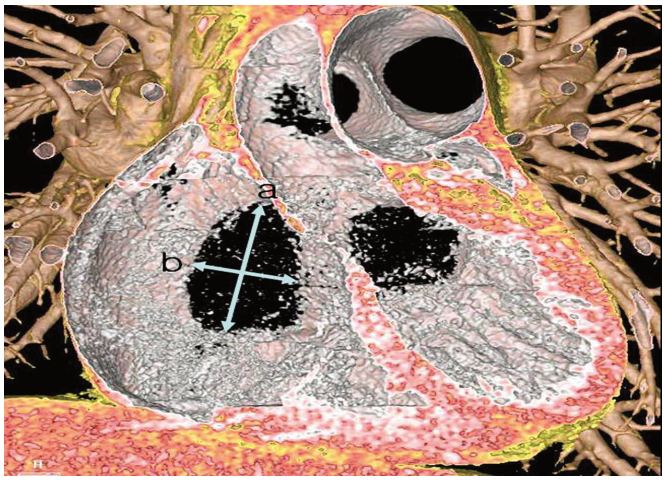

Figure 1. Reconstructed *en face* cardiac computed tomography image shows the longest diameter (a) and the shortest diameter (b).

pulmonary arterial hypertension that was irreversible; no significant arrhythmia; no serious problems with other organs; and presumptive appropriate rims for implanting the Amplatzer septal occluder. Cardiac computed tomography evaluations were performed with the SOMATOM Definition Flash (Siemens, Munich, Germany). If necessary, oral or intravenous beta-blockers were used. Defect closure with the device was performed by a single operator with guidance from an intracardiac echocardiogram. We did not use a balloon sizing technique but based the choice of device size on measurements made from the various echocardiographic and cardiac computed tomography images. Usually, the longest 2-dimensional diameter from all of the available transthoracic echocardiographic, cardiac computed tomography, and intracardiac echocardiography images was the basis for the decision on device size. The longest diameter (a) and the shortest diameter (b) were measured on computed tomography images from the en face view (Figure 1). All defect diameters were measured at the end-systolic phase. Usually, we chose a device 2 to 4 mm larger than the longest diameter of the defect at the first trial, but the choice also depended on the flexibility of the adjacent septal rims. Furthermore, if a successful implantation failed or another consideration indicated oversizing, we changed to a different device size. Before deploying the device, we pushed the cable so that it was positioned to the left side of the atrium for a moment. We then confirmed the stability of the device. We defined the ovoid-defect group of patients as those with an ovoid-shaped septal defect with a ratio of the shortest diameter (b) to the longest diameter (a) of 0.75. The group of patients with round defects was defined as those who had a defect with a b/a ratio >0.75. Differences between the longest diameter of the defect and the device size were calculated for the 2 groups. In addition, we compared the 2 groups with respect to the ratio of the device size to the longest diameter of the defect. We performed a follow-up transthoracic echocardiography examination on day 1 after the procedure and another 6 months later. Any residual shunt and complications were checked.

Data are expressed as the mean ± SD. We used SPSS software (version 11.5; SPSS/IBM, Chicago, IL, USA). Owing to the small sample size, results for the 2 groups were compared with the nonparametric Mann-Whitney U test and the Fisher exact test. Values of $P < .05$ were considered statistically significant. The locally appointed ethics committee (Sejong Institute Clinical Investigation Committee) approved the research protocol.

RESULTS

Of the 78 patients, 25 were male. The means for age and body weight were 40.5 ± 13.3 years and 61.2 ± 13.5 kg, respectively. The hemodynamic results indicated a mean shunt ratio (Qp/Qs) of 2.5 ± 1.0. According to the computed tomography images for the patients in both groups, the mean longest diameter (a) and the mean shortest diameter (b) were 22.5 ± 7.8 mm (range, 8.0-45.0 mm) and 17.7±4.5 mm (range, 4.0-31.0 mm), respectively. The mean ratio of the shortest diameter to the longest diameter (b/a) was 0.75 ± 0.21 (range, 0.5-1.0). Twenty-six patients (33.3%) had ovoid defects according to the above criteria and were assigned to that group; 52 patients (66.7%) had round defects and were assigned to the round-defect group.

Data from 7 male and 19 female patients in the ovoid-defect group were reviewed. The mean age was 36.2 ± 16.5 years (range, 15-77 years), and the mean body weight was 59.2 ± 13.6 kg (range, 38-99 kg). According to computed tomography images, the mean longest diameter (a) was 23.8 ± 8.5 mm, and the b/a ratio was 0.66 ± 0.05 (range, 0.5-0.75). The catheterization results indicated a mean Qp/Qs of 3.0 ±

Table 2. Comparison of Device Sizes Used in the Ovoid- and Round-Defect Groups Shows That a Smaller Mean Size Was Used in the Ovoid-Defect Group*

	Ovoid-Defect Group	Round-Defect Group	*P*
Size difference, mm	1.7 ± 2.9	3.8 ± 2.5	.008
Size ratio	1.1 ± 0.1	1.3 ± 0.2	.018

*Data are expressed as the mean ± SD. Size Difference = Device Size – Longest Diameter of Defect. Size Ratio = Device Size / Longest Diameter of Defect.

1.5. The group with round defects comprised 18 male and 34 female patients. The mean age was 43.2 ± 12.5 years, and the mean body weight was 62.1 ± 12.1 kg. The mean longest diameter (a) and the mean b/a ratio in the round-defect group were 21.2 ± 6.6 mm and 0.83 ± 0.04, respectively. The Qp/Qs in the round-defect group was 2.5 ± 1.3.

Body weights, Qp/Qs values, and longest diameters (a) for the 2 groups were not significantly different, but the patients in the ovoid-defect group were younger (Table 1).

For all of the patients, the mean difference between the longest diameter of the defect (a) and device size was 3.2 ± 2.9 (range, –7.0 to 11.0); the mean ratio of the device size to the longest diameter of the defect was 1.15 ± 0.18 (range, 0.84-1.93).

The mean difference between the longest diameter of the defect and the device size for the ovoid-defect group was significantly smaller than that for the round-defect group (1.7 ± 2.9 versus 3.8 ± 2.5; $P = .008$). Furthermore, the mean ratio of the device size to the longest diameter of the defect in the ovoid-defect group was also significantly smaller than that of the round-defect group (1.1 ± 0.1 versus 1.3 ± 0.2; $P = .018$) (Table 2).

Three patients in the ovoid-defect group had a negative value for the difference between the longest diameter of the defect and the device size (–1, –1, and –7), ie, the longest diameter of the defect was larger than the waist diameter of the device. The values for the ratio of the shortest diameter to the longest diameter (b/a) were 0.72, 0.67, and 0.53, respectively (Table 3). The patient with the largest difference between the longest defect diameter and the device size (–7) had a 45-mm longest defect diameter and a 24-mm shortest defect diameter (ie, b/a = 0.53). For this particular oval defect, a 38-mm Amplatzer occluder was implanted successfully, and complete closure was confirmed by transthoracic echocardiography the next day and 6 months later, even though the immediate cardiac computed tomography image showed a small gap from the waist of the device to an anterior margin of the defect (Figure 2). On the other hand, the minimum magnitude of the difference between the longest diameter of the defect and the device size in the round-defect group was 0 mm.

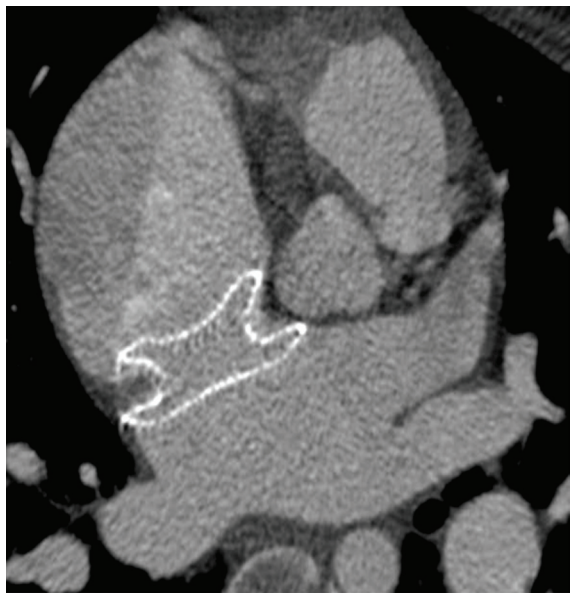

Figure 2. There is a small gap immediately after implantation between the waist of the Amplatzer device and the anterior margin of the defect on the computed tomography image of patient no. 3.

Table 3. Characteristics of the 3 Patients with Ovoid Atrial Septal Defects with a Negative Size Difference (Device Size – Longest Diameter of Defect)*

Patient no.	1	2	3
Age, y	58	68	20
Body weight, kg	71	52	58
Longest diameter (a), mm	29	18	45
Shortest diameter (b), mm	21	12	24
Ratio of shortest to longest diameter (b/a)	0.72	0.67	0.53
Device size	28	17	38
Difference between the device size and (a)	–1	–1	–7
Ratio of the device size to (a)	0.97	0.94	0.84
Qp/Qs	4.0	3.4	2.3

*Data are expressed as the mean ± SD. Size Difference = Device Size – Longest Diameter of Defect. Size Ratio = Device Size / Longest Diameter of Defect.

No significant complications occurred during the procedure. The follow-up results showed no embolization, pericardial effusion, newly developed arrhythmia, or mitral regurgitation. The immediate transthoracic echocardiogram showed complete closure in 19 of the 26 ovoid-defect patients (73.1%), and 12 (92.3%) of 13 patients showed complete closure in the 6-month follow-up transesophageal echocardiogram. In the round-defect group, the defect closure rate was 78.8% (41 of 52 patients) immediately after the procedure and 93.1% (27/29) at the 6-month follow-up; however, the 2 groups were not significantly different ($P > .05$).

DISCUSSION

A transesophageal echocardiogram can assess the size, anatomy, and the suitability for a device to successfully close an atrial septal defect. A 2-dimensional echocardiogram can integrate multiple image planes to allow the operator to reconstruct a 3-dimensional anatomy of the atrial septal defect, but this approach has limitations for accurately visualizing the shape of the defect. A dimension that accurately relates to the shape of the defect is considered important for successful transcatheter closure, because all of the Amplatzer septal occluders are uniform in shape. Studies have used 3-dimensional transesophageal echocardiography to describe the complex shapes of atrial septal defects [Acar 2000; Huang 2010; Johri 2011; Roberson 2011]. Transesophageal echocardiography requires sedation, however, and has the potential to damage the esophagus. Cardiac computed tomography is an alternative, however: Ko et al reported this modality to be very helpful for noninvasively evaluating the implantation of an Amplatzer septal occluder for an atrial septal defect [Ko 2009]. The general concern about cardiac computed tomography is exposure to harmful radiation. We did not check the radiation dose for all of the patients, but cardiac computed tomography examinations were performed with minimal radiation. We could perform cardiac computed tomography with 0.2 to 0.6 mSv for small children and 1.7 to 1.9 mSv for adults. This minimal exposure to radiation helped us evaluate the size of atrial septal defects and their morphology with cardiac computed tomography.

When we defined the ovoid atrial septal defect as the shortest diameter 75% of the longest diameter measured from the en face image obtained in a cardiac computed tomography examination, 34.8% of our patients had ovoid atrial septal defects. Using real-time 3-dimensional echocardiography, Johri et al [2011] reported 42% oval and 33% complex shapes for 25 atrial septal defects. We realized that many atrial septal defects are not round in shape.

When it comes to device size, balloon sizing has been considered an integral aspect of transcatheter closure of an atrial septal defect with an Amplatzer septal occluder; however, several reports have described studies that did not use balloon sizing [Zanchetta 2003; Gupta 2011]. In a particular case of an ovoid atrial septal defect, the effect of balloon inflation altered the shape of the defect to conform to the relatively round shape of the balloon. Moreover, Zanchetta found that the device size appropriate for ovoid atrial septal defects could be smaller than the longest diameter, in accordance with the following intracardiac echocardiogram formula $d = \sqrt{(a \pm b)}$ [Zanchetta 2004]. Although we did not apply Zanchetta's formula, we had 3 cases in which the difference between device size and the longest diameter of the defect were <0; all 3 were in the ovoid-defect group. This was after we considered defect shape in selecting the appropriate device size. For 1 patient with a b/a ratio of 0.53 and a longest defect diameter of 45 mm, we chose a 38-mm Amplatzer septal occluder. That was the maximum size available in our country at the time, and we closed the defect successfully. In fact, even though the waist diameter of the device was smaller than the longest diameter of the defect, the entire length of the device was much larger than 45 mm, and no residual leak was detected by transthoracic echocardiography, either immediately or 6 months later.

Usually, the occluder device should be sized to the largest dimension of the defect, regardless of the measurement modality, but avoiding oversizing is recommended in this situation because of the risks of mushrooming the deformity, impinging on cardiovascular structures, and other serious complications [Amin 2004; Divekar 2005]. Our data showed successful use of the Amplatzer occluder implantation for closing both an ovoid atrial septal defect and a round atrial septal defect. Another study found a residual shunt 1 day after device implantation in 8.6% of the patients; a residual shunt 3 months later occurred in only 1.3% of the patients [Masura 2005]. The complete-closure rates in our study were a little higher, but we can expect similar results going forward. We found no differences in the occurrence of complications, the immediate complete-closure rate, and the midterm complete-closure rate. Interestingly, the mean upsizing of the device in the ovoid-defect group was significantly lower than in the round-defect group, a result predicted by Zanchetta's concept.

The limitation of our study was that it was not a randomized study. This retrospective analysis was based on patients who underwent transcatheter closure of an atrial septal defect with the Amplatzer septal occluder and by experienced operators. Although the sizes of the defects were not significantly different, the occluder sizes used in the ovoid-defect group were larger than in the round-defect group. Generally, for a larger defect a relatively smaller device would be chosen than that used for a small defect. The device size chosen by these operators was based not on a particular equation but on personal experience. It would be better if we had data on device closure of ovoid atrial septal defects with the balloon-sizing method. We need a formula for selecting a device for atrial septal defects that are not round in shape. Although our computed tomography system with low radiation doses is beneficial, for other systems we are not confident that computed tomography would be superior to 3-dimensional echocardiography and the balloon-sizing method.

In our experience, transcatheter closure of an atrial septal defect with the Amplatzer septal occluder is safe and effective, even for ovoid atrial septal defects. Ovoid atrial septal defects can be successfully closed with a smaller Amplatzer septal occluder than those used for round atrial septal defects.

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