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Outcomes After Transcatheter Closure of Atrial Septal Defect Without Using a Balloon-Sizing Technique: A Randomized Controlled Comparison with Closures Using a Balloon-Sizing Technique

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ABSTRACT

Background: The transcatheter closure of atrial septal defect could be completed without the balloon-sizing technique, so we evaluated long-term outcomes compared with closure using balloon sizing, which was the conventional method. Even without using the balloon-sizing technique, transcatheter closure of atrial septal defect might be safe and effective.

Methods: We included 124 patients with isolated atrial septal defects who underwent device closure without balloon sizing between 2012 and 2016, and we further included 257 patients as a control group. Patients who received closure with multiple devices or who experienced postoperative residual defects were excluded. Immediate procedural results, as well as long-term outcomes for closure without balloon sizing, were investigated and compared with the control group.

Results: The procedural success rate was 96.7%, and there were no mortalities. No embolization or cardiac erosions were observed; however, one patient experienced residual shunt, and another developed progressed mitral regurgitation during the follow-up period (983±682 days). Newly onset persistent atrial fibrillation developed in one patient (1.0%). There were no significant differences in procedures or follow-up between the study and control groups. Despite the shorter procedural time in the study group, fluoro time was not different. Atrial arrhythmias were more frequently observed in the control group, but the difference was not significant. Persistent atrial fibrillation was observed in two patients in the control group (0.8%).

Conclusions: Transcatheter closure of atrial septal defect can be performed safely and effectively without using the balloon-sizing technique. The long-term outcomes were similar to outcomes with balloon sizing.

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INTRODUCTION

Transcatheter closure of atrial septal defect (ASD) is currently accepted as the first treatment choice and has been demonstrated to be safe and effective [Salehian 2005; Diab 2007; Jalal 2016; Villablanca 2017]. The balloon-sizing technique has been the standard technique for choosing an appropriately sized transcatheter device [Ewert 2000; Rigatelli 2007]. However, transcatheter ASD closure techniques that deviate from standard practices have been evaluated and showed good results [Godart 1993; Rigatelli 2012; Alqahtani 2017]. Although the balloon-sizing technique is simple and easy to perform, it carries the risk of enlarging the defect and damaging the septum [Godart 1993; Alsaileek 2007]. An accurate measurement of defect size can be accomplished using three-dimensional echocardiography prior to the procedure and intra-cardiac echocardiography (ICE) during the procedure. Thus, some interventional cardiologists discarded balloon sizing from their routine procedures, and there have been a few reports showing good outcomes from device closure of ASD without balloon sizing [Wang 2008; Quek 2010; Rigatelli 2019]. Herein, we evaluated the long-term results from ASD closure without using the balloon-sizing technique and compared them with outcomes from balloon sizing.

PATIENTS AND METHODS

This study was approved by the Institutional Review Board at Samsung Medical Center and the need for informed consent was waived. Between March 2012 and December 2016, 129 patients with isolated ASD underwent transcatheter closure without the balloon-sizing technique at Samsung Medical Center. The patients' ASDs were hemodynamically significant, did not have irreversible pulmonary hypertension, were suitable for device closure, and not associated with medically intractable persistent arrhythmia. Five patients were excluded due to receiving multiple devices for multiple defects (4) or for undergoing device closure for postoperative fenestrated ASD (1). Transcatheter closures were performed by a single pediatric cardiac interventionist with sufficient experience in transcatheter closure of ASD.

All ASD patients were investigated using transthoracic echocardiography (TTE), transesophageal echocardiography

(TEE), and cardiac computed tomography (C-CT). Anatomic and morphologic evaluations, including location, size, and characteristics of adjacent rims, were completed prior to catheterization. The longest diameter at the end-systolic phase was measured. For hemodynamic evaluation, Qp/Qs, pulmonary arterial pressure, and indexed pulmonary vascular resistance, if necessary, were checked by cardiac catheterization.

All transcatheter closures of ASDs were guided by intracardiac echocardiography (ICE) under local anesthesia, according to ICE protocol [Rigatelli 2012]. Device size was based on measurements from images taken prior to the procedure, including the longest two-dimensional diameter regardless of defect shape from all image perspectives and surrounding rim characteristics. Usually, a device that was 100%–150% of the longest diameter was selected. Device sizes were chosen by the same interventionist who performed the closures.

Procedural success was defined as a good device implantation position requiring no surgical intervention, whereas procedure failure was defined as surgical closure of ASD immediately after device placement due to device embolization in the catheterization room or implantation failure. Complications were categorized as procedural complications (device embolization, vascular complication, severe bleeding requiring transfusion, or arrhythmia requiring intervention) or follow-up complications (device embolization, device thrombus, cardiac erosion, pericardial effusion, allergic reaction, migraine, neurologic symptoms, and newly developed or significantly progressed valvar regurgitation). The residual shunt indicated when the shunt diameter was more than 3 mm or when right heart dilatation did not resolve based on echocardiography six months after device closure. New-onset permanent or paroxysmal atrial arrhythmia was investigated using electrocardiography or 24-hour Holter monitoring. Onset time was divided into acute onset before discharge, subacute, and late onset six months after device closure. The follow-up period was limited to a basic examination at the cardiology clinic.

We defined the control group as the group of 257 patients with ASD who underwent closure using the balloon-sizing technique during the same period at the same hospital as the study group. Inclusion and exclusion criteria for the control group were the same as for the study group. Transcatheter closures among the control group were performed by a single interventionist, but not the same one who performed

Table 1. Patient data

	Patients	Controls	*P*-value
N	124	257	
Age (years)	32.7±21.7	37.0±19.8	0.065
<18 years	42 (33.9)	56 (21.8)	0.011
Male sex	40 (32.3)	86 (33.5)	0.815
BSA	1.4±0.4	1.5±0.4	0.082
Valve regurgitation, ≥ moderate			
Mitral	0	1 (0.4)	0.487
Aortic	0	0	1.000
Largest ASD diameter (mm)	16.8±7.0	16.7±6.0	0.926
Device size (mm)	18 (6-40)	17 (8-39)	0.461
Multiple ASDs	2 (1.6)	11 (4.3)	0.179
Qp/Qs	2.3±0.8	2.5±1.1	0.035
Mean PAP (mmHg)	17.9±4.7	18.6±4.5	0.188
Concomitant procedure			
CAG	4 (3.2)	3 (1.2)	0.161
Pulmonary BVP	0	2 (0.8)	0.325
Special technique			
PV deployment	3 (2.4)	12 (4.7)	0.403
Balloon assisted	13 (10.5)	21 (8.2)	0.458
Fluoro time (sec)	12.3±8.7	11.7±8.4	0.535
Procedure time (min)	59.5±29.6	66.1±24.2	0.021

n (%), mean±SD, median (min-max), BSA, body surface area; ASD, atrial septal defect; PAP, pulmonary arterial pressure; CAG, coronary angiography; BVP, balloon valvuloplasty; PV, pulmonary vein

the closures for the study group. We compared outcomes between the groups.

Values are expressed in frequencies and means ± standard deviations (SD). To compare the study outcomes to controls, Student's t-test and the chi-square test were performed using SPSS 25 (SPSS Inc., Chicago, IL, USA). P values <.05 were considered statistically significant.

RESULTS

Procedural data: The mean patient age at the time of procedure was 32.7 years old, and 42 patients (33.9%) were less than 18 years old. (Table 1) There were no patients with moderate or worse mitral or aortic regurgitation. The longest ASD diameter was 16.8 ± 7.0 mm and median device size was 18 mm. The shunt amount and mean pulmonary arterial pressure were 2.3±0.8 and 17.9±4.7 mmHg, respectively. Two patients (1.6%) had multiple ASDs that were successfully closed with one device. Coronary angiography concomitantly was obtained in four patients (3.2%). Special techniques, such as pulmonary vein deployment or the balloon-assisted technique, were applied in 16 patients (12.9%). Mean fluoro and procedure times were 12.3 and 59.5 minutes, respectively.

Procedural and follow-up outcomes: There were no mortalities among the study patients, and the procedure successfully was completed in 120 patients (96.7%). (Table 2) Three patients underwent surgical closure because their devices failed to implant, even with all kinds of modified technique, and one patient experienced device embolization. Two patients experienced vascular complications, including arteriovenous fistula and retroperitoneal hematoma. There were no cases of severe bleeding or arrhythmia.

Neither embolization nor cardiac erosion occurred during the follow-up period (983±682 days). Two patients developed migraines, and one patient had a syncopal episode. Among the 120 patients who had successful device closure, significant residual shunt was observed in one patient (0.8%), and significantly progressed mitral regurgitation was observed in another (0.8%).

Newly developed arrhythmia: Arrhythmia-related outcomes were evaluated in 96 patients. (Table 3) In-hospital acute-onset paroxysmal atrial arrhythmias were observed in three patients. Paroxysmal atrial tachycardia was observed in two patients within six months of device closure. One patient developed a junctional rhythm that spontaneously resolved. Only one patient, six months after device closure, developed persistent atrial fibrillation (1.0%).

Comparison to control: There were no significant differences between the study and control groups, except that there

Table 2. Procedure and follow-up outcomes

	Patients	Controls	*P*-value
N	124	257	
Procedural success	120 (96.7)	253 (98.4)	0.785
Procedural complication			
Embolization	1 (0.8)	5 (2.0)	0.668
Vascular complication	2 (1.6)	2 (0.8)	0.599
Severe bleeding	0	0	1.000
Arrhythmia	0	0	1.000
Follow-up duration (days)	983±682	1088±804	0.047
Follow-up complication			
Embolization	0	2 (1.0)	0.480
Cardiac erosion	0	0	1.000
Pericardial effusion	0	2 (1.0)	1.000
Allergic reaction	0	4 (2.1)	0.178
Migraine	2 (1.6)	0	0.105
Neurologic symptoms	1 (0.8)	1 (0.4)	0.325
Echocardiography			
Residual shunt	1 (0.8)	3 (1.2)	0.116
Aggravation of MR	1 (0.8)	0	0.319
Aggravation of AR	0	0	1.000

n (%), mean±SD, median (min-max), MR, mitral regurgitation; AR, aortic regurgitation

were fewer patients <18 years old in the control group (33.9 % vs. 21.8 %) (Tables 1-3). Defect and device sizes were not different and hemodynamic data were similar. Fluoro times were not different, but the procedural time was shorter in the study group (59.5±29.6 vs. 66.1±24.2).

There were no significant differences in procedural success rates, nor in procedural complication and follow-up complication rates even though the study follow-up duration was slightly shorter than the control duration (983±682 vs. 1088±804 days). Device embolization during the procedure and follow-up occurred more frequently in the control group but not significantly so. Pericardial effusion and allergic reaction in the control group resolved naturally without any intervention.

Regarding arrhythmia, there were no significant differences in newly developed arrhythmia but there were more cases of acute-onset and late-onset arrhythmia in the control group. Persistent atrial fibrillation was observed in two patients (0.8%) but that difference was not significant.

DISCUSSION

This study demonstrated that transcatheter closure of ASD without the balloon-sizing technique yielded good outcomes both during the procedure and long-term follow-up that were not different from outcomes from balloon sizing.

In this study, we show excellent procedural success rates for both patient groups. There were no serious complications either during the procedure or after long-term follow-up among patients who did not undergo balloon sizing. Device embolization occurred in five patients who received the balloon-sizing technique, but the complication rates between the two groups were not significantly different. Amin et al. addressed severe long-term complications, which range in prevalence from 0.1%–2.5% [Amin 2004]. Most cases of new-onset arrhythmia in both groups were transient but post-procedure atrial arrhythmia was less common in patients who did not undergo balloon sizing, although the difference was not significant. Newly developed chronic atrial tachycardia was only observed in one patient (1.0%), which was not a significant difference from the control group (0.8%). A recent study reported that the 10-year cumulative incidence of atrial fibrillation was 11% and no differences between after surgery and device closure were observed [Nyboe 2015]. Aytemir et al. reported that newly developed atrial fibrillation after device closure was observed in 1.0% of patients [Aytemir 2013]. Despite a mean shorter procedural time in the study group, there was no difference in fluoro time between the groups (9.25 vs. 9.55 minutes for the study and control groups,

Table 3. Newly developed arrhythmia

	Patients	Controls	*P*-value
N	96	225	
Acute onset (before discharge)			
Total	3 (3.1)	11 (4.9)	0.479
Paroxysmal AF	1	2	
Paroxysmal SVT	2	1	
Transient 1st & 2nd degree AV block	0	4	
Transient junctional rhythm	0	4	
Subacute onset (≤6 months)			
Total	3 (3.1)	7 (3.1)	0.995
Paroxysmal AF	0	5	
Paroxysmal AT	2	1	
AVNRT	0	1	
Transient junctional rhythm	1	0	
Late onset (>6 months)			
Total	1 (1.0)	5 (2.2)	0.673
Persistent AF	1 (1.0)	2 (0.8)	0.985
Paroxysmal AF	0	1	
AVRT	0	1	
NSVT	0	1	

n (%), mean±SD, median (min-max), AF, atrial fibrillation; SVT, supraventricular tachycardia; AV, atrioventricular; AT, atrial tachycardia; AVNRT, atrioventricular nodal reentrant tachycardia; AVRT, atrioventricular reentrant tachycardia; NSVT, non-sustained ventricular tachycardia

respectively). However, fluoroscopy times in our series were shorter than reported in other studies of closure without balloon sizing (10 minutes) [Rigatelli 2019]. Rigatelli et al. mentioned that ICE-assisted ASD closure without balloon sizing could avoid an unnecessary high radiation dose for both patients and cardiologists [Rigatelli 2007].

Many cardiologists still rely on balloon-sizing techniques to determine the appropriate device size, but a significant and growing number of cardiologists do not use balloon sizing. Instead, they estimate device size, according to the size of the intact defect from images obtained using various techniques, including ICE, TEE, or C-CT [Patel 2006; Wang 2008; Rajiah 2013; Osawa 2015; Rigatelli 2019]. Recently, three-dimensional reconstructed images have been shown to be valuable for successful device-size measurement [German 2015; Jone 2018; Kitakata 2021]. There was no fixed rule for device size based on intact defect size but in two different studies devices, 120% of and 5 mm larger than entire defects were selected [Quek 2010; Rigatelli 2019]. However, in our experience, other factors such as remaining septum stability, septal aneurysm presence, rim deficiency locations, and patient age should be considered. At a minimum, we recommend using a device that is not smaller than the largest diameter of the intact defect.

Despite ongoing debate, over-sizing the defect is generally accepted as the most essential factor associated with cardiac erosion after device closure of ASD [Amin 2004], and the stop-flow technique has been proposed as an alternative [Carlson 2005]. However, the tendency to over-size is still a problem with balloon-sizing techniques, thus challenging the need for balloon sizing at all.

Successful device closure without the balloon-sizing technique might depend on operator's experience. A highly experienced cardiologist carried out procedures without balloon sizing at our institute and all resulted in good outcomes. The intact defect size was measured using one or more imaging technologies. TTE for children and three-dimensional TEE for adults were fundamental for measurement, but three-dimensional C-CT could be used supplementarily in select patients. All patients underwent measurement using ICE during the procedure. Therefore, meticulous evaluation of ASD is very important for our approach.

Our study has several limitations. First, it was a retrospective study that did not include many patients. Second, the observation period was not long enough for long-term follow up. Third, although our patients randomly were distributed without any controlled factors, the operators differed for the two procedure groups. Although the major components of the procedures were the same between the two operators, trivial differences were present. Finally, the process for selecting device size when not using balloon sizing remains non-uniform, more as an artistic feature rather than as a mathematical feature dependent on patient characteristics.

CONCLUSION

Transcatheter closure of ASD without the balloon-sizing technique is safe, effective, and associated with a low incidence of procedural and follow-up complications, including new-onset arrhythmia that was not different from the rate with balloon sizing. Further and longer-duration follow-up studies are needed to confirm these findings.

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