

## Original Article

# Comparison of Transcatheter Atrial Septal Defect Closure Between Children Weighing Less Than 15 kg and Children Weighing 15 to 20 kg

Osman Baspinar<sup>1\*</sup>, MD; Mehmet Kervancioglu<sup>1</sup>, MD; Metin Kılinc<sup>1</sup>, MD; Derya Aydın Sahin<sup>1</sup>, MD; Khaleel Al-Suwayfe<sup>1</sup>, MD; Arif Selcuk<sup>2</sup>, MD; Mehmet Adnan Celkan<sup>2</sup>, MD; Gokhan Gokaslan<sup>2</sup>, MD

## ABSTRACT

**Background:** We investigated the safety, efficacy, and follow-up results of the transcatheter closure of secundum atrial septal defects (ASDs) in children weighing less than 15 kg compared with children weighing between 15 and 20 kg.

**Methods:** During the study, 274 children weighing less than 20 kg underwent transcatheter closure. The patients were divided into 2 groups: Group I comprised 146 patients (53.3%) weighing 15 kg or less and Group II consisted of 128 patients (46.7%) weighing between 15 and 20 kg. Data were analyzed retrospectively.

**Results:** The mean age and weight of the children were  $4.3 \pm 1.3$  years and  $15.2 \pm 2.4$  kg. Totally, 269 interventional operations (98.2%) were considered successful. Major complications occurred in 7 patients (2.5%). The stretched ASD diameter was  $14.7 \pm 3.9$  (7–29) mm in Group I and  $15.9 \pm 4.7$  (7.8–28) in Group II ( $P = 0.063$ ). The defect diameter/body weight was  $0.9 \pm 0.2$  (0.4–1.8) in Group I and  $0.8 \pm 0.2$  (0.4–1.5) in Group II ( $P = 0.001$ ). The Amplatzer-like device diameter was  $16.0 \pm 4.1$  (9–30) mm in Group I and  $17.7 \pm 5.0$  (9–34) mm in Group II ( $P = 0.004$ ). The patch-like device diameter was  $28.8 \pm 4.6$  (20–35) mm in Group I and  $29.4 \pm 4.1$  (20–33) in Group II ( $P = 0.716$ ). The size of the delivery sheath was  $8.4 \pm 1.4$  (6–12) F in Group I and  $8.8 \pm 1.5$  (6–12) F in Group II ( $P = 0.039$ ). There were no statistically significant differences in the rates of unsuccessful procedures and complications between the patient groups ( $P = 0.762$  and  $P = 0.836$ , correspondingly).

**Conclusions:** The transcatheter closure of secundum ASDs in small children is feasible and is not associated with a greater risk of significant complications. (*Iranian Heart Journal 2021; 22(3): 33-43*)

**KEYWORDS:** Transcatheter closure, Atrial septal defects, Small children

<sup>1</sup> Department of Pediatric Cardiology, Gaziantep University Medical Faculty, Gaziantep, Turkey.

<sup>2</sup> Department of Cardiothoracic Surgery, Gaziantep University Medical Faculty, Gaziantep, Turkey.

\*Corresponding Author: Osman Baspinar, MD; Department of Pediatric Cardiology, Gaziantep University Medical Faculty, Gaziantep, Turkey.

Email: osmanbaspinar@hotmail.com Tel: +90 532 345 54 77

Received: February 6, 2021

Accepted: May 9, 2021

**T**ranscatheter secundum atrial septal defect (ASD) closure is an interventional procedure that can be conducted safely and effectively. Patients with ASDs are typically asymptomatic during childhood, and the presence of right ventricular volume overload is a clear indication of the need for closure.<sup>1</sup> In addition, growth retardation, congestive heart failure, or frequent respiratory infections due to increased pulmonary blood may occur in some small children<sup>2</sup> and may indicate that early closure is necessary. Improvements in device design, including the reduced diameter of closure delivery systems, have facilitated the interventional treatment of young children. This study aimed to assess the reliability and efficacy of transcatheter ASD closure in children weighing less than 15 kg relative to transcatheter ASD closure in children weighing 15 to 20 kg, which is the recommended weight for general surgical closure. The results of the procedures conducted at our clinic will be discussed in the context of the current literature.

## METHODS

### Patient and data collection

We retrospectively collected the echocardiographic and angiographic findings and the clinical records of patients who had undergone transcatheter ASD closure and whose weight was less than 20 kg. The patients were divided into 2 groups based on weight to determine closure efficacy in very small children ( $\leq 15$  kg) relative to children who met the current surgical weight recommendations. The data were segregated into the following 2 study groups: Group I (weight  $\leq 15$  kg) and Group II (weight  $>15 \leq 20$  kg). A written and signed consent form regarding ASD closure was obtained from the legal guardians of all the

patients prior to the procedure. The study was conducted in compliance with human study guidelines and approved by our local ethics committee.

The inclusion criteria were as follows: 1) weight less than 20 kg, 2) secundum ASDs of 7 mm or larger in single-hole defects, 3) no absence of rims except for the aortic rim, 4) more-than-moderate dilatation of the right cavities, frequent lower respiratory tract infection, growth retardation, arrhythmias requiring treatment, or cardiac anomalies requiring intervention, and 5) the total length of the atrial septum capable of accommodating device closure.

### Procedures

Transthoracic echocardiography was used to measure the diameter of the defect and aortic, anterior superior, anterior inferior, posterior superior, posterior inferior, and posterior rims and the total septum length in all the study participants. Right ventricular dilatation, atrioventricular valve regurgitation, and additional defects were assessed. The transcatheter closure process was performed under general anesthesia and/or deep sedation with the guidance of transesophageal and/or transthoracic echocardiography during cardiac catheterization. All the closure procedures were performed by the same pediatric cardiologist (OB). The right femoral vein was usually used as a vascular access. Arterial pressure was measured noninvasively in most cases. Pulmonary artery pressure, systemic/pulmonary shunt ratio, and pulmonary resistance were measured for each patient. Pulmonary balloon valvuloplasty, patent ductus arteriosus transcatheter closure, and ventricular septal defect closure were also performed during the same procedure in cases where such procedures were required. The following equipment was used in the

closure procedures based on the preference of the surgeon and availability of the device: the Amplatzer atrial septal occluder (St Jude Medical, Plymouth, MN, USA), the Lifetech CeraFlex atrial septal occluder (Lifetech Scientific Co Ltd, Shenzhen, China), the Occlutech Figulla Flex II atrial septal occluder (Occlutech AB, Helsingborg, Sweden), the Gore atrial septal occluder (WL Gore & Associates, Inc, Flagstaff, AZ, USA), the BioSTAR atrial septal occluder (NMT Medical Inc, Boston, Mass), and the Cocoon atrial septal occluder (Vascular Innovations Co Ltd, Nonthaburi, Thailand). The BioSTAR occluder is a type of septal occluder that is no longer manufactured but was used in the initial period of the study. The structure of the device was bioabsorbable and could be used for defect closure using the patching technique.<sup>3</sup>

### Outcome Measures

Success was defined as the absence of residual defects or minimal residual flow. Major complications were defined as death, device embolization, device erosion, pericardial effusion, stroke, complete atrioventricular block, severe arrhythmias, emergency surgery, and major bleeding requiring blood transfusion. Minor complications were defined as vessel puncture site hematoma, transient arrhythmias, mild bleeding, and mild atrioventricular valve regurgitations.

### Follow-up

Electrocardiography and echocardiography, and if necessary in some cases, Holter monitoring, were performed on the first postprocedural day and then 1 week; 1, 3, and 6 months; and 1 and 5 years after the procedure.

### Statistical Analyses

The results are presented as the mean  $\pm$  the standard deviation (SD) with median values

and upper and lower limits. Differences in outcomes between the groups were analyzed using the Student *t* test. A Friedman 2-way analysis of variance was used to compare the rate of success and various complications among the patients in Group I and Group II. Two-sided statistical tests were used in all the cases. The Mann–Whitney *U* test was utilized to evaluate differences between nonparametric values. A *P*-value of less than 0.05 was considered statistically significant. All the analyses were performed using SPSS, version 17.0, for Windows.

## RESULTS

### Patient characteristics

A total of 276 out of 552 patients taken to the pediatric angiocardiology laboratory for transcatheter ASD closure over the 7.5-year study period weighed less than 20 kg and were considered candidates for this study. Both the posterior rim and the aortic rim were absent in 2 patients, and no closure was performed in these individuals. There were 161 female (58.8%) and 113 male (41.2%) patients among the 274 study subjects. The mean diameter of the ASDs measured on transthoracic echocardiography was  $12.4 \pm 3.7$  (7–30) mm. The mean age of the patient population was  $4.3 \pm 1.3$  years, and the mean weight was  $15.2 \pm 2.4$  (8–19.9) kg. Group I ( $\leq 15$  kg) consisted of 146 patients (53.3%) and Group II ( $>15 \leq 20$  kg) comprised 128 patients (46.7%) (Fig. 1). The demographic characteristics of the patients are presented in Table I.

Growth retardation was present in 115 (42%) of 274 patients, additional cardiac pathologies requiring intervention (pulmonary stenosis, patent ductus arteriosus, and ventricular septal defect)s were present in 24 patients (8.7%), recurrent pulmonary infection was present in 71 patients (25.9%), heart failure requiring the use of anticongestive therapy

was present in 10 patients (3.6%), and mild pulmonary hypertension was found in 3 patients (1%) included in the study group. Noncardiac comorbidities comprised Down syndrome in 13 patients (4.7%) and 1 incident of each of the following conditions: growth hormone deficiency, cystic fibrosis, mucopolysaccharidosis, and surgically treated myelomeningocele.

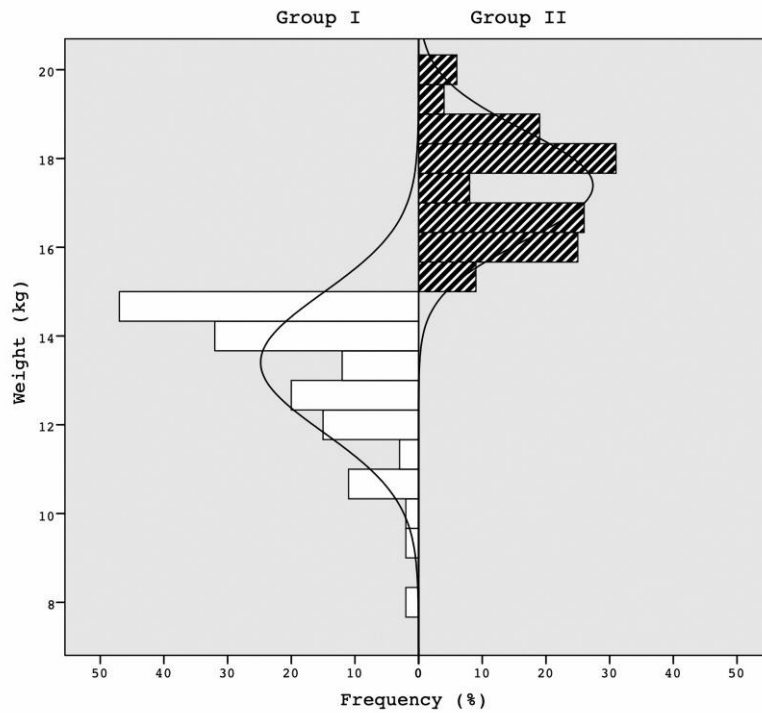
### Procedural characteristics

Patients with congenital defects such as patent ductus arteriosus, ventricular septal defects, and pulmonary stenosis underwent additional procedures during the ASD closure. Pulmonary balloon valvuloplasty was performed in 17 patients, the patent ductus arteriosus was closed in 5 patients, the patent ductus arteriosus was closed prior to ASD closure in a second operation in 1 patient, and ventricular septal defect closure was performed at the same time as ASD in 1 patient. Thrombosis of the iliac vein occurred in 1 patient, who had undergone prior patent ductus arteriosus closure. Secundum ASD closure was performed using the transjugular technique in this patient.<sup>4</sup> Entry was usually performed through the femoral vein (93.4%). Seventy-one patients (25.9%) exhibited multiple defects, and double devices were used in 7 (2.6%) of these patients. Echocardiographic assessment was performed transesophageally in 65 patients (23.7%) and transthoracic route in 209 patients (76.3%). Sedation was administered in 210 patients (76.6%), and general anesthesia was administered in 64 patients (23.4%). The mean rate of shunt flow was  $2.2 \pm 1.1$  (1.1–10), and the mean pulmonary artery

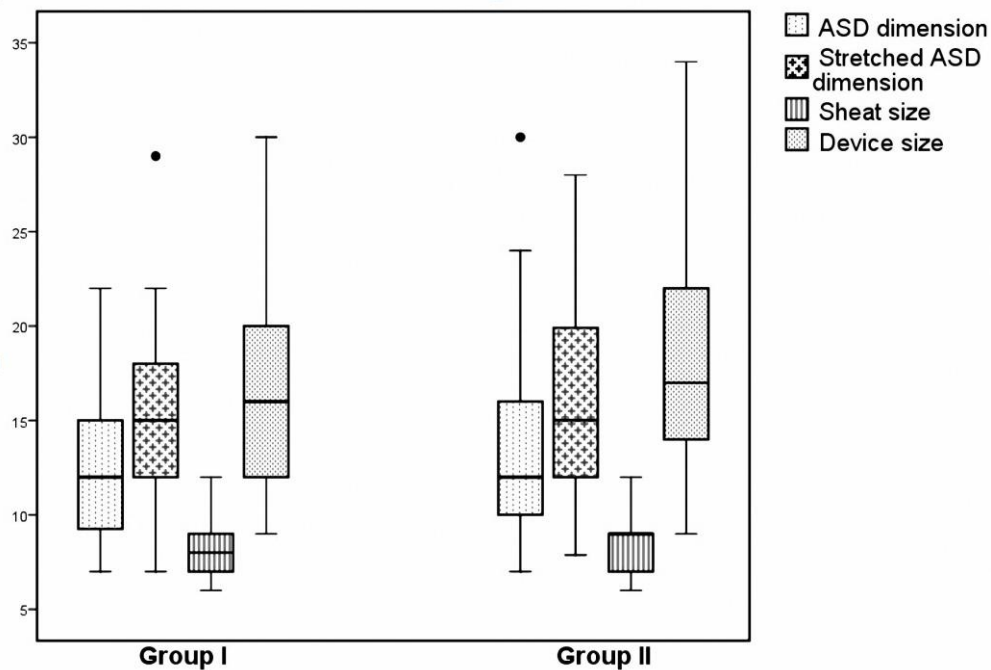
pressure was  $22.9 \pm 5.7$  (9–46) mm Hg. A total of 269 interventional operations (98.2%) were considered successful and 5 (1.8%) were considered unsuccessful. Major complications occurred in 7 patients (2.5%), and minor complications occurred in 12 patients (4.3%).

The standard technique was used in 248 patients (90.5%). Among the remaining patients, the left upper pulmonary vein technique was used in 8 patients, the right upper pulmonary vein technique was used in 5 patients, the auxiliary wire technique was used in 4 patients, and the angled delivery sheath technique was used in 1 patient.

The sizing balloon was used to measure the defect diameter in all the cases except in multifenestrated defects. The stretched ASD diameter was not statistically significant between the groups. The upstretched ASD diameter/body weight, the diameter of the Amplatzer-like device (Amplatzer, Occlutech Flex II, Lifetech CeraFlex, Cocoon), and the delivery sheath sizing were statistically significant between the groups. When cases in which 2 devices were used were included in the data, the Amplatzer-like device diameter was  $16.3 \pm 4.4$  (9–30) mm in Group I and  $17.7 \pm 5.0$  (9–34) in Group II ( $P = 0.027$ ). The patch-like device diameter (Amplatzer, Occlutech multifenestrated septal and patent foramen ovale occluder, Gore and BioSTAR septal occluder) and the fluoroscopy time were not statistically significant between the groups. The details of the defect evaluation and interventional procedures are presented in Table 1, Fig. 2, and Fig. 3.

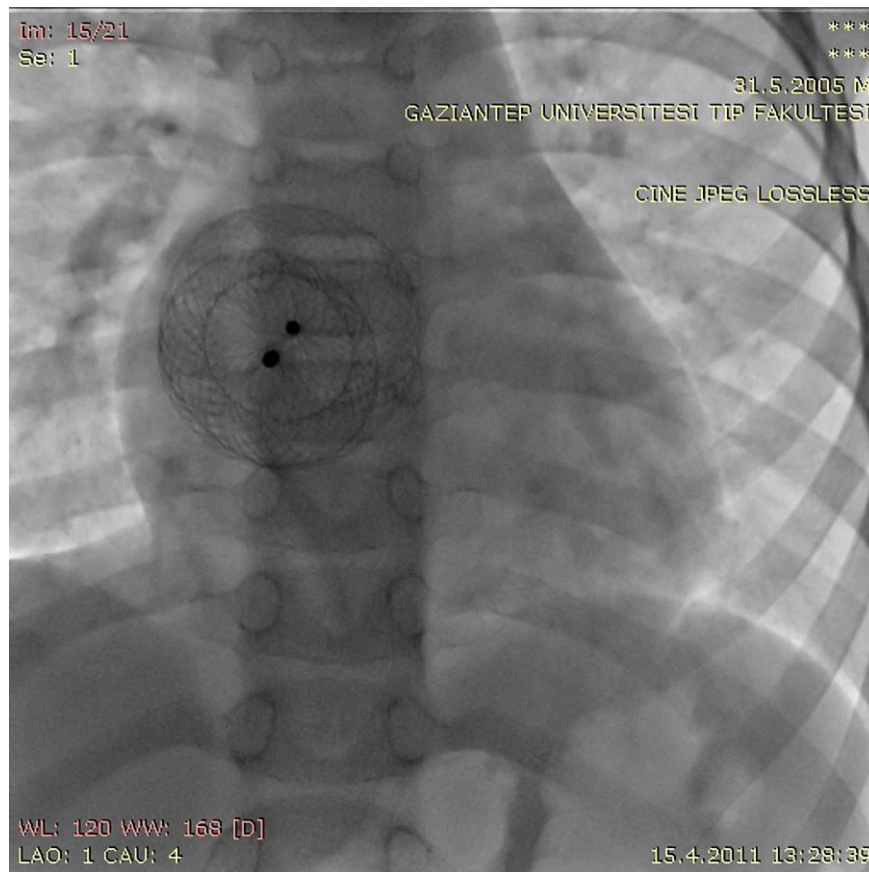


**Figure 1.** The image depicts the weight distribution of the patients in Group I (n =146) and Group II (n =128).



**Figure 2.** A comparison of Group I and Group II in terms of the atrial septal defect dimension, the stretched atrial septal defect dimension, the sheath size, and the Amplatzer-like device (Amplatzer, Occlutech Flex II, Lifetech CeraFlex, Cocoon septal occluder) size is shown using a boxplot. ASD, Secundum atrial septal defect





**Figure 3.** The image illustrates the Amplatzer septal occluder (25 mm occluder) in the heart in the postoperative chest radiograph of a 3-year-old boy, 13 kg in weight, with the highest ratio of septal occluder /body weight.

**Table 1.** Demographic and clinical characteristics of the patients

	Total (N=274)	Group I (n=146)	Group II (n=128)	P- value
Gender	161 girls (58.8%)	87 girls (59.5%)	74 girls (57.8%)	0.766
Age (y)	4.3±1.3 (1.1-9)	3.7±0.9 (1.1-7)	5.1±1.3 (3-9)	0.001*
Weight (kg)	15.2±2.4 (8-19.9)	13.4±1.5 (8-15)	17.3±1.2 (15.1-19.9)	0.001*
ASD upstretched diameter (mm)	12.4±3.7 (7-30)	11.7±3.0 (7-22)	13.2±4.1 (7-30)	0.002*
Upstretched ASD/body weight ratio	0.9±0.2 (0.4-1.8)	0.9±0.2 (0.4-1.8)	0.8±0.2 (0.4-1.5)	0.001*
Stretched ASD diameter with sizing balloon (mm)	15.1±4.3 (7-29)	14.7±3.9 (7-29)	15.9±4.7 (7.8-28)	0.063
Amplatzer-like device diameter (mm)†	16.9±4.6 (9-34)	16.0±4.1 (9-30)	17.7±5.0 (9-34)	0.004*
Patch-like device diameter (mm)‡	29.1±4.3 (20-35)	28.8±4.6 (20-35)	29.4±4.1 (20-33)	0.716
Delivery system sheath size (F)	8.6±1.5 (6-12)	8.4±1.4 (6-12)	8.8±1.5 (6-12)	0.039*
Fluoroscopy time (min)	9.4±7.2 (2.3-48.6)	9.9±7.8 (3.2-48.6)	8.9±6.7 (2.3-30.7)	0.587
Number of unsuccessful processes	5 (1.8%)	3 (2%)	2 (1.5%)	0.762
Major complications	7 (2.5%)	4 (2.7%)	3 (2.2%)	0.836
Follow-up period (mon)	37.5±21.4 (1-88)	38.8±20.8 (1-88)	36.3±22.0 (1-88)	0.362

Data are presented as mean±SD (range). \*  $P < 0.05$  statistically significant

ASD, Secundum atrial septal defect; † Amplatzer-like devices: Amplatzer septal occluder, Occlutech Figulla Flex II septal occluder, Lifetech Cera septal occluder; ‡ Patch-like devices: Amplatzer multifenestrated septal occluder, Amplatzer foramen ovale occluder, Occlutech Figulla multifenestrated occluder, BioSTAR septal occluder, Gore septal occluder

### Device used

A total of 281 devices were used. Two devices each were used in 7 of the 274 patients. The Amplatzer septal occluder was used 160 times (57%): 86 times in Group I and 72 times in Group II. In addition, a multifenestrated and a foramen ovale occluder were used in Group I. Secondly, the Occlutech Flex II was used 66 times (23.5%): 32 times in Group I and 31 times in Group II. A multifenestrated device of the Occlutech Flex II was also used twice in Group I and once in Group II. The BioSTAR device was used on 22 occasions (7.8%): 10 times in Group I and 12 times in Group II. The Lifetech CeraFlex occluder was used 21 times (7.5%): 12 times in Group I and 9 times in Group II. The Cocoon septal occluder was used 7 times (2.5%), and the Gore septal occluder was used 5 times (1.7%). In cases where double devices were used, the Amplatzer septal occluder was used in 3 patients, the Occlutech Flex II septal occluder was used in 3 patients, and the BioSTAR septal occluder was used in 1 patient.

The stretched ASD diameter was measured at 12.5 mm in a 2-year-old patient with Down syndrome weighing 11.1 kg. Reactive pulmonary hypertension was detected during the pulmonary reactivity test; therefore, the hand-made fenestrated Occlutech Flex II device was used.

### Unsuccessful processes

The process was unsuccessful in 3 patients (2%) in Group I. These patients underwent surgical repair. The first case in Group I (3 years 4.5 months, 13.6 kg, girl, stretched ASD diameter 19 mm), and the defect was successfully closed using a 21 mm occluder. A third-degree atrioventricular block with a narrow QRS at 60–70/min speed developed when the device was released. Intravenous steroid administration was initiated, and a temporary pacing electrode was placed in

the right ventricular apex. Third-degree block was persistent after 3 days, and surgical retrieval of the device and surgical closure of the defect was conducted. The second case in Group I (3 years 11 months, 14 kg, girl, with 2 stretched ASDs 9 and 6 mm in diameter) was closed using a multifenestrated septal occluder with a diameter of 33 mm passed through a small defect. On the following day, the device was observed by echocardiogram to be exerting significant pressure on the aortic root. Surgical retrieval of the device and surgical closure of the defect was conducted. A 14 mm diameter was placed in the third patient in Group I (3 years 3 months, 15 kg, boy, and stretched ASD diameter 14 mm). The device was embolized during the process, and it fell into the left ventricle. Therefore, immediate surgical retrieval of the device and surgical closure of the defect was performed.

The closure process was unsuccessful in 2 patients (1.5%) in Group II, and these patients underwent surgery. In 1 patient (4 years, 16 kg, girl, stretched ASD diameter 24 mm), a 24 mm device embolized 1 day after transcatheter closure. The device was retrieved surgically, and the defect was closed primarily. In the second patient in Group II (5 years 2 months, 17.5 kg, girl, 2 large secundum ASDs with stretched ASD diameters of 18.7 and 13.7 mm), closure was attempted using 2 devices with diameters of 20 mm and 12 mm. While the second device was placed on top of the first one using the sandwich technique, the first device embolized. The embolized device was taken from the right ventricle with a snare, and the patient was taken to surgery under elective conditions. There was no statistically significant difference in the rate of unsuccessful procedures between the patient groups ( $P=0.762$ ). Surgical retrieval of embolized devices has been presented previously by Gokaslan et al.<sup>5</sup>

## Complications

Major complications were observed in 7 patients (2.5%). There were 4 complications (2.7%) in Group I. The details of these 3 cases are discussed above. The fourth patient in Group I (6 years, girl, 15 kg, stretched ASD diameter 17 mm) underwent placement of a 17 mm device. The device was observed to be in the correct location, but the aortic edge was directed toward the right atrium during the control echocardiography. The device, which was stable on the septum, was caught from the right atrium hub with a snare. The defect was closed without incident by progressing a 20 mm occluder.

There were 3 complications (2.2%) in Group II. Both of these 2 cases are discussed above. In the third patient (5 years 3 months, girl, 18.4 kg, stretched ASD diameter 19 mm) in Group II, closure of the defect using an 18 mm occluder was attempted. Standard left and right upper pulmonary vein techniques were attempted multiple times without achieving stable placement. The hub system, which was probably attached to the delivery system improperly, was embolized to the right ventricle with deterioration of the tip of the delivery system. The device was retrieved using a snare, and the defect was closed using a 20 mm septal occluder during the same session. There was no statistically significant difference in the complication rate between the 2 study groups ( $P=0.836$ ). One of the minor complications during catheter manipulation was a supraventricular tachycardia requiring the administration of intravenous adenosine 5 times. This patient did not show any other rhythm problems during the follow-up. The other minor complications were transient atrioventricular dissociation in 1 patient, trace mitral regurgitation in 2 patients, vascular puncture site hematoma in 2

patients, minor bleeding in 2 patients, and clinically insignificant atrial extrasystoles in 4 patients.

## Follow-up

The mean follow-up period was  $38.8 \pm 20.8$  (median =42, range = 1–88) months in Group I, and  $36.3 \pm 22.0$  (median =36, range =1–88) months in Group II ( $P=0.362$ ). There was no residual ASD flow in any of the patients during the follow-up.

## DISCUSSION

Immediate ASD closure is not a widely adopted method for the treatment of asymptomatic children due to the high rate of spontaneous ASD closure during the first few years of life, particularly when the defect is less than 8 mm in diameter.<sup>6</sup> Moreover, most children are asymptomatic; therefore, the surgical literature recommends elective ASD closure in children once they are older than 4 or 5 years of age.<sup>7</sup> However, some ASDs may dilate and even exceed percutaneous closure limits during this time.<sup>8, 9</sup> With recent advances, transcatheter secundum ASD closure can be conducted safely and effectively, suggesting that there may be cause to reexamine the current age recommendations for ASD closure procedures. Numerous studies have reported on the transcatheter closure of small and medium-sized ASDs in children.<sup>10, 11</sup> The updated design of the devices used for the closure and the reduction of the diameter of delivery systems now allows for the implementation of this process in smaller patients.

There are several unique challenges involved in transcatheter ASD closure in small children. The vessels are small relative to the major delivery systems; therefore, the potential damage caused by



vascular intervention may be higher. The implantation of large devices can be difficult in small hearts because the small total septum diameter is small; thus, great care should be taken to ensure the process proceeds safely and to prevent damage to the blood vessels and cardiac structures. It is important to remember that closure systems are not designed for use in small children.<sup>12</sup> Delivery system diameters vary by manufacturers even among devices of the same size, and the device should be selected according to the vascular structure of the individual patient. For example, while 6 F is sufficient for the 10 mm ASD occluder in Amplatzer and Cocoon delivery systems, Lifetech CeraFlex and Occlutech Flex II require 7 F. This difference may be more apparent in larger devices. While the 38 and 40 mm devices require 12 F in the Amplatzer, Occlutech, and Cocoon systems, these devices require 14 F in Lifetech CeraFlex (a 2 F increase in diameters).

ASDs may be closed during early childhood in patients for different reasons.<sup>13, 14</sup> A study reported that the most common indications of the need for ASD closure are right heart enlargement and growth retardation.<sup>15</sup> Growth rates may be more likely to approach normal development when cardiac defects are repaired early. Our data also suggest that success and complication rates among patients weighing 15 kg or less are similar to larger patients.

Fraisse et al<sup>16</sup> reported the success rates of transcatheter closure procedures in children weighing 15 kg or less in a multicenter study conducted in France. That study enrolled 35 patients but did not include data regarding the size of the defects repaired. In the present study, the mean diameter of defects was medium-wide (14–15 mm), but we also observed some larger defects, for which Amplatzer-like devices 30 and 34 mm in diameter were used. Petit et al<sup>15</sup>

reported a success rate of 79% in 53 patients younger than 4 years of age. Continuing efforts will be required to determine the appropriate age for ASD closure procedures about which there are not enough scientific clues. The major limitation is the sheath diameter, which could not tolerate the use of a larger sheath in small children. Nevertheless, we used 12 F sheaths in both patient groups (20, 24, and 26 mm Lifetech Ceraflex devices and 34 mm Cocoon devices needed a 12 F sheath in both groups) without significant complications. Diab et al<sup>17</sup> reported vascular intimal damage and iliac vein thrombosis in an infant undergoing transcatheter ASD closure. Therefore, one of the major limitations of transcatheter ASD closure in small children is clearly the sheath size. In addition, a 5.6-month-old boy with Down syndrome died 9 weeks after transcatheter ASD closure due to right heart failure and pulmonary hypertension in the series reported by Diab et al.<sup>17</sup> For this reason, we treated a patient with Down syndrome with pulmonary hypertension using a hand-made fenestration to the device.

The next largest case series in patients weighing less than 15 kg after our case series was reported by Bartakian et al.<sup>13</sup> The major complication rate in that study was reported to be 5.5% of 128 patients. In contrast, in the present case series, 2% of the procedures were unsuccessful in Group I, with 2.7% of the cases involving major complications. We observed no difference in the success rate or the complication incidence between the 2 groups. Bartakian et al<sup>13</sup> concluded that the rate of complication from ASD closure remains high in young patients, and they suggested that treatment be delayed until 4 to 5 years of age unless there is a clear necessity for intervention. Our study may differ from the study conducted by Bartakian et al<sup>13</sup> in several important aspects. Some

complications are also counted as unsuccessful procedures, potentially inflating the overall incident rate. Hence, we propose that delay of ASD closure is unnecessary in cases where a detailed assessment of the patient can be made prior to the procedure. Delayed ASD closure is particularly harmful in symptomatic cases. Indeed, the prior recommendation of ASD closure at 4 to 5 years of age is of largely historical significance and is not well supported given the widespread evidence of the safety and efficacy of ASD closure procedures in small children.<sup>13, 15-19</sup>

A multicenter study on 52 patients by Cardenas et al<sup>18</sup> concluded that ASD closure can be completed safely and successfully in patients weighing less than 15 kg or less, but suggested that ASD closure be conducted in asymptomatic children weighing at least 15 to 20 kg due to the high rate of minor complications. They also noted that the principal concern is not age but weight, which is a viewpoint shared by us. Therefore, most pediatric cardiologists consider 15 kg to be the lower limit for ASD closure. The present study involves a larger number of children weighing less than 15 kg.

Other limitations for ASD application in small children include damage to the cardiac structures due to the use of a device larger than the septum, which theoretically increases the possibility of erosion risk and the risk of rupture. Therefore, it is important to ensure that the left atrial disk size of the device is at least 3 to 4 mm smaller than the total septum diameter and to preserve portions of the septum. Total septum length is a critical factor. As Ammar and Kim et al<sup>1, 12</sup> stated, the device is not designed primarily for small children and little hearts, and a more sophisticated approach is appropriate. Our data are clearly consistent with these observations. Although the defect/weight

ratio in Group I was significantly higher than that in Group II, there was no significant difference between the groups in terms of the diameter of the devices used.

Hill et al<sup>20</sup> stated that the use of a Helex septal occluder (W. L. Gore & Associates, Flagstaff, AZ, USA) in small atriums may be effective in reducing erosion risk based on the results of a study in 34 patients weighing 20 kg or less. In the present study, the mean follow-up periods were longer than 3 years in both groups, and there were no incidents of erosion among our patients. Hill et al<sup>20</sup> also stated that retrieval of the Helex is easier in small children in the event of embolization. We retrieved embolized devices using a snare in 2 patients in Group I and Group II without incidents.

Although the transcatheter closure of secundum ASDs has been reported to reduce future arrhythmia risk, there have been cases in which progressive complete atrioventricular block developed after transcatheter closure.<sup>21</sup> The block did not improve in 1 case in this study even after the device had been retrieved.

## CONCLUSIONS

Transcatheter ASD closure can be a safe and effective procedure in symptomatic and asymptomatic children smaller than 15 kg, as well as in larger children. The key factors are patient selection, technique, and device selection during implantation, as well as the total septum length. Longer follow-up periods are necessary for late erosion risks. Moreover, multicentric studies need to clarify age recommendations vis-à-vis transcatheter ASD interventions.

## REFERENCES

1. Ammar RI, Hegazy RA. Transcatheter closure of secundum ASD using Occlutech Figulla-N device in symptomatic children

- younger than 2 years of age. *J Invasive Cardiol* 2013; 25: 76-79.
2. Bull C, Deanfield J, de Leval M, Stark J, Taylor JF, Macartney FJ. Correction of isolated secundum atrial septal defect in infancy. *Arch Dis Child* 1981; 56: 784-786.
  3. Baspinar O, Kervancioglu M, Kilinc M, Irdem A. Bioabsorbable atrial septal occluder for percutaneous closure of atrial septal defect in children. *Tex Heart Ins J* 2012; 39: 184-189.
  4. Baspinar O, Al-Hadidy KI, Kervancioglu M. Transjugular closure of a two-hole atrial septal defect in a child with iliac vein thrombosis. *Ann Pediatr Cardiol* 2013; 6: 185-187.
  5. Gokaslan G, Ustunsoy H, Deniz H, Ozcaliskan O, Yasim A, Baspinar O, et al. Urgent surgical management for embolized occluder devices in childhood: single center experience. *J Cardiothorac Surg* 2012; 7: 127.
  6. Radzik D, Davignon A, van Doesburg N, Fournier A, Marchand T, Ducharme G. Predictive factors for spontaneous closure of atrial septal defects diagnosed in the first 3 months of life. *J Am Coll Cardiol* 2013; 22: 851-853.
  7. Castaneda AR, Jonas RA, Mayer JE, Hanley FL: Atrial septal defect. In: *Cardiac surgery of the neonate and infant*. Philadelphia, PA: WB Saunders, 1994, pp.143.
  8. McMahon CJ, Feltes TF, Fraley JK, Bricker JT, Grifka RG, Tortoriello TA, et al. Natural history of growth of secundum atrial septal defects and implications for transcatheter closure. *Heart* 2002; 87: 256-259.
  9. Holzer R, Hijazi ZM. Interventional approach to congenital heart disease. *Curr Opin Cardiol* 2004; 19: 84-90.
  10. Vogel M, Berger F, Dahnert I, Ewert P, Lange PE. Treatment of atrial septal defects in symptomatic children aged less than 2 years of age using the Amplatzer septal occluder. *Cardiol Young* 2000; 10: 534-537.
  11. Butera G, De Rosa G, Chessa M, Rosti L, Negura DG, Luciane P, et al. Transcatheter closure of atrial septal defect in young children: results and follow-up. *J Am Coll Cardiol* 2003; 42: 241-245.
  12. Kim NK, Park SJ, Choi JY. Transcatheter closure of atrial septal defect: does age matter? *Korean Circ J* 2011; 41: 633-638.
  13. Bartakian S, Fagan TE, Schaffer MS, Darst JR. Device closure of secundum atrial septal defects in children <15 kg: complication rates and indications for referral. *J Am Coll Cardiol Cardiovasc Interv* 2013; 5: 1178-1184.
  14. Zaqout M, De Baets F, Schelstraete P, Suys B, Panzer J, Francois K, et al. Pulmonary function in children after surgical and percutaneous closure of atrial septal defect. *Pediatr Cardiol* 2010; 31: 1171-1175.
  15. Petit CJ, Justino H, Pignatelli RH, Crystal MA, Payne WA, Ing FF. Percutaneous atrial septal defect closure in infants and toddlers: predictors of success. *Pediatr Cardiol* 2013; 34: 220-225.
  16. Fraisse A, Losay J, Bourlon F, Agnoletti G, Lusson JR, Godart F, et al. Efficiency of transcatheter closure of atrial septal defects in small and symptomatic children. *Cardiol Young* 2008; 18: 343-347.
  17. Diab KA, Cao QL, Bacha EA, Hijazi ZM. Device closure of atrial septal defects with the Amplatzer septal occluder: safety and outcome in infants. *J Thorac Cardiovasc Surg* 2007; 134: 960-966.
  18. Cardenas L, Panzer J, Boshoff D, Malekzadeh-Milani S, Ovaert C. Transcatheter closure of secundum atrial defect in small children. *Cath Cardiovasc Interv* 2007; 69: 447-452.
  19. Narin N, Baspinar O, Pamukcu O, Sunkak S, Tuncay A, Tasci O, et al. Percutaneous ASD closure of children weighing less than 10 kg. *Acta Cardiol* 2019; 3: 1-6.
  20. Hill KD, Lodge AJ, Forsha D, Fleming GA, Green AS, Rhodes CF. A strategy for atrial septal defect closure in small children that eliminates long-term wall erosion risk. *Cath Cardiovasc Interv* 2013; 81: 654-659.
  21. Al-Anani SJ, Weber H, Hijazi ZM. Atrioventricular block after transcatheter ASD closure using the Amplatzer septal occluder: risk factors and recommendations. *Cath Cardiovasc Interv* 2010; 75: 767-772.