

# Transcatheter Closure of Atrial Septal Defect in Children: Single-Center Experience, Mid-Term Follow-up Results

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## What is already known on this topic?

- Transcatheter closure is a common technique used to treat atrial septal defects.
- Any measured diameter usually reflects the maximal diameter of the defect.
- There are few data available on the mid- and long-term tolerance of devices implanted in growing children.

## What does this study adds on this topic?

- The procedure complication rates differ according to the device type that is used for closure.
- Defect sizes that are calculated by transthoracic echocardiography, transesophageal echocardiography, and balloon-sizing are not statistically correlated with each other.
- Transcatheter closure of atrial septal defect can be performed safely in childhood.

## ABSTRACT

**Objective:** Atrial septal defect is a congenital heart disease usually diagnosed in childhood. This study aimed to evaluate the mid-term follow-up results of patients who underwent transcatheter closure of atrial septal defect by comparing the devices and methods used in the procedure and investigating the complications of this procedure in children.

**Materials and Methods:** This study evaluated 232 patient files retrospectively. Of the 232 patients, 24 were excluded from the study due to missing files or data. Also, patients with multi-fenestrated atrial septal defect and aneurismatic septal tissue were excluded from the study. The following data were evaluated: follow-up time, patient complaints, symptoms, transthoracic echocardiography, and transesophageal echocardiography findings (if performed), the size of the defect as measured by balloon-sizing, the size of the device used in the procedure, and major and minor complications.

**Results:** The study included 208 children who were diagnosed with atrial septal defect. The mean age of the patients was  $88.0 \pm 56.5$  months. Of the patients, 170 (81.7%) had no complaints. The success rate of the procedure was found to be 95.7%. While device embolization was the most common major complication, arrhythmia was the most common minor complication. The complication rate was statistically different according to the device type used in the procedure.

**Conclusion:** Transcatheter closure of atrial septal defect is a safe method for atrial septal defect closure in pediatric patients. The study found that defect diameters measured by different methods were not correlated with each other. The procedure complication rates differed according to device type.

**Keywords:** atrial septal defect, catheterization, congenital heart defect, medical device

## INTRODUCTION

Atrial septal defect (ASD) is common, accounting for approximately 8–10% of congenital heart diseases with a prevalence of approximately 56 per 100,000 live births.<sup>1</sup> The number of ASD diagnoses has increased lately, likely due to more frequent usage of transthoracic echocardiography (TTE), and the prevalence of ASD at birth is thought to be 1–2 per 1,000 live births.<sup>2</sup> The impact of race and ethnicity is not yet understood entirely.<sup>3</sup>

ASD closure can be performed by surgical sternotomy, thoracoscopic ASD closure, or transcatheter method. Although transcatheter closure of secundum ASD is preferable when possible, it is not backed by mortality data and that part ought to be respected in a scientific paper.<sup>4</sup> The first attempt at transcatheter ASD closure was performed by Mills and King in 1976.<sup>5</sup> Studies have shown that transcatheter closure of secundum ASD is less invasive and

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has lower complication risks and shorter duration of hospital stay compared with surgical closure.<sup>6,7</sup>

However, the published outcome data on transcatheter closure of ASD and mid-term follow-up in children have been limited. Thus, the objective of this study is to understand the mid-term follow-up results of transcatheter closure of ASD on children by determining the overall procedural complications and comparing device brands and their complication rates. The hypothesis of this study is that although transcatheter closure of ASD is a safe method for children, type of the devices used in the procedure may affect the complication rates differently.

## MATERIALS AND METHODS

### Study Design

This retrospective cross-sectional study evaluated the follow-up results after transcatheter ASD closure for patients who were admitted to the Division of Pediatric Cardiology of the authors' medical center from 2008 to 2017. This analysis was performed to understand the factors affecting the success and complications of the procedure. Of 248 files, 232 were appropriate for evaluation; 24 were not reviewed because of insufficient data or because their files could not be found in the archives. Consequently, 208 patients were included in the study. Ethical approval was obtained from Istanbul University, Faculty of Medicine Ethics Committee (Approval Number: 2018/1286).

The patients were evaluated using 2D TTE and color doppler TTE for the diagnosis. In all patients, the frontal and caval views were evaluated by the subxiphoid view while apical four-chamber, parasternal long-axis, and short-axis were evaluated by the precordial position. The apical four-chamber view evaluated the defect's margin to the pulmonary vein, coronary sinus, and atrioventricular (AV) valve. The defect's margin to

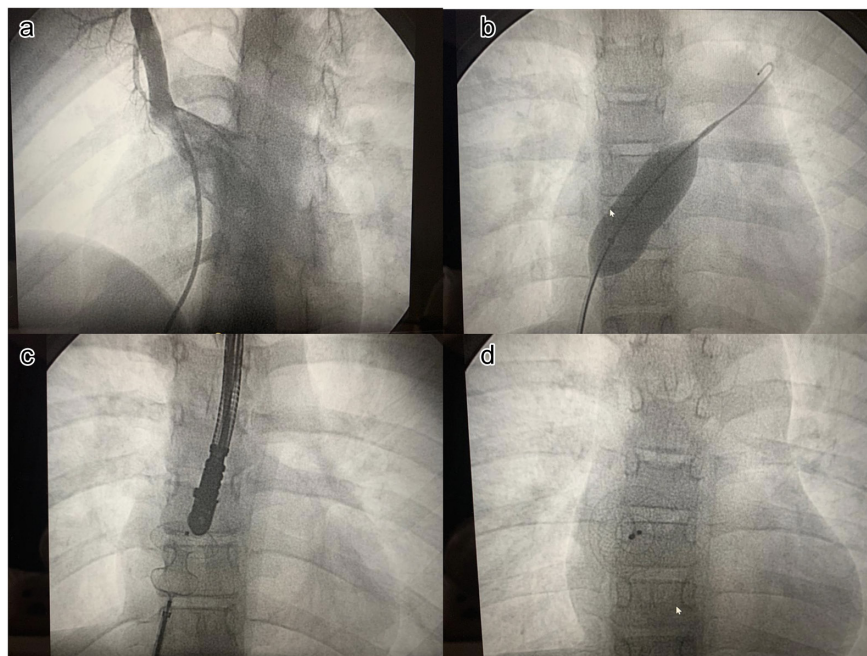
the superior and inferior vena cava (IVC), as well as the anterior and posterior rims, was calculated by the aortic view. Rims surrounding the defect were evaluated as "short rims" if they measured under 5 mm.

### Procedure

Patients older than 2 years who weighed more than 15 kg were eligible for ASD closure. Additionally, patients assessed by TTE whose findings supported dilatation in the right atrium and ventricle or showed a pulmonary/systemic flow rate higher than 1.5 were included. To be eligible for transcatheter ASD closure, the patients were required to have a rim longer than 5 mm between the ASD and the AV valve, IVC, superior vena cava (SVC), coronary sinus, and pulmonary vein. Additionally, one of the posterior or inferior rims had to be longer than 2 mm. Patients who had multi-fenestrated ASD, aneurysmatic septal tissue, large defect, or short rims were referred to the departments of cardiovascular surgery for closure.

Transesophageal echocardiography (TEE) was performed on 168 patients before or after the procedure. The highest number calculated by TTE and TEE before the procedure was accepted as the widest diameter of the defect. Only conventional angiography was performed on patients who did not meet the criteria for transcatheter ASD closure, and these patients were excluded from the study. The stretched diameter of the defect was measured by balloon-sizing. The balloon was inflated to the point where color flow across the ASD was absent. Balloon-sizing was performed on all the patients. Furthermore, diagnostic right heart catheterization was done in all patients before the procedure. But pulmonary vein injection is not routinely applied (Figures 1 and 2).

Patients were followed up in the hospital for 72 hours after the procedure. Early evaluations with TTE after the procedure was



**Figure 1** Angiographic procedure and device images. (a) Secundum ASD view on the injection of the right upper pulmonary vein. (b) Balloon-sizing. (c) Closing procedure with Amplatzer® Septal Occluder. (d) Image of the device after the procedure. ASD, Atrial septal defect.



**Figure 2.** Angiographic view of placement of Solysafe® Septal Occluder over the guide wire to the defect area.

at 24th and 72nd hours after closure. Follow-up appointments were planned at 1 month and 6 months after the procedure. After 6 months, patients were evaluated annually with TTE.

**Devices**

The following devices were used for the procedure: Amplatzer® Septal Occluder (AGA Medical Corp., Golden Valley, Minnesota, Minn, USA), Occlutech® Occluder (Occlutech GmbH, Jena, Germany), Solysafe® Septal Occluder (Swissimplant AG, Solothurn, Switzerland), Cera® Occluder (Lifetech Scientific Shenzhen Co., Ltd., Shenzhen, China), and Biostar® Septal Occluder (NMT Medical, Boston, Massachusetts, Mass, USA).

Although all measurement values are taken into account, patient-based device selection was made by considering the total septum diameter and defect type association with the age of the patient. Balloon-sizing measurement value was evaluated as a primary value in patients without a floppy septum.

**Statistical Analysis**

Frequency and percentage values were given for categorical variables. Mean, standard deviation, median, minimum, and maximum values were given for continuous variables. The normal distribution test of continuous variables was performed by using the Kolmogorov-Smirnov test. Spearman correlation analysis was performed to detect correlational relations between variables where the assumption of the normal distribution is not provided. The Statistical Package for Social Sciences version 23.0 software (IBM Corp.; Armonk, NY, USA) was used for the analysis. *P* < .05 was considered as statistically significant.

**RESULTS**

**Demographical Characteristics**

Of the 208 patients diagnosed with ASD who were included in this study, 83 (39.9%) were male and 125 (60.1%) were female.

The ages of the patients admitted to the clinic ranged from 3 days to 220 months, with an average age of 88.0 ± 56.5 months. The average age of patients diagnosed with ASD was 80.9 ± 58.2 months (range, 3 days to 209 months). Of the total patients, 132 (63.5%) were diagnosed and followed up in other medical centers and only referred for the procedure. The ages of patients at procedure ranged from 26 to 211 months, with an average age of 107.1 ± 42.4 months.

Of the patients, 7 (3.4%) were diagnosed with heart failure, while 201 (96.6%) had no symptoms of heart failure. Of those diagnosed with heart failure, 3 were diagnosed with severe heart failure and needed combined medical therapy. Regarding complaints, 170 (81.7%) patients had no complaints, while 38 (18.3%) patients had complaints related to ASD. The distribution of disease characteristics is shown in Table 1.

**PROCEDURAL RESULTS**

The results of TTE found the median defect size to be 12.6 ± 3.7 mm (range, 4.5–24 mm), and the mean diameter measured with TEE was 13.7 ± 3.8 mm (range, 7–30 mm). According to balloon-sizing, the mean diameter was 15.6 ± 4.4 mm (range, 9–33 mm). The defects sizes that were measured by different methods are detailed in Table 2 and Figures 3.

		n (%)
<b>Heart failure before the procedure</b>	No	201 (96.6)
	In infancy*	7 (3.4)
<b>Severity of heart failure (n = 7)</b>	Mild	4 (57.1)
	Severe	3 (42.9)
<b>Complaints before procedure</b>	No	170 (81.7)
	Yes	38 (18.3)
<b>Additional cardiac anomalies</b>	No	170 (81.7)
	Yes	38 (18.3)
	<b>Additional structural anomalies</b>	27 (71.1)
	<b>Atrial Aneurism</b>	7 (18.4)
	<b>Cardiomyopathy</b>	1 (2.6)
	<b>RBBB</b>	1 (2.6)
	<b>AV block</b>	1 (2.6)
	<b>SVT</b>	1 (2.6)
<b>Extracardiac comorbidities and syndromes</b>	No	184 (88.5)
	Yes	24 (11.5)
	<b>Orthopedic diseases</b>	1 (4.2)
	<b>Hematological-oncological diseases</b>	3 (12.5)
	<b>Neurological diseases</b>	4 (16.6)
	<b>Obesity</b>	1 (4.2)
	<b>Down syndrome</b>	6 (25.0)
	<b>Other syndromes</b>	5 (20.8)
	<b>Preterm birth history</b>	3 (12.5)
	<b>Situs inversus totalis</b>	1 (4.2)

AV, atrioventricular; RBBB, right bundle branch block; SVT, supraventricular tachycardia  
\*Age < 1 year

		n (%)
<b>Defect size measured by TTE (mm)</b>	<i>Min-Max (Median)</i>	6-24 (12)
	<i>Mean ± SD</i>	12.60 ± 3.77
<b>Defect size measured by TEE (mm)</b>	<i>Min-Max (Median)</i>	7-30 (13)
	<i>Mean ± SD</i>	13.78 ± 3.85
<b>Defect size measured by balloon-sizing (mm)</b>	<i>Min-Max (Median)</i>	9-33 (14)
	<i>Mean ± SD</i>	15.64 ± 4.45
<b>Devices</b>	<b>No procedure</b>	22 (10.6)
	<b>Amplatzer®</b>	92 (44.2)
	<b>Occlutech®</b>	53 (25.5)
	<b>Solysafe®</b>	24 (11.5)
	<b>Cera Occluder®</b>	14 (6.8)
	<b>Biostar®</b>	3 (1.4)
<b>Size of device (mm) (n = 186)</b>	<i>Min-Max (Median)</i>	10-35 (16)
	<i>Mean ± SD</i>	17.44 ± 4.95
<b>Complication (n = 186)</b>	<b>No</b>	173 (95.7)
	<b>Major</b>	5 (3.0)
	<b>Minor</b>	7 (4.1)

TTE, transthoracic echocardiography; TEE, transesophageal echocardiography.

Major complications, which occurred in only 5 (2.7%) of the patients, included device embolization, new valvular insufficiency, and thromboembolism. One patient had a stroke 24 hours after the procedure, while another patient developed moderate tricuspid insufficiency due to device interaction with the tricuspid valves. Due to device embolization, 2 patients needed urgent cardiovascular surgical intervention right after the procedure, and in 1 patient, the embolized device was caught by a snare. No deaths, wire frame fractures, or device erosion occurred. Headache, arrhythmia, and thrombus-associated pericardial effusion were classified as minor complications which occurred in 7 patients. The procedure was cancelled for 23 (11.1%) patients. The reasons for cancellation, complications, complaints, and follow-up periods are detailed in Table 3. Complication rates were different when different devices were used for the procedure. When evaluated to total case and complication rates, Amplatzer® Septal Occluder and Occlutech® Occluder have the lowest major complication

rates as compared with the other brands (Table 4). As Biostar® Septal Occluder has the lowest usage rate, reliable evaluation couldn't be made.

**DISCUSSION**

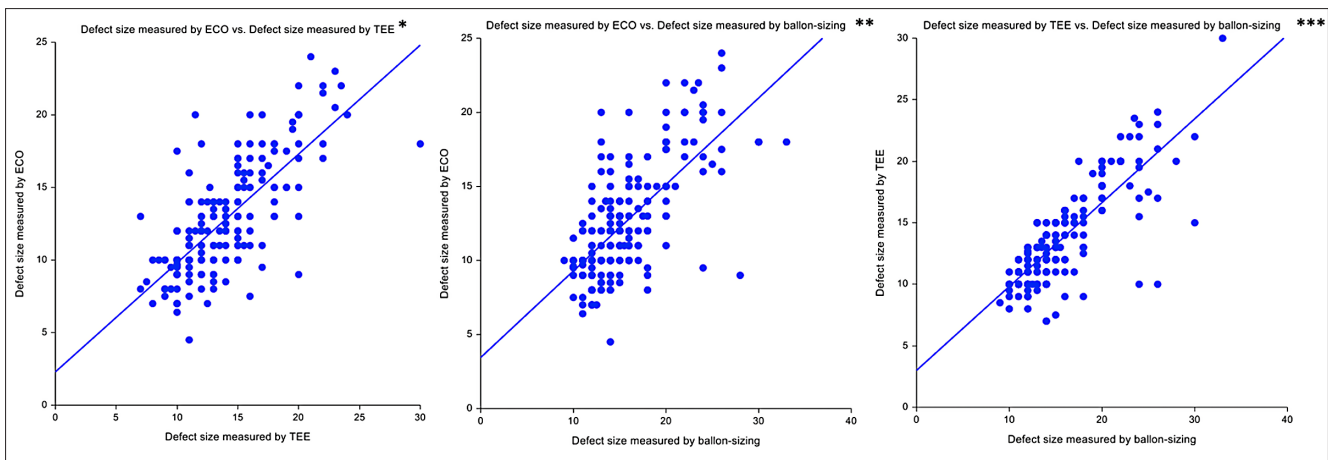
Transcatheter closure of ASD can be performed safely in childhood. In this study, it is found that procedure complication rates differ according to the device type.

ASD prevalence at birth is 1-2 per 1,000 live births, but its distribution by race and ethnicity is still under study.<sup>2,3</sup> The female to male ratio has been found to be 2:1.<sup>8</sup> The current study also determined that ASD prevalence was higher in females than males, but it found a rate of 1.5:1.

In the current study, the mean age at hospital admission was 80.9 ± 58.2 months, and the median age was 74 months. The youngest patient admitted to the clinic was 3 days old. The mean age at diagnosis of ASD was previously found to be 4.5 years.<sup>9</sup> In the current study, the clinic had older patients in admission, likely because the patients were referred from other clinics for the procedure.

Children diagnosed with isolated secundum ASD are often asymptomatic, and the only finding of physical examination is cardiac murmur. Isolated secundum ASDs rarely develop heart failure. In the current study, only 3.4% of the patients developed heart failure, a rate that was consistent with the literature.<sup>10</sup> Of the patients in the study, 7 had heart failure, 3 of whom were classified as having severe heart failure due to their need for combined medical treatment. Therefore, although heart failure in infancy is rare in patients with isolated secundum ASD, all patients should be evaluated for heart failure.

In the present study, the defect sizes as calculated by TTE, TEE, and balloon-sizing were not found statistically correlated. Some studies have stated that balloon-sizing might not be essential for transcatheter closure of ASD and have presented TEE-guided sizing as a successful alternative to balloon-sizing.<sup>11</sup> Additional recent studies have suggested intracardiac TEE-guided closure without balloon-sizing.<sup>12</sup>



**Figure 3.** Distribution of defect sizes measured by ECO, TEE, and balloon-sizing (Spearman Correlation Analysis \* $P < .001$ ,  $\rho = 0.720$ , \*\* $P < .001$ ,  $\rho = 0.654$ , \*\*\*  $P < .001$ ,  $\rho = 0.776$ ).

**Table 3.** Distribution of Post-procedural Characteristics

		n (%)
<b>Canceled procedures</b>	<b>No</b>	186 (89.4)
	<b>Yes</b>	22 (10.5)
	<b>Unable to place the device despite recurrent trials</b>	1 (4.5)
	<b>Unable to place the device due to VCI rim deficiency</b>	6 (27.2)
	<b>Insufficient total interseptum</b>	12 (54.4)
	<b>Floppy interseptum</b>	3 (13.6)
<b>Post-procedural complaints or complications</b>	<b>No</b>	173 (93.5)
	<b>Yes</b>	12 (6.48)
	<b>Headache</b>	3 (1.62)
	<b>Arhythmia</b>	3 (1.62)
	<b>Device embolization</b>	3(1.62)
	<b>Tricuspid insufficiency</b>	1 (0.54)
	<b>Neurological complications—trombus associated</b>	1 (0.54)
	<b>Pericardial effusion (Mild)</b>	1 (0.54)
<b>Follow-up period (months)</b>	<i>Min-Max (Median)</i>	0.03–208.1 (52.4)
	<i>Mean ± SD</i>	57.38 ± 50.83
<b>Post-procedural follow-up period (months)</b>	<i>Min-Max (Median)</i>	0–117.1 (29.4)
	<i>Mean ± SD</i>	36.58 ± 34.20

In the present study, 22 procedures were canceled in the procedure room mainly due to total interseptum deficiency or IVC rim deficiency. This was consistent with the literature; Amedro et al<sup>13</sup> emphasized that transcatheter closure of ASDs with posterior-inferior rim deficiency should not be recommended.

Bergersen et al introduced a classification of adverse events in congenital cardiac catheterization, subdivided into 5 levels according to their severity. This classification was modified to develop the risk adjustment tool CHARM (Catheterization for Congenital Heart Disease Adjustment for Risk Method).<sup>14</sup>

Abacı et al<sup>15</sup> stated their success rate for transcatheter ASD closure was 96.9%; that of the current study was 95.7 and therefore compatible with the literature. In both the study by Abacı et al.<sup>15</sup> and one by Chessa et al.<sup>16</sup> who performed a similar study with adults, device embolization was indicated as a major complication, just as in the present study. In the present study, the device was embolized in 3 cases, while tricuspid insufficiency developed in 1 patient after the procedure.

Atrio-ventricular block and arrhythmias are the most frequent complications in adults after transcatheter ASD closure, and these might lead to a need for a heart pacemaker. Alnasser et al<sup>17</sup> evaluated long-term complications in adults; atrial arrhythmia occurred in 6.5% of their participants, while atrial fibrillation occurred in 4.9%. The current study evaluated arrhythmias; this minor complication was the most frequent complication found in the study and was encountered in 3 patients. All of the patients were diagnosed 72 hours after the procedure and responded well to medical therapy, and none of them needed a heart pacemaker.

Kato et al<sup>18</sup> found new-onset migraine after transcatheter ASD closure in 1 patient; likewise, 3 of the patients in the present study developed headaches after the procedure, which were diagnosed as migraines by a child neurology consultant. In contrast, although Mortelmans et al<sup>19</sup> found that transcatheter ASD closure was not related to a decrease in the prevalence of migraines, the frequency of migraine attacks decreased significantly in a subgroup of patients who had suffered from a typical migraine before ASD closure.

In the current study, patients received prophylactic heparin treatment before the procedure, but 1 patient had a stroke due to mid-cerebral arterial thrombosis despite prophylaxis. Although the Division of Pediatric Hematology was consulted and treatment of the patient started immediately, the patient's muscle weakness was permanent. Thromboembolism is a rare complication of transcatheter ASD closure procedure but may lead to serious results and permanent damages in patients, which are more often seen in adult patients. Abacı et al<sup>15</sup> indicated thromboembolic diseases as the most common complication of transcatheter ASD closure complication; in their study, 1.3% of adult patients had cerebrovascular disease after the procedure.

Pericardial effusion that responds well to anti-inflammatory drugs was seen in one patient in the present study and was categorized as a minor complication. The patient was fully recovered after 1 year of medical therapy. Wilson et al<sup>20</sup> studied 227 patients, including both adults and children, and also found 1 patient with pericardial effusion. Other studies have indicated complications like hematoma in the procedural area, pressure on the sciatic nerve, nickel hypersensitivity, AV fistula, wire frame fractures, cardiac tamponade, and cardiac perforation<sup>8,20</sup>; however, none of these were found in the present study.

The mean total follow-up period and the mean follow-up period after the procedure were 57.3 ± 50.8 months and 36.5 ± 34.2 months, respectively. The maximum follow-up

**Table 4.** Complication Rates of Different Transcatheter ASD Closure Devices

		Complication		
		No	Major	Minor
<b>Device; n (%)</b> (n = 186)	<b>Amplatzer®</b>	88 (50.57)	1 (20)	3 (42.86)
	<b>Occlutech®</b>	51 (29.31)	1 (20)	1 (14.29)
	<b>Solysafe®</b>	21 (12.07)	2 (40)	1 (14.29)
	<b>Cera Occluder®</b>	12 (6.9)	1 (20)	1 (14.29)
	<b>Biostar®</b>	2 (1.15)	0 (0)	1 (14.29)

ASD, atrial septal defect.

durations were 208.1 months and 117.1 months, respectively. The mean follow-up period after the procedure was shorter because a group of patients who consulted for the procedure from other clinics continued their after-procedure follow-ups in the clinics from which they were referred. No other study included only child patients and had as broad a scope as the present study; therefore, the follow-up periods could not be compared with other research.

In the present study, Amplatzer® Septal Occluder, Occlutech® Occluder, Solysafe® Septal Occluder, Cera® Occluder, and Biostar® Septal Occluder devices were used for the procedures. Various studies have compared the brands of ASD closure devices, their performance on large defects, and their complication rates. However, most of these studies were supported or sponsored by the device brands. In the present study, 5 different device brands were used in 186 cases. De Wolf<sup>21</sup> stated that CardioSEAL®/STARflex® devices have a higher risk of device embolization, and this finding was supported by the present study. Knirsch et al<sup>22</sup> stated that long-term follow-up of procedures performed with Solysafe® device revealed abnormalities with the device and faced an increased risk of developing new abnormalities each year. In the present study, the complication risk of Solysafe® devices was found to be significantly higher than that of other devices. Roymanee et al<sup>23</sup> compared the success and complications rates of Amplatzer® and Occlutech®; these brands were the most frequently used devices in the current study. They found both devices safe and effective for transcatheter closure of ASD.

In summary, the present study was unique because it investigated one of the largest child populations in the literature. No other studies that had a population of only children or as long a period of follow-up were found in the literature. However, the study also had some limitations. Because it was retrospective, some of the patient files were unavailable, and some data were missing. Second, all patients were evaluated by 2D-TTE and color doppler, as 80.7% of patients appraised with TEE. But 3D-TTE evaluation was not performed in any of the patients. Therefore, these patients were excluded from the study. Additionally, the study discussed the mid-term follow-up results, so evaluation of long-term results and complications could be more comprehensive.

## CONCLUSION

The rate of congenital heart diseases is increasing, and this presents an important public health problem. Transcatheter ASD closure can be done safely in the pediatric population. This study found that device type affects the complication rates in mid-term follow-up in children.

**Ethics Committee Approval:** This study was approved by Ethics committee of İstanbul University, Faculty of Medicine (Approval Number: 2018/1286).

**Informed Consent:** Written informed consent was obtained from the patients who agreed to take part in the study.

**Peer-review:** Externally peer-reviewed.

**Author Contributions:** Concept – Y.Ş.Ö., K.N.; Design – K.N., A.D.; Supervision – Y.Ş.Ö., Ü.A., R.E.; Funding – K.N., R.E., A.D.; Materials – Ü.A., Y.Ş.Ö.; Data Collection and/or Processing – Y.Ş.Ö., K.N., Ü.A.; Analysis and/or Interpretation – Y.Ş.Ö., K.N.; Literature Review – Y.Ş.Ö., R.E.; Writing – K.N., Y.Ş.Ö.; Critical Review – K.N., Y.Ş.Ö., A.D.

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