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Transthoracic Echocardiography and Fluoroscopy Guided Transcatheter Atrial Septal Defect Closure with Device in Children, Adolescents, and Young Adults

Çocuklarda, Ergenlerde ve Genç Yetişkinlerde Transtorasik Ekokardiyografi ve Floroskopi Kılavuzluğunda Cihazla Transkateter Atriyal Septal Defekt Kapatılması

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ABSTRACT

Objective: The aim of this study was to evaluate the safety and efficacy of transcatheter atrial septal defect (ASD) closure guided by fluoroscopy and transthoracic echocardiography (TTE) and to present our experiences.

Material and Methods: In this study, we evaluated 108 patients' files taken to the catheter laboratory for transcatheter ASD closure retrospectively. The procedure was abandoned in ten patients because of septum device disproportion (6) and deficient rims (4), mainly inferior vena cava rim.

Results: Transcatheter ASD closure guided by TTE was performed in 98 patients (59 female). The mean age of patients was 9.5±6 years (2.6-46), and the mean weight was 30.3±15.3kg (12-80). TTE-guided ASD closure was successfully performed in 92 of 98 (94%) patients. The median largest ASD diameter measured by TTE was 10.75 mm (interquartile range (IQR) 9.12-14. The median stretched balloon diameter measured by fluoroscopy was 14 mm (IQR 12.4-18). The median device waist diameter was 14 mm (IQR 13-18), the median device left atrial (LA) disk diameter was 28 mm (IQR 26-31), and the median ratio of LA disc diameter to total septal diameter was 75% (IQR 68-81). The median fluoroscopy and procedural times were 8 minutes (IQR 5.6-13.75) and 36.5 minutes (IQR 30-49) respectively.

Conclusion: Transcatheter ASD closure guided by TTE and fluoroscopy is safe and effective in children, adolescents, and young adults.

Key Words: Atrial septal defect, Transthoracic echocardiography, Transcatheter ASD closure

ÖZ

Amaç: Bu çalışmanın amacı, floroskopi ve transtorasik ekokardiyografi (TTE) eşliğinde transkateter atriyal septal defekt (ASD) kapatılmasının güvenlik ve etkinliğini değerlendirmek ve deneyimlerimizi sunmaktır.

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Ethics Committee Approval / *Etik Kurul Onayı*: This study was conducted in accordance with the Helsinki Declaration Principles. The study was approved by the Ankara City Hospital Ethics Committee (E2-22-1688/27.04.2022).

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Gereç ve Yöntemler: Bu çalışmada transkateter ASD kapatılması için kateter laboratuvarına alınan 108 hastanın dosyası geriye dönük olarak incelendi. On hastada septum/cihaz orantısızlığı (6) ve başta vena cava inferior rimi olmak üzere eksik rimler (4) nedeniyle işlemden vazgeçildi.

Bulgular: Toplam 98 hastaya (59 kadın) TTE rehberliğinde transkateter ASD kapatma uygulandı. Hastaların ortalama yaşı 9.5 ± 6 yıl (2.6-46) ve ortalama ağırlığı 30.3 ± 15.3 kg (12-80)'di. TTE kılavuzluğunda ASD kapatma 98 hastanın 92'sinde (%94) başarıyla uygulandı. TTE ile ölçülen en büyük ASD çapı ortanca değeri 10.75 mm (çeyrekler arası aralık (ÇAA) 9.12-14)'dü. Floroskopi ile ölçülen gerilmiş balon çapı ortanca değeri 14 mm (ÇAA 12.4-18)'di. Ortanca cihaz bel çapı 14 mm (ÇAA 13-18), ortanca cihaz sol atriyal (SlA) disk çapı 28 mm (ÇAA 26-31) ve SlA disk çapının toplam septal çapa oranı ortanca değeri %75 (ÇAA 68-81)'di. Ortanca floroskopi ve işlem süreleri sırasıyla 8 dakika (ÇAA 5.6-13.75) ve 36.5 dakika (ÇAA 30-49)'du.

Sonuç: TTE ve floroskopi kılavuzluğunda transkateter ASD kapatılması çocuklarda, ergenlerde ve genç erişkinlerde güvenli ve etkilidir.

Anahtar Sözcükler: Atriyal septal defekt, Transtorasik ekokardiyografi, Transkateter ASD kapatma

INTRODUCTION

Successful nonsurgical closure of atrial septal defect (ASD) was first reported in 1974 by King and Mills (1). Today, transcatheter device closure of secundum ASDs has become the preferred method of treatment over surgery in suitable anatomies (2,3).

Echocardiography guidance is critical in the transcatheter closure of ASDs (4). Correct device selection requires careful evaluation of defect size, morphology, and rims with echocardiography and balloon sizing. Also, echocardiography for allows proper positioning of the device in the defect and determining any residual shunts, obstruction to venous inflow, and atrioventricular valve regurgitation.

Transesophageal echocardiography (TEE) or intracardiac echocardiography (ICE) were widely used to guide the procedure (5,6). However, since patients cannot tolerate TEE, it is usually performed under general anesthesia and endotracheal intubation. Also, TEE use may lead to oropharyngeal and oesophageal traumas (7-9). ICE is expensive and still large, creating a risk of vascular injury, especially in small children (10)

However, comparative studies are showing that transthoracic echocardiography (TTE) can be considered an effective alternative to TEE for the evaluation and guidance of pediatric ASD closure (11, 12).

Herein, we present a single center's experience on TTE guidance in transcatheter ASD closure.

MATERIALS and METHODS

Study population

This was a retrospective study including all patients who had cardiac catheterization for ASD closure in the pediatric cardiology department of Ankara City Hospital, University of Health Sciences between December 2019 and March 2022. The study was approved by the Ankara City Hospital Ethics Committee (E2-22-1688/27.04.2022).

Patient records were reviewed for demographic data also including previous echocardiograms and catheterization reports and angiograms. Patients' age, weight, height, ASD diameter, total septal diameter, balloon-stretched ASD diameter, left atrium (LA) disk diameter of the device, type of device, procedure, and fluoroscopy time were all recorded.

Length of follow-up and complications including device migration/ embolization, residual shunt, device-related cardiac perforation, valve regurgitation, endocarditis, thromboembolism, conduction disorders, hemolysis, stroke, and migraine-like headaches associated with nickel allergy were also recorded.

For transcatheter ASD closure under the guidance of TTE, 108 consecutive patients with a definite diagnosis of secundum type ASD were admitted to the catheterization laboratory at our institute. The procedure was abandoned in ten patients because of septum device disproportion (6) and deficient rims (4), mainly inferior vena cava rim. Therefore, TTE-guided transcatheter ASD closure was performed on 98 patients.

Pre-interventional TTE evaluation

Cardiac anatomy was evaluated by 2D-TTE using a Vivid-S60N machine (General Electric, Norway) before the procedure in all patients.

A detailed 2D-TTE was performed using standard protocol for the atrial septal and defect anatomy including measurement of defect size, its rims, and total septal length in different views; subxiphoid long-axis (frontal) or left anterior oblique, subxiphoid short-axis (sagittal), apical four-chamber and parasternal short-axis. The defect was measured in each of these views and a maximum defect diameter was determined. The atrial septal rims were also measured in these views (13).

The exclusion criterion for TTE-guided transcatheter ASD closure was poor transthoracic acoustic windows.

The interventional procedure, TTE assessment during the procedure

The Vivid-7 machine (General Electric, Norway) was used for TTE assessment during the procedure in all patients. If the images from the initial diagnostic TTE were not considered adequate, additional TTE imaging was performed in the catheterization laboratory before the procedure. This was carried out following induction with general anesthesia and before the patient was prepared.

In all patients, a sizing balloon catheter was inflated at the defect level until a waist was detected in the middle of the balloon. The waist was measured and calibrated on the sine-angiographic frame. These measurements were used to determine the diameter of the ASD occluding device. An identical device with the stretched ASD diameter was used in patients with sufficient rims, whereas 1 to 2 mm larger devices were selected in patients with borderline ASD rims.

The implant procedure was guided by fluoroscopy. In addition, gently pulling and pushing the delivery system were done to ensure a stable position. Some different deployment maneuvers, such as rapid deployment technique, left atrial roof technique or right upper pulmonary vein technique were used in cases where the standard deployment maneuvers have failed. Once the device was in place and felt to be in a good position, the drape was pulled back, allowing the echocardiographers to access the chest to perform a brief assessment of the device. If TTE imaging was reassuring and confirmed an adequate positioning, the patient was re-draped, and the device was released under fluoroscopic observation.

Oximetric, hemodynamic and angiographic studies were performed only if there was an additional cardiac anomaly detected or suspected in echocardiography (eg a partially pulmonary venous connection or pulmonary hypertension).

Procedural success was defined as the presence of all three following criteria: successful device delivery without peri-procedural complications; well-positioned device as assessed by TTE after 6 and 24 hours with no device migration; and hospital discharge on the first day after the procedure.

Devices

We used Amplatzer Septal OccluderTM (Abbott St. Paul, MN, USA) in 86 patients, Amplatzer Multi-fenestrated Septal Occluder (AGA Medical Corporation, Golden Valley, MN, USA) in 1 patient, Cera Septal Occluder™ (CSO, Lifetech Scientific Corporation, Shenzhen, China) in 2 patients, MemoPart™ Atrial Septal Occluder (MASO, Shanghai Shape Memory Alloy Co., Ltd. Shanghai, China) in 9 patients.

Follow-up

Aspirin was given in a dose of 3–5 mg/kg until 6 months after closure. TTE was performed immediately after the procedure, at the 24th hour, and 1, 3 and 6 months after the procedure in all patients to systemically evaluate the therapeutic effects and complications of transcatheter ASD closure. A residual shunt was considered if Doppler color flow mapping showed a left-to-right shunt across the interatrial septum.

Complications

Cardiac erosion, pericardial effusion, air embolus, device-related valvular regurgitation, thromboembolism, pulmonary edema, stroke, atrioventricular block, major atrial arrhythmias (minor transient short-term atrial arrhythmias not included) or ventricular arrhythmias, hemolysis, and infective endocarditis were considered major complications at peri-procedural or follow-up.

Statistical analysis

Statistical Package for the Social Science (SPSS_17.0.1 for Windows; SPSS Inc) was used for statistical analysis. The normal distribution test of continuous variables was performed by using the Shapiro-Wilk test. Spearman correlation analysis was performed to detect correlational relations between variables where the assumption of the normal distribution is not provided. Normally distributed continuous data were presented as mean ± standard deviation (SD) (minimum-maximum) and the nonnormally distributed continuous data were reported as median {interquartile range (IQR)}. Categorical data are presented as numbers (n) and percentages (%). Statistical significance was defined as a two-tailed p value of<0.050.

RESULTS

Transcatheter ASD closure guided by TTE was performed in 98 patients (59 female). The mean age of patients was 9.5±6 years (2.6-46), the mean weight was 30.3±15.3 kg (12-80), the mean

Table I: General characteristics of the patients.

	Patients (n=98)
Age (years)	9.5±6 (2.6-46)
Gender (female) number (%)	59 (59.5%)
Body weight (kg)	30.3±15.3 (12-80)
Height (cm)	129±21 (82-173)
BSA (m^2)	1±0.34 (0.5-1.9)

Mean ± SD (min-max), or n (%) ***BSA:*** *body surface area*

Table II: Procedural characteristics and outcomes

	Patients (n=98)
Procedural success n %	92 (94%)
ASD diameter by TTE (mm)	10.75 (9.12-14)
Total septal diameter (mm)	39 (34-42.75)
ASD diameter/ Total septal ratio (%)	28 (24-36)
Multipl ASD n (%)	6 (6.1%)
Balloon-stretched diameter (mm)	14 (12.4-18)
Balloon-stretched diameter index (mm/m^2)	15 (11.5-20)
Device waist diameter (mm)	14 (13-18)
Device LA disk diameter (mm)	28 (26-31)
Device LA disk / Total septal ratio (%)	75 (68-81)
Fluoro time (min)	8 (5.6-13.75)
Procedure time (min)	36.5 (30-49)
Length of follow-up (months)	9.6±7.6 (2-28)

Values are mean±SD (minimum-maximum) or median (interquartile range), n (%). ***ASD:*** *atrial septal defect,* ***LA:*** *left atrial,* ***TTE:*** *transthoracic echocardiography*

Table III: Procedural and Follow-up complications

	Patients (n=98)
Device migration	0
Residual shunt	7 (7.6%)
Device-related cardiac perforation	0
Device -related valve regurgitation	0
Device -related endocarditis	1 (1.1%)
Device -related thromboembolism	0
Device -related major conduction disorders	0
Device -related hemolysis	0
Stroke	0
Migraine-like headaches associated with nickel allergy	1 (1.1%)

height was 129±21 cm (82-173) and the mean body surface area (BSA) was 1±0.34 m^2 (0.5-1.9) (Table I).

Procedural characteristics and outcomes are shown in Table II. TTE-guided ASD closure was successfully performed in 92 of 98 (94%) patients. The median largest ASD diameter measured by TTE was 10.75 mm (IQR 9.12-14), the median total septal diameter measured by TTE was 39 mm (IQR 34-42.75), and the median ratio of ASD diameter to total septum diameter was 28% (IQR 24-36). The median device waist diameter was 14 mm (IQR 13-18), the median device left atrial (LA) disk diameter was 28 mm (IQR 26-31), and the median the ratio of LA disc diameter to total septal diameter was 75% (IQR 68-81). The median stretched balloon diameter measured by fluoroscopy was 14 mm (IQR 12.4-18). The median fluoroscopy and procedural times were 8 minutes (IQR 5.6-13.75) and 36.5 minutes (IQR 30-49) respectively. The mean duration of follow-up for our patients was 9.6±7.6 months (2-28 months).

In two patients, pulmonary balloon valvuloplasty was performed in addition to transcatheter ASD closure.

TTE-guided transcatheter ASD closure was performed in 6 (6.1%) patients with multiple ASDs (Table II). Four of these ASDs were closed successfully, only one had a residual shunt. In patients with multiple ASD, ballon sizing was performed through the largest defect, and this defect was closed in such a way that the discs would cover the other defects as much as possible.

Complications during the procedure and follow-up are shown in Table III. A mild residual shunt was detected immediately after the procedure in 7 of the patients who underwent successful transcatheter ASD closure. During the follow-up, it was determined that the residual shunt improved in two of these patients.

A patient who underwent successful ASD closure presented with fever four days after the implantation. Acute phase reactants were increased, and also three consecutive blood cultures were positive (*Staphylococcus aureus*). There was

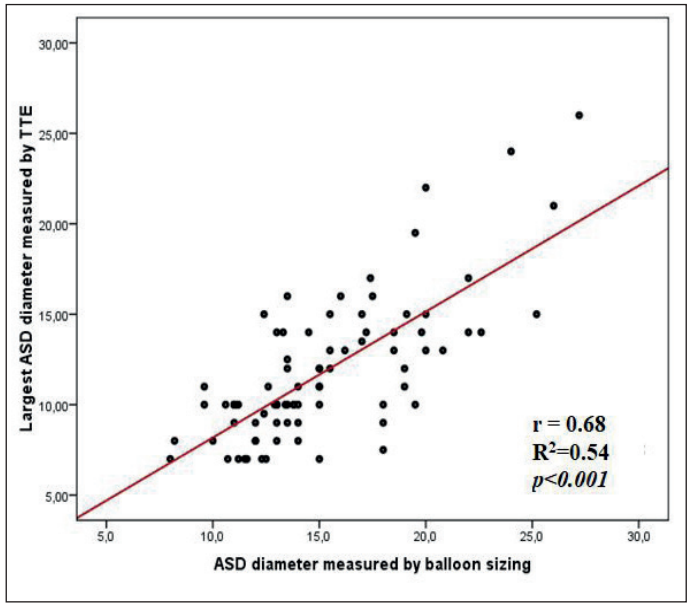

Figure 1: Correlation graph between the largest atrial septal defect (ASD) diameter measured by transthoracic echocardiography (TTE) and ASD diameter measured by balloon sizing (stretched balloon diameter measured angiographically) (Spearman Correlation Analysis, r = 0.68 R^2=0.54 p<0.001).

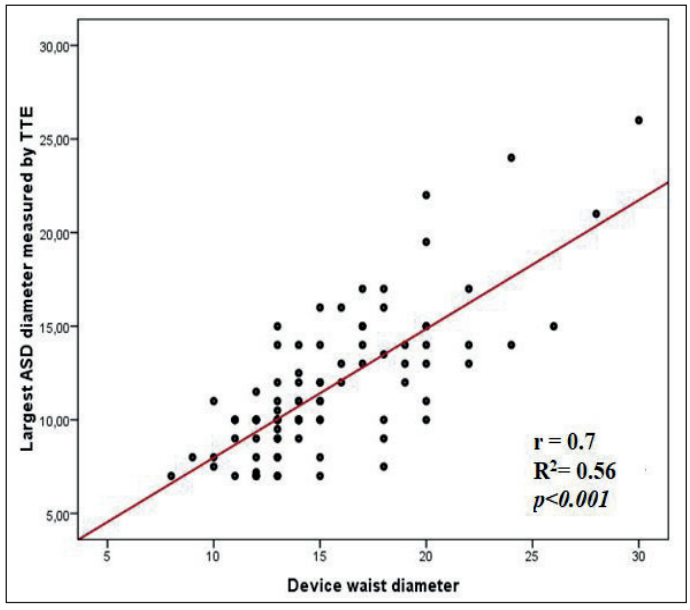

Figure 2: Correlation between the largest ASD diameter measured by TTE and device waist diameter (Spearman Correlation Analysis, r = 0.7 R^2= 0.56 p<0.001)

no echocardiographic evidence of vegetation or thrombus. However, echocardiography revealed moderate mitral valve regurgitation that was not detected after the procedure, newly emerged. After 6 weeks of appropriate antibiotic treatment, blood cultures became negative, AFR returned to normal, and no mitral valve insufficiency was detected in echocardiography. No recurrent infective endocarditis or any other complication was observed during the 1-year follow-up. Endocarditis prophylaxis was consistently recommended.

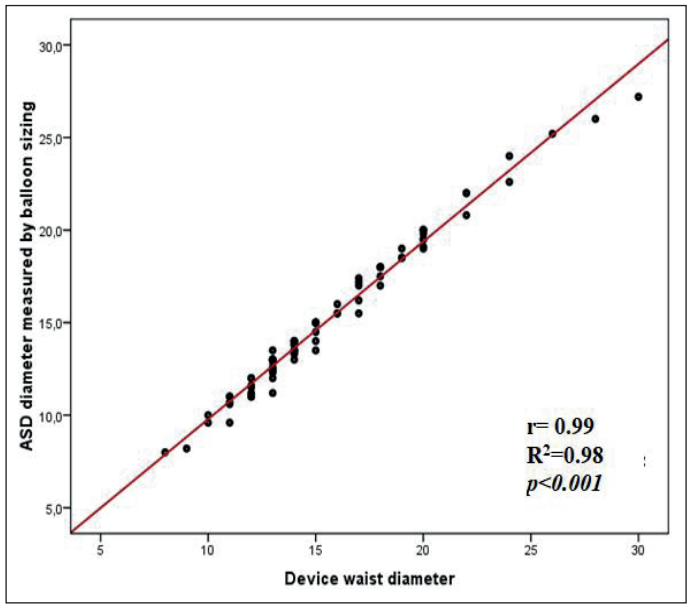

Figure 3: Correlation between ASD diameter measured by balloon sizing and device waist diameter (Spearman Correlation Analysis, r= 0.99 R^2=0.98 p<0.001).

Migraine-like headache associated with nickel allergy was considered in only one patient. In this patient, 16 mm Amplatzer Septal Occluder was implanted and the ratio of left atrial disc diameter of the septal occluder to total septal diameter was 0.76. He had no complaints before implantation. Nausea, vomiting, and migraine-like headaches started within 1 day of device implantation. Nickel allergy was confirmed by the patch test. Symptoms were controlled with aspirin, clopidogrel, and acetaminophen. At 3 months of follow-up, the symptoms disappeared completely.

The largest ASD diameter measured by TTE showed a moderate correlation with the ASD diameter measured by balloon sizing (stretched balloon diameter measured angiographically) and device waist diameter (r = 0.68 R^2=0.54 p<0.001 and r = 0.7 R^2= 0.56 p<0.001, respectively) (Figure 1,2). On the other hand, the correlation between ASD diameter measured by balloon sizing and device waist diameter was fairly strong (r= 0.99 R^2=0.98 p<0.001) (Figure 3).

DISCUSSION

TEE has been widely used for ASD assessment, device selection, and guidance during implantation (14-16).

In the last 10 years, TTE has begun to replace TEE to guide transcatheter closure in most patients with secundum ASD due to its various advantages. In previous studies, the advantages of TTE were stated as; allowing to shorten both procedure time and fluoroscopy time in spontaneously breathing children and avoiding general anesthesia, orotracheal intubation, and TEE-related complications (11,12,17).

In our clinic, we prefer TTE guiding for all transcatheter ASD closures, except for patients with poor transthoracic acoustic windows.

With TTE guidance, our successful ASD device implant rate was 94 %. This was similar to procedural success rates of 95.7% in the Amplatzer Septal Occluder FDA study, 96.7% in the study of Baruteau AE et al. (11), 96% in the MAGIC report, 95% in the C3PO report, and 95.7% in the IMPACT Registry (3,16,18,19).

In our study, major complication rate was 1%. This rate compares with 1.6% in the FDA study, 1.3% in the report of Baruteau et al., (11) 7.6% in the study of Erdem A et al., (12) 1.1% in MAGIC patients, 4.7% in C3PO patients, and 1.2% in IMPACT patients (3,16,18,19).

In studies comparing TEE and TTE guidance in transcatheter ASD closure, no significant difference was reported between procedural success rates (11,12,17, 20). Also, in another study, it was reported that there was no difference in TTE-guided transcatheter ASD closure success rate compared to TEE in anterior superior rim insufficiency (21).

In the study of Baruteau AE et al. (11), no significant difference was found between the TEE and TTE groups in the ratio of ASD diameter to total septum diameter and the ratio of LA disc diameter to total septal diameter. In our study, the ratio of ASD diameter to total septum diameter (28% versus 38.4%), and the ratio of LA disc diameter to total septal diameter (75% versus 86.3%) were similar to the results in Baruteau AE et al's study (11). We think that the selection of the device by balloon sizing under fluoroscopy and TTE guidance is successful in choosing a proper device.

In addition, fluoroscopy time and procedure time of transcatheter ASD closure by TTE guidance were reported significantly lower than TEE guidance (12,17). In our study, the procedure and fluoro times (median 36.5 and 8 min respectively) were comparable to the procedure time and fluoro time of transcatheter ASD closure in the TTE group in the study of Erdem A et al. (12) (median 60 and 13 min respectively) and in the study of Bartakien S et al. (17) (mean 95.7 and 8.9 min respectively).

However, complication rates were found to be significantly higher in the TEE group in the study of Erdem A et al. (12), and no difference was found between the two groups in the study of Bartkian et al. (17). In the study of Baruteau et al. (11), device migration was reported significantly higher in the TTE group, whereas no significant difference was found between the two groups regarding other complications. In another study, device embolization was reported in one patient in a group of 22 children <13 years who underwent TTE-guided ASD closure (22). While there was no device migration in our study, the only major complication was infective endocarditis in one patient. Procedure-related early infective endocarditis was developed

in this patient. However, vegetation thrombus was not detected on the device or other cardiac structures by imaging methods. He was treated with appropriate antibiotic therapy for 6 weeks.

Device-related aortic erosion has been reported as 0.3% in the literature (23). We did not see this frightening late complication in the follow-up. Also, we did not detect rare late adverse events such as conduction abnormality, late infective endocarditis, thrombo-embolism or aortic valve regurgitation (18,23,24).

The activation of local inflammatory reaction by the device that causes the formation of platelet adhesions or release of inflammatory mediators into the left atrium is thought to be the possible mechanism of migraine-like headache (25,26).

In one study, new-onset or increased postprocedural migraine headaches were reported in 7 of 150 patients who underwent transcatheter patent foramen ovale or ASD closure (27). Migraine-like headache related to nickel allergy generally lasts for several months and is controllable with aspirin, acetaminophen, or clopidogrel (25,28). In our study, there was one patient with a migraine-like headache due to nickel allergy, his symptoms completely resolved in 3 months with medical treatment.

In a recent study evaluating 208 patients who underwent transcatheter ASD closure, it was found that there was no correlation between the defect diameters measured by TTE, TEE, and balloon sizing (29). On the other hand, in our study, there was a strong positive correlation between the angiographically measured stretched balloon diameter and the device waist diameter, while there was a moderate positive correlation between the ASD diameter measured by TTE and the device waist diameter. We think that the reason for the correlation difference is that we used balloon sizing measurements in device selection. Therefore, our study supports that nowadays transcatheter ASD closure with TTE and fluoroscopy guidance and balloon sizing is safe and effective. However, in some recent studies, TTE or TEE-guided transcatheter ASD closure without fluoroscopy guidance has been shown to be feasible, safe, and effective in children and adults (30-33). Also, It has been reported that successful transcatheter ASD closure can be performed with expert operators without balloon sizing under the guidance of fluoroscopy and TTE in suitable adult cases (34).

The main limitation of our study is that we did not have a control group that underwent TEE-guided transcatheter ASD closure.

CONCLUSION

This study supports the view that TTE with angiographically stretched balloon diameter measurement is sufficient to evaluate isolated secundum ASD and guide device selection and implantation in most patients with adequate windows.

In the future, comparative studies with large patient groups are needed for TTE-guided transcatheter ASD closure in children without balloon sizing and/or fluoroscopy, in order to reduce radiation exposure.

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