Transcatheter closure of large ostium secundum atrial septal defects in symptomatic small children: A single-center retrospective study

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ABSTRACT

Background : **In general, the risks associated with transcatheter atrial septal defect (ASD) device closure are reported to be relatively low, but the evidence stems from trials involving adults and older children. Current guidelines do not recommend ASD device closure in children with defect sizes >20 mm due to limited data available in this group of patients. This retrospective study sought to determine the clinical and procedural characteristics of successful transcatheter ASD device closure in small children with large defects and assess the complication rates and reasons for unsuccessful device closure.**

Methods : **We retrospectively reviewed the data of all patients who underwent elective transcatheter closure of ostium secundum ASD in our department between September 2013 and February 2022. All children weighing <20 kg, requiring a device of size 20 mm or greater, were included. Major and minor complications were predefined and indications for referral were evaluated. Echocardiogram reports were reviewed from the time of referral, postcatheterization day 1, and at 1-year follow-up.**

Results : **We identified 40 patients meeting inclusion criteria with a median (interquartile range [IQR]) procedural age of 5 (4–7) years and median (IQR) weight of 14 (12–18) kg. Successful device closure was achieved in 39 patients with a success rate of 97.5%. The total complication rate was 2.5% (95% confidence interval: 0.44%– I2.8%) with only 1 major complication. All children had right heart enlargement and exertional dyspnea, 30% of patients had recurrent lower respiratory tract infections, and 10% had failure to thrive. At 1-year follow-up, a transthoracic echocardiogram showed a well-endothelialized device in a stable position in all the patients, and none of the patients had a residual shunt.**

Conclusion : **In experienced centers, percutaneous ASD closure of large defects in symptomatic small children can be done effectively and safely with a great degree of predictability and a low complication rate.**

Keywords : Large atrial septal defect, small children, transcatheter device closure

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INTRODUCTION

Transcatheter closure of small- and medium-sized atrial septal defects (ASDs) in children is well established;[1-3] however, the data on the feasibility of transcatheter closure of large defects in smaller children are scarce, and closing such defects is considerably challenging.[4-7] Current guidelines do not recommend transcatheter closure of ASD in children if the defect size is more than 20 mm, due to the high likelihood of complications.[8] Since there is no universally accepted definition of large ASD in children, for the purpose of this study, we defined a defect requiring more than 20 mm device size in children weighing <20 kg as large ASD.[7] We aimed to assess the clinical and procedural characteristics of successful device closure in these children, determine the complication rates, and evaluate the various reasons for unsuccessful device closure and referral for surgical closure.

METHODS

This was a single-center retrospective study conducted in the Department of Cardiology, Christian Medical College, Vellore, India. Our electronic medical records database which included details of cardiac catheterization was searched for all patients who had undergone a successful or attempted but aborted percutaneous ostium secundum ASD (OS ASD) closure during a 9-year period (September 2013 to February 2022). The study analyzed all patients with OS ASD who weighed <20 kg and required a device size more than or equal to 20 mm.

In all cases, the procedure was carried out under general anesthesia and assisted by fluoroscopy and transthoracic echocardiography (TTE). Standard catheterization of the right heart was performed with measurement of pulmonary artery (PA) pressure before deployment of the device. The records were reviewed, including preprocedure and all follow-up clinical notes, admission and discharge documentation, catheterization reports, electrocardiograms, and Holter reports. Echocardiogram reports were reviewed from the time of referral, postcatheterization day 1, and at 1-year follow-up. Additional echocardiogram reports were reviewed as needed if complications occurred.

The primary objective was to assess procedural success, defined by the deployment of the device in a stable position with no residual shunt as assessed by fluoroscopy and TTE, respectively. The secondary objectives included: (1) to assess the rate and types of complications and (2) residual shunt rate.

The complications were predetermined and stratified into major and minor categories [Table 1]. Short-term complications were predefined to include anything discovered during the procedure as well as within the first 30 days of the procedure.

Table 1: Predetermined major and minor complications

Major complications	Minor complications
Death	Transient arrhythmia resolving with only catheter manipulation
Cardiac or respiratory arrest	Rebleeding from access site (not necessitating transfusion)
Stroke	Significant access site hematoma
Device erosion	Prolong transient access site paresthesia
Device embolization	Trivial pericardial/pleural effusions
Need for emergent surgical procedure	Deployment malfunctions
Need for re-catheterization for device removal	Development of postprocedural lower respiratory tract infection
Significant pericardial/pleural effusion requiring intervention	
Persistent dysrhythmia or lethal intraprocedural arrhythmia requiring cardioversion/resuscitation	
Any new valvular insufficiency or pulmonary vein obstruction	
Access site complications requiring intervention or prolonged hospital stay	
Need for transfusion due to significant bleeding	
Permanent limb injury	

Statistical analysis

For all patient and procedural data, medians with ranges or means with standard deviation were calculated for continuous variables and frequencies with percentages for categorical variables. The independent *t*-test and Chi-square test were used to compare means and proportions of continuous and categorical variables, respectively. Multivariable adjusted odds ratio with accompanying 95% confidence intervals (CIs) was reported. $P < 0.05$ was set for statistical significance. Statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS), version 21 (IBM, Armonk, NY, USA).

RESULTS

The baseline characteristics of patients who underwent a percutaneous OS ASD device closure are summarized in Table 2. A total of 40 patients weighing <20 kg underwent device closure with a device size ≥20 mm. The median (interquartile range [IQR]) age of these patients was 5 (4–7) years. Failure to thrive as defined by weight for height below the 5th percentile on a standard growth chart or Z-score <−2[9] was seen in 9.9% (8/81) of patients. Frequent respiratory tract infections, defined as ≥6 events per year (or part

Table 2: Baseline characteristics

Characteristic	*n*=40
Age (years), median (IQR)	5 (4–7)
Male, % (*n*/*N*)	57.5 (23/40)
Female, % (*n*/*N*)	42.5 (17/40)
Weight (kg), median (IQR)	14.50 (12–18)
Failure to thrive, % (*n*/*N*)	10 (4/40)
Recurrent lower respiratory tract infection, % (*n*/*N*)	30 (12/40)
Associated cardiac conditions, % (*n*/*N*)	12.5 (5/40)
Pulmonary stenosis	2.5 (1/40)
Persistent LSVC	2.5 (1/40)
Mitral valve prolapse	2.5 (1/40)
VSD (perimembranous)	5 (2/40)
Echo findings	
ASD diameter by TTE (mm), median (IQR)	20 (18–22)
Deficient rims, % (*n*/*N*)	40 (16/40)
Aortic rim	22.5 (9/40)
Posterior	10.0 (4/40)
IVC	5.0 (2/40)
Others/superior	5.0 (2/40)
Absent rims, % (*n*/*N*)	5 (2/40)
Aortic rim	2.5 (1/2)
Posterior	2.5 (1/2)
RA and RV dilatation, % (*n*/*N*)	100 (40/40)
TR, % (*n*/*N*)	
Mild	80 (32/40)
Moderate and severe	5.0 (8/40)
PAH, % (*n*/*N*)	
Mild	87.5 (35/40)
Moderate and severe	12.5 (5/40)
RV dysfunction, % (*n*/*N*)	0 (0/40)

IQR: Interquartile range, PAH: Pulmonary artery hypertension, RA: Right atrial, RV: Right ventricular, TR: Tricuspid regurgitation, IVC: Inferior vena cava, ASD: Atrial septal defect, TTE: Transthoracic echocardiography, LSVC: Left superior vena cava, VSD: Ventricular septal defect

thereof) requiring antibiotics,[10] were present in 30% (12/40).

TTE and if required transesophageal echocardiography (TEE) were done for all the patient's preprocedure and day 1 postprocedure, and a follow-up echocardiogram was done after 1 year. Since TEE requires general anesthesia in small children, it was only done in two patients. The median (IQR) diameter of ASD as per TTE in our patient population was 20 mm (18–22 mm). Deficient rims, defined by the septal rim length of any of the aortic rim, atrioventricular valve rim, superior vena cava rim, inferior vena cava (IVC) rim, posterior rim, or right upper pulmonary vein (RUPV) rim, <5 mm in length[11] were present in 40% (16/40) of patients. The most common deficient rim was the aortic rim (22.5%) followed by the posterior rim (10%). Absent rims were seen in 5% (2/40).

About 80% of patients underwent additional balloon sizing during the procedure.[12] Balloon sizing was done by stop-flow technique using an Equalizer Balloon (Boston Scientific, Natick, MA, USA) following which the device size was determined. In our study, the device was on average oversized by 4.38% (min 0–max 22%) compared to balloon size, whereas the average device oversizing as per the TTE measurements was 16.28% (min 0–max 57%), thus indicating that balloon sizing led to the use of comparatively small-sized devices which were best fit across the defect when compared to sizing by TTE.

Out of 40 patients who underwent ASD device closure, 97.5% (39/40) were successful and 2.5% (1/40) were unsuccessful. The only patient in which device closure was unsuccessful was a 3-year-old girl who presented with recurrent lower respiratory tract infection (LRTI) and failure to thrive, TTE revealed 22 mm OS ASD with a deficient aortic rim, despite multiple attempts the device (22 mm–24 mm) did not show good apposition across the defect. Her ASD diameter (mm)-to-weight ratio (kg) was 2.1:1 (large ASD size for body weight).

The devices implanted included Amplatzer, LifeTech, and MemoPart [Table 3]. The median size of the device implanted was 22 mm (min 20 mm–max 32 mm). The median size of the venous sheath used was 9 Fr (7–9 Fr), and the arterial sheath used was 5 Fr (4–6 Fr). In our study population, the mean ASD diameter (mm)-to-weight (kg) ratio was 1.40 ± 0.41:1. Standard deployment of ASD devices was done in the majority 72.5% (29/40). Overall, 27.5% (11/39) of patients required modification in the technique of deployment. In 7 children, the device was deployed from the left upper pulmonary vein, deployment was done from the RUPV in 3 children, and one child required balloon-assisted device closure [Table 3].

Out of 40 procedures done, only one patient had a complication of right common femoral artery thrombosis (a major complication), which was managed with therapeutic anticoagulation, and at 3-month follow-up, there was spontaneous recanalization. All the other children had an uneventful procedure and were discharged postprocedure day 1 or 2. The residual shunts postdevice implantation were seen in none of the patients on postprocedure day 1. All the patients were asymptomatic. TTE at 1-year follow-up showed the device in a stable position in all the patients and no residual shunt. Right atrial (RA) and right ventricular (RV) dilatation had normalized in 95% of children (37/39) and persisted in 5% of children (2/39).

DISCUSSION

OS ASD closure is not recommended until 4 years of age in asymptomatic children[13] as natural history suggests that defects up to 10 mm in size tend to close spontaneously in the early years of life.[14] However, for symptomatic children with large defects that are unlikely to close spontaneously, the data on transcatheter closure of OS ASD are scarce.[1,4,7] Indications for earlier closure of OS ASD in small children have been evaluated in the past and include RV volume overload with worsening right heart enlargement, recurrent LRTI, poor growth, and failure to thrive.[3,15-17] Earlier studies have advised

Table 3: Device and defect characteristics

Device (*n*=39), *n* (%)	
Amplatzer septal occluder	18 (46.1)
LifeTech Cera ASD occluder	16 (41)
MemoPart ASD occluder	5 (12.8)
Technical modification during deployment (*n*=39)	
Conventional deployment	72.5 (28/39)
Left upper pulmonary vein deployment	17.9 (7/39)
Right upper pulmonary vein deployment	7.6 (3/39)
Balloon-assisted deployment	2.5 (1/39)
Defect size by TTE (mm), median (IQR) (*n*=40)	20 (18–22)
Additional balloon sizing of defect	80 (32/40)
Defect size by balloon (mm), median (IQR) (*n*=32/40)	20 (20–24)
Device oversize based on echo sizing of defect (average [minimum–maximum] %)	16.28 (0–57)
Device oversize based on balloon sizing of defect (average [minimum–maximum] %)	4.38 (0–22)
Device size (mm), median (IQR)	22 (20–24)
Defect-to-weight ratio (mean±SD)	1.40±0.41
Device-to-weight ratio (mean±SD)	1.61±0.38
Device-to-defect ratio (mean±SD)	1.16±0.14
Sheath size used (Fr), median (IQR)	
Venous	9 (7–9)
Arterial	5 (4–6)

IQR: Interquartile range, ASD: Atrial septal defect, TTE: Transthoracic echocardiography, SD: Standard deviation

against closing the ASD in children when the size of the defect is 1.5–2 times the weight of the defect in kg,[1,18] and the current guidelines do not recommend transcatheter closure of OS ASD's more than 20 mm due to increased risk of complications.[8] In small children with large ASD, the rims are usually deficient and the left atrial (LA) size is usually small resulting in its inability to accommodate the opened up LA disc, especially when the device required is large, thus resulting in the malalignment of the LA disk with the plane of the interatrial septum causing prolapse of the device across the defect and thus hindering the correct apposition of the device across the defect.[19] However, with advances in transcatheter interventions, defects of more than 300% of the size of the body weight have been closed effectively and safely.[7,15] This single-center retrospective study sought to report our experience of transcatheter closure of large ASD in small children. In our study, successful device implantation was established in 97.5% (39/40) of our patients.

All the patients had features of RV volume overload and right heart enlargement (40/40). Thirty percent of children (12/40) had a history of LRTI, and failure to thrive was seen in 10% (4/40). The median ASD diameter in our study was 20 mm, and the mean defect-to-weight ratio was 1.40 ± 0.41, and around 30% of patients in our study had a defect-to-weight ratio of more than 1.5 and the largest defect which was closed safely and successfully was 2.85 times the weight of the child. Thus, demonstrating that in the current era, defect-to-weight ratio is not a limitation for transcatheter ASD closure.

The success of device closure greatly depends on choosing the correct size of the device. In our study, the device was on average oversized by 4.38% (min 0–max 22%) compared to balloon sizing, whereas the average device oversizing as per the TTE measurements was 16.28% (min 0–max 57%), Our institutional practice is to use balloon sizing only for large defects, and a conscious effort is made not to oversize the device at all after the balloon sizing, to deploy the smallest device which can be the best fit across the defect. However, when only TTE is used for sizing the defect, we oversize the device by up to 20% compared to the largest measured defect size by TTE to avoid inadvertently using smaller devices which can prolapse through the defect. This may be the reason for device oversizing being more when sizing by TTE is compared to balloon sizing in our study.

The routine method of deployment can fail when the device is large as the small LA cannot accommodate the opened LA disc and under such circumstances, slight modifications in the technique of deployment help achieve an appropriate position of the device across the defect.[19] Several techniques have been described such as delivery of the LA disc at the RUPV and LA junction, which is known to prevent the rotation and prolapse of the device through a large ASD,[20] engagement of the opened LA disc within the left upper pulmonary vein which lets the RA disc form before the LA disc engages the septum, and balloon-assisted deployment,[21] in which inflated balloon across the septum supports the device during deployment. Although in most of the cases, the device deployment was done conventionally, about one-third of patients required technical modification for successful device closure.

Device closure was unsuccessful in only one (2.5%) child. This child had a large defect (defect/weight ratio 2.1) with a deficient aortic rim and probably the failure was due to a small LA that could not accommodate a large LA disc causing repeated prolapse of the device across the defect.

TTE postdevice closure at 1-year follow-up showed a well-endothelialized device in a stable position in all the patients. There was no device erosion or device malposition observed, and none of the patients had a residual shunt. Remodeling of the RA/RV after ASD device closure due to a decrease in right heart volume leading to a reduction in PA pressure and right heart cavity dimensions is well established,[22,23] and some studies have shown that up to 30% of the patients can have persistent RV enlargement on follow-up.[23,24] In our study on follow-up visits at 1 year, subjective assessment of RA/RV by TTE demonstrated that in 95% (37/39) patients, RA/RV had completely normalized, and in 5% (2/39) patients, the RA/RV dilatation, although regressed, persisted.

The complication rate in our study was 2.5% (95% CI: 0.44%–12.8%) which is very low as compared

to other studies.[25,26] Device-related complications such as device erosion, device embolization, device retrieval, large pericardial effusion, cardiac tamponade, heart blocks, or mortality were seen in none of our patients.

In our center, the practice is to send for surgical closure if 2 or more of the IVC, superior, or atrioventricular valve rims are deficient or absent. A deficient or absent aortic rim is not considered a contraindication for transcatheter closure. In our study, 22.5% of patients had a deficient aortic rim, despite which the device closure was successful.

Limitations

This is a retrospective study, and the population size remains small; thus, more research is needed in this area. Furthermore, our cohort is heterogeneous, making it difficult to have a control group.

CONCLUSIONS

Transcatheter closure of large ASD in symptomatic small children is effective with a 97.5% procedural success rate and a very low complication rate. However, for asymptomatic small children with large ASD, deferral of closure until the historically established timeline of around 4–5 years of age should be strongly considered.

Authors' contribution

All authors have helped in manuscript preparation, and they read and approved the manuscripts.

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Conflicts of interest

There are no conflicts of interest.

REFERENCES

1. 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;42:241-5.
2. Berger F, Ewert P, Björnstad PG, Dähnert I, Krings G, Brilla Austenat I, *et al.* Transcatheter closure as standard treatment for most interatrial defects: Experience in 200 patients treated with the Amplatzer septal occluder. Cardiol Young 1999;9:468-73.
3. Vogel M, Berger F, Dähnert 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;10:534-7.
4. Cardenas L, Panzer J, Boshoff D, Malekzadeh Milani S, Ovaert C. Transcatheter closure of secundum atrial defect in small children. Catheter Cardiovasc Interv 2007;69:447-52.
5. Varma C, Benson LN, Silversides C, Yip J, Warr MR, Webb G, *et al.* Outcomes and alternative techniques for device closure of the large secundum atrial septal defect. Catheter Cardiovasc Interv 2004;61:131-9.
6. Berger F, Ewert P, Abdul Khaliq H, Nürnberg JH, Lange PE. Percutaneous closure of large atrial septal defects with the Amplatzer Septal Occluder: Technical overkill or recommendable alternative treatment? J Interv Cardiol 2001;14:63-7.
7. Dalvi B, Pinto R, Gupta A. Device closure of large atrial septal defects requiring devices >or=20 mm in small children weighing <20 kg. Catheter Cardiovasc Interv 2008;71:679-86.
8. Saxena A, Relan J, Agarwal R, Awasthy N, Azad S, Chakrabarty M, *et al.* Indian guidelines for indications and timing of intervention for common congenital heart diseases: Revised and updated consensus statement of the working group on management of congenital heart diseases. Ann Pediatr Cardiol 2019;12:254-86.
9. Hamill PV, Drizd TA, Johnson CL, Reed RB, Roche AF, Moore WM. Physical growth: National center for health statistics percentiles. Am J Clin Nutr 1979;32:607-29.
10. Burgio GR. IIbambino con infezioniricorrenti. In: Plebani A, editor. Immunologia Pediatrica. Milan: McGraw Hill Libri Italia; 1998. p. 17.
11. Silvestry FE, Cohen MS, Armsby LB, Burkule NJ, Fleishman CE, Hijazi ZM, *et al.* Guidelines for the echocardiographic assessment of atrial septal defect and patent foramen ovale: From the American Society of Echocardiography and Society for Cardiac Angiography and interventions. J Am Soc Echocardiogr 2015;28:910-58.
12. Hijazi ZM. Device closure of secundum atrial septal defects: To balloon size or not to balloon size. Ann Pediatr Cardiol 2011;4:34-5.
13. Castaneda AR, Jonas RA, Mayer JE, Hanley FL, editors. Atrial septaldefect. In: Cardiac Surgery of the Neonate and Infants. Philadelphia, PA: WB Saunders; 1994. p. 143.
14. Allen HD, Shaddy ES, Driscoll DJ, Feltes TF, editors. Atrial septal defects. In: Moss and Adams Heart Disease in Infants, Children, and Adolescents; Including the Fetus and Young Adult. 7th ed. Philadelphia, PA: Lippincott Williams & Wilkins; 2008. p. 641.
15. Sharma B, Pinto R, Dalvi B. Transcatheter closure of atrial septal defect in symptomatic children weighing ≤10 kg: Addressing unanswered issues from a decade of experience. Ann Pediatr Cardiol 2020;13:4-10.
16. 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;134:960-6.
17. Wyss Y, Quandt D, Weber R, Stiasny B, Weber B, Knirsch W, *et al.* Interventional closure of secundum type atrial septal defects in infants less than 10 kilograms: Indications and procedural outcome. J Interv Cardiol 2016;29:646-53.
18. Justino H. Transcatheter device closure of atrial septal defects in small children: Sound judgment is key. Rev

Bras Cardiol Invasiva 2013;21:101-2.

19. Pillai AA, Satheesh S, Pakkirisamy G, Selvaraj R, Jayaraman B. Techniques and outcomes of transcatheter closure of complex atrial septal defects – Single center experience. Indian Heart J 2014;66:38-44.
20. Kannan BR, Francis E, Sivakumar K, Anil SR, Kumar RK. Transcatheter closure of very large (>or=25 mm) atrial septal defects using the Amplatzer septal occluder. Catheter Cardiovasc Interv 2003;59:522-7.
21. Dalvi BV, Pinto RJ, Gupta A. New technique for device closure of large atrial septal defects. Catheter Cardiovasc Interv 2005;64:102-7.
22. Pascotto M, Santoro G, Cerrato F, Caputo S, Bigazzi MC, Iacono C, *et al*. Time-course of cardiac remodeling following transcatheter closure of atrial septal defect. Int J Cardiol 2006;112:348-52.
23. Kaya MG, Baykan A, Dogan A, Inanc T, Gunebakmaz O, Dogdu O, *et al*. Intermediate-term effects of transcatheter secundum atrial septal defect closure on cardiac remodeling in children and adults. Pediatr Cardiol 2010;31:474-82.
24. Veldtman GR, Razack V, Siu S, El Hajj H, Walker F, Webb GD, *et al*. Right ventricular form and function after percutaneous atrial septal defect device closure. J Am Coll Cardiol 2001;37:2108-13.
25. Chessa M, Carminati M, Butera G, Bini RM, Drago M, Rosti L, *et al*. Early and late complications associated with transcatheter occlusion of secundum atrial septal defect. J Am Coll Cardiol 2002;39:1061-5.
26. Hizaji ZM, Ted F, John PC, Horst S, editors. Complications during Percutaneous Interventions for Structural and Congenital Heart Disease. UK: Informa Healthcare; 2009. p. 211.