Cardiology in the Young

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Safety and feasibility of transcatheter closure of atrial septal defects in small children weighing less than 10 kg

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Original Article

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Abstract

Background: When young patients with an oval fossa defect present early with symptoms of heart failure and pulmonary hypertension, surgical treatment is recommended in small bodyweight rather than transcatheter closure. *Methods:* Outcomes of device closure in consecutive symptomatic children weighing under 10 kg were compared with young children aged below 4 years but weighing above 10 kg. Transthoracic echocardiography under conscious sedation guided the procedure in all without need for balloon sizing, transesophageal echocardiogram, and intubation anaesthesia. Symptoms, anthropometry, shunt ratio, pulmonary pressures, defect and device size, percentage oversizing, device/body weight ratio, complications, and post-procedural growth spurt were compared. *Results:* Ninety-six patients weighing under 10 kg were compared with 160 patients weighing above 10 kg. In total, 83.3% of patients in the study group and 25% of controls were severely malnourished. The median indexed defect size was 35.2 mm/sq.m and 27.4 mm/sq.m, and the device was oversized by 8.7% and 14.2% in the study group and controls, respectively. The device/body weight ratio was 1.93 in study group and 1.4 in controls. Procedure was successful in all except one patient weighing under 10 kg who had a device embolisation. Both groups showed significant growth spurts and proportion, with severe malnutrition reduced to 42% and 11% in the two groups. *Conclusions:* Device closure was feasible and safe in patients under 10 kg. Transthoracic echocardiographic imaging on conscious sedation provided adequate guidance. Symptoms and growth significantly improved after intervention. Despite a larger defect size, smaller patients had comparable outcomes. In symptomatic children under 10 kg needing early closure, transcatheter intervention should not be deferred.

Introduction

Transcatheter closure of atrial septal defects is preferred over surgery in adults as well as children due to lower complications and shorter hospitalisation.[1–4] But treatment guidelines do not endorse device closure in children weighing under 15 kg.[5] A single institution study in the United States suggested deferral of elective device closure beyond 4–5 years of age due to higher complication rates in these smaller patients.[6] A large multicenter French study and multicenter Swedish study too reported frequent complications in children weighing under 15 kg.[7,8] But recent reports with limited patient numbers in the current decade reported good outcomes in children weighing less than 10 kg and even in those under 8 kg.[9–14] Our present study analysed the clinical characteristics and procedural outcomes of all consecutive children weighing under 10 kg who underwent device closure at our institute in the last 10 years and compared them with a group of preschool children aged under 4 years but weighing more than 10 kg.

Methods

This is a single-centre retrospective analysis of clinical characteristics and procedural outcomes of children weighing under 10 kg who underwent oval fossa defect device closure from January 2013 to December 2022. Case records of all children aged under 4 years who underwent device closure were retrospectively reviewed and were grouped into children weighing ≤10 kg and those weighing >10 kg for comparative analysis. Informed parental consent was taken for the procedure. Institutional ethics committee approval was sought for anonymised reporting of case details.

Patient selection

While elective device closure was routinely considered in any child demonstrating right heart volume overload on echocardiogram, the following strict inclusion criteria were followed for children weighing ≤10 kg. They were either features of congestive heart failure manifesting as

feeding difficulty or tachypnoea at rest, significant growth failure defined as weight *Z*-score <−2, plateaued growth curves over one year, or recurrent respiratory infections defined as ≥6 episodes/year or part thereof.

Preprocedural evaluation

All children were evaluated in detail by history, clinical examination, chest X-ray, electrocardiogram, and transthoracic echocardiography. The latter assessed the defect size in various planes, adequacy of the margins, and associated heart defects that need to be addressed. Patients with deficiency of one of the margins (<−5 mm) were included with surgical standby only when parents desired a non-surgical correction despite a detailed counselling. Such patients were included after an informed parental consent if the other margins were considered adequate. Pulmonary artery pressures were determined from Doppler interrogation of the tricuspid regurgitation jet. Transesophageal echocardiography was not done in any patient, as thoracic images were adequate. The baseline demographic data, anthropometry, clinical profile, and echocardiographic parameters were recorded.

Vascular access and hemodynamics

The procedure was done under monitored intravenous conscious sedation using ketamine and midazolam in all patients under transthoracic imaging. Heparinisation, a preprocedural single antiplatelet dose of aspirin, and single intraprocedural intravenous antibiotic prophylaxis were given according to standard guidelines.[2] Single femoral venous access was used for the procedure in all patients. Jugular venous access was used only when transfemoral access failed. Baseline pulmonary arterial and right heart filling pressures were measured in all patients. Arterial access was obtained if patients with severe pulmonary hypertension needed assessment of vascular resistance ratio.

Device closure

The defect was crossed using an angled catheter that was advanced into the left upper pulmonary vein and exchanged for a superstiff guidewire. An appropriately sized Mullin sheath (Cook Medical, Bloomington, IN) was advanced over the superstiff wire. An occluder 1–4 mm larger than the maximal echocardiographic diameter on B-mode images was chosen and deployed in the standard manner in most cases.[2] Oversizing was minimal when the rims were sturdy and adequate; defects with floppy and deficient margins needed more oversizing. In large defects and defects with floppy or deficient margins, modified techniques like pulmonary vein deployment or left atrial roof deployment were electively used.[10] Hemostasis after sheath removal was achieved by manual compression.

Follow-up

All patients underwent echocardiogram on the day following the procedure and were discharged on aspirin at a dose of 3–5 mg/kg/day. Follow-up visits were scheduled at 1 month, 6 months, and yearly thereafter. Symptom status, weight gain, and echocardiography were evaluated on each visit.

Statistical analysis

The baseline demographic data, anthropometry, clinical profile, and echocardiographic parameters were recorded. The hemodynamic data, device size, deployment technique, device/body weight ratio, percentage oversizing of the device compared to the defect size, sheath size, and vascular access were recorded. Statistical analysis used IBM SPSS Statistics version 25 software (IBM, NY, USA). Categorical variables were expressed as a frequency or a percentage. Continuous variables were presented as median with range or mean with standard deviation as appropriate. Differences between the subgroups were tested using the chi-square test for categorical data, Mann–Whitney *U* test for continuous data in non-normal distribution, and student-t test for continuous data in normal distribution. The improvement in continuous variable (weight *Z*-score) was analysed by Wilcoxon signed rank test. A value for $p < 0.05$ was considered statistically significant.

Results

A total of 256 preschool children aged less than 4 years (median 34 months, range 9–48 months) underwent device closure over the last 10 years. In total, 62% were females. A subgroup of 96 children weighing ≤10 kg formed the study group, and the rest were controls. During the 10-year study period, 44 patients weighing ≤10 kg underwent surgical closure of secundum defects, of whom one had mitral valve repair and two had anomalous pulmonary vein drainage. Apart from the abovementioned anatomical reasons in three patients, the others were referred for surgery due to confluent postero-inferior margin deficiency, large defect/body weight ratio >3, and patient preference.

Clinical status in study group

The indications for device closure in the children weighing less than 10 kg were listed in Table 1. Eighty (83.3%) children were severely malnourished with *Z*-score <−2. Four patients had genetic anomaly (ring chromosome 18, NOTCH-1 mutation, DiGeorge and Noonan syndrome in one each), and three had non-cardiac anomaly (tracheo-esophageal fistula, duodenal web, and anorectal malformation).

Cardiac comorbidities

One child with dilated cardiomyopathy on guideline-directed medications underwent device closure to reduce the left to right shunt. Pulmonary stenosis in five children, patent arterial duct in two children, and perimembranous ventricular septal defect in one were all corrected during the intervention. A 2-year-old child weighing 7.1 kg with scimitar variant underwent interventional closure of aortopulmonary collateral earlier in infancy. One child with congenital heart block underwent concurrent transvenous single-chamber permanent pacemaker implantation. Mild to moderate mitral regurgitation in three patients and left ventricular non-compaction in one patient augmented the shunt and were medically followed after device closure.

Echocardiography

The median defect size was 16 mm (range 6–24 mm), with 85 (93.4%) patients having a large defect defined as >20 mm/m^2 body surface area.[7] Thirty-seven (38.5%) patients had at least one inadequate margin. Twenty-eight patients had deficient retro-aortic margin, and 9 patients had deficiency of either inferior or posterior margin. Five (5.2%) children had multi-fenestrated atrial septal defects.

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Table 1. Demography, echocardiography, and hemodynamics

	≤10 kg, $n = 96$	>10 kg, $n = 160$	p value
Age (months)	24.8 (8.7, 44.2)	39.1 (19.7, 48)	
Female gender	62 (64.5)	96 (60)	
Weight (kg)	9 (5,10)	12.6 (10.1, 20)	
Weight *Z*-score	−3.1 (−7.2, −0.66)	−1.3 (−4, 2.9)	<0.001#
Severe growth failure (Z-score <−2)	80 (83.3)	40 (25)	<0.001*
Height (cm)	82 (62, 98)	94 (54, 108)	
Height *Z*-score	−2.11 (−6.7, 4.3)	−0.64(−8.2, 3.3)	<0.001#
Body mass index (kg/m^2)	13.8 (9, 17.6)	14.5(11, 30.3)	
Body mass index *Z*-score	−1.9 (−7.01,0.88)	−1.16 (−5, 5.26)	<0.001#
Body surface area (m^2)	0.45 (0.3, 0.5)	0.57 (0.4,0.8)	
Birth weight (kg)	2.5 (1.2, 4)	3.0 (1.4, 4)	<0.001#
Prematurity	18 (18.9)	10 (6.5)	0.03*
Symptoms			
Poor weight gain	62 (64.5)	54 (33.8)	<0.001*
Tachypnoea	17 (17.7)	10 (6.2)	0.004*
Feeding difficulty	13 (13.5)	7 (4.3)	0.008*
Recurrent lung infections	40 (41.7)	40 (25)	0.002*
Prior hospitalisation	28 (29.2)	22 (13.8)	0.003*
Defect size on echo (mm)	16 (6, 24)	16 (8, 29)	
Defect size mm/m^2 body surface area	35.2 (13.3, 50.4)	27.4 (12.3,48.5)	
Defect size>20mm/m^{2}body surface area	85 (93.4)	132 (84.1)	
Inadequate margins	37 (38.5)	64 (40)	
Significant pulmonary hypertension	15 (18.3)	6 (4.3)	<0.001*
Pulmonary: systemic shunt	2.2 (1.3, 5.1)	1.9 (1.2, 3.5)	
Indexed pulmonary vascular resistance (woodunits.m^2)	1.7 (0.5, 13.1)	1.43 (0.3, 4.0)	

*Chi-square test, #Mann–Whitney *U* test. Continuous variables expressed in median and range.

Hemodynamic data

The median pulmonary-to-systemic shunt ratio of the cohort was 2.2:1 (range 1.3–5.1), and the indexed pulmonary vascular resistance was 1.7 (range 0.5–13.1) wood units. Fifteen (18.3%) patients had significant pulmonary hypertension that was hyperkinetic in all with indexed resistance <6 wood units, except one boy. The shunt ratio, pulmonary artery pressures, and indexed pulmonary vascular resistance in the 8-month-old boy were 1.94, 75/40 (51) mmHg, and 13.1 wood units, respectively. Upon acute vasoreactivity testing using 40 parts per million nitric oxide with oxygen, the indices improved to 2.2, 62/20 (38) mmHg and 6.6 wood units, respectively. After device closure, he was continued on bosentan and sildenafil.

Procedural data

The median device size was 18 mm (range 8–24 mm). The median device/body weight ratio in study group was 1.92 (range 0.8–2.8). The most commonly used device was the Amplatzer septal occluder (Abbott Medical, Plymouth, MN) in 65 (67.7%) patients. Among 4 children with two defects, two devices were required in one case, and the rest underwent closure with an adequately oversized single device. Appropriate-sized cribriform devices were used in the 5 children with multi-fenestrated defect. The median sheath size used was 9F (range 6–12F). The device was deployed using pulmonary venous deployment technique in 18 (18.8%) cases. Left atrial roof deployment technique and prophylactic snare were used in one patient each.[15] One patient with abnormal anteriorly draining inferior caval vein with altered septal orientation required a right jugular access (Figure 1). A handmade fenestration was made in the occluder in the patient with dilated cardiomyopathy to control the elevation of the left atrial pressure. Downsizing of a 30 mm cribriform device to a 25 mm device in one patient with multi-fenestrated defect due to mitral valve interaction was the only change in the initial chosen occluder. The device deployment was successful in the first attempt in 81 (82.3%) of the cases. Procedure was technically successful in all patients with a stable device position before shifting out of the catheterisation laboratory.

Procedural complications

Only one child (1%) had a major complication among our cohort of 96 children. A 2-month-old child weighing 8.3 kg with 19 mm

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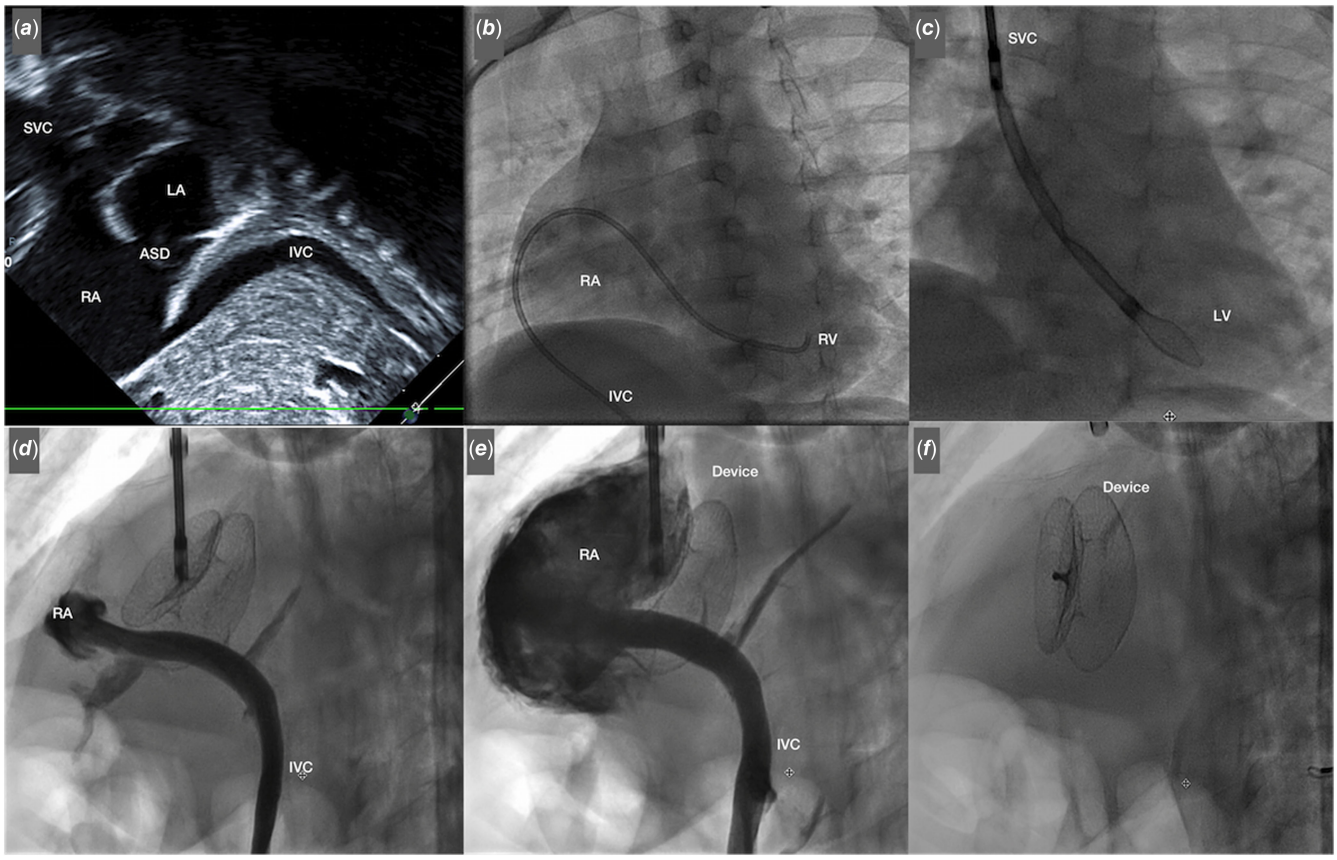

Figure 1. Abnormal anterior drainage of inferior vena cava (IVC) into the right atrium (RA) identified on subxiphoid short axis view (***a***) prevented an access to the atrial septal defect (ASD) and entry to the left atrium (LA) in a small child. The superior vena caval (SVC) drainage provided a more favourable access than a tortuous femoral catheter entry. (***b***) introduction of jugular sheath (***c***) facilitated device closure (***d***), while an inferior vena cava angiogram (***e***) showed unfavourable angulation. The final device orientation (***f***) was very stable.

defect and deficient inferior margin underwent device closure with a 22 mm occluder after parental counselling considering the deficient margin. The device embolised to the left atrium on the next day, necessitating surgery.

Two patients had insignificant residual flows through an additional small defect. Minor complications in 4 (4.1%) patients included self-limiting supraventricular tachycardia in one, transient Mobitz type I atrioventricular nodal block in one, and cobra deformation of the left atrial disc in two patients.[16] The median duration of hospital stay was 2 days (range 1–13 days).

Follow-up data

No patients were lost to follow-up. The median follow-up duration was 21 months (range 4–92 months). None of the patients were symptomatic on follow-up except the child with dilated cardiomyopathy, who continued on guideline-directed medications. The handmade fenestration in this device remained patent for six months and spontaneously closed later. Hemodynamic study in the lone patient with severe pulmonary hypertension after two years of dual vasodilators showed a drop of pulmonary artery pressure to 40/15 (28) mmHg, further reducing to 32/12 (21) mmHg on oxygen. There were no significant residual shunts on follow-up echocardiography. The child who underwent device closure along with pacemaker implantation developed pacing lead endocarditis after four months necessitating removal of the pacemaker and pacing lead. Four years later, the child underwent an uneventful dual-chamber pacemaker implantation.

Post-intervention growth spurt

The median age of the patient cohort on follow-up was 48 (range 18–127) months. Patients who did not complete one year after intervention were not included in the analysis. After one year, 42.3% of patients continued to be underweight (weight *Z*-score <2) compared to 83.3% of patients before the procedure. Poor growth was associated with genetic, other cardiac, and non-cardiac anomalies. The pre-intervention median weight *Z*-score of −3.1 (range from −7.2 to −0.7) significantly improved to −1.83 (range −6.7 2) at one-year follow-up.(Figure 2)

Comparison of patients >10 kg and ≤10 kg

Ninety-six children weighing ≤10 kg were compared to 160 children weighing >10 kg during the same 10-year period. The weight, height, and body mass index *Z*-scores were significantly low in the study cohort, indicating marked growth failure in this group. Proportion of symptomatic patients, growth failure, as well as hyperkinetic pulmonary hypertension was significantly higher in the study group compared to the controls (Table 1). The indexed defect size, device/body weight ratio, and the size of the delivery system corrected for body surface area were more in the study group, while the percentage of device oversizing more than the

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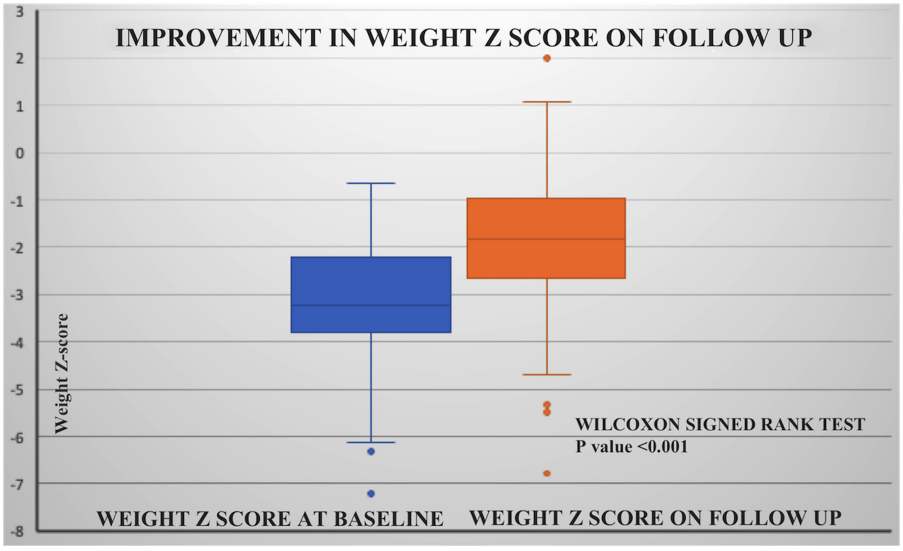

Figure 2. The improvement of weight *Z*-score from −3.1 to −1.8 after intervention at one-year was statistically significant.

echocardiographic diameter was less than the controls (Table 2). The procedural duration and fluoroscopy time as well as the duration of hospitalisation were comparable between the two groups. In the group >10 kg, there were no major complications, and two patients had insignificant residual flows on follow-up. The follow-up duration of both groups was comparable. Both groups showed a significant increase in weight *Z*-score compared to their preprocedural values (Table 3).

Discussion

Transcatheter closure has evolved as the procedure of choice over surgery in those with clear indications for oval fossa defect closure. Paediatric cardiac interventionists are increasingly considering this intervention, even in smaller children and infants.[6–14]

Need for early oval fossa defect closure

Elective closure of the oval fossa is usually indicated at 3–4 years of age before their school entry in children with features of right heart enlargement.[5] Early closure is not recommended, as these defects seldom cause symptoms in early childhood. Yet another reason to defer intervention is spontaneous closure of small defects in their natural history.[17] But a subset of infants manifest significant symptoms, growth failure or pulmonary hypertension, to warrant early defect closure. Preterm birth, genetic anomalies, pulmonary diseases, and other associated cardiac anomalies are shown to be predictors for early defect closure.[18]

Indications and timing

The Mid Atlantic Group Interventional Cardiology Registry analysed 68 children weighing less than 8 kg and found association of cardiac or non-cardiac anomalies in 88%, prematurity in 47%, and chromosomal anomalies in 22% of patients.[14] However, these associations were only found in 19%, 19%, and 3%, respectively, in our study group. The most common indication for early oval fossa defect closure in young children in earlier studies was growth failure, similar to our observation.[8–11] Early onset of symptoms were attributed to larger shunt, early fall of pulmonary vascular resistance, altered ventricular compliance, or subclinical left heart disease.[19] In total, 93% of the defects in our study group were very large (defined as >20 mm/m^2), similar to previous studies, and would never close spontaneously in their natural history.[8–11,15]

Mode of closure in small children

Large comparative studies and a meta-analysis in adults and children demonstrated the safety of device closure over surgery with lower complications and shorter hospital stay.[2–4] However, transcatheter closure group was older than surgical group, and robust data on children aged under 2 years or weighing under 15 kg were lacking.[2–4] Higher complication rates in small children in few studies led to recommendations for surgery as the preferred mode of treating these patients.[5–7] While frequent complications could be a result of small patient size, operator inexperience could be another factor.[6] A few recent studies with smaller patient numbers confirmed safety and feasibility of transcatheter closure in small children.[8–11] Our present analysis too confirmed that device closure could be preferred to surgery in children weighing <10 kg with low complication rates.

Intraprocedural imaging

Intraprocedural transesophageal echocardiogram was a vital part of procedural protocol in most of the previous studies.[8–11] Despite the safety of transesophageal study in small children, insertion of the probe could be traumatic, might need deep anaesthesia, and may compress and reduce the left atrial volume.[20] Thin body habitus of these small patients provided good thoracic echocardiographic windows similar to the spatial resolution provided by transesophageal study to allow precise assessment of defect size and margins. None of the patients required balloon sizing, thus simplifying the procedure.[21] Apart from a single instance of downsizing of a cribriform occluder, no other patients needed a change of device due to suboptimal assessment.

Technical aspects

Groin veins, atrial chambers, and pulmonary veins were small relative to the large delivery sheaths and device size in these young patients. Small left atrium predisposed to prolapse of the occluder necessitating assisted techniques such as pulmonary venous deployment or balloon assisted technique.[10] Assisted techniques

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Table 2. Procedural details

	≤ 10 kg, $n = 96$	>10 kg, $n = 160$	p value
Procedural duration (min)	40 (15, 135)	35 (6, 205)	0.46*
Fluoroscopy time (min)	7.7 (2.4, 39.3)	8.1 (2.2, 33.4)	0.94*
Sheath size (French)	9 (6,12)	9 (7, 12)	<0.001*
Sheath size/m^2body surface area	19.7 (14.6, 26.9)	16.5 (10.9, 25.1)	<0.001*
Device size (mm)	18 (8, 24)	18 (10, 30)	0.007*
Device oversizing in %	8.7 (−14.2, 55.5) IQR (0, 15.6)	14.2 (−14.2, 58.3) IQR (6, 22.2)	0.001*
Device/weight ratio (mm/kg)	192.5 (80, 280)	140 (65, 262)	<0.001*
Device			
Amplatzer	65 (67.7)	75 (46.9)	
Lifetech	14 (14.6)	33 (20.6)	
Occlutech	15 (15.6)	44 (27.5)	
Others	2 (2.1)	8 (5)	
Pulmonary vein deployment	18 (18.8)	41 (25.6)	
Number of attempts			
1	51 (82.3)	114 (91.2)	0.21
2	8 (12.9)	8 (6.4)	
3	2 (3.2)	3 (2.4)	
4	1 (1.6)	0	
Minor complications	4 (4.1)	9 (5.6)	0.2#
Major complications	1 (1)	0	
Duration of hospital stay (days)	2 (1,13)	2 (1,6)	0.09*

*Mann–Whitney *U* test, #Chi-square test. Continuous variables expressed in median and range.

Table 3. Follow-up of both groups

	<10 kg, $n = 96$	>10 kg, $n = 160$	p value
Follow-up duration (months)	20.93 (0.5, 92.7)	20.68 (0.9, 99.7)	
Age at last follow-up (months)	48.5 (17.9, 126.8)	55.1 (23.2, 142)	
Weight at last follow-up (kg)	13 (6.6, 39.6)	16.6 (10.9, 48.6)	
Weight *Z*-score at last follow-up	−1.83 (−6.7, 2)	−0.49 (−3.46, 3.98)	<0.001*
Severe underweight at follow-up (*Z*-score <−2)	33 (42.3)	14 (10.8)	<0.001#

*Mann–Whitney *U* test, #Chi-square test. Continuous variables expressed in median and range.

were required in 20.8% in our cohort, and pulmonary vein deployment was preferred over others. Balloon assisted technique was avoided due to the need for an additional venous access.[10] Gentle manipulation of hardware in a small heart need not be overemphasised.[7]

Choice of device

As Amplatzer septal occluders need a small delivery system, they were preferred in small patients in most of the previous reports.[8–11] We also preferred this occluder, which was used in two-thirds of our patients; but occluder devices from other vendors that needed a larger sheath were also successfully used in one-third of patients without any vascular complications.

Sizing the occluder

Most studies on small children limited the oversizing of the occluder device to 1–2 mm above the maximal defect diameter measured on transesophageal echocardiogram or balloon waist.[8–11,18] As some of these defects were oval with varying dimensions in different planes, we even undersized the device compared to the maximal echocardiographic measurement in 6.1% of patients. Device size was equal to the largest echocardiographic diameter in 15.7% of our patients. The median device oversizing compared to the echocardiographic diameter was 8.7% (range −14.2% – 55.5%; interquartile range 0, 15.6). Significant oversizing was done only in few patients with very thin and floppy margins. Septal length and left atrial dimensions were not considered during the device choice

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as a well-deployed occluder remodelled itself within the atrial three-dimensional space.[21] While a device/body weight ratio exceeding 1.2 was considered a risk factor for unsuccessful deployment in the past, experienced operators had successfully implanted devices in recent times with a maximal ratio of 2.9.[10,23] The median device/body weight ratio in our study group was 1.9 (range 0.8–2.8).

Adequacy of margins

Selection of candidates for device closure was based on the presence of margins of atleast 5 mm in all echocardiographic planes in most studies. However, improved operator experience permitted safe inclusion of patients without retro-aortic margin.[10] Thirty-seven (38.5%) patients in our study had a deficient margin, and 9 among them had a deficiency of either the inferior or the posterior margin. Procedure in one such patient was complicated by device embolisation on the next day warranting surgery. This was the only complication in this study group. Despite clear transthoracic echocardiographic views that demonstrated deficient inferior margin, this child was accepted for catheter intervention due to parental insistence on non-surgical approach. As retrieval of embolised devices in small children involved additional radiation and large access sheaths, the child was immediately referred for surgery.

Risk-benefit ratio

Surgical studies have demonstrated utility of closure in symptomatic small babies.[24] Transcatheter closure carries the merits of avoiding open incisions, general anaesthesia and mechanical ventilation, cardiopulmonary bypass, intensive care unit stay, chest drains and scars, and long hospitalisation. Infant surgery may lead to problems related to reasoning, learning, executive function, inattention and impulsive behaviour, language skills, and social skills.[25] Our comparison between the standard cohort of preschool children weighing >10 kg and small children weighing ≤10 kg showed similar procedural and follow-up outcomes. Safety of the procedure and improvement of growth were clearly demonstrated in small patients. However, it should be stressed that complications were more frequent in smaller weight patients, and due caution should be paid during patient selection for non-surgical closure.

Limitations

This study is limited by its retrospective nature. However, procedural steps utilising transthoracic imaging alone without the use of intraprocedural transesophageal echocardiography and balloon sizing were uniform throughout the 10-year study period. Larger patient volume compared to many previous studies and complete acquisition of follow-up data too strengthened the study results.

Conclusions

While treatment guidelines advocate surgical closure of large symptomatic secundum atrial septal defects in young children weighing under 10 kg, our study with a large number of patients shows the safety of transcatheter device closure in this subgroup. Transthoracic echocardiogram is sufficient to provide anatomical information instead of a transesophageal study, thereby simplifying the intervention. The device oversizing is minimal in these small patients compared to a group of larger patients. Significant improvement of symptoms and growth is expected in most patients following the intervention. The outcomes are similar between children weighing less than 10 kg and a more traditional cohort of patients weighing more than 10–15 kg. In small children with strong indications for early closure, it may not be necessary to wait till the child grows to a weight exceeding 10–15 kg for a transcatheter device closure.

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Competing interests. None.

Ethical standard. The authors assert that all procedures contributing to this work comply with the ethical standards of the Indian Council of Medical Research and with the Helsinki Declaration of 1975, as revised in 2008, and has been approved by the institutional committee of Madras Medical Mission, Chennai, India.

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