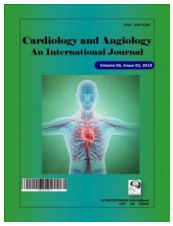

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Mid-term Safety and Efficacy of Transcatheter Closure of Ostium Secundum Atrial Septal Defect under Transthoracic Echocardiographic Guidance in Children Weighing Less than 15 Kg

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Authors' contributions

This work was carried out in collaboration among all authors. Author HSA designed the study, performed the statistical analysis, wrote the protocol and the first draft of the manuscript and did the initial literature search and analysis. PB conceptualized the study. Author DSC managed the analyses and fine tuning of the study along with author HSA. Other authors managed the literature searches. All authors read and approved the final manuscript.

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ABSTRACT

Background: Transcatheter device closure of ostium secundum atrial septal defect is a safe & effective intervention in older children, & is usually done under transesophageal echocardiography guidance. However, the procedure under transthoracic echocardiography guidance, especially in smaller children, is done only at few centers, the data of which is scarce.
Methods: A prospective study was undertaken to assess the mid-term efficacy and outcome of transcatheter device closure of ostium secundum atrial septal defect under transthoracic echocardiographic guidance, in children <15 Kg.
Results: Eighty three children with ostium secundum atrial septal defect were included in the study. Median age of the study population was 3.5 years (1.9-5.6 years), and median weight of 11.6 Kg (7.6 - 14.9 Kg). The primary and secondary procedural success rates were 94% and 96.4% respectively. Post procedure patients were followed up for 12-30 months. Device related major complications were encountered in 4 (4.8%) cases. The total occlusion rates of the defect at 24 hours, 1 month and 3 months post procedure were 94%, 98.8% and 100% respectively.
Conclusion: The transcatheter device closure of ostium secundum atrial septal defect under transthoracic echocardiography guidance, in children <15 Kg, has a high short and mid-term safety and efficacy.

Keywords: Ostium secundum atrial septal defect; transthoracic echocardiography; transesophageal echocardiography; right heart enlargement.

1. INTRODUCTION

The incidence of congenital heart defect in general population is 6-9 per 1000, with atrial septal defect being the commonest (8-10%) one, excluding bicuspid aortic valve. Ostium secundum atrial septal defect is the commonest (70%) type of atrial septal defect. [1,2] If left untreated, it can lead to complications including arrhythmias, pulmonary hypertension, paradoxical thromboembolism, heart failure, and Eisenmenger syndrome.

The ostium secundum atrial septal defect is amenable to both surgical & transcatheter closures, with comparable success rates. However, the significant morbidity associated with surgical closure leads to higher preference for percutaneous closure over it, whenever indicated. The first nonsurgical percutaneous closure of ostium secundum atrial septal defect was first described by King & Mills in dogs in 1974, using a double umbrella device. [3] Over the years, this intervention has evolved enormously, especially with newer devices & hardware being invented & improvised techniques adopted. Many studies describe its safety & efficacy in older & larger patients, under transesophageal echocardiographic guidance. However, the same in younger & smaller children, under transthoracic echocardiographic guidance, is done at only few centers, the data of which is scarce. We carried out a prospective study to assess the mid-term safety & efficacy of transcatheter device closure of ostium secundum atrial septal defect in children weighing less than 15 Kg, under transthoracic echocardiographic guidance.

2. SUBJECTS AND METHODS

2.1 Patient Population

A total 202 patients (including adults) were diagnosed to have ostium secundum atrial septal defect during the study period from March 2014 till March 2017 at a tertiary care cardiac centre. Out of this, 136 patients fell in the pediatric age group and were screened for potential transcatheter device closure of the ostium secundum atrial septal defect. The intervention in these patients was in accordance with the guidelines by American Heart Association. [4] Patients with associated additional cardiac defects were offered transcatheter closure of atrial septal defect only if the associated defect warranted either no intervention or was amenable to additional transcatheter intervention.

2.2 Inclusion Criteria

Of the 136 pediatric cases with ostium secundum atrial septal defect, 83 patients with body weight < 15 Kg were included in the study.

2.3 Exclusion Criteria

Patients with associated cardiac lesions requiring surgical correction or those with deficient rim(s)

(except isolated deficient aortic rim in few cases) were excluded.

2.4 Methods

A thorough and comprehensive pre procedure assessment for suitability for device closure was done with transthoracic echocardiography using standard acoustic windows and views. The transthoracic real time Philips iE33 (Bothell, USA) echocardiography machine was used in all cases. The standard echocardiographic views used to study various rims of ostium secundum atrial septal defect in all patients included subcostal bicaval [inferior and superior vena caval rims], apical four chamber [anteroinferior and anterosuperior rims] & parasternal short axis view [aortic and posterior rims] (Fig. 1). A minimum of 5 mm rim was considered adequate, except the aortic rim which even partially deficient was acceptable. The total interatrial septal length was also noted using apical and subcostal four-chamber views, to decide the maximum size of the device that could be used. While selecting the size of the device it was also kept in mind that the length of the left atrial disc would not exceed the total interatrial septal length. The size of the device used was same or upto 2mm more than maximum size of ostium secundum atrial septal defect measured on transthoracic echocardiography. Generally, we did not use the device size more than 150% of weight (Kg) of the child, except in two cases where we went upto about 170% of the same. The pulmonary artery pressures were assessed with standard continuous & pulsed wave Doppler interrogation of tricuspid and pulmonary regurgitation jets. All cases were performed under inhalational & parenteral general anesthesia without endotracheal intubation. All cases were administered minimum four doses of parenteral antibiotics (a 3rd generation cephalosporin and an aminoglycoside) peri-procedure. The written informed consent for both the procedure as well as anesthesia was obtained from the parent(s).

Trans-femoral venous and arterial access was obtained in all cases using standard Seldinger technique. The right heart study, including measurement of pulmonary arterial pressures, was done in all cases. The associated cardiac defects were assessed thoroughly with transthoracic echocardiography and relevant hemodynamic and angiographic study. All cases were administered unfractionated heparin at the dose of 100 units per kg body weight, intravenously. Additional dose of 50 units per Kg body weight was administered every one hour of the procedure, guided by automated measurement of activated clotting time, which was maintained between 200-250 sec.

The standard technique involved crossing the defect with an end-hole catheter passed over a terumo wire to enter the left upper pulmonary vein, followed by exchanging with extra stiff wire over which the delivery sheath was advanced, which was de-aired at inferior vena cava- right atrial junction. The device was then advanced through the delivery sheath, left atrial disc of device partially released in left upper pulmonary vein, whole delivery assembly withdrawn while releasing complete left atrial disc in left atrium, followed by release of right atrial disc, the whole procedure being done under transthoracic echocardiographic & fluoroscopic guidance. After three unsuccessful attempts of standard technique, alternative right upper pulmonary vein ('American rugby') technique was adopted where-in the left atrial disc is completely released in proximal part of right upper pulmonary vein, followed by release of right atrial disc, and finally the entire delivery system is gently pushed to disengage the left atrial disc out of right upper pulmonary vein, rendering the device to attain its appropriate position. After two unsuccessful attempts of right upper pulmonary vein technique, the procedure was abandoned. However, in few cases with borderline posterior or inferior vena caval rims, this technique was directly used. Before final release of the delivery cable, the device position was thoroughly assessed with standard transthoracic echocardiographic & fluoroscopic views, and a gentle/vigorous push & pull maneuver ('Minnesota wiggle') was performed in all cases.

Periodic clinical, electrocardiographic & echocardiographic follow up was done. The primary success rate was defined as percentage of cases who underwent successful device closure in the initial admission. Secondary success rate was primary success rate plus success rate in patients in whom the device closure could be done successfully subsequently after initial failure.

Most of the patients were followed up for a variable period of 12-30 months post procedure. A list of various probable major and minor complications (Table 1) was prepared and all the patients were monitored closely for the same. All patients were administered single or dual anti-platelet agent(s) for six months.

3. RESULTS

During the study period, out of the total 136 pediatric cases with ostium secundum atrial septal defect, 11 were anatomically unsuitable for transcatheter closure, and were thus directly referred for surgical intervention. Out of the remaining 125 cases, 83 (51 females & 32 males) met the inclusion criteria. The primary and secondary procedural success rate for the device closure was 94% (78 out of 83) and 96.4% (80 out of 83) respectively.

The various indications for the closure of ostium secundum atrial septal defect were as listed in Table 2. The patient characteristics and other clinical variables are as noted in Table 3. The mean age at time of procedure was 3.5 years (1.9 to 5.6 years), and the mean weight 11.6 Kg (7.6 to 14.9 Kg). The mean defect size was 16 mm (9 to 22 mm). Various non-cardiac and cardiac co-morbidities noted have been listed in Table 4.

Conventional left upper pulmonary vein technique for the device deployment was used as primary technique in 67 (80.7%) patients. Right upper pulmonary vein ('American rugby') technique was used in the remaining 16 (19.3%) patients, and additionally in 15 patients where the initial attempts of closing the defect using the left upper pulmonary vein technique failed. Right upper pulmonary vein technique was preferred in patients with borderline posterior or inferior vena caval rims. Thirty-four (41%) patients required more than two attempts for device closure, out of which 11 (13.3%) required 4-5 attempts. Defect in 4 (4.8%) patients could not be closed despite multiple unsuccessful attempts. While one of these was referred for surgical closure, the remaining 3 underwent successful percutaneous device closure after about six months.

The septal occluders randomly used were Amplatzer (St. Jude Medical, St. Paul, MN, USA) in 51 & Lifetech (Shenzhen, China) in 32 cases. The median size of device used was 18 mm (10 to 24 mm). Eight (9.6%) patients had multiple (2-3) closely located atrial septal defects, all of which were closed using single device. Twenty-five (30.1%) patients underwent additional transcatheter intervention for an associated congenital cardiac defect in the same setting (Table 5). The most common additional intervention was pulmonary valve balloon dilatation which was done in 10 (12%) patients. The median fluoroscopic time was 4.1 minutes (range 2.8 – 9.6 minutes). The average hospital stay post procedure was 2.3 days (range 1.5 to 4.5 days). The total occlusion rates of the defect at 24 hours, 1 month and 3 months post procedure were 94%, 98.8% and 100% respectively.

The various minor and major complications encountered were as noted in Table 6. Major complications were noted during the procedure and follow up in 6 (7.2%) patients, 4 of these were device related. One child aged 4 years, developed high grade non remitting fever along with other constitutional symptoms two months post atrial septal defect device closure. Transthoracic echocardiography revealed 3-4 vegetations over the right atrial disc of the device & atrial surface of septal leaflet of tricuspid valve with no residual shunt. Blood culture was sterile. He was managed aggressively with antibiotics. The child responded completely to therapy over 8 weeks, and had no recurrence till at least 24 months post procedure. Three (3.6%) patients developed device embolization within 12 hours of implant. The devices embolised to right ventricular outflow tract, main pulmonary artery, and bifurcation of main pulmonary artery respectively. In latter two, the device was successfully retrieved percutaneously and redeployed later, whereas one patient who developed recurrent premature ventricular ectopics required urgent surgical retrieval and closure of the defect. We did not encounter any case of late device embolisation, arrhythmia, cardiac perforation, significant atrio-ventricular valvular insufficiency, pulmonary venous/vena caval obstruction, pericardial/pleural effusion requiring drainage, cardiac or aortic erosion, limb ischemia, thrombus over left atrial disc, or intolerance to anti-platelet agent. Right heart enlargement regressed in all cases as noted during follow up over time.

4. DISCUSSION

Ever since the first successful percutaneous closure of atrial septal defect in 1974 [3], a significant advancement has taken place in various aspects relating to the procedure. Although ostium secundum atrial septal defect device closure is generally done in children weighing more than 15 Kg, only few studies have shown its high efficacy and safety in smaller symptomatic children. [5,6,7] However, in most of these studies the procedure has been done under transesophageal echocardiographic guidance. The procedure under transthoracic

echocardiographic guidance has also been reported, but in larger patients. [8,9] In the first of its kind Indian study, we report high short as well as mid-term safety and efficacy of ostium secundum atrial septal defect device closure under transthoracic echocardiographic guidance in children weighing < 15 Kg.

The indication of treatment of ostium secundum atrial septal defect in the present study was as per the existing guidelines for these patients. [4] Defects of larger than 8mm with hemodynamically significant left to right shunt (pulmonary/systemic flow ratio — Qp/Qs > 1.5) were considered for closure as they were unlikely to close spontaneously. [10,11] Majority of the patients in our study were asymptomatic, commonest indication for the device closure was right heart enlargement due to volume overload. Few patients had reported with recurrent respiratory tract infections and inadequate weight gain. The above pattern of presentation was in concordance with other studies [5,6,7].

Table 1. List of probable complications for which patients were monitored during and post transcatheter closure of os ASD

S No	Major complications	Minor complications
1.	Cardio-respiratory compromise/arrest Need for device retrieval after 12 hours post procedure	Requirement of multiple attempts leading to prolonged procedural time
2.	Device embolization/migration requiring urgent trancatheter retrieval (within 12 hours post-procedure)	Transient arrhythmia settling spontaneously or with minimal intervention
3.	Device embolization/migration requiring urgent surgical retrieval (within 12 hours post-procedure)	Abandoning of procedure due to repeated failures
4.	Loss of limb pulsation warranting administration of heparin infusion for more than 12 hours & evaluation	Abandoning of procedure due to deformed device
5.	Prolonged arrhythmia	Right iliac vein dissection
6.	Potentially fatal arrhythmia requiring cardioversion/drugs	Retropharyngeal hemorrhage
7.	Cardiac perforation	Need for blood transfusion due to blood loss
8.	Any new or worsening AV valvular insufficiency	Insignificant pleural / pericardial effusion
9.	Pericardial/Pleural effusion requiring drainage	Post procedure respiratory infection
10.	Pulmonary venous/ vena caval obstruction	Aspirin intolerance
11.	Thrombus over left atrial disc	

Table 2. Indications for closure of ostium secundum atrial septal defect

S No	Primary indication	n=83 (%)
1	Recurrent respiratory tract infections	32(38.5)
2	Inadequate weight gain	29(34.9)
3	Severe Pulmonary arterial hypertension	5(6%)
4	Right heart enlargement (Volume overload)	79(95.2)
5	Recurrent lower respiratory tract infection	4(4.8)
6	Asymptomatic (Incidental detection of cardiac murmur)*	29(34.9)
7	Combination of more than one of above	81(97.6)

Table 3. Patient characteristics and other variables

Characteristic/variable	n=83
Age (year)	3.5 (1.9-5.6)
Gender (Female)	51 (61.4%)
Weight (kg)	11.6 (6.8-14.9)
ECG features (Pre-procedure)	
Incomplete right bundle branch block	72 (86.7%)
rSR' pattern	76 (91.6%)
Right atrial enlargement	79 (95.2%)
Chest roentgenogram (Antero-posterior view)	
Cardiomegaly	79 (95.2%)
Increased pulmonary blood flow	81 (97.6%)
Lower respiratory tract infection	4 (4.8%)
TTE features of defect	
Mean defect size (mm)	16 (9-23)
Borderline osASD rims(%)	
Isolated aortic rim (Deficient in 11 cases)	21(25.3)
Aortic + posterior rims	11 (13.6)
Aortic + IVC rims	6 (7.2)
Isolated posterior rim	17 (20.5)
Isolated IVC rim	4 (4.8)
Cardiac catheterization parameters	
Mean pulmonary artery pressure (mm Hg)	18 (12-58)
Qp:Qs	2.4 (1.5–4)

Table 4. List of comorbid conditions noted in the study population

	Comorbid condition	N = 83 (%)
Non Cardiac		
	Down's syndrome,	6(7.2)
	Turner's syndrome,	2(2.4)
	Noonan's syndrome,	1(1.2)
	Developmental delay,	4(4.8)
	Severe Pulmonary arterial hypertension	6(7.2)
	Thalassemia major	2 (2.4)
	Nephrotic syndrome	2 (2.4)
Cardiovascular		
	Patent ductus arteriosus	8(9.6)
	Restrictive VSD (Requiring no intervention)	11(13.2)
	VSD (Amenable to transcatheter intervention)	4(4.8)
	Mild Valvular Pulmonary stenosis	20(24.1)
	Significant Valvular Pulmonary stenosis	10(12.0)
	Severe valvular Aortic stenosis	2(2.4)
	Coarctation of aorta	2(2.4)
	Post cardiac surgery residual ASD	4(4.8)
	Bicuspid aortic valve with no AS/AR	5(6.0)
	Persistent left superior vena cava (Draining into right atrium through roofed coronary sinus)	4(4.8)

When morphologically suitable, transcatheter rather than surgical closure of ostium secundum atrial septal defect is the treatment of choice in many institutions. The literature reveals sufficient evidence of its superiority over surgical closure, in terms of length of hospital stay, rate of complications, cost effectiveness, rate of infection and morbidity, in appropriately selected patients. Specifically, studies have revealed higher incidence of arrhythmias, pulmonary

complications, pericardial effusion/tamponade, left ventricular dysfunction, and hemiparesis, in surgical closure of ostium secundum atrial septal defect as compared to device closure, both in children and adults [12,13,14,15].

Though recommended by some studies [16,17] balloon sizing of ostium secundum atrial septal defect was not done in the present study as most of the patients had good echocardiographic window. Percutaneous ostium secundum atrial septal defect device closure may be done under transthoracic, transesophageal or intracardiac echocardiographic guidance, latter being done only in adults. All the patients in the present study underwent ostium secundum atrial septal

Table 5. Additional transcatheter interventions for other accompanying lesions

S No	Intervention	n = 83 (%)
1	Balloon pulmonary valvuloplasty	10(12.0)
2	Branch pulmonary artery balloon angioplasty	4(4.8)
3	Patent ductus arteriosus device closure	6(7.2)
4	Ventricular septal defect device closure	2(2.4)
5	Balloon aortic valvuloplasty	2(2.4)
6	Balloon coarctoplasty	2(2.4)

Table 6. Frequency of major & minor complications noted during and post device implantation

	Complications	n=83 (%)
Major		
	Cardio-respiratory compromise/arrest	2(2.4)
	Device embolisation/migration requiring urgent surgical retrieval (within 12 hours post-procedure)	1(1.2)
	Device embolisation/migration retrieved percutaneously (within 12 hours post-procedure)	2(2.4)
	Infective endocarditis	1(1.2)
Minor		
	Transient arrhythmia resolving spontaneously or with minimal intervention	2(2.4)
	Non progressive first degree heart block	2(2.4)
	Loss of limb pulsation warranting administration of heparin infusion for more than 12 hours & evaluation	5(6.0)
	Prolonged or recurrent bleeding from puncture site	2(2.4)
	Local Hematoma	1(1.2)
	Need for blood transfusion due to significant blood loss	1(1.2)

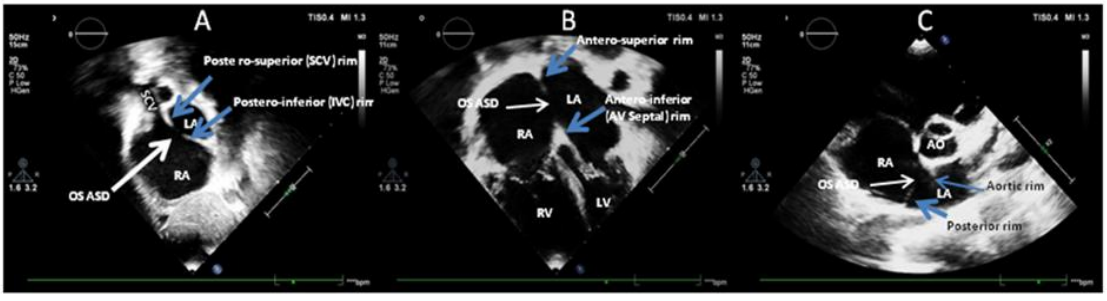

Fig. 1. TTE views showing various rims of Os ASD: A – Modified sagittal subcostal view; B Apical 4-chamber view; C- Parasternal short axis view; RA = Right atrium; LA = Left atrium; RV = Right ventricle; LV = Left ventricle; SCV = Superior caval vein; Ao = Aorta

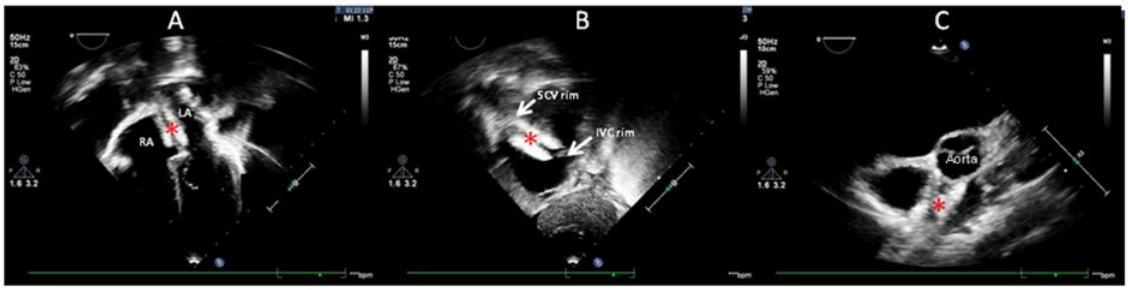

Fig. 2. TTE views showing post deployment, ASD device (*) holding the antero-inferior and antero- superior rims (A), postero-inferior (IVC) and postero-superior (SCV) rims (B), and straddling the aorta (C) ; RA = Right atrium; LA = Left atrium

defect closure under transthoracic echocardiographic guidance. Most of the published data is on ostium secundum atrial septal defect closure under transesophageal echocardiographic guidance, [5,6,7,18] and limited data is available on transcatheter device closure of ostium secundum atrial septal defect in smaller children (< 15 Kg). The drawback of transesophageal echocardiography is the difficult availability, need for anaesthesia and endotracheal intubation, the morbidity associated, and longer procedural time [19,20].

Majority of the ostium secundum atrial septal defect in the present study were closed using conventional technique involving left upper pulmonary vein. The 'American rugby" technique, was used in 31 (37.3%) cases. We did not use any other modified technique as described in literature, [21,22] in any of our patients. Use of more than one device for closure of multiple defects has been described. [23] However, we successfully closed five cases with multiple (2-3) defects with a single device, without any residual shunt. All these patients had closely located defects.

Our study population was noted to have a number of cardiac and non cardiac comorbidities along with ostium secundum atrial septal defect. Downs syndrome and valvular pulmonary stenosis were the commonest non-cardiac and cardiac anomalies respectively noted in the present study. The pattern of this involvement was in concordance with what has been reported in the literature. [5,6,7,24] Combined cardiac intervention with ostium secundum atrial septal defect closure and correction of the associated anomaly was done in 25 (30.1%) patients; balloon pulmonary valvuloplasty was the commonest combined intervention done, as has been reported in other studies. [25,26] Balloon coarctoplasty and balloon aortic valvuloplasty along with ostium secundum atrial septal defect closure were done in two patients. This combination of intervention in the same sitting has not been reported earlier in literature. Other than increased fluoroscopy and procedure time no increase in morbidity was noted in any of the combined interventions.

Minor complications were reported in 15.7% of patients in the present study, which is little higher than that reported in literature. [5,6,7,9] However, all these events were transient (except first degree heart block in two cases), with no long term implication. Major complications were reported in four (4.8%) patients. The overall major complications rate in our study is comparable to that reported in other studies. [5,6,7]. A recent study reported 10% incidence of major complications in children <15 kg, this higher incidence was attributed to inclusion of discharge from hospital later than 24 h as a criteria for major complication. [6] A total of three patients in the study had device embolization. Two of these devices could be retrieved percutaneously while third one required surgical removal. The incidence of device embolization reported in experienced hands is about 0.5–1%, with successful percutaneous retrieval being reported in approximately 70% of these cases. [27,28] The common causes of embolization as reported in the literature are under sizing of the device, inadequacy of the rims of ostium secundum atrial septal defect, inadvertent improper deployment, overzealous 'Minnesota wiggle', excessive tension on the loading cable during release, and vigorous Valsalva maneuver. [27,28,29] Infective endocarditis as an early or late complication post ostium secundum atrial septal defect device closure has been described in occasional case reports mainly in adults, and rarely in pediatric population. [30,31,32] Urgent

surgical management is recommended in case if there is an evidence of septal perforation, dehiscence, fistula formation, vegetation or embolization. [30,32,33] Interestingly, in one of the published reports in a 4-year-old child, authors have proposed incomplete endothelization of the device as a mechanism of late endocarditis. [34] In our case of infective endocarditis, since the patient showed excellent response to aggressive medical management under close supervision, surgical option was not entertained. There was no mortality reported in our study. A few studies have reported occasional late death both in children [35] and adults [29].

The unique attributes of our study are that all cases with weight < 15 Kg were done under pre & post procedure transthoracic echocardiographic guidance and were monitored for a wide spectrum of minor & major complications. The main limitations of this study are lack of long term follow up and comparison of outcome with procedure under tranesophageal echocardiographic guidance and in larger children.

5. CONCLUSION

Transcatheter device closure of ostium secundum atrial septal defect under transthoracic echocardiographic guidance, in children weighing less than 15 kg, has a high short as well as mid-term safety and efficacy, with a very low incidence of major complications.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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