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Research Article

Trans-Catheter Device Closure of Atrial Septal Defect in Symptomatic Children Up to 10 Kg of Body Weight: A Multicentric Retrospective Observational Cohort Study to Assess Feasibility, Safety and Midterm Results After Closure

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ABSTRACT

Background: Atrial septal defect (ASD) is the second most prevalent congenital heart diseases (CHD) encompassing 8-10% of all CHDs beyond neonatal period. Although relatively benign, if left untreated can amount to several adverse outcomes. Trans-catheter Device closure of ASD is a preferred therapy for a hemodynamically significant shunt. Despite multitude of septal occluders being available these days, paucity of literature concerning appropriateness of device sizing, and various adaptations of techniques for device deployment in large ASDs with deficient rims and their outcomes in children up to 10 kg weight nevertheless still exists.

Aims and Methods: A retrospective multi-centric observational study, was conducted in a cohort of children who underwent ASD device closure weighing up to 10 kg conducted over a period of 4 years, to assess its safety and feasibility.

Results: Of the included 85 patients, 63% were females and 37% were males with mean age at intervention being 32 months. The mean weight and height were 9.17 Kg and 88 cm respectively. Mean of maximum ASD dimension was 14.92mm. Hemodynamic assessment with invasive PA pressures recordings suggested normal PA pressure in 82%, while 18% had pulmonary arterial hypertension. Mean Qp/Qs and PVR was 2.58 and 1.8 Wood units respectively. Average device: weight ratio was 1.9. Arrhythmias occurred in 6 children, five had Adenosine sensitive SVTs and one had persisting CHB necessitating surgical device retrieval and Permanent pacemaker implantation. No mortality occurred in this study.

Conclusion: Trans-catheter closure of ASD is indeed safe and effective procedure if performed in children weighing up to 10 Kg, in a hemodynamically significant shunt, adopting modified techniques, even in presence of flimsy or deficient rims with device weight ratio up to 3:1.

Keywords

Atrial septal defect, Device closure, Less than 10 kg.

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Introduction

Atrial septal defect (ASD) constitutes 8%–10% of the congenital heart defects in children beyond neonatal period. Ostium secundum ASD accounts for nearly 75% of all cases of ASD [1]. Trans-catheter device closure of secundum ASD was introduced in 1974 by King and Milk [2]. Multiple fenestrations or complete absence of the atrial septum could also result during embryogenesis. The hemodynamic manifestations of ASD transpire secondary to large magnitude of left to right shunt described conventionally as a pre-tricuspid shunt. Increased magnitude of shunt results in dilation of Right atrium, Right ventricle and Pulmonary artery, owing to enhanced capacitance of these chambers in response to additional volume of blood being received from pulmonary venous circulation. Although ASD closure in a hemodynamically significant shunt is advised in children around 3-4 years of age, typically during pre-school years of life, the manifestations can be sometimes inconspicuous, consequently presenting in adulthood in the fourth or fifth decade of life, either as an incidental detection during Echocardiography performed for other indications or with symptoms related to cardiac insufficiency, obstructive pulmonary arterial hypertension (PAH) or arrhythmias [3].

During infancy and early childhood period, patients with ASD and hemodynamically significant shunts, present with recurrent respiratory infections, features of cardiac failure like diaphoresis and suck rest suck cycles during infancy or bit older children may present with reduced exercise tolerance in the form of decreased playing capacity in comparison to their peers. Failure to thrive with height and weight below expected percentiles for their age, can also be implied secondary to decreased systemic cardiac output or enhanced catabolism resulting from repeated respiratory tract infections. It is hence imperative to discuss in details with the by-standers, regarding multiple etiologies of failure to thrive if present, while obtaining consent for device closure, elucidating and emphasizing that it may persists even after ASD closure. In some instances, the shunt and volume overload resulting from the defect may cause reactive pulmonary arterial hypertension, which if left untreated can result in permanent pulmonary vascular remodeling resulting in pulmonary vascular obstructive disease, which is eventually detrimental and fatal, with Cardio-pulmonary transplant available as the only rescue treatment in such scenarios [4]. Device closure has eventually become the preferred modality of therapy for hemodynamically significant ASD with suitable anatomy owing to its added advantages of being minimally invasive, less traumatic including better cosmetic outcomes [5,6]. Also, use of cardiopulmonary bypass would also be unmerited. From the available literature involving large cohorts of patients with ASD undergoing trans-catheter device closure, the risk of serious complications is very low (1.8 %) [7] and reported mortality was extremely rare (0.093%) [8]. Most septal occluders exhibit user-friendliness and offer high success rates post implant [8]. Studies have described the effectiveness and safety of trans-catheter device closure of ASD, being similar to surgical closure [9-11]. However, most of these studies have included bigger children, adolescents, and adults. Although a few studies have demonstrated the feasibility and reasonable safety of trans-catheter ASD device closure in relatively younger children [12,13] , none of them have addressed concerns like how large a defect is too large for an ASD device closure, how to select the size of device for the size of defect, whether estimating the length of interatrial septum (IAS) is essential for device selection, and what adaptations or modifications are essential in the existing deployment techniques to achieve success in the subset of patients characterized by large defects in relatively smaller hearts [14,15].

Materials and Method

This retrospective study was conducted in a cohort of children who weighed up to 10kg and underwent ASD device closure between 2019 to 2023 in two different tertiary cardiac care centers in India. Individual approval was obtained from respective institutional ethical committee. The total sample size consisted of 85 children. Inclusion criteria comprised of children who underwent device closure for ostium secundum ASD and body weight up to and less than 10kg. The cases in whom parental consent for device closure was not obtained or those opting for surgical closure of ASD, or defects with other associated cardiac anomalies which would have otherwise needed surgical or multiple trans-catheter interventions, Ostium Primum defect, sinus venosus defect, defects with more than one fenestration, or defects with more than 2 deficient rims were excluded from the study. After obtaining a detailed history from the parents, all the children underwent thorough physical examination, a baseline electrocardiogram (ECG), and chest X-ray. A transthoracic echo (TTE) was performed, and the diameter of the ASD and length of all the rims were measured in multiple planes from various echocardiographic views. The pulmonary artery pressures were estimated from peak velocity of tricuspid regurgitation jet by continuous-wave Doppler using modified Bernoulli equation. Amplatzer Septal Occluder (Abbott Laboratories, USA) and CeraFlexTM ASD occluder (Lifetech Scientific Co., Shenzhen, China) were used to close the secundum ASDs. Data was analyzed using SPSS software 23.0. The data was then represented in the form of percentage, mean and SD values. The parameters with p value of less than or equal to 0.05 were considered being statistically significant.

Results

In our study a total 85 patients underwent device closure for atrial septal defect (Table 1), 54(63%) were females and 31(37%) were males and the mean age was 32 months (7months-6 years). The mean weight in this study was 9.17Kg (5.9-10) and mean height was 88cm (65-122). On echocardiographic assessment mean ASD size (considering largest dimension obtained in any Echocardiographic imaging plane was 14.92mm (7.5-26). Hemodynamic assessment with Right heart catheterization study suggested 70 (82%) patients had normal PA pressure (No PAH), in the other 15 patients with pulmonary arterial hypertension 10 patients (12%) had mild PAH, 3(3.5%) had moderate PAH and 2(2.5%) had severe PAH. Mean Qp/Qs ratio was 2.58 (1.5-4.2) mean PVR was 1.8 (0.6 – 4.6WU). 9 children had dysmorphisms, of which six had Down syndrome, and we had one patient each with congenital rubella syndrome

and Noonan's syndrome and Goldenhar syndrome. 2 patients had cerebral palsy and developmental delay owing to birth asphyxia. 11 patients resided in high altitude areas, and this background probably contributed to variability in the estimated pulmonary arterial pressures during serial visits to the hospital. 26 (30%) children had history of neonatal hospitalization in the past for respiratory tract infection necessitating noninvasive respiratory ventilatory assistance.28 (32%) children had history of at least two hospitalization post neonatal period requiring noninvasive respiratory assistance. The most common technique used for device deployment was Left atrial disc Engagement Disengagement (LADED) technique using the left superior pulmonary vein 57 (67%) whereas in 15(18%) of cases conventional technique was used and in 13(15%) of our patients we have used right upper pulmonary vein (RUPV) for left atrial disc engagement. Individual techniques are described later in this text. We have not used Balloon assisted or catheter assisted techniques for device deployment in our patients, however these techniques are described in literature, and they are momentous when deploying large ASD devices in a scenario of deficient ASD rims. In our cohort of 85 children, 24(28%) had adequate rim sizes and thickness, 21(24%) children had isolated floppy IVC rim, 18(21%) had isolated deficiency of retro aortic rim and 22(25%) had floppy IVC rims in addition to deficient posterior inferior rims. The average Device size to defect ratio was 1.90 (1.2-3.3). About half of the cases, that is 44(52%) had device/weight ratio in the range of 1.0-2.0. 35(45%) patients had ratio in the range of 2.01-3.0 and only 3(3%) patients had this ratio of more than 3.01.Mean fluoroscopic time was 7min 25 seconds (2-22min 4sec) Among procedure related complications arrhythmias were reported in 6 patients (ill-sustained supraventricular arrhythmias occurred in five responsive to Adenosine therapy and complete Heart block necessitating surgical device retrieval after 5 days of device implantation followed by Permanent pacemaker implantation, occurred in one such case). Transient atrial arrhythmias during device deployment including enhanced atrial ectopy or first-degree heart block were commonly observed. The device was released only on restoring sinus rhythm with normal PR interval. In those patients in whom transient first-degree heart block was appreciated, a short course regime of Intravenous steroids was administered to alleviate effects from AV nodal injury. Post procedure headache, was reported in 2 of our cases which was self-limiting. There were no vascular access related complications and no mortality occurred amongst this study cohort. Of the 28 (32%) children who had prior history of hospital admissions attributed to hemodynamic effects of large pre-tricuspid shunt beyond neonatal period, 5 children with concurrent comorbidities including perinatal asphyxia and dysmorphisms as described prior, continued to have admissions for various indications, predominantly consequent to noncardiac-vascular etiologies. Reduced frequency of hospitalization was appreciated in the rest. Catch up growth was documented at one year follow up in almost the entire cohort, post device therapy for ASD. We followed up these children at 24 hrs,1 month, 3-month ,6 months and then annually. Transthoracic Echocardiography (TTE) performed in the immediate post intervention period, on the same day of implant, revealed stable device position with no residual pre-tricuspid shunt in 85 (100%) cases. None of the cases had any evidence of increase in One of the devices was retrieved on day 7 due to persistent congenital heart block. Were there any cases with increased MR/TR? Impressive cardiac remodeling was appreciated amongst the entire cohort at 1 year follow up with normalization of chamber and pulmonary artery vascular dimensions on TTE assessment.

Discussion

Trans-catheter Device closure in the current era has become the preferred therapy for hemodynamically significant Ostium Secundum ASD subjected to anatomical suitability for the procedure. Although there are a wide variety of devices available to the operators today, dearth of literature concerning appropriateness of device sizing, and various adaptations of techniques involving device deployment in large ASDs with deficient rims and their outcomes in children up to 10 kg weight still exists. From our experience of trans Catheter closure of ASD in children up to 10kg we have tried to address some of these concerns. The usual time of referral for children with atrial septal defect for treatment (surgical or trans-catheter) with mild or no symptoms is around 4 years which corresponds to preschool going age and weight of 15kg in a relatively well-nourished child in our subcontinent [16-19]. However, there are certain special situations where an early therapy in the form of either a surgical or a percutaneous device closure is obligatory. Some of the indications include, large left to right shunts resulting in repeated lower respiratory tract infections, frequent use of IV antibiotics or hospitalization, significant failure to thrive, frequent episodes of wheezing requiring nebulization, presence of heart failure, or early onset of pulmonary hypertension [20,21].

There could be associated confounding factors to failure to thrive like genetic syndromes, metabolic defects and developmental delay in this age group, along with manifestations of a significant pre- tricuspid shunt. Presence of these associated issues not only make these procedures more complicated and necessitates proper counselling regarding residual failure to thrive despite device closure for ASD. Surgical closure of ASD is the gold standard therapy in this particular cohort, however since trans-catheter therapy provides excellent outcomes comparable to surgical closure, with an added advantage of less procedural times, better cosmesis, avoidance of CPB related complications, shorter duration of hospital stay and attenuated pain burden to the patient and their families, it could be effectively performed with mandatory surgical back-up in case of procedural failure or complications [22,23]. Recently, trans-catheter closure in this cohort has been proposed in several trials, but the complication rates have been relatively higher, particularly in patients with severe failure to thrive and bronchopulmonary dysplasia consequent to prematurity at birth [23,24]. Safety of device closure is always a concern in such small patients. In our cohort the highest weight to device ratio was 3.3, and this was not associated with any complications analogous to study done by Bharat Dalvi et al. [30], and the maximum device to weight ratio was 2.92 in their study.

Size of Atrial septal occluder was decided after defect sizing and assessment for adequacy of rims on TTE. The maximum dimension in any plane was considered as the defect size, and assessment was performed in at least 3 Echocardiographic views. Any rim of <5mm was considered as rim deficiency. Device size was selected 2mm higher than defect dimension in an ASD with all adequate rims, 4mm higher if solitary rim deficiency and 6mm higher if dual rim deficiency was illustrated. As described prior, any ASD with more than two rim deficiency was excluded from this study. Some of the previous reports have recommended estimation of the length of the Inter Atrial Septum (IAS) and have suggested contradiction to device therapy if estimated left atrial disc length was greater than the obtained total IAS length, usually assessed in apical 4 chamber view in atrial diastole on TTE [25]. However, with advancement of 3D Echocardiography we know that the IAS is a curvilinear structure and hence consequently the length of IAS is usually underestimated by 2D TTE. With this enlightenment we have not preferred assessment of IAS length for device sizing. Also, with the increasing elasticity of devices available in the current times, they can easily conform to the IAS. Some groups even suggested balloon sizing using stop flow technique [26], while others proposed measuring ASD size using Trans Esophageal Echocardiography (TEE) assessment in various planes [27,28]. This would be of paramount importance in the adult cohort with ASD in whom limited views for sizing and assessment on TTE, poses a major challenge. Such methods were not adopted in our study as we invariably had good echocardiographic views. Although some of the earlier publications have negative recommendations for using device sizes beyond 200% of device weight percentage, however such recommendations have been empirical and ever evolving [29]. Rim length is a major deciding factor for a successful device closure in our study. Rarely, inadequate rim strength (floppy rims) can result in device embolization despite adequate length of rims [31-33], hence it is imperative to assess for same, prior to device closure.

The techniques we have utilized to deploy devices across atrial septal defect included, conventional technique, LADED technique from left and right upper pulmonary veins. The conventional method of deployment for ASD septal occluder includes complete formation of LA disc in LA cavity followed by controlled release of RA disc in to Right atrium by constantly maintaining a gentle tug against the septal rims all throughout RA disc deployment. LADED is a common strategy being used for device deployment with large atrial septal defects. In this technique the left atrial disc is partially deployed in to the upper pulmonary vein with majority of disc being formed in LA cavity, following which controlled release of right atrial disc is performed, after which LA disc is quavered out of pulmonary vein to disengage the deployed disc from the vein and engage across the left aspect of the atrial septum. Majority of times we could deploy the device without any issues however in few of our cases we did encounter difficulties with orientating the devices perfectly, particularly in large ASDs with deficient rims, due to decreased capacity of left atrium to accommodate a large left atrial disc. This entity could be easily identified on TEE and fluoroscopy and subsequently the devices in these patients were recaptured in to delivery sheaths and re-deployed using alternative techniques from above three that we have described. We could successfully deploy devices in 100% of our study cohort. The upper pulmonary veins were preferred for deployment of devices owing to being in straight course for device alignment along the plane of ASD, thereby reducing the torque over the device and its delivery cable during deployment. Most of these children in this study underwent successful device closure using one of the LADED techniques. Among these, the left upper pulmonary vein technique was most commonly used (67%) being the simplest to be executed. Balloon Assisted or catheter assisted technique [30] was not attempted in our study.

Our data brings to light that the device closure in children up to 10 Kg is not only feasible, but it can be done with a great degree of predictability. Except for one patient (case 6), who developed complete heart block after device deployment, no other patient developed major complication during recuperation. There were no access site or vascular complications. We have observed significant headache in 2 of our patients, which was self-limiting, and subsided with a single dose of oral analgesia. However incidentally we appreciated prolonged fluoroscopy exposure times of 22.4 minutes and 15 minutes in comparison to a mean of 7.25 mins. Since headache is a known manifestation of acute radiation sickness, we therefore postulate its correlation being a possible reason for the same in two of our patients. In a recent study by Joshua D Grissman et al. incidence of headache was reported as high as 15% of study cohort after ASD device closure. In their study no such association with fluoroscopic exposure times has been emphasized upon, however changing antiplatelet strategy from Oral Aspirin to Clopidogrel had been recommended. In five of our patients, we have observed transient intra-procedural SVT, which was responsive to Adenosine. This could be attributed secondary to catheter or device manipulation in the atria. In all the patients with SVT, Device: Weight ratio was more than 1.5. One of our patients (CASE 6) had developed complete AV block 48hrs after the procedure. The ventricular rate was between 65-70 beats/min however the patient was asymptomatic. In this patient the device to weight ratio was 2.0, and two of the defect rims were deficient. Astonishingly we did not see such rhythm issues in patients who received devices with much larger device: weight ratio, up to 3.4. Parenteral steroid therapy was promptly initiated to alleviate tissue edema surrounding the AV node. The condition of patient remained the same, and hence surgical device retrieval was performed on the 5th post procedure day. Despite surgical retrieval of device AV block persisted hence a single chamber permanent pacemaker was implanted on Day 7 of device closure. Residual heart block could be attributed to enhanced peri-nodal fibrosis, which occurs eventually as a part of physiological healing response.

Conclusion

This study confirms the feasibility, effectiveness, and safety of device closure of ASD in young children weighing up to 10 kg. The defect assessment and sizing can be reliably performed using TTE in this cohort. Devices with LA discs larger than the length of the IAS can be accommodated in these small hearts and hence IAS length is probably not a limiting factor in determining the size of the device. Device closure can be attempted with adaptations

in conventional deployment techniques in defects with flimsy or deficient rims using up to 3:1 device to weight ratio with expectant predictability and safety if cautiously performed. While there was one major complication in this cohort, and we strongly feel that pacemaker implantation could be have been averted if device was retrieved earlier. From this complication we could also infer that it is not presumably the device: weight ratio, instead it is rim adequacy which is the key deciding factor regarding device sizing. Based on our data, we suggest offering and attempting device therapy in children with indications for early closure of ASD regardless of a rigid weight criterion, owing to procedural safety, ease and efficacy.

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