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Very Large Atrial Septal Defect Device Closure, Feasibility and Safety

Goutam Datta

Abstract

Background: There is limited data regarding feasibility and safety of very large ASD devices deployment. Percutaneous closure of very large atrial septal defect (ASD) is a valid alternative to surgical approach. But complications like erosion, cardiac perforation, atrioventricular block, pericardial effusion, infective endocarditis, or cardiac arrhythmias may occur following ASD device closure.

Methods: Forty four patients with very large ostium secundum ASD were studied in a tertiary medical centre. Adult patients with defect size of 38 mm or more and device size of 40 mm or more were selected for device closure. Patients having suitable anatomy, significant left to right shunt(>1.5:1) ,right ventricular volume overload and without significant pulmonary arterial hypertension were chosen for device closure.

Results: There were thirty six female patients and eight male patients in our study. Majority of our patients (twenty four) were in forty to fifty years age group. Device could be deployed successfully in forty two (95.5%). Twelve patients had device size of 46 mm (27%). Eight patients had 44 mm devices (18%). Forty two millimeter devices were used in sixteen patients (36%). Eight patients had device size of 40 mm (18%).Device embolization occurred in two patients. There were two cases of pericardial effusion and pericardiocentesis was needed in one patients. Transient complete heart block was seen in one patient. Four patients had suffered from transient and self terminating atrial arrhythmias. There was no mortality or erosion in our study.

Conclusion: Percutaneous closure of very large ASD is feasible and associated with low complication rate.

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Keywords: ASD device closure, very large devices, complications.

Associate professor Department of cardiology Burdwan medical college and Hospital West Bengal, India

Correspondence:
Goutam Datta
Associate professor Department of cardiology Burdwan medical college and Hospital West Bengal, India
Email: goutamdattadn@yahoo.in

Introduction

Atrial septal defects (ASD) is a common congenital heart disease and it accounts for approximately 10% of all congenital heart defects in children. The prevalence of ASD is 1 /1000 live births.[1] Ostium secundum type ASDs constitute for 75% of all ASDs and it is amenable to device closure. The first successful surgical closure of an ASD was performed by F. John Lewis in 1952. Transcatheter closure of ostium secundum ASD is a safe and effective procedure. The first ASD device closure was performed by King and Mills in 1974.[2] The devices most commonly used are Amplatzer Septal Occluder (ASO; nickel and titanium alloy wire mesh, polyester fabric filling, US Food and Drug Administration approved in 2001) and the Helex occluder (nitinol wire covered with an ultrathin polytetrafluoroethylene membrane, US Food and Drug Administration approved in 2006). There is a paucity of data on transcatheter closure of very large ASDs (defect size 38 mm or more),[3] especially using the 40-mm devices.Surgical closure is the preferred approach for very large ASDs.This very large defect comprises approximately 20% of patients with ASDs.[4] But device closure is not free of complications. Device embolization is the most common adverse event (0.2%-1%). Major early adverse events occurred in 1.2 % of the cases. Some of the documented risks of ASD device closure include device embolization (1%), temporary or permanent tachyarrhythmia and heart block (0.3%), erosions (0.28%), thromboembolic complications, fractures, valve injury, pericardial effusion, infections and mortality (0.05%).[5] Our aim is to study feasibility and safety of very large ASD device closure.

Methods

Forty four patients with very large ostium secundum ASD were studied from January, 2018 to December, 2020. Study was done in a tertiary care University hospital. Study protocol was ethically approved and informed consents were taken from patients. Patients with very large ostium secundum ASDs were defined as defect size of 38 mm or more by Transesophageal echocardiography. Device size of 40 mm or more was selected as very large devices. Our objective was to study feasibility and safety of device closure in these large defects. All cases were selected based on both transthoracic and trans esophageal echocardiographic evaluation. All procedures were done under conscious sedation and transesophageal echocardiography guidance (TEE). Balloon sizing was not done in any of the cases. Invasive arterial blood pressure monitoring were done in all cases.

Selection criteria:

(1) Age more than eighteen years
(2) Very large ostium secundum ASD.
(3) Evidence of right ventricular volume overload
(4) Significant left to right shunt (>1.5:1)
(5) No significant pulmonary arterial hypertension (pulmonary artery systolic pressure less than half of systemic arterial pressure)
(6) Anatomical suitability of device closure.
(7) Minimum follow up period was six months.

Statistical Analysis

It was an prospective, observational epidemiological study. Results are expressed in absolute numbers and percentage only.

Results

Thirty six patients were female and eight patients were male. Female male ratio in our study was 4.5:1 (chart 1). Female patient overwhelmingly predominates in our study in contrast to male predominance in ASD population.

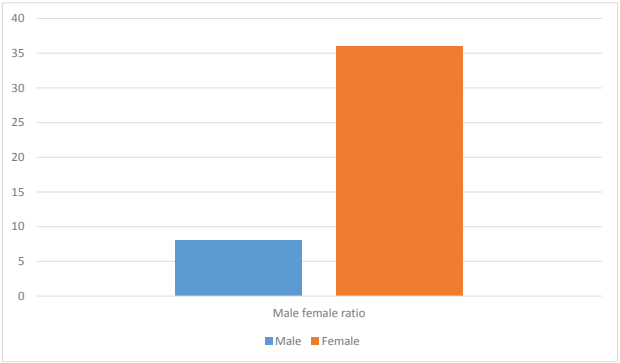

Figure 1. Male to female ratio

Majority of our patients (twenty eight) were in between forty one to fifty years age group (64%). Four patients were in thirty one to forty years age group (9%). There were twelve patients in eighteen to thirty years age group (27%). (Chart 2)

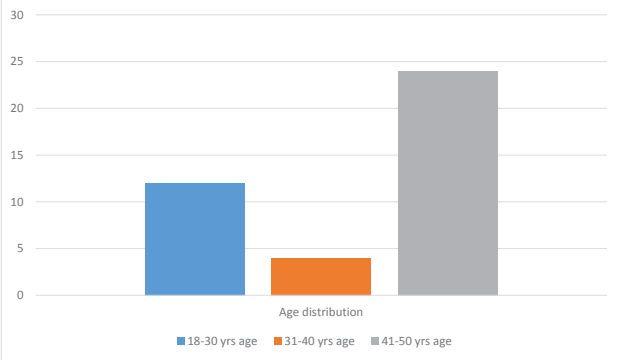

Figure 2. Age distribution

Anatomically there was deficient aortic rim in thirty two patient (73%). Posterior rim was inadequate in eight patients (18%). Five millimeter was taken as adequate rim. Superior and inferior vena caval rims were adequate in all cases. Devices were deployed successfully in forty cases(95.5%). Life Tech ASD devices were used in all patients. Twelve patients had device size of 46 mm (27%). Eight patients had 44 mm devices (18%). Forty two millimeter devices were used in sixteen patients (36%). Eight patients had device size of 40 mm (18%). (Chart 3)

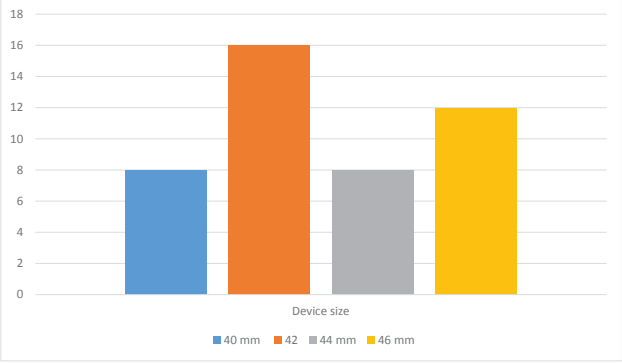

Figure 3. Device size

There was no mortality in our study group. Even in our follow up of six months to two year no patient died. We have no attrition in our follow up. But complications did happen in our procedure. There were two incidence of device embolization (4.5%). Both cases device size were 42 mm and 44 mm respectively. In one case device got embolized immediately after deployment. In another patient there was device embolization after five minutes of successful deployment. Both cases devices were retrieved surgically and patients underwent surgical closure of the defects. We have experienced one cases of transient complete heart block in peri procedure period (2.2%). Device size was 44 mm and complete heart block persisted for four minutes. There was spontaneous recovery but temporary pacemaker support was kept for twenty four hours. Coronary angiography was done immediately and there was no impingement on right coronary or left circumflex artery. Pericardial effusion were observed in two patients (4.5%). (Table 1)

Table 1. Procedure-related complications.

Name of complication	Number	Percentage
Embolization	2	4.5%
Pericardial effusion	2	4.5%
Complete heart block	1	2.2%
Atrial arrythmias	4	9%

It was 10 -12 mm in one patents and did not require any pericardiocentesis. Effusion subsided of its own in follow up. But there were moderate to massive effusion in one patients with haemodynamic compromise. Pericardiocentesis was done immediately and patient recovered uneventfully. There was no recurrent pericardial collection. There were four cases of atrial arrhythmias during device closure (18%). Atrial fibrillation occurred in two patients and atrial flutter in two patients. Atrial flutter and fibrillation did not last long. All arrhythmias subsided without any pharmacological or electrical cardioversion. There was no haemodynamic instability. There is no incidence of erosion or air embolism in our study

Discussion

Transcatheter closure has now become the standard treatment strategy for ostium secundum ASD . Device closure is indicated for ostium secundum ASD patients if rims are suitable and there is significant left to right shunt (>1.5:1) without any evidence of significant pulmonary arterial hypertension (pulmonary artery systolic pressure

less than half of systemic arterial pressure). There are six rims which are evaluated by echocardiography. These are superior, inferior, aortic, posterior, superior vena cava and inferior vena caval rims. Ideally all rims should be present and at least five millimeter in length. But in cases of very large ostium secundum ASD retro aortic rim is not adequate in many times.[6]

Data regarding very large ASD device closure is limited. There is no consensus or guideline about definition of very large ASD device. Here we have taken 40 mm or more device size as very large ASD device. Till now maximum size available is 46 mm. Problem with very large devices are a) challenging deployment b) increased risk of embolization c) complications particularly aortic erosion in follow up. Majority of very large ASD had deficient aortic rim. In our study incidence is around 73 %. There is belief that deficient aortic rim may help to position very large devices. But on the flipside it increases incidence of aortic erosion and device embolization. Success rate of device deployment was in twenty cases (95.5%). Device embolized in two cases-one immediately and one after five minutes after deployment. There were no incidence of air embolism, thrombus formation or infection in our study.

Device embolization is a known phenomenon. Incidence varies between 1 to 3%.[7] Failure of rim assessment and large device size are two important factors for device embolization. Percutaneous retrieval is possible in many cases but surgical help should be sought in failed cases. In our study it happened in two patients. Both the cases we failed to retrieve them percutaneously. Devices size were 42 mm and 44 mm respectively. They went for surgical retrieval and closure successfully. In one case inferior vena caval rim was not adequate and other case Eustachian valve was mistaken as inferior vena caval rim. These were surgical finding in two patients. There were twenty one device embolizations out of 3,824 implants (0.55%) in USA in 2003. Fifteen were retrieved using a transcatheter approach (71.4%) and six were retrieved surgically (28.5%).[8] In another study device was retrieved surgically in 77.2% of cases and by transcatheter approach in

16.7% of cases. There were 2 deaths related to embolization.[9] It is difficult to retrieve very large ASD devices and repeated attempt to retrieve may invite more complications. In one of our case we have perforated right atrial wall and left atrial roof leading to massive pericardial effusion, cardiac tamponade, haemodynamic instability leading to urgent cardiac surgery. It is preferable to opt directly for cardiac surgery rather than prolonged percutaneous retrieval. There was another case of pericardial effusion in our study. Mechanisms of pericardial effusion is unclear. Probably it was terumo wire induced pulmonary vein perforation which sealed off of its own. Inadvertently LA appendage also may get perforated by terumo wire. Terumo wire was used to cross the defect and to guide delivery sheath to pulmonary veins. Device erosion was another possibility. Cardiac CT was done to find out the site of perforation but nothing could be found in post operative period.

There was one incidence of complete heart block in our study but rhythm reverted back to sinus after four minutes. Right coronary artery was checked and it was found to be normal as also left circumflex artery. Mechanism of complete heart block in ASD device closure is unknown. It could be due to stretching of interatrial septum which may interfere with atrio ventricular (AV) nodal conduction time. Large device may impinge on right coronary artery or rarely left circumflex artery which are supplying AV nodal artery. The risk of bundle branch block in patients with large ASD, particularly patients with deficient rims, may be increased, A retrospective study of six hundred and ten device closure patients showed clinically significant AV block occurring in 0.3% of patients.[10]

Incidence of erosion is around 0.043-0.3%.[11] Deficient retro aortic rim and oversized devices are two important predisposing factors for erosion. Erosion usually occurs within one to three months of device deployment. Erosion will lead to fistula formation and it may communicate with different cardiac chambers. It is a lethal complication of device closure and necessitates surgical intervention. Rarely late erosion may occur. In our study we did not experience any case of erosion in one year follow up though many of our patients had very large devices with deficient retro aortic rims. Twenty eight cases of erosion with hemodynamic compromise were reported between 1998 and March 2004 in USA. Erosion rate in USA was 0.1% (9 of 9,000 known U.S. implants). Aortic or superior rim was deficient in twenty five patients. Amongst twenty eight patients: Five involved perforation at the roof of the left atrium and the aorta; six had perforation at the roof of the right atrium and the aorta; in one case, both atria were

involved; in three cases, there was aortic perforations.[12] Atrial arrhythmia was observed in perioperative period in four patients. Two cases of atrial flutter and two cases of atrial fibrillation were seen in our study. All of them were self terminating and did not produce any haemodynamic instability. These are may be due to guidewire, sheath or device induced irritation of atrial wall. In the MAUDE analysis, arrhythmias were seen in five percent of patients. There is a concern that device closure of ASD may preclude future electrophysiology procedures that require transseptal access.[13]

The FDA analysis of the MAUDE medical-device reports (MDR) showed 0.8% incidence of infection or endocarditis.[14] There is no case of nitinol allergy, infection or haemoglobinuria in our device closure patients. All the cases we tried to deploy device from left pulmonary vein approach. We succeeded in all cases barring one where we had to come from right superior pulmonary vein. In the setting of a very large ASD maintaining the posterior orientation of LA disc is difficult. Often the LA disc tilts tangentially across the defect and prolapse back in to the RA. There are notably two manoeuvres which facilitate successful device deployment a) BAT (Balloon assisted technique) b) Greek manoeuvre.In BAT technique one can place inflated Tyshac balloon either in the contralateral pulmonary vein or ipsilateral pulmonary vein which will prevent prolapse of left atrial disc in right atrium. Even few have kept in at left atrium itself to prevent left atrial disc prolapse.(14) The Greek maneuver is applied when there is left atrial disc protrusion into the right atrium from aortic end. To circumvent this, left disk is recaptured and the whole delivery system is pushed inward and leftward into the left atrium. After that left atrial disk and the 2/3 of right atrial disk are simultaneously released into left atrium and positioned properly. Left atrial disc becomes parallel to the septum preventing the protrusion of the device into the right atrium.[15] We didn't use any of the manoeuvre for device deployment. Our inference is key to success are proper sizing of the defect and rims by TEE. Vena caval rims are of utmost important for device deployment. The success of very large ASD closure mainly lies on the proper imaging techniques. We have used 2D TEE but 3D TEE is preferable. Complex anatomical features like extreme malalignment with sinusoidal septum, aneurysm, and fenestrated defects require careful delineation before intervention. Balloon sizing was used in these cases by many operators but we have never used it.

Conclusion

Transcatheter closure of very large ASDs is safe and effective procedure. Complications after device closure is rare. There was no mortality in our study. Proper assessment of rims and defect size are key to success.

Limitations

It is an observation study. Study population size is small. Both Type 1 and type 2 error may occur in interpretation as it is a small single centre study.

Financial Disclosure

None.

Conflict of Interest

None.

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