

Selection of Device Size for Atrial Septal Defect Closure Using Transesophageal Echocardiography without Balloon-Sizing: Experience at Queen Alia Heart Institute

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ABSTRACT

Objective: To report our experience of percutaneous atrial septal defect closure using different devices, stressing the role of transesophageal echocardiography in defect sizing between December 2010 and December 2012.

Methods: Retrospective study of 105 patients that had hemodynamically significant left to right shunt ($\geq 1.5:1$), atrial septal defect secundum underwent trans-catheter closure of the septal defect using different devices at Queen Alia Heart Institute between December 2010 and December 2012. All the closures were performed under general anesthesia in the catheterization laboratory. Detailed study of the defect with measurement of its dimensions, in at least two planes, was performed in a precise way through transesophageal echocardiography. We reviewed the medical records for the size of the defect measured by the transesophageal echocardiography without balloon sizing and the size of the device selected, looked for immediate complications and follow up transthoracic Echocardiography for residual shunts or any other reported complication at one, three, six months and one year follow up.

Results: The patient population consisted of 54 (52%) females and 51 (48 %) males. The mean age was 16.5 years with a range between 6- 63 years. The defect size was between five and 28 millimeters with a mean of 14 millimeters. The device size was between six and 30 millimeters with a mean of 17 millimeters. The upsizing of the device in relation to the defect size measured by transesophageal echocardiography was $3.5\text{mm} \pm 2.5\text{mm}$. Among 105 cases in which Atrial Septal Defect device closure was attempted, two cases underwent surgical closure of the defect due to multiple failed attempts in device closure and the third patient developed device embolization despite demonstrating stability during the “pull back” technique. The device was retrieved successfully with surgical closure of the defect. Follow ups for the patients showed no residual flow at one month, six months and one year follow up.

Conclusion: Secundum atrial septal defect device closure is safe and effective. With increasing experience, device selection for atrial septal defect closure can be accurately done by transesophageal echocardiography without the need for the balloon stretch diameter.

Key words: ASD, Balloon sizing, Device closure, TEE

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Introduction

Secundum atrial septal defect (ASD) is a common congenital heart disease and accounts for about 6% -10% of all congenital cardiac defects.⁽¹⁾ Since 1976, when King and associates⁽²⁾ attempted the first transcatheter closure of a secundum ASD in humans, device closure has evolved significantly. Since then, significant device development and modifications have been made.⁽³⁾ Previous reports have shown that it is easy to use and has a high success closure rate.⁽³⁻⁶⁾ The advantages of percutaneous closure over surgical closure was shown by some studies in older children and adults including avoidance of cardiopulmonary bypass, decreased complication rates, shorter hospital stays,^(7,8) and greater cost-effectiveness.⁽⁹⁾

The multiple roles of intra procedural Transesophageal echocardiography(TEE) include confirmation of inter atrial septal anatomy, size of the defect by measuring the minimal and maximal diameter of the defect using atrial end-diastolic frames in different angles.^(8,9) In the presence of a very floppy and mobile rim, measurement of defect diameter should be made between steadier and firm rims and the color flow jet width across the defect,^(1,3,9) monitoring of the procedure, pre and post closure assessment of adjacent cardiac structures, including the mitral and aortic valves, systemic and pulmonary veins, and direct visualization of device position and stability.⁽⁷⁻⁹⁾

In this study our experience with percutaneous closure of ASD by means of different devices, stressing the role of TEE measurement without the need of the balloon stretch diameter in device selection.

Methods

This was a retrospective study of 105 patients that had secundum atrial septal defect with hemodynamically significant left to right shunt $\geq 1.5:1$ that were admitted for the attempt of trans-catheter closure of the septal defect using different devices at Queen Alia Heart Institute, between December 2010 and December 2012. All closures were performed under general anesthesia in the catheterization laboratory. We reviewed the medical records for the size of the defect measured by the TEE at the time of closure (that was done by the same cardiologist

for all the closures) and the size of the device selected, looked for any immediate complications and reviewed the follow up transthoracic echocardiography for leaking devices or any other reported complication.

In the catheterization laboratory, TEE was used to demonstrate the defect to the interventional team, to measure the diameter of the defect and to help with the selection of the device size. During closure TEE was used in monitoring the opening and placement of the discs and waist of the device in the atrial septum and checking the position of the implanted device and its relation to nearby structures prior to the withdrawal of the delivery catheter; and finally, for evaluation of Residual Flow (RF) whenever present.

After implantation, the patients stayed in the ward for observation until the next morning, being discharged after performing electrocardiography (ECG), and transthoracic echocardiogram. Salicylic acid was prescribed at a dose of 5 mg/kg/day for six months, and prophylaxis for infectious endocarditis was indicated for six months. The protocol for follow-up consisted of clinical evaluation, ECG, and echocardiography scheduled for one month, three months, six months and 12 months after implantation.

The Closure Protocol

All patients were given Salicylic acid at a dose of 5mg/kg/day three days prior to device closure. A written consent was signed by the patient or the care giver after explaining the procedure including the expected complications. All patients were sent to the catheterization laboratory after full evaluation by the anesthesiologist. All closures were done under general anesthesia regardless of age.

The technique of deployment of the devices was similar to that described in the literature for Amplatzer septal occluder device.⁽⁴⁾ TEE was performed in each patient after endotracheal intubation and assisted ventilation under general anesthesia. Dimensions of the defect were measured in various imaging planes. The minimal and maximal diameter of the defect was measured using atrial end-diastolic frames in 0°, 35°, 90°, and 110-135°. In the presence of a very floppy and mobile rim, measurement of defect diameter was made between steadier and firm

rims and the color flow jet width across the defect was also measured to provide supplementary information. The largest dimension was used to select device size.

Procedural success was defined as the ability to close ASD percutaneously with no or insignificant residual shunt on echocardiography. Failure was defined as inability to close ASD percutaneously with atrial septal occluder. Following the procedure, patients were monitored for 24 hours in the ward and echocardiographic evaluation was done before discharge. Patients were discharged 24 hours after the procedure. Low dose of aspirin (5 mg/kg/day) was given for six months. Infective endocarditis prophylaxis was advised for six months after the device implantation.

Results

The patient population consisted of 54 (52%) females and 51(48 %) males (Table I). All the patients underwent the attempt of device closure. It was successfully implanted in 102/105 patients (97%). All patients showed good rims (any rim equals or more than 5 mm) all over except for the anterior superior (retro aortic) one which was insufficient in 29/105 (27.6%) of our cases and yet the closure was done successfully in all of them (100%). One patient developed device embolization despite demonstrating stability during the “push pull” maneuver, and the stability of the device by TEE post procedure with no residual flow. It was detected the second day in the descending aorta by transthoracic echocardiography. The device was retrieved successfully by snaring through the femoral artery using goosneck snare with surgical closure of the ASD. The other two patients were sent to surgical closure due to multiple failed attempts in device closure.

The mean age was 16.5 years with a range between 6-63 years. The defect size was between five and 28 millimeter with a mean of 14 millimeter. The device size was between six and 30 millimeter with a mean of 17 and a mean of device upsizing of $3.5\text{mm} \pm 2.5\text{mm}$, median of 3mm. The devices used were as follows: Occlutech Figulla ASD occluder device (n=81), Amplatzer Septal Occluder device (n=14), Cera septal defect occluder device (n=6) and Figulla Flex II device (n=2) (Table I).

Table I: Demographic and clinical features of ASD patients (N=105)

Age median (range)	12 years (6-71)
Gender	
Males	51(48%)
females	54 (52%)
The maximum diameter of defect as measured by TEE	13mm (5-28)
Selected device diameter	16mm (6-32)
Device type	
Occlutech Figulla	81 (79%)
Amplatzer	14 (13%)
Cera	6 (6%)
Figulla Flex 2	2 (2%)

During follow up of these patients, none had serious complications like late embolization, mitral, aortic or tricuspid regurgitations, significant pericardial effusion or significant tachyarrhythmia.

Discussion

ASD closure via transcatheter route was pioneered by King and Mills in 1975.⁽²⁾ Since then percutaneous closure is the preferred way for ASD closure over the surgical approach, by both patients and physicians, due to its simple technique and the negligible morbidity and mortality.^(7, 8)

The success of percutaneous closure of ASD is directly related to the proper selection of the patients for implantation. Defects should be of the secundum type, located in the central portion of the atrial septum, with thick borders large enough to sustain the device, except for the anterior superior rim which seemingly if it is absent it is not a contraindication for a closure trial,⁽¹⁰⁾ and as was shown by our patients in whom the closure was done successfully in all of them; success rate of 100%. In addition, to patient selection, TEE has been used for the continuous monitoring during the procedure, providing additional safety and significantly reducing radiation-exposure, the TEE also helped in verifying the position of the Device in relation to the ASD and evaluating residual shunt (RS),⁽¹¹⁾ the impact of the device on neighboring structures like the mitral, tricuspid and aortic valves immediately after implantation. TEE is therefore important in conjunction with this procedure.

Over the years, with increasing experience with

trans-catheter closure, device selection was the most important part in transcatheter closure. Larger devices carry the risks of mushrooming deformity of the device, affecting near structures, and other serious complications, such as cardiac erosion^(12,13) while smaller devices carries the risk of instability, distal embolization and residual shunt.^(14,15) So, device sizing and not the device type was the crucial point in ASD closures. In our institution we are using different devices with no significant differences in deployment, and complications. We did not encountered any of the above mentioned complications of erosions, mushrooming nor fatal atrial arrhythmias, only one case of embolization that was detected the second day and may be attributed to the floppy posterior rim and the insufficient oversizing that was needed to ensure the stability of the device.

Balloon sizing of the defect was considered as the most important part of trans-catheter closure of ASD.^(15,16) The selected device is usually identical to or two mm larger than the stretched balloon diameter (SBD) of the defect.⁽¹⁵⁻¹⁷⁾ However, there are many reported disadvantages of balloon sizing; it may cause enlargement of the defect by tearing of the flap valve of the septum primum.^(18,19) Bradycardia and hypotension may occur during prolonged inflation of the balloon due to the obstruction in diastolic filling.⁽²⁰⁾ In addition, due to the 3dimensional shape of the ASD it may be inaccurate measurement secondary to inadequate profiling of the defect and the measuring balloon catheter.⁽¹⁶⁾

However, ASD device closure is increasingly being done successfully by trans-catheter closure techniques without balloon sizing using various imaging modalities. Zanchetta *et al*, did not use balloon sizing during trans-catheter closure of ASD, where waist diameter was chosen based on the r value obtained from intracardiac echocardiographic images [$r = \sqrt{C^2 + P^2}$], C is the foci half-distance of the fossa ovalis and P is its semi-latus rectum.⁽¹⁵⁾ In another study of Zanchetta, an equation of $d = \sqrt{a \times b}$ was obtained, in which a and b were major axes of intracardiac echocardiography on aortic and four-chamber plane, respectively, and d was the diameter of device used.⁽¹⁸⁾ In a study by Amin and Daufors, balloon sizing was considered

unnecessary and a device that was 2–4 mm larger than intracardiac echocardiographic (ICE) diameter was chosen.⁽²¹⁾

In our institution we stopped using the balloon sizing for closure since December 2010 and the success rate was high despite that. The mean upsizing of the device was around $2.5\text{mm} \pm 3.5\text{mm}$. The majority of the upsizing were between 2-4 mm, the mean of 3mm, which correlate better with the study done by Amin and Dauffers as mentioned before. We could not reach a mathematical relationship between the ASD size and the device size as Zanchetta *et al*. The larger upsizing that were done in our device selection depending on color flow and the presence of floppy rims highlighting the importance of measuring the defect from the firm rims by the TEE which provides better anatomic information required for device closure as shown recently by a published study assessing feasibility and safety of trans-catheter closure of ASD without balloon sizing, the mean diameter of the device used in nonballoon sizing group was larger than trans-catheter closure with balloon sizing.⁽²²⁾ This highlights the importance of the better imaging obtained by TEE which is the most important factor influencing the outcome. Sizing obtained by TEE is adequate for successful device closure and may be superior to balloon sizing as it avoids oversizing and is more physiological. Better imaging in these patients may have been provided due to increasing experience in TEE that has resulted in successful closure in the majority of these patients.

Limitations of the Study

This was not a randomized, controlled study. It was a retrospective study documenting our experience in ASD device closure without balloon sizing done by our pediatric cardiologist team using different devices. It was done to emphasize the benefits of TEE imaging during device deployment.

Conclusion

Transcatheter closure of ASD is safe and effective. Device size selection using TEE without balloon sizing is (with increasing experience) accurate, safe and effective.

References

1. **Stevenson JG.** Transesophageal echocardiography. In: Lai WW, Mertens LL, Cohen MS, *et al* editors. Echocardiography in Pediatric and congenital heart disease. UK; blacwell publishing ltd; 2009: 671-686.
2. **King TD, Thomopson SL, Steiner C, Mills NL.** Secundum atrial septal defect: nonoperative closure during cardiac catheterization. *JAMA* 1976; 235: 2506-2509.
3. **Masura J, Gavora P, Formanek A, Hijazi ZM.** Transcatheter closure of secundum atrial septal defects using the new self-centering Amplatzer septal occluder: initial human experience. *Cathet Cardiovasc Diagn* 1997; 42: 388-393.
4. **Thanopoulos BD, Laskari CV, Tsaousis GS, et al.** Closure of atrial septal defects with the Amplatzer occlusion device: preliminary results. *J Am Coll Cardiol* 1998; 31: 1110-1116.
5. **Hijazi ZM, Cao Q, Patel HT, et al.** Transesophageal echocardiographic results of catheter closure of atrial septal defect in children and adults using the Amplatzer device. *Am J Cardiol* 2000; 85: 1387-1390.
6. **Cao QL, Radtke W, Berger F, et al.** Transcatheter closure of multiple atrial septal defects. Initial results and value of two- and three-dimensional transoesophageal echocardiography. *Eur Heart J* 2000; 21: 941-947
7. **Berger F, Vogel M, Alexi-Meskishvili V, et al.** Comparison of results and complications of surgical and Amplatzer device closure of atrial septal defects. *J Thorac Cardiovasc Surg* 1999; 118:674-678.
8. **Kim JJ, Hijazi ZM.** Clinical outcomes and costs of Amplatzer transcatheter closure as compared with surgical closure of ostium secundum atrial septal defects. *Med Sci Monit* 2002; 8: CR787-CR791.
9. **Vladimirio L, Vida MD, Joaquin Barnoya MD, Mauricio O'Connell, MD, et al.** Surgical versus percutaneous occlusion of ostium secundum atrial septal defects. Results and cost-effective considerations in a low-income countries. *J Am Coll Cardiol* 2006; 47(2): 326-331.
10. **Thomas B, Silvana M.** Contemporary echocardiographic guiding tools for device closure of Interatrial communications. *Cardiovasc Diagn Ther* 2013; 3(1):38-46.
11. **Koneti NR, Shelke A, Arramraj SK, et al.** Unexpepected difficulty during Transcatheter device closure of atrial septal defect associated with right aortic arch. *Ann Pediatr Cardiol* 2012; 5 (2); 185-187.
12. **Amin Z, Hijazi ZM, Bass JL, et al.** Erosion of secundum atrial septal defects: Review of registry of complications and recommendations to minimize future risk. *Catheter Cardiovasc Interv* 2004; 63:496-502.
13. **Divekar A, Gaamangwe T, Shaikh N, et al.** Cardiac perforation after device closure of atrial septal defects with the Amplatzer septal occluder. *J Am Coll Cardiol* 2005; 45: 1213-8.
14. **Levi DS, Moore JW.** Embolization and retrieval of the Amplatzer septal occluder. *Cateter Cardiovasc Interv* 2004; 61: 543-571.
15. **Zanchetta M, Onorato E, Rigatelli G, et al.** Intracardiac echocardiography-guided transcatheter closure of secundum atrial septal defect. *J Am Coll Cardiol* 2003; 42:1677-1682.
16. **Saurabh Kumar Gupta, S. Sivasankaran, S. Bijulal, et al.** Trans-catheter closure of atrial septal defect: Balloon sizing or no Balloon sizing – single centre experience. *Ann Pediatr Cardiol* 2011; 4:28-33.
17. **Fischer G, Kramer HH, Stieh J, et al.** Transcatheter closure of secundum atrial septal defects with the new self centering Amplatzer Septal occluder. *European Heart Journal* 1999; 20: 541-549.
18. **Zanchetta M.** On line echocardiography alone for Amlatzer Septal Occluder selection and device deployment in adult patients with atrial septal defect. *Int L Crdiol* 2004; 95: 61- 68.
19. **Harikrishnan S, Narayanan NK, Sivasabramonian S.** Sizing balloon-induced tear of the atrial septum. *J Invasive Cardiol* 2005; 17:546-547.
20. **Rao PS, Langhough R.** Relationship of echocardiographic, shunt flow, and angiographic size to the stretched diameter of the atrial septal defect. *Am Heart J* 1991; 122: 505-508.
21. **Amin Z, Daufors DA.** Balloon sizing is not necessary for closure of secundum atrial septal defects. *J Am Coll Cardiol* 2005; 45:317.
22. **Wang JK, Tsai SK, Lin Smet AL.** Transcatheter closure of atrial septal defect without balloon sizing. *Catheter Cardiovasc Interv* 2008;71:214-221