

PROCEDURAL TECHNICALITIES AND OUTCOME OF TRANSCATHETER CLOSURE OF ATRIAL SEPTAL DEFECT USING OCCLUTECH DEVICE IN TERTIARY CARE CENTRE

Asma Kanwal, Abdul Malik Shiekh, Kiran Azim, Khushal Khan Khattak

Rawalpindi Institute of Cardiology, Rawalpindi Pakistan

ABSTRACT

Objective: To determine the safety and efficacy of transcatheter closure of atrial septal defects and to evaluate the initial, mid-term and long-term results of the treatment.

Study Design: Cross sectional study.

Place and Duration of Study: Department of Paediatric Cardiology, Rawalpindi Institute of Cardiology, Rawalpindi, from Jul 2017 to Jun 2018.

Methodology: Sixty-four patients underwent transcatheter closure of atrial septal defect. Size of the defect was measured by Transoesophageal/Transthoracic. Follow up was carried out at twenty-four hours, one month, six months and at twelve months. Early, Midterm and late complications after device occlusion were analysed using SPSS-22 statistical software.

Results: Minimum size of atrial septal defect on echocardiography was 7 mm and maximum size was 31 mm with mean of 18.3 ± 5.7 mm. The procedure was successful in 96.8% cases. There was only one device embolization (1.56%). Cobrahead" configuration malformation of the device occurred in one case (1.56%). Mitral valve regurgitation did not occur in any of the case. There was no residual shunt across the device in the present study. ECG abnormalities associated with transcatheter closure did not occur in any of the patient. In intermediate and long-term follow up, no complication like cardiac erosion was seen in all cases under study.

Conclusion: Transcatheter occlusion of ASD with device was found effective and safe procedure with minimal complication rate, short hospital stay, good short, intermediate and long-term results.

Keywords: Atrial septal defects, Congenital heart defects, Occlutech device, Transcatheter closure.

How to Cite This Article: Kanwal A, Shiekh AM, Azim K, Khattak KK. Procedural Technicalities and Outcome of Transcatheter Closure of Atrial Septal Defect Using Occlutech Device in Tertiary Care Centre. *Pak Armed Forces Med J* 2021; 71(6): 2170-2174. Doi: <https://doi.org/10.51253/pafmj.v71i6.3342>

This is an Open Access article distributed under the terms of the Creative Commons Attribution License (<https://creativecommons.org/licenses/by-nc/4.0/>), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

INTRODUCTION

Atrial septal defect (ASD) is the most common among the congenital heart diseases with an incidence of 10%.¹ ASDs are usually asymptomatic and possibly remain undiagnosed until the late ages. They come into medical attention insidiously because of auscultatory findings when patient presents to general practitioner because of some other ailment. Later in life, untreated ASD could perhaps cause various other medical complications such as right ventricular failure, arrhythmias and pulmonary hypertension.² Percutaneous transcatheter occlusion of atrial septal defects (secundum type) has revolutionized the management of ASDs. During the last decades, there has been a remarkable change in the treatment strategy of ASD, shifting the therapeutic gold standard from surgery to transcatheter closure, along with changes in device design and the deployment techniques.³ The contemporary devices are much safer than the conventional devices as their properties of re-capturability and repositioning

make them user friendly. Use of biocompatible materials with better design and lesser use of metal promotes re-endothelialization and decrease chances of trauma to the surrounding structures.⁴ Most of the currently available devices show excellent efficacy and comparable outcome. Although the results of surgical closures are also encouraging because of negligible mortality, however, on the contrary associated with various morbidities including pain, thoracotomy scar, anaesthesia complications. These problems have not been reported in case of transcatheter closure.⁵

Device closure of ASD has several advantages over the conventional strategies such as lesser complication rates, short anaesthesia time, short hospital stay and no scar. Transcatheter technique has gained significant place and popularity in field of Paediatric interventional cardiology. A variety of devices have been evolved over a period of time for percutaneous closure of ASDs.⁶ The first non-surgical ASD closure was done in 1975 by Mills and King. In 1983, Rashkind developed a double-disc system for transcatheter closure of ASD.⁷ Newly developed devices include amplatzer and occlutech. These latest devices have many

Correspondence: Dr Asma Kanwal, Department of Cardiology Rawalpindi Institute of Cardiology Rawalpindi-Pakistan

Received: 13 Oct 2019; revision received: 24 Apr 2020; accepted: 24 Apr 2020

advantages over older ones in terms of flexibility, self-centering, easy retrievability, ability to close larger defects and relatively large left atrial disc to close additional fenestrations.⁸ In addition, these devices are proven technically safe and feasible though not free from complications like embolisation, device malalignment, residual shunts, thrombosis of device, fracture of device, impingement of adjacent structures and cardiac erosion.⁹

Various studies have shown high success rate, less complications and low discomfort with atrial septal occluders (ASO). Recently, Mitchelson *et al.* have examined the transcatheter device closure of atrial septal defects for the period of 17 years in which they have found a higher rate of embolisation than the general expectation.¹⁰ Due to these contrary findings, present study was designed to evaluate the efficacy and safety of the occlutech ASO for the short, intermediate and long term period for closure of ASD in children and adolescents. Furthermore, complications occurred during a period of one year were also studied. Taking together, current study will provide a very useful overview of the occlutech ASD device and its technical advantages which could possibly impact the future clinical practices.

METHODOLOGY

The cross section study conducted at Rawalpindi Institute of Cardiology, Rawalpindi, from July 2017 to June 2018 (IERB Approval No. 02/19). A total of 64 patients were examined which undergone for ASD device occlusion using consecutive sampling. Initial echocardiography was done and patients were registered for device occlusion. Transesophageal echocardiography (TEE) was performed in which assessment of size of defect and rims were evaluated. Younger patients in whom TEE was not possible without general anaesthesia considered for device occlusion under transthoracic echocardiography.

Inclusion Criteria: All the patients above 4 years of age with ASD secundum, shunting left to right, right ventricular volume over load and suitable rims of more than 4mm were included in the study.

Exclusion Criteria: Atrial septal defect other than secundum type, patients having larger ASD more than 34mm, right to left shunt, anomalous pulmonary venous drainage and defect with inadequate rims were excluded from study.

The device we used for our study was Occlutech Figulla Flex II ASD Occluder. It is the third generation

Occlutech device for ASD closure. This device is composed of Nitinol mesh coated with titanium with interwoven polyester fibres. It has two disc left atrial (LA) and right atrial (RA) disc and a waist. Occlutech has minimal metal contents that makes it flexible to recapture and re position the device during deployment and makes it less traumatic. The occlutech device has a different release mechanism as compare to amplatzer that enables flexible movement between the device and delivery cable.

Almost all the procedures were done under general anaesthesia. Pre-procedure evaluation done by transesophageal echocardiography to assess the size and rims of ASD in all views. Access was taken from the femoral vein, antibiotics given and I/V heparin was administered after vascular access was taken.¹¹

A 0.035" extra stiff exchange length Amplatzer wire was engaged in left upper pulmonary vein. Delivery sheath was passed on the wire. Dilator, wire and sheath were removed. A Septal occluder device was selected and passed through the delivery sheath and deployed. The LA disc was released in LA. RA disc was released subsequently. A final TEE examination was undertaken to demonstrate the position of the device and any residual shunting.^{12,13}

Patients were kept admitted in ward for 24hrs. Echocardiography was done before discharge to look for position of device, any residual shunts and mitral regurgitation. Anticoagulation was given in form of Acetylsalicylic Acid for 6months. Echocardiographic follow up was done after 1 month, 3 months, 6 months and 12 months apart. Proforma was used to identify the clinical spectrum, age and gender distribution. ASD sizes on transesophageal echocardiography, Margins of ASD, device sizes in relation with sizes of ASD were noted. Early, mid-term and late complications after device occlusion were analyzed using Statistical Package for the social sciences (SPSS) version 23. Categorical variables were analyzed through frequencies; continuous variables were analyzed as mean and SD.

RESULTS

A total of 68 patients were considered for device occlusion. Minimum age of patient was 4 years and maximum age was 61 years with mean age of 20.2 ± 2.80 years. Among 68 patients, 4 (5.8%) procedures were abandoned because ASD were not suitable for device occlusion on final TEE assessment. Out of total patients 22 (34%) were male and 42 (66%) females. Minimum size of ASD on TEE was 7.0mm and maximum size was 31mm with mean of 18.3 ± 5.7 mm.

Minimum procedure time was 10 minutes and maximum time was 180 min with mean 38.7 ± 31.4 min. Minimum fluoroscopy time was 1.6 minutes and maximum time was 51 minutes with mean of 8.6 ± 2.03 min (Table).

Table: Procedural outcomes.

Parameters	Mean \pm SD
Atrial Septal Defect Size	18.38 ± 5.74 mm
Mean Fluoroscopy time	8.69 ± 2.03 minutes
Mean Procedure time	38.63 ± 31.39 minutes

Out of 64 patients, 34 (53.1%) ASDs were closed with large devices of 20-36 mm. "Cobrahead" configuration malformation of the device occurred in one case (1.56%). There was one device embolization (1.56%). Size of defect was 25mm and closed with 27mm device. Device was embolised just after it was released. In another case due to prolong procedure time, a streak of clot was formed over the device seen on transthoracic echocardiography despite repeating heparin, so the procedure was abandoned in order to prevent embolization of the clot.

Procedure related complication occurred in one case where delivery sheath was broken in femoral vein while removal and retrieved by surgeon, however, there was no sequel to this event. Mitral valve regurgitation occurred in none of the case. The residual shunt across the device was also not encountered in the present study. ECG abnormalities associated with transcatheter closure like atrial premature contractions, SVT, atrial flutter or fibrillation did not occur in any of the patient. In the intermediate and long-term follow up, no complication like cardiac erosion was seen in all cases under study.

DISCUSSION

Atrial septal defect is one of the most common congenital cardiac defects. After introduction of transcatheter closure of ASD in 1990 for secundum type of defects, it has become the procedure of choice.¹⁴ Transcatheter closure has less complications and morbidity compared to surgical procedures. In most of the cases, success rate of device closure has been reported as 98%.¹⁵ However, there are some discrepancies in the data regarding efficacy of the contemporary devices being used for the closure of ASD. Present study was designed to investigate the efficacy of the occlutech device for the closure of ASD in Pakistani population for a period of one year. Our results indicated successful device implantation in 96.8% of cases and major cause of failure was short rims especially SVC rim. Selection of size of device is considered as an important

decision. Smaller device has increase chances of embolization and residual leaks however larger devices have chances of impingement of adjacent structures. Interatrial septal length is also an important consideration during implantation of device especially in smaller children with larger defects.^{16,17}

Devices with a waist diameter larger than 2mm were implanted in 56.25% of cases. Device size ranging between 3-6 mm increments for the size of ASD. In our study maximum size was 31 mm which was closed with device size of 36mm. In another series largest ASD size was 34 mm and smallest rim was 4mm. This defect was closed with Amplatzer device no 36 mm. Rania *et al.* demonstrated the mean upsizing of the device was around $2.5\text{mm} \pm 3.5\text{mm}$.¹⁸ The majority of the upsizing were between 2-4 mm, the mean of $3\text{mm} \pm \text{SD } 3.5$, which correlate better with the study of Amin and Dauffers.¹⁹ However, none of study demonstrated the mathematical relation of sizing of device which may have significant role in ASD closure. Therefore, a focused study should be carried out in order to establish the mathematical relation of ASD and sizing of device. Transesophageal Echocardiography was performed in all the patients for varying size of ASD. Balloon sizing was performed in 7 patients and devices 2 mm larger after balloon sizing were used, however, the results of our study was found to be in line with most of the previous studies of Pillai *et al*, Amin *et al*, and Narin *et al*, which suggested that TEE was sufficient for sizing the ASD.^{17,19,20} Besides, present study suggests that balloon sizing is usually not required since it has least role in sizing the device.

One of the major complications of device occlusion reported so far is embolization of devices. In our study, the embolization was occurred in only one case (1.56%) and it was just after implantation. It was 25mm defect which was closed with a 27mm device. Possible cause of embolisation was relatively short SVC margin. In another study, out of sixty three patients two devices were dislodged and incidence of embolisation was around 3.17%.¹⁴ The Meta-analysis of the incidence of device embolization was found to be 0.2-0.43% and all were within 24 hours of procedure.²¹ Recently, Mitchellson *et al*,¹⁰ reported comparatively higher incidence of device embolisation (1.7%) which suggested deviance in the efficacy of the procedure and emphasized on the need for data collection and complications incidence for improvement of future practices. Present study also suggested the collection of data from various cardiac centres in Pakistan regarding the success and

complications of ASD device in order to refine the information for users.

Cobra head deformity is also a known complication of ASD device occlusion. Device takes a cobra like shape and its configuration need to be corrected by repositioning of device, it is sometimes challenging in case of less available space in atrium and device has to be retrieved in most of the cases and re-poisoned outside for next attempt.²² In our study, one cobra head deformation was occurred. Besides multiple attempts of reconfiguration, the device remained malformed. Therefore, device was replaced with a similar size and implanted successfully. Hoole *et al*, reported an incidence of 3% of cobrahead deformity and reported that cobrahead deformity occur due to twisting of nitinol mesh and larger devices.²² In present study, 1.56% cobrahead deformity was observed which is fairly lower than the reports of Sephen *et al*. Several reasons have been postulated for cobrahead deformity, including opening the device against the body of the left atrium, difficulty in device deployment; twisting the device be due to the smaller space available in atrium for larger devices as suggested in the literature (Kilic *et al*).²³ However, exact cause of cobrahead deformation yet remains elucidative.

Atrial arrhythmias (AR) are known to be determinant causes of late cardiac morbidity in the patients which had trans-catheter closure of ASDs. In literature, new onset arrhythmias after ASD device are significantly higher. Kyoung-Min Park *et al*,²⁴ have reported that 4.4% of the patients suffered with atrial tachyarrhythmia during the follow-up period of 11.4 months. It has been proposed that mechanical irritation caused by the device could be associated with some arrhythmias (Spies *et al*).²⁵ In present study, no case of arrhythmias in early, mid-term and long-term follow up was observed. The possible explanation of finding might be care full selection of device size and not too much upsizing. However, no consolidated information regarding new-onset atrial tachyarrhythmia after ASD closure is available so far. Erosions are important cardiac complications occur post-transcatheter closure of ASD and their rates have been reported between 0.05 and 0.46%. Cardiac erosion is a late complication of device. In case of present investigation, erosion has not been reported in any of the device. Despite so many benefits and advantages, the major technical shortfall of occlutech device was the limited size options (1.5mm increments up to 12mm and in 3mm increments thereafter) that

cause difficulty in selection of device size at certain times.

LIMITATION OF STUDY

In present study, only occlutech devices are used other type devices could be used to compare results of different devices.

CONCLUSION

Present work highlighted the safety and efficacy of occlutech septal occluders and we concluded that transcatheter closure of ASD was found safe and effective technique for the closure of ASD with less complication rate and morbidity. The occlutech septal occluders are appropriate devices that warrant less operational risks and higher reliability.

Conflict of Interest: None.

Authors' Contribution

AK: Design, analysis, AM: Concept, Review, KA: Analysis review, KKK: Analysis, Interpretation.

REFERENCES

1. Liu Y, Chen S, Zühlke L, Black GC, Choy M-k, Li N, et al. Global birth prevalence of congenital heart defects 1970-2017: updated systematic review and meta-analysis of 260 studies. *Int J Epidemiol* 2019; 48(2): 455-463.
2. Nashat H, Montanaro C, Li W, Kempny A, Wort SJ, Dimopoulos K, et al. Atrial septal defects and pulmonary arterial hypertension. *J Thorac Dis* 2018; 10(Suppl-24): S2953.
3. Fan H, Ximing Q. Treatment options for the closure of secundum atrial septal defects: A systematic review and meta-analysis. *Int J Cardiol* 2018; 254(1): 89.
4. Jung SY, Choi JY. Transcatheter closure of atrial septal defect: principles and available devices. *J Thorac Dis* 2018; 10(Suppl-24): S2909.
5. Siddiqui WT, Usman T, Atiq M, Amanullah MM. Transcatheter versus surgical closure of atrial septum defect: a debate from a developing country. *J Cardiovasc Thorac Res* 2014; 6(4): 205.
6. Suchon E, Pieculewicz M, Tracz W, Przewlocki T, Sadowski J, Podolec P. Transcatheter closure as an alternative and equivalent method to the surgical treatment of atrial septal defect in adults: comparison of early and late results. *Med Sci Monit* 2009; 15(12): CR612-CR617.
7. Mills NL, King TD. Nonoperative closure of left-to-right shunts. *J Thorac Cardiovasc Surg* 1976; 72(3): 371-378.
8. Faccini A, Butera G. Atrial septal defect (ASD) device transcatheter closure: limitations. *J Thorac Dis* 2018; 10 (Suppl-24): S2923.
9. Villablanca PA, Briston DA, Rodés-Cabau J, Briceno DF, Rao G, Aljoudi M, et al. Treatment options for the closure of secundum atrial septal defects: A systematic review and meta-analysis. *Int J Cardiol* 2017; 15(241): 149-155.
10. Mitchelson B, O'Donnell C, Ruygrok P, Wright J, Stirling J, Wilson N. Transcatheter closure of secundum atrial septal defects: has fear of device erosion altered outcomes? *Cardiol Young* 2017; 27(6): 1153-1161.
11. Mortezaeian H, Zanjani KS, Rad EM. Transcatheter atrial septal defect closure using OcclutechFigulla device: A two-center experience. *J Tehran Heart Cent* 2013; 8(4): 197.
12. Bissessor N. Current perspectives in percutaneous atrial septal defect closure devices. *Med Devices (Auckl)* 2015; 8(1): 297-303.

Procedural Technicalities

13. Ackermann S, Quandt D, Hagenbuch N, Niesse O, Christmann M, Knirsch W, et al. Transcatheter atrial septal defect closure in children with and without fluoroscopy: a comparison. *J Interv Cardiol*. 2019 [Internet] Available at: <https://www.hindawi.com/journals/jitc/2019/6598637/> (Accessed on July 20, 2018)
 14. Kazmouz S, Kenny D, Cao QL, Kavinsky CJ, Hijazi ZM. Transcatheter closure of secundum atrial septal defects. *J Invasive Cardiol* 2013; 25(5): 257-264.
 15. Turner DR, Owada CY, Sang-Jr CJ, Khan M, Lim DS. Closure of secundum atrial septal defects with the AMPLATZER septal occluder: a prospective, multicenter, post-approval study. *Circ Cardiovasc Interv*. 2017; 10(8): e004212.
 16. Baruteau AE, Hascoët S, Fraisse A. Transthoracic echocardiography is a safe alternative for assessment and guidance of transcatheter closure of secundum atrial septal defect in children. *J Thorac Dis* 2017; 9(5): 1247.
 17. Pillai AA, Balasubramanian VR, Selvaraj R, Saktheeswaran M, Satheesh S, Jayaraman B. Utility of balloon assisted technique in trans catheter closure of very large (≥ 35 mm) atrial septal defects. *Cardiovasc Diagn Ther* 2014; 4(1): 21-25.
 18. Haddadin R, Al-Ga'afreh MK. Selection of device size for atrial septal defect closure using transesophageal echocardiography without balloon-sizing: experience at queen alia heart institute. *J Royal Soc Med* 2013; 102(903): 1-5.
 19. Amin Z, Hijazi ZM, Bass JL, Cheatham JP, Hellenbrand WE, Kleinman CS. Erosion of Amplatzer septal occluder device after closure of secundum atrial septal defects: review of registry of complications and recommendations to minimize future risk. *Catheter Cardiovasc Interv* 2004; 63(4): 496-502.
 20. Narin N, Baykan A, Argun M, Ozyurt A, Pamukcu O, Bayram A, et al. New modified balloon-assisted technique to provide appropriate deployment in the closure of large secundum atrial septal defect using amplatzer septal occluder in children. *J Invasive Cardiol* 2014; 26(11): 597-602.
 21. Yang MC, Wu JR. Recent review of transcatheter closure of atrial septal defect. *Kaohsiung J Med Sci* 2018; 34(7): 363-369.
 22. Hoole SP. Room to rotate encourages amplatzer septal occluder cobra head configuration. *Interv Cardiol J* 2015; 1(1): 1-3.
 23. Kilic T, Ural E, Sahin T. Cobrahead deformity in the right atrial disc of a new-generation Occlutech Figulla Flex II atrial septal defect occluder device. *Tex Heart Inst J* 2015; 42(5): 454-457.
 24. Park KM, Hwang JK, Chun KJ, Park SJ, On YK, Kim JS, et al. Prediction of early-onset atrial tachyarrhythmia after successful trans-catheter device closure of atrial septal defect. *Med (Baltimore)* 2016; 95(35): e4706.
 25. Spies C, Khandelwal A, Timmermanns I, Schröder R. Incidence of atrial fibrillation following transcatheter closure of atrial septal defects in adults. *Am J Cardiol* 2008; 102(7): 902-906.
-