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*International Journal of Current Research*
*Vol. 10, Issue, 02, pp.65934-65938, February, 2018*

**INTERNATIONAL JOURNAL OF CURRENT RESEARCH**

**ISSN: 0975-833X**

## RESEARCH ARTICLE

# PERATRIAL DEVICE OCCLUSION OF LARGE SECUNDUM ATRIAL SEPTAL DEFECT IN ADULTS: LONG TERM FOLLOW-UP RESULTS

**[1]Zeeshan Farhaj, [1,*]Li Hongxin, [2]Guo Wenbin, [1]Zhang Wen-Long, [1]Zhang Hai-Zhou, [1]Fei Liang, [1]Yuan Gui-Dao, [1]Geoffrey Joseph Changwe and [1]Cheng-Wei Zou**

[1]Department of Cardiovascular Surgery, Shandong Provincial Hospital Affiliated to Shandong University, No 324 Jingwu Road, Jinan 250021, China
[2]Ultrasound Department, Shandong Provincial Hospital Affiliated to Shandong University, Jinan 250021, China

**ARTICLE INFO**

*Article History:*
Received 21st November, 2017
Received in revised form
10th December, 2017
Accepted 16th January, 2018
Published online 28th February, 2018

*Key words:*
Large secundum ASD,
Peratrial device occlusion,
Short rim,
Large device,
TEE.

**ABSTRACT**

**Background:** There are few reports on peratrial device occlusion of large secundum atrial septal defect in adults and long term follow-up post occlusion.
**Objectives:** This study aims to provide evidence of safety, efficacy, feasibility and simplicity of peratrial device occlusion of large secundum atrial septal defects in adults.
**Method:** Ninety patients with maximum diameter of ≥ 30mm of secundum atrial septal defects underwent peratrial device occlusion. A 2 to 3cm incision was made in right 4th parasternal intercostal space. The pericardium was suspended. A specially designed short delivery sheath loaded with device was advanced through the purse-string sutures placed on projecting part of right atrium. The device was deployed under transesophageal echocardiographic guidance.
**Results:** The procedure was successful in all patients. The age ranged from 18-70 years (mean 40.6 ± 13.6). The body weight ranged from 43 - 87 KG (mean 61 ± 10). The maximum diameter of ASD ranged from 30 – 43 mm (mean 32 ± 2.4). The one of rims was short (≤5mm) in 19/90 patient and sufficient in remaining 71/90 patients. The mean size of implanted devices was 36 ± 2.7 for all patients. The device was replaced with a smaller and larger size in 7/17 and 10/17 patients respectively. The total intracardiac manipulation time was 8.1±7.9 minutes. The total procedural time was 57±14 minutes. The total occlusion rate was 91% immediately after occlusion, 97% at 6 months, 98% at 1 year, and 100% at ≥2 years follow-up. There were no early or late complications during the follow up period of 6-72 months (mean 54 ± 36months).
**Conclusions:** Peratrial device occlusion of large secundum atrial septal defect is safe, effective, feasible and simplest of atrial septal defects' procedure. The long term results are very promising. The short rim and consequent selection of larger device had no negative effects on outcomes.



**Citation: Zeeshan Farhaj, Li Hongxin, Guo Wenbin, *et al.* 2018.** "Peratrial device occlusion of large secundum atrial septal defect in adults: Long term follow-up results", *International Journal of Current Research*, 10, (02), 65934-65938.

## INTRODUCTION

The transcatheter device occlusion of secundum atrial septal defect (ASD) is a very well-known accepted alternative of surgical closure (SC) since 1990s. It has shown its superiority in terms of lesser complications and as an effective alternative to surgery (Chen *et al*., 2015; Lock *et al*., 1987; Du *et al*., 2002; Masura *et al*., 1997; Losay 2001). It is perhaps noteworthy that transcatheter occlusion (TO) of ASD is more expensive than SC in developing countries (Vida *et al*., 2006). Although with increasing number of expert centers and advances in techniques TO yet presents number of risks such as device embolization, residual shunt, malposition and a certain percentage of failure in patients where one of the rims is short (≤5) (Losay *et al*., 2001; Chessa *et al*., 2002; Fischer *et al*., 2003; Chan *et al*., 1999; Varma *et al*., 2004). Since beginning of this century, peratrial device occlusion of ASD has been performed in our center and its results are well documented (Hongxin, *et al*., 2003; Hongxin *et al*., 2005; Liang *et al*., 2006; Hongxin *et al*., 2007; Hongxin *et al*., 2008).

***Corresponding author:*** **Li Hongxin,**
Department of Cardiovascular Surgery, Shandong Provincial Hospital Affiliated to Shandong University, No 324 Jingwu Road, Jinan 250021, China.

## MATERIAL AND METHODS

### Patients and Clinical Details

Between July 2001 and January 2018, 90 adult patients were diagnosed with large (≥30 mm) secundum ASD by transthoracic echocardiography. All patients underwent peratrial device occlusion. Among them 38/90 patients were

symptomatic. The symptoms were shortness of breath on exertion, palpitations, exercise intolerance, and chest pain. The presence of pulmonary hypertension was noted in 43/90 patients. Nineteen of 43 patients had mild pulmonary hypertension (pulmonary artery systolic pressure 30-45) and rest of them had moderate pulmonary hypertension (pulmonary artery systolic pressure 46-75). All patients were assigned to Group A or B as sufficient rim group or deficient one of rims, respectively (Table 1). There were 71/90 patients with sufficient rim and 19/90 patients with deficient one of the rims. Routine preoperative examinations including electrocardiogram, chest x-ray and blood test were done to screen for any other abnormalities. Informed written consent was obtained from all patients or their guardians. The peratrial device occlusion of large secundum ASD was approved by Ethics Committee of our hospital.

**Procedure and Transesophageal Echocardiography**

Under general anesthesia, patients were placed in supine position. All patients were assessed preoperatively by transesophageal echocardiography (TEE) to measure the size of defect, location of defect and suitability for device occlusion. The maximum unstretched longitudinal and horizontal diameters of the defects were noted to determine if the defects were round or elliptical. Then the device was selected according to their shape. The device selection has been explained previously (Hongxin *et al*., 2008). The delivery system consists of specially designed short delivery sheath with side arm and a short delivery cable (Figure 1).

**Figure 1. Delivery System**

The Delivery system consisted of a short delivery sheath with a side arm, and a short delivery cable.

The procedure has been explained in previous report (Hongxin *et al*., 2007). The anticoagulation was achieved by unfractionated heparin intravenous bolus (100units/kg). In summary, a 2 to 3 cm incision was made in right 4$^{th}$ parasternal intercostal space (Figure 2). The pericardium was excised and suspended. The purse-string sutures were placed on projecting part of right atrium using 4-0 Polypropylene suture. The device was loaded into the short delivery sheath. The heparinized normal saline 0.9% was used to de-air the device and sheath. A puncture was made on right atrium within purse-string sutures. Under TEE guidance the delivery sheath was advanced through the ASD into left atrium (Figure 3).

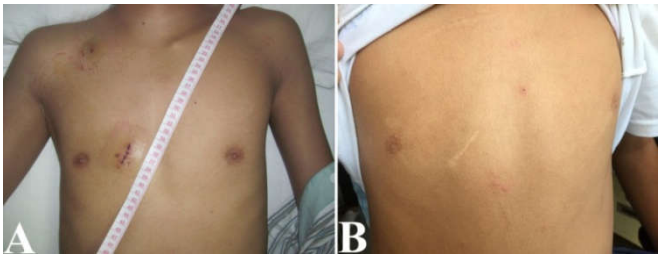


**Figure 2. Peratrial Device Occlusion Scar**

A right 4$^{th}$ parasternal intercostal incision scar on day 2 (Panel A). The scar on follow-up at 2 years in a different patient.

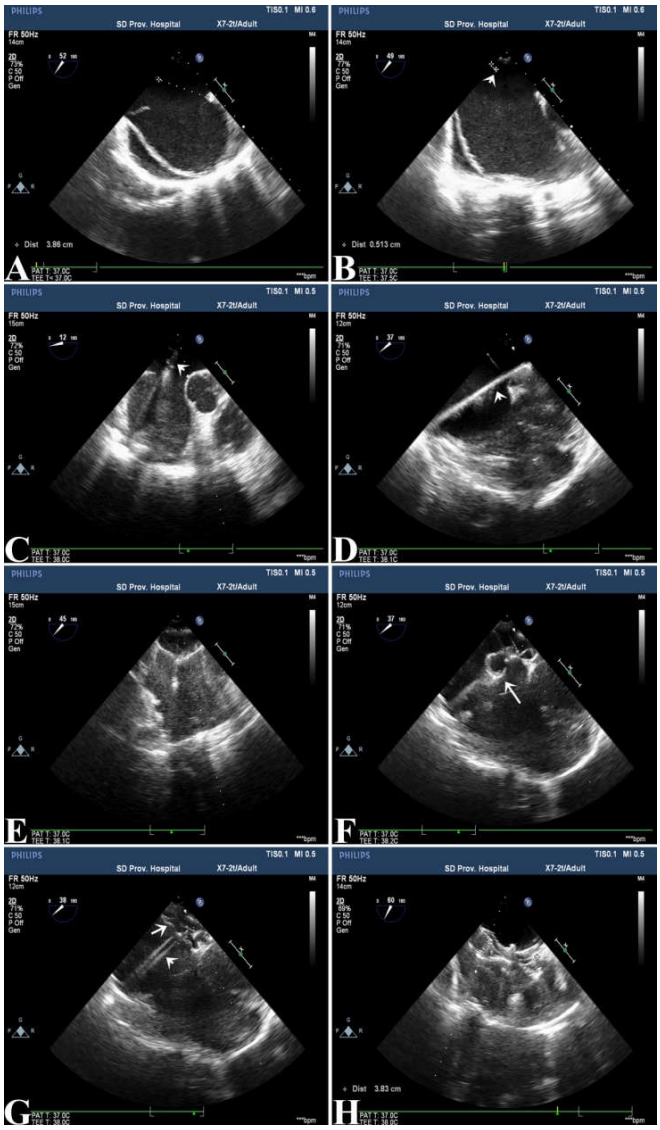


**Figure 3. Peratrial Device Occlusion under Transesophageal Echocardiographic Guidance**

An atrial septal defect measuring 38mm on TEE (Panel A). A short and thin inferior vena cava rim measuring 5mm (arrowhead Panel B). The short delivery sheath is seen across the ASD into left atrium (arrowhead, Panel C and D). The left disk of device is seen expanded in left atrium (Panel E). The right disk of the device during expansion in right atrium (arrow, Panel F). The device (arrow) is seen in situ after deployment with delivery cable (arrowhead) attached to device (Panel G). The TEE view after successful device deployment (Panel H).

**Table 1.**

| Clinical Characteristics of Patients | | | | |
|---|---|---|---|---|
| Variables | Total | Group A | Group B | *p* value |
| Patient number (n) | 90 | 71 | 19 | -- |
| Age (years) | 40.6 ± 13.6 (range 18-70) | 41.4 ± 13.9 | 37.4 ± 12.4 | 0.24 |
| Gender (F/M) | 68/22 | 55/16 | 13/6 | 1.00 |
| Weight (kg) | 61 ± 10 | 61.9 ± 10.9 | 60 ± 9 | 0.56 |
| Maximum Diameter of ASD (mm) | 32.2 ± 2.3 | 32.4 ± 2.5 | 31.6 ± 1.7 | 0.13 |
| ≥30 - ≤ 34 mm (n) | 78 | 60 | 18 | -- |
| ≥35 - ≥ 40 mm (n) | 12 | 11 | 1 | -- |
| Device size (mm) | 36.4 ± 2.7 | 36.4 ± 2.5 | 36.3 ± 3.4 | 0.07 |
| D value | 4.2 ± 2.5 | 4 ± 2.4 | 4.6 ± 2.9 | 0.03 |
| Device redeployment (%) | 18.9% | 17% | 26% | 0.44 |
| Intracardiac manipulation time(min) | 8.1 ± 7.9 | 7.4 ± 6.5 | 9 ± 9 | 0.007 |
| Procedural time (min) | 57.6 ± 14.7 | 56.8 ± 14.6 | 59 ± 14.4 | -- |

ASD= Atrial Septal Defect, D value= difference between the implanted device size and maximum diameter of ASD,

**Table 2.**

| Residual shunt follow-up | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Types / Time line(n) | Immediate after device release (90) | Discharge (90) | 3 months (90) | 6 months (90) | 1 year (90) | 2 years (86) | 3 years (71) | ≥5 years (70) |
| Group A (71) | 8 | 7 | 6 | 2 | 1 | 0 | 0 | 0 |
| Group B (19) | 1 | 1 | 1 | 1 | 1 | 0 | 0 | 0 |

Each follow-up time column shows the total number of patients available for follow-up and number of patients with residual shunt.

Then blood was withdrawn from side arm for further de-airing. The device was deployed under complete TEE guidance without the use of fluoroscopy. After deployment of device, standard push and pull maneuver was done to ensure the stability. Redeployment of the device was done if the device position was unsatisfactory, residual shunt (RS) more than 3 mm or infringement of the adjacent structures was demonstrated by TEE. Once satisfactory results were seen on TEE, the device was released. Further assessment was done by TEE to ensure device position and to measure the RS if present. The delivery sheath was then removed. The purse-string sutures were tied. The hemostasis was achieved. The incision was closed in layers without drainage tube. **Follow-up.** Aspirin (3-4mg/kg/day) was continued for 6 months. All patients were given prophylactic antibiotics. Follow-up investigation including electrocardiography and transthoracic echocardiography were scheduled at discharge, 1, 3, 6 and 12 months then yearly afterwards.

**Statistical Analysis**

The data is expressed as mean ± SD and range. The independent sample *t*-test and Mann-Whiteny test were used to compare the clinical parameters between two groups. The nominal variables between two groups were compared using Fisher's exact test. A *p* value of <0.5 was considered significant.

## RESULTS

The maximum diameter of the ASD ranged from 30 to 43 mm (mean 32 ± 2.4). There were 78 patients with ASD diameter of 30 – 34 mm and 12 patients with ASD diameter of ≥35 mm. The mean size of devices was 36 ± 2.7 for all patients. The D value (difference between the implanted device size and maximum diameter of ASD) was 4 ± 2.5 for all patients. The procedure was successfully completed in all patients. Redeployment of the device was done in 17/90 patients. In 7/17 patients the device was changed with a smaller one due to infringement on adjacent structures such as coronary sinus and mitral valve or over estimation of size by TEE. The device was replaced with larger one in 10/17 patients due to instability or residual shunt. The redeployment of devices was more common in patients with deficient one of the rims 5/19 (26%) than in those with sufficient rim 12/71 (17%). The intracardiac manipulation time ranged from 2 to 42 minutes in all patients (mean 8.1 ± 7.9). Seventy four percent of operations were completed within one hour. The post operation length of hospital stay was 3-4 days. The total follow up period ranged from 6 months to 72 months (mean 54 ± 36 months). The short and long term follow up results were available for 90 patients at 6 months and 1 year, 86 patients at 2 years, 71 patients at 3 years and 70 patients for 4-6 years of time. The symptoms were improved in all patients or resolved completely over the follow-up. The pulmonary hypertension declined in all 43 patients which was noted over follow-up period by echocardiography.

The RS was noted in 9/90 patients (10%) immediately after operation which disappeared over follow-up. It was less than 3mm in all patientsand resolved on follow-up. The prevalence of RS or complete occlusion rate is shown in Table 2. The complete occlusion rate at discharge was 91%, at 6 months follow-up 97 %, at 1 year 98% and 100% thereafter. The transient bradycardia and premature atrial contractions were noted in 5/90 (5%) patients early postoperative period (within 24hours) which were treated medically. There were no thromboembolic events or other early or late complications.

## DISCUSSION

The SC is gold standard treatment for ASD and has provided with unsurpassed results (Baskett *et al*., 2003). However, SC is associated with other debilitating effects of large incision, cardiopulmonary bypass, blood transfusion, longer hospital stay and postoperative pain. Comparing SC with peratrial device occlusion, device occlusion betters in many ways such as shorter hospital stay, no cardiopulmonary bypass, no need

of blood transfusion, minimal scar and far less postoperative pain, quicker recovery and early ambulation (Hongxin *et al*., 2003; Hongxin *et al*., 2005; Liang *et al*., 2006; Hongxin *et al*., 2007; Hongxin *et al*., 2008). The TO of ASD has been in practice for over 20 years since its first clinical use (Masura *et al*., 1997), and its results and favorable factors have been described in detail in previous reports (Vida *et al*., 2006; Chessa *et al*., 2002; Fischer *et al*., 2003). Although its favorable facts over SC, device malposition, embolization, failure in deployment and residual shunt are common (Chessa *et al*., 2002; Fischer *et al*., 2003; Chan *et al*., 1999; Varma *et al*., 2004). The TO and peratrial device occlusion were compared extensively in previous report (Hongxin *et al*., 2008). When compared peratrial device occlusion has very simple route of occlusion. The perpendicular entry to ASD and use of shorter sheath allows practitioner to guide the sheath towards defect more easily and with absolute accuracy. The ASD can be occluded under TEE guidance without the use of fluoroscopy which in TO is the fate of practitioners, patients, nurses and technicians altogether. There is no need of longer sheaths which is cost effective and less in technical demand, where by use of more advance equipment TO is expensive in third world nationsas compared to SC and is not readily available (Vida *et al*., 2006).

Moreover there is no limitation of TO when it comes to pediatrics population where it is bound by body weight and size of vessels when larger sheaths and devices are needed (Baskett *et al*., 2003). Large ASD are a risk for incomplete closure no matter what approach is used (Losay *et al*., 2001; Varma *et al*., 2004). In our series the occlusion rate has been demonstrated above 98% at 1 year follow-up. Another study has reported difficulties in TO of ASD size > 30mm where procedure completion rate was 65% (Suarez De Lezo *et al*., 2000). In our series all of the patients had ASD size > 30mm, and procedure success rate was 100%. This explains superiority of peratrial device occlusion of ASD no matter the size of defects. The larger the size of ASD the higher the possibility of shorter rims or absent rims which upon review of literature was associated with unsuccessful attempts of percutaneous ASD closure (Losay *et al*., 2001; Varma *et al*., 2004). Our series included 19 patients (21%) where one of the rims was deficient, yet procedure success rate was 100%. This success belongs to intentional positioning of sheath while deploying devices which is not possible to attain during TO. Another advantage is that device selection for a complete occlusion is smaller in peratrial approach than in TO approach.

**Residual Shunt and Arrhythmia**

Residual shunt is one of concerns post TO closure (Du *et al*., 2002). Although small or trivial shunts are usually ignored by practitioners as they usually disappear during follow-up period (Table 2) which is also demonstrated in previous study (Hongxin *et al*., 2007). In this study we have demonstrated 100% complete occlusion rate at 2 years follow-up and onwards. Postoperative arrhythmias were reported immediately and early period in 5 patients (5%) which were controlled medically. This relates to previous report where it was only reported early after device deployment and no late cases were seen (Hill *et al*., 2000). Recently a report mentioned TO of large ASD in pregnant women of 26 weeks gestation (Stokes *et al*., 2017). Where a fetus was exposed to radiation, although a healthy baby was delivered but potential risks of radiation could have been avoided by peratrial device occlusion.

The short or absent rim is one of the factors that influences device closure. Most of large ASD are associated with deficiency of rims which causes device malposition or deployment failure. Previous studies indicated (Du *et al*., 2002; Wang *et al*., 2004) deficiency in the anterior superior rim did not influence the success rate of ASD closure with the Amplatzer device. It was noted in some studies that deficiency of inferior posterior rims was more commonly associated with deployment failure (Losay *et al*., 2001; Chessa *et al*., 2002; Varma *et al*., 2004). According to our experience, the most important rim is the IVC and SVC rim in peratrial approach. The aortic rim is the least important and is usually absent in larger defects.The minimum rim length of 5mm is one of the criteria for device closure (Mazic e*et al*., 2001). In our series redeployment was frequently needed in patients where either one the rim was deficient (except aortic rim), it correlates with another study where deficiency of one of rims was frequently associated with redeployment or residual shunt (Du *et al*., 2002).

The recommendations to overcome hurdle faced when occluding ASD with short or absent rim were discussed previously (Hongxin *et al*., 2008). In summary larger devices would need to be selected, which will result in longer intracardiac manipulation time and redeployment of the devices would be frequent when adjacent structures are impinged. This is shown in Table 1. where the intracardiac manipulation time was longer in short one of rims Group B than in sufficient rim Group A ($p<0.007$). This also influenced on selection of device size and larger devices were selected in group B than A ($p<0.07$). Consequently when occlusion of ASD with deficient rim is done it is better to choose the device with 5-6mm larger than the maximum diameter of ASD. The excellent results seen in our study are due to careful selection of patients, where all the factors were taken into account before decision was taken to perform device occlusion in large ASD patients (Hongxin *et al*., 2007).

**Study Limitations**

There are no children in this study. The device occlusion is more challenging in children than adults. Although this study shows excellent results, a longer follow-up period is required to determine the safety of peratrial device occlusion of large ASD.

**Conclusion**

Peratrial device occlusion of large secundum atrial septal defect is safe, cost effective, feasible and simplest of atrial septal defects' procedure. The long term results are excellent. The short or absent rim and consequent selection of larger device had no negative effects on outcomes. The peratrial device occlusion can be safely considered an alternative to surgical or TO for large secundum ASD.

**Funding:** This study was supported by the Natural Science Foundation of Shandong Province, China (Grant No. ZR2013HM063).

**Conflicts of Interest:** None Declared.

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