

Safety and feasibility of intra-operative device closure of atrial septal defect with transthoracic minimal invasion

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Abstract

OBJECTIVE: The study aims to evaluate the safety and feasibility of intra-operative device closure of atrial septal defect with transthoracic minimal invasion.

METHODS: From May 2006 to June 2009, 252 patients with secundum-type atrial septal defect closure were enrolled in our institution. The patients were divided into two groups, with 182 patients in group I with intra-operative device closure and 72 in group II with surgical closure. In group I, the patients' age ranged from 3 months to 62 years (mean \pm standard deviation, 19.0 ± 16.7 years). This approach involved a transthoracic minimal invasion that was performed after full evaluation of the atrial septal defect by transthoracic echocardiography, deploying the device through the delivery sheath to occlude the atrial septal defect.

RESULTS: In group I, 180 patients were occluded successfully under this approach. The size of the occluder device implanted ranged from 6 to 48 mm. Minor complications occurred, which included transient arrhythmias ($n = 23$) and pleural effusion ($n = 15$). Two patients with postoperative cardiac arrest were successfully cardiopulmonary resuscitated. Another two patients with occluder dislodged back into the right atrium were turned to surgical repair with cardiopulmonary bypass on the postoperative day. In group II, all patients were occluded successfully, and almost all patients needed blood transfusion and suffered from various minor complications. All discharged patients were followed up for 1–5 years. During this period, we found no recurrence, no thrombosis, even no device failure. In our comparative studies, group II had significantly longer intensive care unit (ICU) stay and hospital stay than group I ($p < 0.05$). The cost for group I was less than group II ($p < 0.05$).

CONCLUSIONS: Intra-operative device closure of atrial septal defect with transthoracic minimal invasion is a safe and feasible technique. It had the advantages of cost savings, yielding better cosmetic results, and leaving less trauma than surgical closure.

Keywords: CHD • Septal defects • Cardiac intervention • Surgery

INTRODUCTION

Atrial septal defect (ASD) is one of the most common congenital cardiac defects and accounts for approximately 6–10% of all congenital cardiac defects [1]. Most of the patients with ASD are usually asymptomatic and could wait for elective surgical or catheter-based closure for 3 years. Open-heart repair with midline sternotomy and cardiopulmonary bypass (CPB) has been considered as the standard treatment for the closure of ASDs [2]. In recent years, trans-catheter closure with the Amplatzer septal occluder has become another standard treatment for most secundum ASDs [3–5]. Although the above two methods had been proven safe and feasible, the use of CPB is still necessary and the midline incisions would reserve the physical and psychological trauma in surgical secundum ASD closure, and the catheter-based closure needs 'selective and suitable' patients [6] and more advanced equipments. Meanwhile, the costs of the catheter-based closure are much higher than surgery in the Third World nations [7]. Our approach is to use an intra-operative device and minimally invasive surgery to close ASD, which results in better

cosmetic incisions than open-heart surgery. Moreover, it is easy to learn and is cost-acceptable in the Third World nations. The aim of this study is to evaluate the safety and feasibility of intra-operative device closure of secundum ASDs with transthoracic minimal invasion. The results are encouraging.

MATERIALS AND METHODS

The present study was approved by the ethics committee of our university and adhered to the tenets of the Declaration of Helsinki. In addition, written informed consent was obtained from the patients or their relatives.

Device

The ASD occluder was modified from the Amplatzer atrial septal occluder manufactured at Dong Guan Ke Wei Medical Apparatus Co. Ltd. of China (595.6 €) (Fig. 1). The device consists of an occluder made from an alloy of nickel and titanium, a metal

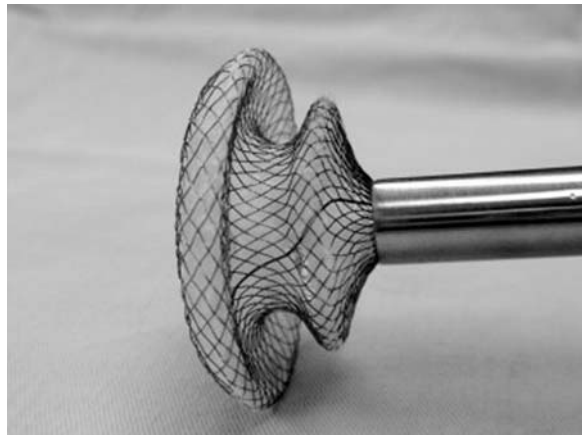


Figure 1: The occlusion device.

sheath, a pushing rod, and a hook. The double disk occluder has a loop on the right disk with a 100-cm thread through the loop, facilitating its withdrawal into the 40-cm-long and 4–10-mm-diameter sheath. The occluder was selected in accordance with the corresponding transthoracic echocardiography (TTE) result, a maximum defect diameter plus 2–6 mm. The occluder was loaded into the sheath [8].

Patients

Based on the method of the closure chosen by the patients, the latter were divided into two groups. Those with other co-existing cardiac anomalies were excluded from our study. The participants were enrolled in our institution between May 2006 and June 2009. Group I included 182 patients (81 males and 101 females), who received intra-operative device closure treatment. The patients were aged from 3 months to 62 years (mean \pm standard deviation, 19.0 ± 16.7 years). Their weights ranged from 3.5 to 70 kg (38.6 ± 21.1 kg). Group II included 72 patients (32 males and 40 females), who refused device closure and received surgical closure. Their ages ranged from 4 months to 60 years (19.5 ± 18.1 years), and their weights ranged from 3.5 to 76 kg (38.0 ± 20.0 kg). No difference in age- and body-weight distribution was found in either group.

TTE was used to confirm the diagnosis of the ASD in those patients and assess the circumferential margins for closure. Routine examinations included a standard electrocardiogram, a chest X-ray, and blood tests. Indications for ASD closure were the same as those used for surgical closure, which included hemodynamically significant left to right shunts and (or) significant chamber enlargement, and (or) mild to moderate to severe pulmonary hypertension, despite medical therapy and (or) history of infective endocarditis [9]. In group I, 145 patients were symptomatic, which included frequent respiratory infection, palpitations, shortness of breath, exercise intolerance, and insignificant chest pain. Of all the patients, 90 had mild pulmonary hypertension (which was assessed by TTE and pulmonary artery systolic pressure 30–45 mmHg), and 45 patients had moderate pulmonary hypertension (pulmonary artery systolic pressure 45–75 mmHg), and 20 patients had severe pulmonary hypertension (pulmonary artery systolic pressure 75–90 mmHg).

Protocol

In group I, general anesthesia was applied to patients. They were then placed in a supine position and draped to expose the entire chest, with the right hemithorax elevated approximately 30°. Intra-operative TTE was used to assess the ASD; in particular, the defect size and circumferential margins adjacent to the superior and inferior vena cava, pulmonary vein, mitral valve, and aortic sinus [10]. The atrial septal occluder was chosen according to the largest diameter of the ASD, allowed for a margin of 2–6 mm in excess of the diameter. A right anterior sub-mammary minithoracotomy (nearly 3 cm in length) was made through the fourth intercostal space. A small rib spreader was used in this manipulation incision to facilitate instrumentation. The pericardium was opened and suspended to expose the right atrium. In the anterolateral right atrium, two parallel sutures of approximately 8–16 mm in diameter were stitched, heparin was intravenously given at 1 mg/kg body weight, and the activated clotting time was monitored to be >250 s. The occluder was drawn into the delivery sheath; then, a 1-cm incision was opened in the right atrium and the delivery sheath was inserted. Under continuous TTE guidance, the sheath was advanced through the ASD into the left atrium (Fig. 2). The left disk was deployed first by pushing the rod (Fig. 3). As the left disk was adjusted to be parallel to the atrial septum, the sheath was withdrawn, and then the right disk was deployed on the other side to occlude the ASD (Fig. 4). A to-and-fro motion of the sheath was performed to ensure a secure position across the defect [11,12]. After the TTE was evaluated, there was no significant residual shunt, no atrioventricular valve distortion, even no obstruction of the venae cavae or coronary sinus. The thread was cut and the sheath was withdrawn with the suture snugly tied. The chest was closed routinely. Oral dipyridamole or aspirin had been taken for 3 months as an anticoagulant.

In group II, all patients had been attempted with open-heart repair with a right lateral thoracotomy or a median sternotomy employing about 16–20-cm incision and CPB.

Statistical analysis

Continuous data were presented as mean \pm standard deviation and range. Clinical parameters between the two groups were

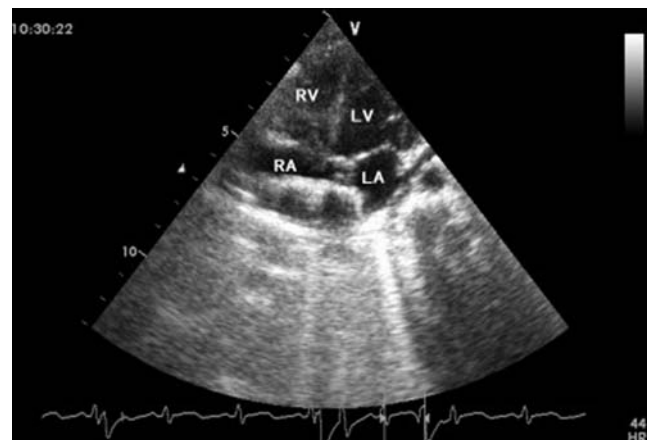


Figure 2: The sheath positioned from the right atrial free wall into the left atrial cavity across the atrial septal defect (ASD). LA: left atrium; LV: left ventricle; RA: right atrium; RV: right ventricle.

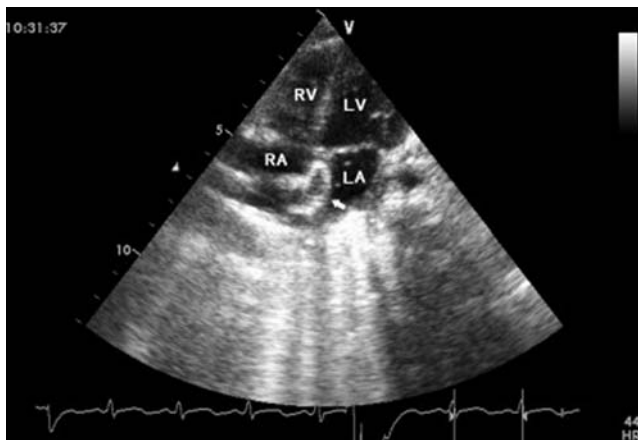


Figure 3: The left disc (arrow) of a 28-mm occluder was deployed in the left atrial cavity. LV: left ventricle; RA: right atrium; RV: right ventricle.

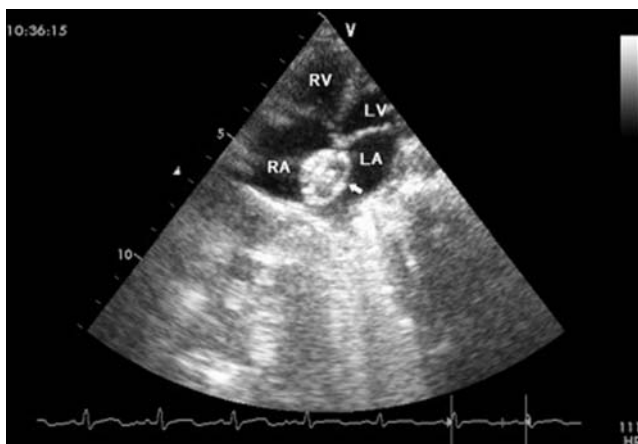


Figure 4: Final image shown after both discs were deployed (arrow) and the sheath was withdrawn. LA: left atrium; LV: left ventricle; RA: right atrium; RV: right ventricle.

compared with the independent samples *t*-test. A *p* value of <0.05 was defined as statistically significant.

RESULTS

In group I, delivery of the occluder was successful in 180 patients; two other patients turned to surgical closure, and device dislodgment back into the right atrium occurred on the postoperative day. The size of the ASD as measured by TTE ranged from 5 to 44 mm (mean 20.9 ± 10.9 mm). The size of the occluder implanted ranged from 6 to 48 mm (mean 23.9 ± 11.2 mm) and the diameter of the sheath was 4–10 mm. The duration of the procedure was 30–70 min (mean 42.5 ± 8.6 min). The intensive care unit (ICU) stay was nearly 6–24 h (mean 17.2 ± 20.5 h), and hospital stay was 4–12 days (mean 6.2 ± 1.1 days). In those who had a successful attempt, the overall immediate complete closure rate was 87.9%. A tiny smoke-like residual flow through the device or the junction of the occluder and the rims of the ASDs was seen immediately after the procedure in 22 patients. However, the closure rate remained 100% at 1 year's follow-up.

Minor complications were encountered in some patients, including transient arrhythmia ($n=23$), in the course of the device deployment. Temporary sinus bradycardia, atrial premature beats, and transient left-bundle branch block were observed in these patients immediately, which were easily treated by drugs or spontaneous recovery. Immediate postprocedure third-degree atrioventricular block (AVB) was observed in one patient with an ASD diameter of 40 mm and an occluder size of 44 mm. As heart rates were ranging about 50–55 bpm, no intervention was needed, except closed observation. After being treated by glucocorticoid, the AVB resolved spontaneously after 1 week. Two patients with postoperative cardiac arrest were successfully cardiopulmonary resuscitated. These patients had preoperative left-bundle branch block and AVB. After occlusion, transient left-ventricular volume overloaded, and slow heart rate may result in cardiac arrest. After treatment with dopamine and furosemide for several days, both patients recovered well. In some patients, the device needed to be retrieved several times, which occurred in the apparent residual fistula and the deficiency of the rim. In 20 early cases, blood loss requiring transfusion occurred due to lack of experience. In these 20 patients, the closure device models were replaced several times during the operation. Therefore, it is important to prepare plenty of blood products before the operation starts. However, with the previous experience of the surgeons, the last patients of the series did not require the transfusion, and the repeated times gradually reduced. Large pleural effusion occurred in 15 patients, which were treated with drainage tube placement. Three patients developed tricuspid regurgitation. There had been no episodes of hydrothorax, endocarditis, thrombo-embolism, device disruption or failure, aortic valves distortion, complete AVB, or permanent rhythm disturbances.

In those who had a successful attempt, the total follow-up period ranged from 1–5 years (2.7 ± 1.1 years). Outpatient follow-up was by functional, echocardiographic, and electrocardiographic (ECG) assessment. Symptoms had been either resolved totally or improved significantly in all symptomatic patients. Those patients with mild-moderate pulmonary hypertension had significantly decreased, as evaluated by the tricuspid regurgitation jet. Eight patients were still in severe pulmonary hypertension after the operation and needed long-term drug treatment, such as inhaled Ventavis or oral Viagra. Symptoms, such as palpitations, shortness of breath, and exercise intolerance, had been improved significantly in these patients. However, long-term effect needs further follow-up. The overall immediate complete closure rate was 87.9%. Those patients have small residual shunts and the position of the shunt was the junction of the occluder and the rim of defects or the device itself. However, the closure rate remained 100% at 1 year's follow-up. No progressive moderate-severe pulmonary regurgitation occurred. No thrombo-embolic event or other major complications were found during the follow-up period. To date, none of the patients in our group has developed complete heart block or/and mitral regurgitation. The incision in the chest was minor and cosmetic.

In group II, all patients needed blood transfusion. Sinus bradycardia and atrial premature beats were observed in 25 patients, especially during the operation. Some patients would recover immediately, whereas others needed medication for 3–5 days. During the follow-up period (2.5 ± 1.1 years), there were no episodes of ASD residual fistula, hydrothorax, endocarditis, thrombo-embolism, or permanent rhythm disturbances. The incision in the right lateral or median chest was nearly 16–20 cm.

Table 1: Comparison of clinical data in both groups

	Group I	Group II	<i>p</i> value
Number of patients	182	72	
Male/female	81/101	32/40	
Age (years)	19.0 ± 16.7	19.5 ± 18.1	>0.05
Body weight (kg)	38.6 ± 21.1	38.0 ± 20.0	>0.05
ASD size (mm)	20.9 ± 10.9	18.5 ± 8.7	>0.05
Operative time (min)	42.5 ± 8.6	107.6 ± 19.0	<0.05
ICU stay (h)	17.2 ± 20.5	26.6 ± 27.0	<0.05
Hospital stay (days)	6.2 ± 1.1	7.1 ± 1.2	<0.05
Follow-up (years)	2.7 ± 1.1	2.5 ± 1.1	>0.05
Total cost (€)	2686.6 ± 118.8	2227.7 ± 134.9	<0.05

Table 1 demonstrates the clinical data comparison of all patients in both groups. Group II required longer operative time, ICU stay, and hospital stay than group I ($p < 0.05$). The average total cost in the surgical group (2686.6 ± 118.8€) was higher compared with the device group (2227.7 ± 134.9€) ($p < 0.05$).

DISCUSSION

Patients with ASD are usually asymptomatic and no further treatment is needed during the first few years of life. Hence, they could wait for elective surgical or catheter-based closure in 3 years time. With the development of various devices, percutaneous trans-catheter occlusion of ASD gradually becomes the first choice for selected patients. However, due to the poor medical resources and knowledge, many hospitals have no resources in developing this technology in the low-income areas, such as China; elective open-heart repair with midline sternotomy and CPB has been considered as the gold standard for the closure of ASD in such patients. Although surgical closure of ASD has been proved safe and effective, it is still associated with midline sternotomy and CPB in a longer hospital stay. We applied a new minimally invasive technique, intra-operative device closure of ASD, imitating percutaneous closure of ASD [13–16]. The same criteria with cardiologists were also applied to allow us to choose 'suitable' secundum ASD in patients for the device closure. The open-chest approach offered an operative field and allowed the cardiac surgeons to do better with traditional surgical techniques. Because of the avoidance of CPB, we could limit the length of incision between 2.5 and 3 cm. Moreover, it was easy to extend for conversion to a regular open-heart procedure once the intra-operative device closure failed. The procedure time could be significantly shortened. In our series, the skin-to-skin time could be limited to 30–70 min. In addition, this method provides a perpendicular angle to the atrial septum, which may result in easily deploying the occluder into the defect. Because of the smaller incision and absence of CPB, there is less pain, quicker recovery, shorter hospital stay, and better cosmetic incision.

To place suitable devices to close an ASD, a rim of tissue around the defect is required. Accurate measurement of the size of the defect was essential for intra-operative device closure [17–19]. TTE played a crucial role in the procedure. In our study, this technique was used in diagnosis and to guide device deployment in all patients. Although Jen-Chung Chien reported that transesophageal

echocardiography (TEE)'s assessment of the size, number and position of the defects prevails over traditional TTE [20], in our opinion, with the experienced operators, TTE is a reliable method in quantitating ASD diameters and circumferential margins. The residual septum around the ASD can be accurately measured ultrasonically and the distance from the edge of the ASD to superior vena cava, right pulmonary vein, aortic root, atrioventricular valves, and coronary sinus can be reasonably obtained, especially the inferior vena cava rim [24]. Meanwhile, TTE is also useful for monitoring and guiding device-deployment procedures.

In our series, device closure was successful in all patients. In those who had a successful attempt, closure rate was 87.9% immediately after operation, and 100% at 12 months' follow-up. Trivial or small residual shunts can be ignored immediately after the release of device, as they usually disappeared during the follow-up period. This early shunting was associated with the loose links between the occluding device and the rim of defects or the device itself. Several weeks later, endothelialization would cover the surface of the device, and neo-intima would form and would fully close any residual shunting. Minor complications were encountered in some patients, including transient arrhythmias ($n=23$), in the course of the occluder deployment. Temporary sinus bradycardia and atrial premature beats were observed in these patients immediately, which were easily treated by medicine or automatic recovery [21]. The atrial septum would be deformed, possibly when the occluder released, which may temporarily affect the heart conduction system. The occluder we chose must be large enough to close the ASD, but not change cardiac geometry structure. If any deformation or interference of the device were found, redeployment of the device would have to be undertaken. Reducing intra-operative stimulus would also benefit transient arrhythmias. In studies involving trans-catheter closure, comparison of successful and unsuccessful deployment revealed a significant association of the deficiency of the rim and a large defect diameter with failure of implantation [22,23]. In our study, we did not encounter failure in the implantation of the device using intra-operative device closure of ASDs.

A certain failure rate percentage exists in device closure, especially in those with deficient rims. Trans-catheter closure of this type of ASDs is challenging, and has been frequently associated with complications, such as residual shunts, subsequent malposition, and embolization of the device. We have experience in these ASD patients' closure with our method [24]. In most cases, the occluder would have been easily dislodged back into the right atrium through the deficient rim; hence, we added some new technology. During occluder deployment, the occluder was moved to the sufficient rims by moving the shield as close as possible; then, the 'left atrium – occluder – the right atrium' suture through the Waterston's groove was made to fix the occluder, although some patients had small residual shunts and the position of the shunt was the junction of the occluder and the deficient rim. Several weeks later, endothelialization would cover the surface of the device, and neo-intima would form and would fully close any residual shunting.

Some infants with ASD suffered from congestive heart failure, frequent respiratory infection, failure to thrive, and progressive moderate-severe pulmonary hypertension needing early medical treatment. No general agreement on the medical treatment for these infants has been reached, and there is still an intense debate regarding both the optimal timing and the mode of closure of ASDs in infancy. In our opinion, it is necessary to

close the ASDs of these infants. Due to patient weight and limited vascular access, the percutaneous approach sometimes could not be used for young children. Referring to our report [25], 17 symptomatic infants received successful occlusion with intra-operative device closure. Delivery of the occluder was successful in all. There was no recurrence, thrombosis, or device failure in midterm follow-up. Symptoms had been either resolved totally or improved significantly in all symptomatic infants. All infants with feeding problems and failure to thrive had gained weight considerably.

Relatively higher medical costs always present a real challenge in popularizing a percutaneous approach in the Third World nations. We chose a domestically made device to maximally reduce the medical costs. In our study, the intra-operative occluder was cheaper in comparison with the Amplatzer occluder. This technique did not need an expensive X-ray machine, and also could be easily mastered. However, our study was conducted in low-income countries, where health-care resources were limited. Given these circumstances, the cost-effective intra-operative device closure should be the choice to allow the ASD to be effectively treated.

Like any retrospective study, there is bias associated with data collection and the incomplete data for some patients. As a result of the mentioned 180 successful device-closure cases, our experience was still limited, and longer follow-up was needed in future research. This study was limited to one institution, and other institutions may find different results.

In conclusion, our study demonstrated that intra-operative device closure of the ASDs was a safe and feasible alternative to surgery. It had the advantages of cosmetic results, and left less trauma than surgical closure. Intra-operative device closure of the ASD should be recommended.

Conflict of interest: none declared.

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