Intraoperative device closure of atrial septal defects with inferior vena cava rim deficiency: A safe alternative to surgical repair

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Objective: Our objective was to evaluate the safety and feasibility of intraoperative device closure of atrial septal defects with inferior vena cava rim deficiency.

Methods: From January 2005 to December 2008, we enrolled 65 patients who had a secundum atrial septal defect with inferior vena cava rim deficiency closure in our institution. Patients were divided into 2 groups: 35 patients in group I underwent intraoperative device closure with a right lateral minithoracotomy and 30 in group II underwent open cardiac repair with a right lateral thoracotomy and cardiopulmonary bypass. Intraoperative device closure involved a minimal intercostal incision that was performed after full evaluation of the atrial septal defect by transthoracic echocardiography and the insertion of the device through the delivery sheath to occlude the atrial septal defect.

Results: The procedure was successful in all patients. In group I, the diameter of the atrial septal defect ranged from 30 to 44 mm (mean, 35.3 $\pm$ 3.9 mm), and the size of the implanted occluder ranged from 34 to 48 mm (mean, 40 $\pm$ 2.1 mm). The total occlusion rate was 82.9% immediately after the operation, 97.1% at 3 months, and 100% at 12 and 24 months of follow-up. In group II, all patients had successful closure. A follow-up period of 12 to 24 months was obtained in both groups. During the follow-up, there was no recurrence, thrombosis, or device failure. In our comparative studies, group II had significantly longer operative time, intensive care unit stay, and hospital stay than group I ($P < .001$). The cost of group I was less than that of group II (20,450.9 $\pm$ 840.8 RMB vs 25,884.9 $\pm$ 701.8; $P < .001$).

Conclusions: Intraoperative device closure of atrial septal defects with inferior vena cava rim deficiency is a safe and feasible technique. It has the advantages of cost savings, cosmetic results, and less trauma than surgical closure. Early and midterm results are encouraging. (J Thorac Cardiovasc Surg 2011;141:631-6)

Secundum atrial septal defect (ASD) is one of the most common congenital cardiac defects and accounts for approximately 6% to 10% of all congenital cardiac defects.[1] In 1976 King and associates[2] attempted the first transcatheter closure of a secundum ASD in human beings. Transcatheter closure with the Amplatzer septal occluder (AGA Medical Corporation, Plymouth, Minn) has become standard treatment for most secundum ASDs.[3-5] Defects with inferior vena cava (IVC) rim deficiency continue to be challenging to close in the catheterization laboratory. Open cardiac repair with midline sternotomy and cardiopulmonary bypass (CPB) has been considered as the standard for the closure of this type of ASD.[6] Although surgical closure of secundum ASD with IVC rim deficiency can be reliably achieved with no mortality and minimal morbidity,[7,8] the use of CPB is still necessary and the midline incisions result in physical and psychologic trauma for the patients in the future. Although some reports have confirmed that secundum ASD with IVC rim deficiency may be an acceptable candidate for device closure,[9,10] there is no other report involving a large number of patients until now. Furthermore, this technique needs more advanced equipment and the costs are much higher than surgery in the Third World nations.[11] Our approach is to use an intraoperative device and a minimally invasive surgical technique to close this type of ASDs, which will result in better cosmetic incisions than open cardiac surgery. Moreover, the technique is easy to learn and its cost could be acceptable in the Third World nations. The aim of this study is to evaluate the safety and feasibility of intraoperative device closure of secundum ASDs with IVC rim deficiency. The initial results are encouraging.

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Abbreviations and Acronyms
ASD = atrial septal defect
CPB = cardiopulmonary bypass
IVC = inferior vena cava
TEE = transesophageal echocardiography
TTE = transthoracic echocardiography

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. Additionally, written informed consent was obtained from the patients.

Device

The ASD occluder was modified from the Amplatzer atrial septal occluder. It was made in Dong Guan Ke Wei Medical Apparatus Co Ltd of China (Figure 1). The device consists of an occluder made from an alloy of nickel and titanium, a metal sheath, a pushing rod, and a hook. The double disc occluder has a loop on the right disc with a 100-cm thread through the loop, facilitating its withdrawal into the 40-cm long and 8- to 10-mm diameter sheath. The occluder was selected in accordance with the result of the corresponding transthoracic echocardiogram (TTE), a maximum defect diameter plus 4 to 6 mm. The occluder was loaded into the sheath.[12]

Patients

The IVC rim was classified as either adequate (>5 mm) or deficient (≤5 mm).[13] Those with other rim deficiency or other coexisting cardiac anomalies were excluded from our study. From January 2005 to December 2008, we enrolled 65 patients undergoing closure of secundum ASD with IVC rim deficiency in our institution. TTE was used to confirm the diagnosis in those patients and to access the circumferential margins for closure.

On the basis of the method of closure that the patients chose, the patients were divided into 2 groups. Group I included 35 patients (15 men and 20 women) who received intraoperative device closure treatment. The patients ranged from 19 to 44 years in age (mean ± standard deviation, 29.5 ± 7.1 years). Their weights ranged from 46 to 75 kg (58.8 ± 7.6 kg). Group II included 30 patients (13 men and 17 women) referred for surgical closure. The patients ranged from 20 to 43 years in age (28.9 ± 6.3 years). Their weights ranged from 46 to 76 kg (58.1 ± 7.4 kg). There were no differences in gender, age, and body weight distribution in the 2 groups.

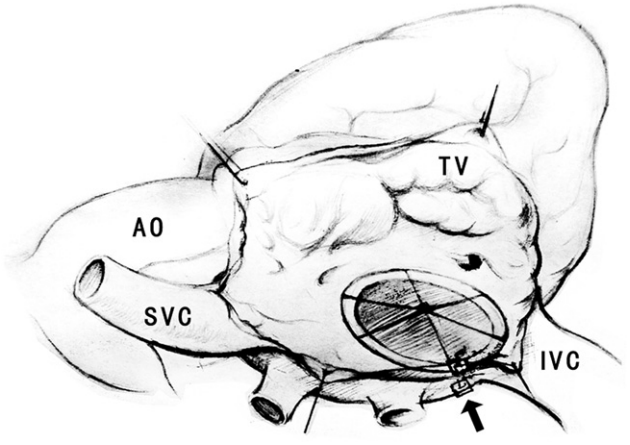

FIGURE 1. The occlusion devices.

Routine examinations included a standard electrocardiogram, a chest radiograph, and blood tests. All patients were adults. Twenty-five patients were symptomatic between both groups; symptoms included palpitations, shortness of breath, exercise intolerance, and insignificant chest pain. Of all patients, 45 had mild pulmonary hypertension (assessed by TTE; pulmonary artery systolic pressure, 30–45 mm Hg), and 15 patients had moderate pulmonary hypertension (pulmonary artery systolic pressure, 45–75 mm Hg). Twelve patients between both groups had unsuccessful percutaneous closure. The indications for ASD closure included hemodynamically significant shunts and/or significant chamber enlargement and/or mild to moderate pulmonary hypertension despite medical therapy in all patients.

Protocol

In group I, the patient was given general anesthesia and then placed in a supine position and draped for exposure of the entire chest, with the right hemithorax elevated approximately 30°. Intraoperative TTE was used to assess the ASD, in particular, the defect size and circumferential margins adjacent to the superior vena cava, pulmonary vein, mitral valve, and aortic sinus[14] (Figure 2). The atrial septal occluder was chosen according to the largest diameter of the ASD, allowing for a margin of 4 to 6 mm in excess of the diameter in patients. A right anterior submammary minithoracotomy (about 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, 2 parallel 4–0 Prolene polypropylene sutures (Ethicon, Inc, Somerville, NJ) of approximately 15 mm in diameter were stitched, heparin was intravenously given(1 mg/kg body weight), and the activated clotting time was monitored to be greater than 250 seconds. The occluder was drawn into the delivery sheath, and then a 15-mm 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. The left disc was deployed first by pushing the rod. After the left disc had been adjusted to be parallel to the atrial septum, the sheath was withdrawn, and then the right disc was deployed on the other side to occlude the ASD. A to-and-fro motion of the sheath was performed to ensure a secure position across the defect.[15,16] The occluder could easily be dislodged back into the right atrium through the deficient IVC rim, so we added some new techniques. During the process of occluder deployment, the occluder was moved to the rim of the superior vena cava by moving the shield as close as possible; then the ''left atrium–occluder–right atrium'' suture was placed through the junction of the Waterston groove and the IVC to fix the

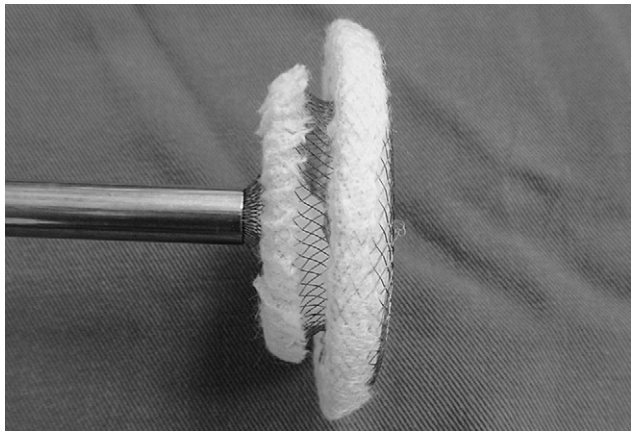

FIGURE 2. Transthoracic echocardiographic image showed the circumferential margins of the ASDs with IVC rim. *SVC,* Superior vena cava; *IVC,* inferior vena cava; *ASD,* atrial septal defect; *IAS,* interatrial septum; *LA,* left atrium; *RA,* right atrium.

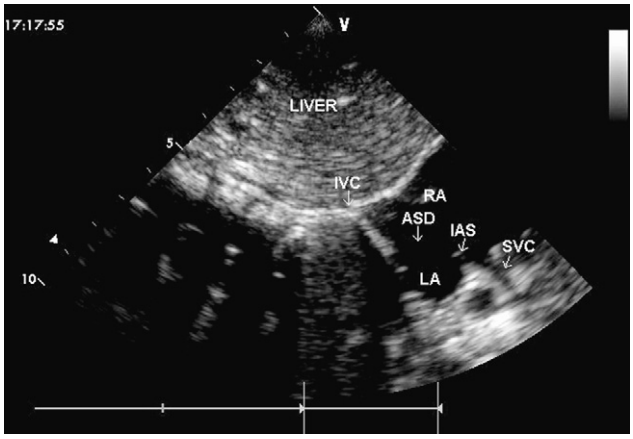

FIGURE 3. The *arrow* shows the suture through the "left atrium–occluder–right atrium." *AO,* Aorta; *SVC,* superior vena cava; *IVC,* inferior vena cava; *TV,* tricuspid valve.

occluder (Figure 3). After TTE evaluation no significant residual shunt, no atrioventricular valve distortion, and no obstruction of the coronary sinus were detected. The thread was cut and the sheath was withdrawn with the suture snugly tied. The chest was closed routinely with a drainage tube in place. Oral aspirin had been taken for 3 months as an anticoagulant.

In group II, all patients had undergone attempted open cardiac repair with a right lateral thoracotomy of 16 to 20 cm and CPB.

Statistical Analysis

Continuous data are given as mean ± standard deviation and range. Clinical parameters between the 2 groups were compared with the independent samples *t* test. Nominal variables were compared between the 2 groups using Fisher's exact test. Arrhythmia was analyzed by the χ^2 test.

RESULTS

Delivery of the occluder was successful in all patients in group I. The size of the ASD as measured by TTE ranged from 30 to 44 mm (mean, 35.3 ± 3.9 mm). The size of the occluder implanted ranged from 34 to 48 mm, (mean, 40 ± 2.1 mm) and the diameter of the sheath was 8 to 10 mm. The duration of the procedure was in 40 to 70 minutes (mean, 54.0 ± 9.2 minutes). The intensive care unit stay was about 6 to 12 hours (mean, 9.5 ± 2.6 hours), and hospital stay was 4 to 7 days (mean, 5.6 ± 0.8 days).

In those who had a successful attempt, the overall rate of immediate complete closure was 82.9%. Those patients have small residual shunts and the position of the shunt was the junction of the occluder and the IVC. At 3 months, 1 of 35 patients still had a small residual shunt. However, the closure rate remained 100% at 1 year's follow-up.

In group I, minor complications were encountered in 15 patients, including transient arrhythmia in the course of device deployment. Temporary sinus bradycardia and atrial premature beats were observed in these patients immediately and were easily treated by medicine or else they resolved spontaneously. Immediate postprocedure third-degree atrioventricular block was observed in 1 patient with an ASD diameter of 40 mm and a occluder size of 44 mm. Because heart rates were about 50 to 55 beats/min, no intervention was needed except close observation. After treatment by glucocorticoid, the atrioventricular block resolved spontaneously after 1 week. Blood loss requiring transfusion occurred in 9 early cases owing to lack of experience. There had been no episodes of hydrothorax, endocarditis, thromboembolism, device disruption or failure, or atrioventricular valve distortion.

Total follow-up period ranged from 12 to 24 months (18.2 ± 6.1 months) in group I. Out-patient follow-up was by functional echocardiographic assessment. Symptoms had been either resolved totally or improved significantly in all symptomatic patients. Those patients with mild to moderate pulmonary hypertension had a significant decreased in hypertension as evaluated by the tricuspid regurgitation jet. The complete closure rate was 100% during 1 year of follow-up. No thromboembolic event or other major complications were found during the follow-up period. The incision in the chest was minor and cosmetically acceptable.

In group II, all patients needed a blood transfusion. Sinus bradycardia and atrial premature beats were observed in 18 patients, especially during the operation. Some patients recovered immediately, and others needed medicine treatment for 3 to 5 days. During the follow-up period (18.0 ± 6.0 months), there were no episodes of ASD residual fistula, hydrothorax, endocarditis, thromboembolism, or permanent rhythm disturbances. The incision in the right lateral chest wall was about 16 to 20 cm.

Table 1 demonstrates the clinical data comparison of all patients in both groups. Group II required longer operative time, intensive care unit stay, and hospital stay than group I ($P < .001$). Thirty patients had postoperative arrhythmia,12 in group I and 18 in group II ($P < .05$). The average total cost in the surgical group (25,884.9 ± 701.8 RMB) was higher than in the device group (20,450.9 ± 840.8 RMB) ($P < .001$).

DISCUSSION

Patients with secundum ASD are usually asymptomatic. However, owing to poor medical resources and knowledge,

TABLE 1. Comparison of clinical data in both groups

	Group I	Group II	*P* value
No. of patients	35	30	
Male/female	15/20	13/17	>.05
Age (y)	29.5 ± 7.1	28.9 ± 6.3	>.05
Body weight (kg)	58.8 ± 7.6	58.1 ± 7.4	>.05
Operative time (min)	54.0 ± 9.2	110.5 ± 7.4	<.001
ICU stay (h)	9.5 ± 2.6	17.9 ± 3.9	<.001
Hospital stay (d)	5.6 ± 0.8	6.4 ± 0.7	<.001
Arrhythmia (%)	12/35	18/30	<.05
Follow-up (mo)	18.2 ± 6.1	18.0 ± 6.0	>.05
Total cost (RMB)	20,450.9 ± 840.8	25,884.9 ± 701.8	<.001

ICU, Intensive care unit; *RMB,* Renminbi, the Chinese currency.

some patients with ASD miss their best treatment period and wait until they are adults. This phenomenon is prevalent in low-income countries, such as China. Elective open cardiac 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 with a longer hospital stay. With the developments of various devices, percutaneous transcatheter occlusions of ASD have gradually become the first choice for selected patients. For the device to be placed to close the ASD, a rim of tissue around the defect is required. A certain failure rate exists, especially in those with deficient rims. Owing to the deficiency of the ASD rim, transcatheter closure of this type of ASD is challenging and has frequently been associated with complications such as residual shunts, subsequent malposition, and embolization of the device. Furthermore, owing to expensive equipment and high cost, many hospitals in low-income nations have no resources to develop this technology. Thus, surgical closure of ASD with IVC rim deficiency is still the first choice for these patients. In group II, instead of a midline sternotomy, a right anterior submammary thoracotomy (about 16–20 cm in length) was selected, which would be more cosmetically pleasing than the midline incision.

In group I, we applied a minimally invasive technique, intraoperative device closure of ASD, which imitates percutaneous closure of the ASD.[17-21] The open-chest approach offered an operative field and allowed the cardiac surgeons to do this technique. Because of the avoidance of CPB, we could limit the length of the incision to between 2.5 and 3 cm. Moreover, it was easy to extend for conversion to a regular open cardiac procedure if the intraoperative device closure failed. The procedure time could be significantly shortened; in our series, the skin-to-skin time could be limited to 40 to 75 minutes. This method provides a perpendicular angle to the atrial septum, which may result in easily deploying the occluder into the defect. A dilemma for a large ASD is choosing the location for the placement of the occluding device, especially for our patients with an uneven septum. Because larger devices may interfere with the neighboring structure, the device size and position must be verified carefully by TTE after deployment. During the operation, it is advisable to retract the right disc into its sheath, then push the sheath by hand against the IVC rim, move the occluder to the rim of the superior vena cava, aortic sinus, and mitral valve, and then reopen the right disc. The occluder can easily be dislodged back into the right atrium through the deficient IVC rim. Thus we suture the ''left atrium–occluder–right atrium'' through the junction of the Waterston groove and the IVC to fix the occluder. A single stitch is enough to fix the atrial septal occluder. Because of the smaller incision and no use of CPB, the procedure results in less pain, quicker recovery, shorter hospital stay, and a more cosmetically acceptable incision.

Zhanjun Guan and associates[22] reported a series of 18 large secundum ASDs on transcatheter closure. They proclaimed that 3 aspects must be considered before a large ASD transcatheter procedure: (1) accurate measurement of the ASD size and shape, (2) choice of the occluding device with proper diameter, and (3) accurate measurement of the residual septum surrounding the ASD. We applied the same criteria with cardiologists to allow us to choose ''suitable'' patients. TTE also plays a crucial role in the procedure.[23-25] In addition to the deficient IVC rim, the other rims should be sufficient. Jen-Chung Chien and coworkers[26] reported that transesophageal echocardiography (TEE) improves assessment of the size, number, and position of the defects over traditional TTE. In early some cases, we used TEE to gain experience and then transferred TEE to simplied TTE. In our opinion, TTE is also a reliable method in quantitating ASD diameters and circumferential margins. The residual septum around the ASD can be accurately measured by TTE 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,[27] especially the IVC rim. It has also been 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 82.9% immediately after the operation, 97.1% at 3 months, and 100% at 12 months' and 24 months' follow-up. Trivial or small residual shunts in the IVC rim can be ignored immediately after the release of device inasmuch as they usually disappear during the follow-up period (Figure 4). This early shunt was associated with the loose links between the occluding device and the deficient IVC rim. Several weeks later, endothelialization will cover the surface of the device, and neointima will form and fully

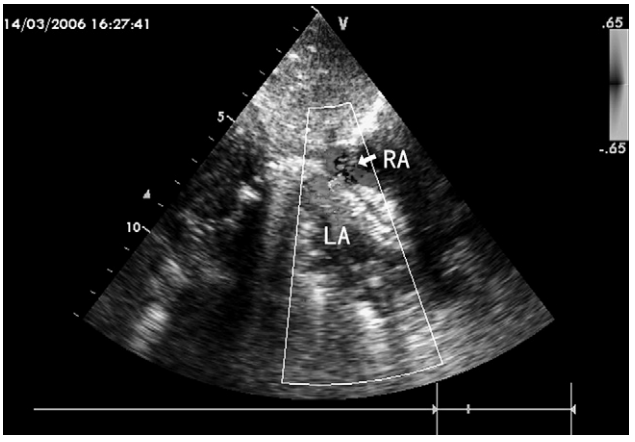

FIGURE 4. The arrow show trivial or small residual shunts in the inferior vena cava rim, which can be ignored. *LA,* Left atrium; *RA,* right atrium.

close any residual shunting. Minor complications were encountered in 15 patients, including transient arrhythmias in the course of occluder deployment. Temporary sinus bradycardia and atrial premature beats were observed in these patients immediately, but these were easily treated by medicine or else they resolved spontaneously.[28] If we use the larger sized occluder, the atrial septum would be more easily deformed. Such deformity may temporarily affect the heart conduction system. The occluder chosen must be large enough to close the ASD but cannot change the structure of the cardiac geometry. If any deformation or interference of the device had been found, the other size of device would have been redeployed. Reducing intraoperative stimulus was also beneficial for transient arrhythmias. In 9 early cases, blood loss requiring transfusion occurred owing to lack of experience. Thus it is important to prepare plenty of blood products before the start of the operation. However, in our past experience, the last patients of the series did not require a transfusion. In studies involving transcatheter 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.[9,29] In our study, we did not encounter failure in the implantation of the device using intraoperative device closure of ASD with IVC rim deficiency.

Relatively higher medical cost always presents a real challenge in popularizing a percutaneous approach in Third World nations. We chose a domestically made device to maximally reduce the medical costs. In our study, treating the intraoperative device group was still cheaper than treating the surgical group. 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 intraoperative device closure should be the treatment of choice to allow the ASD with IVC rim deficiency to be effectively treated.

As in any retrospective study, there is bias associated with data collection and the enrolling patients in the 2 groups, which were not randomized. As a result of the 35 cases in group I and 30 cases in group II, our experience was limited, and longer follow-up is needed to determine future research. We just speculated on its advantages according to our experience. The group of patients selected comprised only adults, with no small and young children being included. In general, placement of ASD devices is more challenging and complicated in small children. We did not include the small and young patients with this type ASD. This study was limited to one institution, and other institutions may find different results. The other limitation was that this study was conducted in a low-income country, and there might be different cost-effectiveness results in high-income countries.

In conclusion, our study demonstrated that intraoperative device closure of ASDs with IVC rim deficiency was a safe and feasible alternative to surgery. It had the advantages of cost savings, cosmetically acceptable results, and less trauma than surgical closure. Intraoperative device closure of ASDs with IVC rim deficiency should be recommended.

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