Intraoperative device closure of large secundum atrial septal defects; a safe alternative to transcatheter closure

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Abstract

Objective: The aim of this study is to report our short and mid-term results of intraoperative device closure (IODC) in large secundum atrial septal defects (ASD), to evaluate its safety and to determine the impact of ‘short’ rim on the results. Methods: Sixty-eight patients with an ASD underwent IODC through a right minithoracotomy. Patients were divided into two groups: 37 patients in group I with one short rim (≤ 5 mm) and 31 in group II with sufficient rims. A 2.5—3 cm parasternal incision was made in the right third or fourth intercostal space. A specially designed plastic sheath loaded with the device was inserted through the purse-string sutures placed on the right atrium. Under transesophageal echocardiographic guidance, it was advanced through the ASD into the left atrium and the device was deployed in place. Results: The procedure was successful in all patients. The maximum diameter of the ASD ranged from 20 to 37 mm (mean 25 ± 5 mm). There were 16 patients with the diameter of ASD more than 30 mm. The mean size of implanted devices was 29 ± 4 mm. Redeployment with larger device occurred in seven patients in group I and three in group II (p > 0.05). Intracardiac manipulation time was 22 ± 10 min in group I and 16 ± 11 min in group II (p < 0.01). The total occlusion rate was 84% immediately after operation, 97% at 3 months, 98% at 1 year, and 100% at 2-, 3-, 4-year follow-up. There were no other late complications during the follow-up period of 3—63 months (mean 27 ± 18 months). Conclusions: IODC is a safe and feasible technique in closing large ASDs. It has the advantages of cost savings, cosmetic results, and less trauma. Early and mid-term results are encouraging. In patients with ASD of a short rim, a larger device is recommended which does not influence the success rate of IODC.

1. Introduction

Since 1980s, transcatheter closure of secundum atrial septal defect (ASD) has been increasingly developed and is becoming an effective alternative to surgery [1—4]. However, this technique needs more advanced equipment and costs are much higher than surgery in Third World nations [5]. Additionally, transcatheter closure of large ASDs is challenging, and has been frequently associated with complications like residual shunts, subsequent malposition and embolization of the device. A certain failure rate percentage exists, especially in those with deficient rims [4,6—9].

At the beginning of 2000s, a new minimally invasive technique, intraoperative device closure (IODC) of ASD was developed, imitating percutaneous closure of ASD [10—14]. Using this technique, the patients with secundum ASD underwent device closure through a right minithoracotomy under transesophageal echocardiographic (TEE) guidance without cardiopulmonary bypass (CPB) and fluoroscopy. It is less invasive and has better cosmetic results than surgical repair. Furthermore, it is simple, easy to learn and has cost-saving advantages in Third World nations. However, its safety and feasibility, especially in patients with large ASD of a short rim, has not been previously reported. The aim of this study was to evaluate the short and mid-term results as well as the impact of short rims on the results of this technique.
Among them, 17 children were under 16 years of age. Three patients failed in the attempt of percutaneous closure. Three patients had double defects. Thirty-nine patients were symptomatic, which included exercise intolerance, palpitations, and chest pain. Of these 39 patients, 11 patients had mild pulmonary hypertension (pulmonary artery systolic pressure 30–45 mmHg), and four had moderate pulmonary hypertension (pulmonary artery systolic pressure 45–75 mmHg) (Table 1).

Routine examinations including a standard electrocardiogram (ECG), a chest X-ray, and a TTE were obtained on admission. Blood tests were done to exclude coagulation disorders.

Informed consent about IODC was obtained from the patients or their guardians. The ethics committee of our hospital approved this new technique.

2.2. Transesophageal echocardiography and device selection

Under general anesthesia, the patients were placed in a supine position with a single-lumen tracheal intubation. TEE was done at the beginning of the procedure to identify the site, size, rims of the defect and suitability for device closure.

The maximum (unstretched) longitudinal and horizontal diameters of the defect were measured to determine if the ASD was round or elliptical. In a round shaped defect, the chosen size of the device exceeded the maximum diameter of the defect by 4–6 mm. In an elliptical one, the device was chosen with a size equal to or up to 4 mm larger than the maximum longitudinal diameter. The rims from defect edge to superior vena cava, inferior vena cava (inferior rim or IVC rim), aortic annulus (anterior superior rim or aortic rim), coronary sinus, atrioventricular valves and right pulmonary vein were measured, respectively. In patients with double ASDs, the diameter of the two defects and the edge-to-edge distance between the communications were determined. The size of the device was selected by adding 4 or 6 mm to the sum of the diameter of the larger defect and the edge-to-edge distance between the defects.

2.3. Patient classification

Based on measurements of TTE and TEE, the patients were divided into two groups: 37 patients (54%) with 1 short rim were included as group I and the remaining 31 patients with sufficient rims (each rim ≥ 5 mm) were included as group II. In group I, 29 patients had a deficient aortic rim (< 5 mm) and eight patients had an IVC rim of 5 mm.

Patients with the rim of < 5 mm away from the above structures (except aortic rim) and those with other coexisting cardiac anomalies were excluded from IODC and considered for CPB surgery.

2.4. Implantation technique

Details of this procedure have been described in recent reports [13,14]. The delivery system only included a short plastic sheath with a side arm and a delivery cable.

In brief, heparin and antibiotic prophylaxis were given routinely. A 2.5–3 cm incision was made in the right anterior third or fourth intercostal space of the right sternal border (Fig. 1). Exposure was optimized with a mini-retractor. The pericardium was incised and cradled to suspend the heart. A purse-string suture was placed on the right atrium. Then the selected device was loaded into the sheath with the tip outside. Under TEE guidance, it was advanced through the ASD into the left atrium. After drawing blood from the side arm for de-airing the sheath, the left atrial disc was extruded first by advancing the delivery cable. Adjusting the left disc to be parallel to the atrial septum, the sheath and the cable were...

![Fig. 1. A 2.5 cm incision in the right anterior third intercostal space.](https://academic.oup.com/ejcts/article-abstract/33/6/1055/505689)
Comparisons of results of IODC between group I and group II

Tab le 2

<table>
<thead>
<tr>
<th></th>
<th>Total (n = 68)</th>
<th>Group I (n = 37)</th>
<th>Group II (n = 31)</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Redeployment with larger device (%)</td>
<td>10/68 (15)</td>
<td>7/37 (19)</td>
<td>3/31 (10)</td>
<td>0.33</td>
</tr>
<tr>
<td>Redeployment with smaller device (%)</td>
<td>5/68 (7)</td>
<td>2/37 (5)</td>
<td>3/31 (10)</td>
<td>0.65</td>
</tr>
<tr>
<td>Intracardiac manipulation time (min)</td>
<td>17 ± 12</td>
<td>22 ± 10</td>
<td>16 ± 11</td>
<td>0.006</td>
</tr>
<tr>
<td>RS immediately after IODC (%)</td>
<td>11/68 (16)</td>
<td>7/37 (19)</td>
<td>4/31 (13)</td>
<td>0.74</td>
</tr>
<tr>
<td>RS at discharge (%)</td>
<td>5/68 (7)</td>
<td>3/37 (8)</td>
<td>2/31 (6)</td>
<td>1.00</td>
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<tr>
<td>RS at 3 months (%)</td>
<td>2/68 (3)</td>
<td>1</td>
<td>1</td>
<td></td>
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<tr>
<td>RS at 6 months (%)</td>
<td>2/61 (3)</td>
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<td>RS at 2 years (%)</td>
<td>0/39 (0)</td>
<td>0</td>
<td>0</td>
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</tbody>
</table>

Comparison of clinical characteristic data between group I and group II is shown in Table 1. The mean size of implanted devices was 29 ± 4 mm in total, 30 ± 3 mm in group I and 28 ± 4 mm in group II (p > 0.05). The difference between the implanted device size and the maximum diameter of ASD (named D value) was calculated, with the average result of group I 4.6 ± 2.0 mm and group II 3.2 ± 2.1 mm (p < 0.05).

The device was implanted successfully in all 68 patients, including three patients with double ASDs occluded with a single device through the larger defect. In 15 patients (22%), positioning of the device was unsatisfactory at the first trial and repositioning of the device was required. In 10 of them, seven in group I and three in group II (p > 0.05), the device was replaced with a larger one due to the unstable position and residual shunts. In five patients, two in group I and three in group II (p > 0.05), the device was overestimated and needed to be changed with a smaller one, owing to the inaccurate measurements on TEE, the obstruction of coronary sinus (n = 2), or the encroachment of the device upon the mitral valve (n = 3) after the first deployment (Table 2).

3.2. Postoperative results

The intracardiac manipulation time ranged from 4 to 45 min in total, with the average of 22 ± 10 min in group I and 16 ± 11 min in group II (p < 0.01). Seventy-one percent of the operations were accomplished within an hour. Postoperative length of stay was 3—4 days normally.

Temporary sinus bradycardia and atrial premature beats were observed in eight patients (12%) immediately and 24 h after the procedure, which were easily treated medically. Hydrothorax was noted in two patients and required drainage. Blood loss requiring transfusion occurred in two early cases (3%) due to lack of experience.

3.3. Follow-up results

Total follow-up period ranged from 3 to 63 months (mean 27 ± 18 months). The short and mid-term follow-up results were available by TTE in 68 patients at 3 months, 61 patients at 6 months, 54 patients at 1 year, 39 patients at 2 years and in 21 patients at more than 4 years. Symptoms had resolved totally or were much improved in all symptomatic patients. Pulmonary artery pressure declined in all 15 patients who had pulmonary hypertension before IODC as estimated with Doppler echocardiography during follow-up. Residual shunts were found in 11 patients (16%) immediately after operation,
trivial shunts in six, small shunts in three and moderate shunts in two patients. Time course of residual shunts disappearance after IODC is represented in Table 2. The only patient with a moderate residual shunt (still currently present) was the one with double defects in whom the larger defect was 25 mm and the distance between the defects was 8 mm. The complete occlusion rate was 93% at discharge, 97% at 3 months, 98% at 1 year, and 100% at 2-, 3-, 4-year follow-up. No thromboembolic event or other major complications were found during follow-up period.

4. Discussion

4.1. Comparisons between IODC and conventional surgery

Surgical closure has been considered as a standard technique for patients with ASDs for nearly five decades and has yielded optimal long-term results [16]. However, operative trauma, scar formation, adverse effects of CPB, postoperative discomfort and the possible risks of blood transfusion may annoy patients. Compared with conventional surgery, the advantages of IODC are that there is no need for a drainage tube, ICU stay or blood transfusion. Because of the smaller incision and no use of CPB, operative trauma is minimized. This results in less pain, quicker recovery, shorter hospital stay and better cosmetic results [11—13].

4.2. Comparisons between IODC and percutaneous closure

Since the first clinical use of the Amplatzer device was reported in 1997 [3,8], percutaneous closure of ASDs has been offered in many countries as an accepted alternative to cardiac surgery. Details of this procedure and its favorable results have been extensively described in previous reports [5—7]. However, residual shunts, device malposition, embolization, and failure in deployment are not uncommon [4,6—9]. Meanwhile, serious complications, including perforation of the heart, atrioventricular valve damage and mortality, have also been reported in patients undergoing percutaneous occlusion [6,17]. Additionally, this technique needs more advanced equipment and costs are much higher than surgery in Third World nations [5], where health care resources are limited.

Compared with the percutaneous procedure, several advantages of IODC can be speculated [13]:

Firstly, in the process of IODC, the short delivery sheath approaches the ASD directly. It is easier to guide the sheath across the defect and adjust the device to anchor properly. In patients with a large ASD of a short rim, the surgeon can push the sheath by hand against the short rim and deploy the device in the proper position, which is unattainable in the percutaneous approach. Secondly, more stability of the device is available with IODC. Because the delivery cable is perpendicular to the atrial septum after device deployment, the surgeon can give more strength to the cable to test its stability by a push—pull maneuver. Although there is a low probability of postoperative bleeding and lung injury, there is no probability of perforation of the heart and vessels, because no guide wire is used in IODC. Thirdly, IODC is not limited in small children in whom the femoral sheath is prohibitively larger in the percutaneous approach, where a larger device is needed [14]. Lastly, IODC leads to less resource utilization and reduced costs. The fact that IODC does not require fluoroscopy and that there are no X-rays injury to worry about is an added advantage of this technology.

4.3. Safety of IODC

The first requirement for any device occlusion method is effective closure rates. The present study demonstrates a 98—100% complete closure rate of IODC during a follow-up period ranging up to 5 years. Irrespective of which procedure you use, IODC or percutaneous closure, large ASDs are a risk factor for unsuccessful closure [4,9]. In a recent report, difficulties in device closure have been encountered in patients with a defect of ≥30 mm in stretched diameter. The procedural attempt success rate was 65% [18]. In our series, there were 16 patients (24%) with a defect of ≥30 mm in the maximum diameter, all of who succeeded in IODC.

Several factors contribute to the difficulty involved in closing large ASDs with devices. These include deficient rims, small LA cavity, flappiness of the interatrial septum, etc. 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 [4,9]. Even in group I, we did not encounter failure in the implantation of the device using IODC.

Residual shunt is a common complication in device closure of a large ASD [2]. Trivial or small residual shunts immediately after the release of device can be ignored, since they usually disappear during follow-up period [12,13]. In this series we observed a complete occlusion rate of 98% at 1-year and 100% at 2-, 3-, 4-year follow-up. In patients with double ASDs, the distance between the defects is an important factor. In the literature [19], it has been suggested less than 7 mm. This might be the reason why the patient who had a double ASDs with the distance of 8 mm between the defects still has a moderate shunt currently in our series.

Other complications were rare after percutaneous closure or IODC. So far, arrhythmias were reported only in the early period after device implantation [6,20]. Similarly, we noted an increase of arrhythmia (12%), which was well controlled with antiarrhythmic agents, immediately and 24 h after the procedure. The incidence of thrombus formation on device closure is low [21]. Neither thrombus formation nor systemic embolic events were detected in our group of patients during follow-up periods.

4.4. Impact of a ‘short’ rim on the results

Deficiency in the superior anterior rim is rather common in ASD patients, which may cause difficulty and failure in the deployment of the device [22,23]. While the most important factor associated with the failure of device implantation is the deficiency of the posterior and inferior rims, it does not allow the LA disk to anchor well and can cause an early device embolization and malposition [4,6,9]. A minimum of 5 mm
rim of atrial septum around the defect has been suggested as a prerequisite for device closure in previous reports [3,22]. This minimal rim length is crucial for safe and stable positioning of atrial discs. In a recent study [23], deficiency in the anterior superior rim did not influence the success rate of ASD closure with the Amplatzer device, although redeployment of the device tended to be more frequently required, and the incidence of residual shunts immediately after device deployment was slightly higher.

The same results were obtained in IODC patients. The redeployment with larger devices (19% vs 10%) and the incidence of residual shunts immediately after IODC (19% vs 13%) in group I was higher than in group II (p > 0.05). The fact that we did not find a significant p value for this difference might be the result of the small size of our sample.

More maneuvers and larger devices are needed to anchor the device properly because of the short rim. This results in longer intracardiac manipulation time in group I compared to group II (22 ± 10 min vs 16 ± 11 min, p < 0.01). The difference between the device size and the maximum diameter (D value) of ASD is larger in group I than in group II (4.6 ± 2.0 mm vs 3.2 ± 2.1 mm, p < 0.05) for the same reason. According to our results, it is recommended that in such cases with ASD of a short rim, the size of the device should be 5 or 6 mm larger than the maximum diameter of ASD, when choosing a device. Because larger devices may interfere with the neighboring structures, the device size and position must be verified carefully using TEE after deployment. If any deformation or interference of the device were found, redeployment of the device would have to be undertaken. In our series, there were five patients in whom the larger devices interfered with the mitral valve or coronary sinus after the first deployment. Repositioning of the device had to be done in all of them. Up till now we have not encountered device erosion or other complications during follow-up.

Our excellent results were attributed to careful patient selection [13], precise evaluation of the defect, and the safe deployment of the device. The short sheath, its direct position, and flexibility make it easy to anchor the device well in IODC.

This study has several limitations. It is not a prospective randomized study comparing IODC with transcatheter closure. We just speculated its advantages according to our experience and results in IODC. The group of patients selected was older. No small children (<15 kg) were included. In general, placement of ASD devices is more challenging and complicated in small children. Despite the excellent results, long-term follow-up is still needed to determine whether the device closure is safe after IODC.

5. Conclusions

IODC is a safe and feasible technique in closing large ASDs. It has the advantages of cost savings, cosmetic results, and less trauma. Early and mid-term results are encouraging. In patients with ASD of a short rim, a larger device is recommended and does not influence the success rate.

References

