Surgical atrial septal defect closure after interventional occluder placement: Incidence and outcome

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Objective: Closure of ostium secundum atrial septal defects is generally performed by using an interventional approach. We evaluated the outcome of patients requiring secondary surgical therapy.

Methods: From September 1996 until December, 2005, 418 patients received interventional and 297 patients underwent surgical closure of an ostium secundum atrial septal defect at our center. Another 15 patients (local, 5; regional, 5; and national, 5 referrals) had complications after occluder placement, and they form the study population.

Results: Indications for surgical repair in these 15 patients were dislocation of the occluder in 5, neurologic events after occluder placement in 5, residual defects in 4, and sepsis with questionable occluder infection in 1 patient. A total of 7 patients had neurologic events, 5 of embolic origin. The interval between interventional occluder placement and definitive surgical repair was 319 ± 416 days (median 123 days; range 0–1395 days). Patient age at operation was 34.9 ± 18.6 years. Nine patients were operated on via an anterolateral minithoracotomy, and 6 received a conventional sternotomy. One patient with sepsis underwent abdominal surgery on postoperative day 1 and subsequently died of multiorgan failure; there was no proof of occluder endocarditis. At 2.2 ± 1.9 years of follow-up, all other patients had returned to full-time work without residual neurologic impairment.

Conclusions: Complications may arise after interventional ostium secundum atrial septal defect closure. This must be evaluated against the extremely low risk of a standard surgical closure. The functional outcome after secondary surgical ostium secundum atrial septal defect closure with removal of an occluder system is excellent.

Atrial septal defect (ASD) closure is indicated according to standard criteria. This includes patients having dyspnea, recurrent respiratory tract infections, or atrial arrhythmia, having a significant shunt at the atrial level leading to a pulmonary/systemic flow ratio greater than 1.5:1, or being at risk for paradoxical embolization.

Interventional therapy with ASD occluder systems has gained widespread acceptance during the past few years. It is performed whenever technically feasible, usually in patients with ostium secundum ASD. By comparison, standard surgical therapy is performed whenever patients are referred by the cardiologists because of defects not amenable for interventional closure. Thus, the cardiologist is the “gate-
keeper,” deciding on which therapeutic option to choose. Most patients, without knowing too many details, are in favor of avoiding an operation. There are no randomized studies comparing interventional and surgical therapies, nor are there any regarding short- or long-term outcomes at the present time.

Despite the success of occluder placement in most circumstances, some patients need to be referred for standard surgical therapy after failure of the procedure. These patients have different diagnoses, comprising a rather heterogeneous population. Indications for definitive surgical therapy may be residual defects, occluder dislocations, thrombus formation, embolization, and infection. The aim of this study was to evaluate the results after secondary surgical closure of ostium secundum ASD after occluder placement, gathered from a heterogenous population of local, regional, and distant referrals.

Patients and Methods

Overall Patient Population

Interventional ASD closure has become a routine procedure, performed successfully in many patients. However, occasionally patients have complications that require secondary surgical correction. In this report, we present data from a regional center summarizing our experience with an equal number of local (n = 5), regional (n = 5), and national (n = 5) referrals receiving secondary surgical correction after having complications after occluder placement.

All patients admitted for ASD closure are routinely evaluated by transthoracic and transesophageal echocardiography preoperatively. Specific criteria for optional occluder placement include the presence of at least a 3-mm wide rim at all margins of the defect to allow for safe anchoring of the device. During the early years of occluder placement, from 1995 until 1999, patients having defects larger than 30 mm were directly referred for surgical therapy. Since then, in parallel with the development of larger devices, patients with defects up to 40 mm have been accepted for occluder placement.

The following numbers should give an idea of the regular caseload of patients treated with ASD at our center: From September 1996 until December 2005, a total of 418 patients were scheduled for interventional ASD closure. Of these patients, 38 had ASDs that were more complex, that is, larger or consisting of several defects. The Amplatzer system was used to treat 96.7% of these patients. A total of 36 patients (9.4% of the total) were referred for surgical treatment, mostly on an elective basis without any complications. Reasons for elective referral were no attempt at occluder placement owing to larger defect size or missing tissue rim to anchor the device in 12 patients, interrupted placement procedure owing to technical reasons, mostly during the learning curve in 18 patients, residual defects in 3 patients, and late embolization in 1 patient. Early embolization requiring urgent surgical therapy occurred in 2 patients in this series. Mostly independent of this series during the same time interval, a total of 15 patients (equal numbers of local, regional, and national referrals) had complications after unsuccessful occluder placement. These patients formed the study population.

Indications for Surgical Repair

Indications for surgical repair in these 15 patients were dislocation of the device in 5 patients, a neurologic event (transient ischemic attack) with or without embolism in 5 patients, residual defects with significant shunting causing clinical symptoms in 4 patients, and sepsis with the suspicion of an infected device in 1 patient.

From the study population of 15 patients, a total of 7 had had neurologic incidents at any time, 5 resulting from residual defects, 1 resulting from endocarditis, and 1 resulting from heparin-induced thrombocytopenia. Patient age was 34.9 ± 18.6 years and 11 were female.

Surgical Technique

A standard surgical technique using a lateral minithoracotomy for ASD closure is routinely applied at our institution whenever feasible, as described previously. This approach is being used in patients with sufficiently large femoral vessels for extracorporeal circulation (ECC) and a body weight of more than 30 kg. In the presence of additional diagnoses, a conventional sternotomy approach was chosen. All operations were performed with trans-
esophageal echocardiographic monitoring. One venous return cannula was introduced percutaneously in the right or left internal jugular vein by the anesthetists. The anterior aspect of the right or left femoral artery and vein was dissected through a 3-cm incision in the inguinal fold for ECC access. Secured by purse-string sutures (Prolene 5–0; Ethicon, Inc, Somerville, NJ), a 16F to 20F arterial and a 30F venous return cannula were positioned by the Seldinger technique. The heart was accessed via a right anterolateral minithoracotomy in the submammary fold through the fourth intercostal space. The lung (single-lumen intubation) was disconnected under ECC support. The pericardium was entered with a horizontal incision at least 2 cm anterior to the phrenic nerve (Figure 1). The superior and inferior venae cavae were dissected and snared or a large bulldog clamping device was applied. A purse-string suture was made on the right lateral aspect of the ascending aorta to apply cardioplegic solution. The aorta was partially dissected from the pulmonary artery at the anterior and posterior aspects. A special endoscopic aortic clamp was then introduced through the second intercostal space in the right ante-

or axillary line. The heart was fibrillated, the aorta clamped, a long needle inserted in the ascending aorta, and cardioplegic solution administered. In parallel, the right atrium was opened. After cardioplegia was finished, the ASD occluder was inspected, and the correction performed. The aortic clamp was released after definitive ASD closure, usually with an autologous pericarial patch. The right atrium was then closed on the beating and reper-

fused heart.

Details of the Patient Population

The interval between occluder placement and definitive surgical correction was 319 ± 416 days at a median of 123 days (range 0-1395 days). Specific details on each patient are given in Table 1.

Statistics

Results are given as mean ± standard deviation. Absolute and relative frequencies were calculated. The Kolmogrov–Smirnov test was used to assess normal distribution and the Student t test or Mann–Whitney U test was applied as appropriate.

Results

Perioperative Results

There were no surgical complications in all patients. A minimally invasive approach was chosen in 9 patients. In these patients no conversions to median sternotomy were required. In 5 patients additional procedures were performed: pulmonary embolectomy in 1, mitral valve repair in 1, left atrial cryoablation to treat atrial fibrillation in 1, reconstruction of the noncoronary aortic sinus with a pericardial patch after resection of an occluder that had eroded into the aortic wall in 1, and redirection of the right inferior pulmonary veins in the presence of partially anomalous pulmonary venous drainage in 1 patient. An

### Table 1. Detailed patient information

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<th>Pt. No</th>
<th>Age (y)</th>
<th>Sex</th>
<th>Weight (kg)</th>
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OR, Operation; ASD II, secundum atrial septal defect; POD, postoperative day; PFO, patent foramen ovale; HIT, heparin-induced thrombocytopenia; NE, neurologic event during the interval between occluder placement and definitive surgical therapy. HZL in the last column indicates Heartcenter Leipzig, the authors’ own institution.
overview on the individual patient profiles is given in Table 1.

ECC duration was 65 ± 12 minutes and aortic cross-clamp time was 30 ± 11 minutes. Duration of postoperative intubation was 7.4 ± 6 hours and mean left ventricular ejection fraction was 66% ± 7%. An example of a residual defect at the superior rim of the occluder is shown in Figure 2.

One patient died on postoperative day 1. She was in stable cardiac condition. However, she was in profound sepsis preoperatively and underwent emergency explantation of the occluder owing to suspected infection of the device. There was no microbiologic proof of endocarditis from intraoperatively taken cultures. The next day the patient died of progressive septic multiorgan failure with sepsis preoperatively and underwent emergency explantation of the occluder owing to suspected infection of the device. There was no microbiologic proof of endocarditis from intraoperatively taken cultures.

Discharge and Follow-up
The 14 survivors were discharged from the hospital without further complications. Transthoracic echocardiography revealed good functional results in all of them. There were no relevant further lesions, especially no relevant tricuspid valve incompetence in any of the patients and good aortic valve function in the 1 patient undergoing reconstruction of the noncoronary aortic sinus.

All patients were contacted by telephone interview for further follow-up. All were alive. The interval between surgical correction and the follow-up interview was 2 ± 1.9 years. All patients had returned to full-time work. Most important, there was no relevant residual neurologic impairment in any of the patients. None of the patients had had any repeat symptoms. All patients were in New York Heart Association class I. Regarding quality of life, 12 patients mentioned that it had improved and 2 that it was unchanged compared with the preoperative status.

Discussion
The definitive therapy for ASDs has been surgical closure for more than 5 decades with excellent long-term results.2-9 Interventional approaches involving approved and commercially available occluder systems have been performed in patients who have ostium secundum ASDs since the 1990s.10-12 Recently, more complex and larger defects are being treated interventionaly, and overall numbers are increasing. Future directions may aim at avoiding the implantation of relatively large discs of foreign material by using a direct suturing technique.

At present, only patients with complex defects are being referred for definitive surgical therapy. Another group of referrals includes those who have had unsuccessful attempts to place an occluder or who have experienced complications after undergoing interventional procedures for ASD closure. Communication with several cardiac surgeons from different centers reveals that most have experience with explanting a smaller number of devices for different reasons. However, the overall number of patients requiring explantation of occluder devices may be low in relation to the total implantation rate.

One important and interesting article has been recently published by Divekar and colleagues.13 They focused on device-related cardiac events and especially on the incidence of cardiac perforations. From among more than 34,000 implanted occluder devices, a total of 29 cardiac events were reported, including 5 deaths and 3 neurologic events. This underlines the fact that there is a low but inherent risk. Another overview on potential erosion of the Amplatzer septal occluder device identified 28 patients, at an overall incidence of 0.1%.14 Patients with deficient aortic and/or superior rim were judged as being at higher risk to have such a complication. Unfortunately, it seems that few patients know much about these potential risks. For planned occluder placement, informed consent will most certainly be obtained by the cardiologists only before starting the procedure. Patient knowledge about potential complications, however, might lead to a change in the preferred treatment approach of some. Nevertheless, most patients will not choose surgery as an option because they believe that interventional therapy is safe. Furthermore, cardiologists see the patients first, underlining their specific role as “gatekeepers” for further referral while keeping their own interests of interventional closure in mind. Obviously,
Walther et al. Surgery for Congenital Heart Disease

problems with occluder devices are rare. However, patients should be informed objectively about all potential risks. Definitive surgical therapy has some perioperative impact but hardly any risk and, most important, excellent long-term functional outcome. Use of a flexible autologous pericardial patch for defect closure guarantees an almost perfect physiologic outcome without any reported risk of endocarditis. There is essentially no mortality in the current era. Minimally invasive techniques have evolved as very reliable and have become the clinical standard in experienced hands.

The most important result from this study is that definitive surgical therapy can be performed safely with good functional outcome after complications of occluder placement. This is even true in the presence of severe complications: for example, impairment of tricuspid valve function or penetration of the device into the aortic root. Another important finding is that a significant number of these patients—one third after occluder placement and almost half of the patients in total—had some form of neurologic insult before definitive surgical closure of the defect. Despite this, the postoperative functional outcome was good. This is clearly underlined by the fact that all patients fully returned to their preoperative routine work.

When evaluating the overall data, cardiologists and surgeons should agree on what has to be considered a complication and what complication rate with interventional ASD closure should be considered as being acceptable. From the patient’s perspective, any nonoptimal outcome, a residual defect or additional complication, is unfavorable. Therefore, the cardiologist and surgeon must strive for an optimal result regardless of the technique that is chosen. The attempt at interventional ASD closure during routine cardiac catheterization with subsequent elective referral to surgical therapy was occurring in close to 10% of patients from our local series, but this should not be considered a complication. This rate reflects the current practice of attempted interventional closure, triggered by the patient’s interest, whenever a minimal chance of successful percutaneous treatment is present. In contradiction, any residual defect with imperfect outcome or a severe complication, such as a neurologic event, should lead to surgical therapy. The incidence of severe complications should be well below 1% in experienced centers.

Interventional cardiologists are gaining experience with occluder placement. With the exception of the rare event of partial embolizations, no real life-threatening complication will arise from failed attempts. Therefore, no surgical standby will be required. However, the conduct of interventional approaches in close proximity to a surgical center with some cardiac surgical backup will always be preferable in our opinion.

Are there any factors that will enable cardiologists and surgeons to foresee potential complications? There may be a relation between occluder size and the risk of complications. The size of the relatively stiff discs being implanted may be one factor, and the direct distance to the aortic root and especially the presence of a sufficient rim at the superior aspect may be important when judging the risks of cardiac perforation. However, as we evaluate our own data, the patients requiring surgical therapy after occluder device placement are a rather heterogenic population. Equal numbers of patients having complications after device placement have been referred over the years. Therefore, at present, no clear risk factors can be identified.

References


Discussion

Dr Carl L. Backer (Chicago, Ill). My only conflict of interest is that I am a surgeon. The first question is, are there any cardiologists in the audience?

I want to congratulate Dr Walther and colleagues for focusing our attention, and ideally that of the interventional cardiologists, on this relatively new indication for surgery in patients with congenital heart disease. That new indication is surgical ASD closure after attempted device placement in the cardiac catheterization laboratory.
Of concern, Dr Walther has reported a nearly 10% incidence of surgical intervention for patients having complications of device placement. Within that group of patients, the most concerning are those requiring emergency surgery or those who had neurologic events. Two patients required an emergency operation and 7 patients had serious neurologic issues. One of those patients, in fact, died of sepsis after surgical device removal and ASD closure. Dr Walther appropriately compares these results with a 0% mortality with negligible morbidity in a series of surgical ASD closures totaling nearly 1000 patients.

At Children’s Memorial Hospital in Chicago, our series of surgical ASD closures is now 237 patients since 1990 with no mortality. Since 1997, of 143 patients undergoing attempted device closure, there were a total of 11 patients who underwent an interventional catheterization procedure and then were referred for surgery. Two patients were referred because the defect was too large and there was no room for device placement. Seven patients had attempted closure in the catheterization laboratory with the device, but were referred for elective surgery because the device closure was not successful. Two patients had attempted device closure and required emergency operation when the device embolized to the mitral valve and to the left atrium. Our incidence of requirement for surgical intervention of 7.7% is very similar to yours.

I have 3 questions and a comment. First, should surgical backup always be available on site when these interventional cases are done?

Dr Walther. Thank you very much for that question. I personally think that interventional procedures should only be done in a center where there is a cardiac surgeon in-house. However, the cardiologists will probably go on and implant the devices in a center where there is a cardiac surgeon in-house. However, the cardiologists will probably go on and implant the devices in patients as much as they want because no one can stop them. They probably will not accept it if they are told they can only do that if a backup is available.

Dr Backer. My second question relates to the patients who have an attempted but unsuccessful transcatheter closure with the device and are hence exposed to general anesthesia, potential problems of femoral vessel cannulation, possible device embolization, etcetera. What do you think is an appropriate incidence of unsuccessful device placement during this procedure? To me, 7% to 10% seems to be rather high.

Dr Walther. You are right. The procedure is getting clinically routine now. I think it should have a failure rate of less than 1%. I do not consider it a device failure when the patient is taken to the catheterization laboratory, the defect is found to be too large, and the cardiologists choose to send the patient to us for elective surgical repair. Failures are cases in which there is an embolization of the device or there is a marked position of the device wherein the tricuspid valve is impaired, for example. I think such complications should be below 1%.

Dr Backer. Finally, can we somehow decrease the number of patients subjected to the expense and risk of device closure without a successful result by establishing better patient selection criteria?

Dr Walther. That is a very important question, but a very difficult one. The cardiologist is the gatekeeper, and he or she will only send us those patients whose ASDs cannot be closed inter-ventionally.

One of the goals in our group is to bring this issue to the attention of more patients. It would be very good to have a joint discussion to set up syndication between cardiologists and surgeons after the diagnosis is made. However, we are not able to get the patients unless the cardiologist sends them.

Dr Backer. I had a comment to make, but I will save that because of the number of discussers yet to come.

I will say, though, that surgical ASD closure is an extraordinarily safe and efficacious operation with minimal morbidity that should not be forgotten but actually considered the benchmark when considering alternative methods for ASD closure.

Dr Christopher Knott-Craig (Oklahoma City, Okla). Was there a common denominator in the patients who required surgery after ASD device closure? For example, were the sizes of the devices that were placed unusually large?

Dr Walther. It is difficult to say because we have different referrals from different areas. It is not an all-comers series. But basically, so far as I understand, cardiologists are going up with the sizes. Five to 8 years ago they did not use a 38-mm Amplatzer device; the upper limit was 30 mm in the late 1990s. Now they use almost 40-mm devices. Therefore, I think it is a change in indication for them.

Dr Giovanni Stellin (Padova, Italy). I have just reviewed a manuscript that will be published in the Italian journal, reporting on a case of late embolization after device ASD closure. The device embolized in the pulmonary artery and that was discovered 6 months after the implantation. I was wondering whether, in your experience, you have found any late embolizations? This has already been reported as a possibility.

Dr Walther. There was one such case, but it was after a few weeks; it was not that late.

Dr Stellin. That was 6 months later.

Dr Backer. They are basically talking about these patients to other surgeons. We have discussed this situation in the German congenital surgical group. Everyone has seen a few such cases, I think. We need to set up a multicenter evaluation to really bring together all data from different centers.

Dr Backer. I just want to ask, with a raise of hands, how many people have taken Amplatzer devices out of the atrium or femoral vessels or elsewhere? [Show of hands.] That is nearly everyone! Let me ask in a different way: Are there any congenital heart surgeons here who have not removed an Amplatzer device sometime in their career? [Show of hands.] Only three hands go up!

Dr Charles D. Fraser, Jr (Houston, Tex). I would like to make a couple of comments.

The first problem, of course, is the issue that Dr Backer observed in his opening sentence. There are no pediatric cardiologists here. To really make an impact on these various issues, which are continuing to evolve, we are going to have to make sure that these data are shared in a forum where a truly meaningful discussion can go on about what is the best therapy for closing holes in hearts.

Might you reconsider what a failure is? Of course, the failure to a patient is when you are told you have an ASD and you come to the hospital to get it closed and you go home still having an ASD.

In our institution, what happens frequently is that the patient comes to the hospital, undergoes a general anesthetic, possibly a transesophageal echocardiogram, perhaps an intravascular ultrasound, and then is told that the defect is too large and is sent home.
The patient gets charged, the insurance company gets charged, and then the patient comes back for surgical closure. That, to me, is a failure. I think that should be considered in the statistics. It is certainly a very expensive mode of therapy. Might you look at your data a little bit differently in that regard?

**Dr Walther.** Basically, you are right. That if the patient leaves the hospital with a residual ASD, that is a failure. But we were looking at severe complications, for instance, if there are no symptoms in such a patient. It is a question of definition.

**Dr Pedro del Nido (Boston, Mass).** The device industry is what I would call disruptive technology. As such, it is always worse than the standard therapy for a period of time. Eventually, however, the technology gets better. All you have to do is look at computers to have a good example; a lot of the original equipment that we had years ago, now we would not even look at. I do not know that it is a good idea to just dismiss the problems with devices as complications of a bad system.

The cardiologists are very much aware of these problems. Aortic erosion has been described, but it has been primarily described for the larger devices, and interventionalists are changing their practice. Do you have an idea what the size was in the devices implanted? Did you actually measure the size of your devices or get the procedure notes to determine the size of the devices that were put in?

**Dr Walther.** Unfortunately, I do not have all those data because these were natural referrals and we do not get the procedure reports from all of those.

**Dr del Nido.** It is important to try to learn from these cases. In the interventionalal world, such cases are coming out now, although some of them have not made it to print yet. The larger devices, and anything over about 36 mm is considered the larger size, are the ones that are causing the complications. This problem occurs with much less frequency with the smaller devices. The importance of this is that if you have a large cohort of patients who are out there with larger devices in place, then close follow-up is absolutely imperative. There have been instances of late left atrial erosion, aortic root erosion, and mitral valve erosion, especially the cases in which there was no rim and the device was deliberately oversized to capture the rim of the aorta.

**Dr Backer.** Can I just make a quick comment? I was going to add this to my discussion.

I agree with you, Dr del Nido, that the cardiologists are aware of this problem. But I disagree with the way they interpret the data. This article that I am quoting is from *Catheterization and Cardiovascular Interventions* (2004;63:496-502), and it is the Amplatzer study group. They discuss erosion of Amplatzer septal occluder devices and their recommendations are as follows: “Patients with deficient aortic rim and/or superior rim may be at higher risk for device erosion. Oversized Amplatzer device may increase the risk of erosion. The defect should not be overstretched during balloon sizing. Patients with small pericardial effusion at 24 hours should have closer follow-up.”

Nowhere in that conclusion does it say that thought should be given to sending the patient to surgery if an oversized device is needed or if there is lack of a superior rim or of an aortic rim.

The cardiologists are not looking to the surgeons to treat these patients; they are looking for ways of tweaking their system to keep the patients within the device closure strategy.