Minimally Invasive or Interventional Repair of Atrial Septal Defects in Children: Experience in 171 Cases and Comparison With Conventional Strategies

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OBJECTIVES The goal of this study was to evaluate percutaneous interventional and minimally invasive surgical closure of secundum atrial septal defect (ASD) in children.

BACKGROUND Concern has surrounded abandoning conventional midline sternotomy in favor of the less invasive approaches pursuing a better cosmetic result and a more rational resource utilization.

METHODS A retrospective analysis was performed on the patients treated from June 1996 to December 1998.

RESULTS One hundred seventy-one children (median age 5.8 years, median weight 22.1 kg) underwent 52 device implants, 72 minimally invasive surgical operations and 50 conventional sternotomy operations. There were no deaths and no residual left to right shunt in any of the groups. The overall complication rate causing delayed discharge was 12.6% for minimally invasive surgery, 12.0% for midline sternotomy and 3.8% for transcatheter device closure (p < 0.01). The mean hospital stay was 2.8 ± 1.0 days, 6.5 ± 2.1 days and 2.1 ± 0.5 days (p < 0.01); the skin-to-skin time was 196 ± 43 min, 163 ± 46 min and 118 ± 58 min, respectively (p < 0.001). Extracorporeal circulation time was 49.9 ± 10.1 min in the minithoracotomy group versus 37.2 ± 13.8 min in the sternotomy group (p < 0.01) but without differences in aortic cross-clamping time. Sternotomy was the most expensive procedure (15,000 € ± 1,050 € vs. 12,250 € ± 472 € for minithoracotomy and 13,000 € ± 300 € for percutaneous devices).

CONCLUSIONS While equally effective compared with sternotomy, the cosmetic and financial appeal of the percutaneous and minimally invasive approaches must be weighed against their greater exposure to technical pitfalls. Adequate training is needed if a strategy of surgical or percutaneous minimally invasive closure of ASD in children is planned in place of conventional surgery. (J Am Coll Cardiol 2001;37:1707–12) © 2001 by the American College of Cardiology

Conventional surgical closure through midline sternotomy is considered the gold standard in the treatment of children with secundum type atrial septal defect (ASD) due to very low mortality and morbidity rates among these children and the availability of long-term follow-up data available for this procedure. Recent advances in the use of minimally invasive surgical techniques (characterized by very small incisions with minimal exposure of the operative field) and of interventional percutaneous device applications are now challenging the role of the conventional approach, especially in the cases of small to medium sized defects. Supposed advantages of the new approaches include a more cosmetic skin incision, less postoperative pain, shorter hospital stay and earlier return to physical activity (1–5). However, minimally invasive surgery appears more technically demanding than conventional surgery, while percutaneous closure entails the need for otherwise unnecessary intracardiac prostheses. Therefore, the issue of abandoning the well-established midline sternotomy approach in favor of the newer techniques remains highly controversial. The main argument is whether cosmetic and financial goals should divert the management philosophy toward more audacious solutions.

From March 1996 to November 1998, our institution offered three different techniques to pediatric patients with secundum ASD, that is, conventional sternotomic surgery, minimally invasive surgery and interventional device-closure. We retrospectively analyzed our experience regarding the efficacy and safety of minimally invasive surgery and percutaneous devices with respect to a control group of patients of similar age and weight treated by conventional midline sternotomy.

Patient selection. All 171 consecutive patients with an isolated secundum ASD referred to our institution from March 1996 to December 1998 were included. Patients with partial anomalous pulmonary venous return or other associated defects were excluded. During this time frame, there was no established institutional policy for selecting any of the three available techniques for ASD closure. However, patients with an isolated and centrally located secundum ASD not exceeding a size of 20 mm and at a safe distance from the pulmonary veins, the mitral valve and the caval veins were generally referred for device closure. All candidates for percutaneous ASD closure had a 24-h day-hospital admission before the procedure for transesophageal echo-
cardiography (TEE) screening to minimize the risk of aborted procedures in the catheterization laboratory. With respect to surgical indication for ASD closure, the choice of a minimally invasive surgical approach was initially based mostly on the personal confidence of the surgeon with this technique or, occasionally, on the parental preference.

**METHODS**

The following parameters were calculated: 1) mortality and morbidity (including all events causing a delayed discharge of the patient); 2) length of the procedure, that is, skin-to-skin time for the surgical procedures and catheter in-catheter out for the percutaneous approach (anesthesia induction time was not taken into account); 3) cardiopulmonary bypass and aortic cross-clamp times for the surgical groups; 4) duration of hospitalization (the amount of time from the procedure until the discharge from the hospital); and 5) costs.

**Operative techniques. PERCUTANEOUS CLOSURE.** The technique was the same for each type of device and was always carried out by the same group of cardiologists.

After routine cardiac catheterization with oxymetric and pressure recordings, a Mullins sheath was advanced over an exchange guidewire into the left atrium. The device was inserted into the sheath and carefully deployed under TEE surveillance. Device release was followed by control right-atrial angiography. Fluoroscopic equipment was the same throughout all procedures, and, for echocardiographic assessment, a Sonos 2500 (Hewlett & Packard, Amsterdam, The Netherlands) echocardiograph was used. Antibiotic prophylaxis was given for 48 h, and aspirin was administered for six months. The follow-up schedule included a full clinical and transthoracic echocardiography (TTE) evaluation at one, three and six months after the procedure and yearly thereafter.

**Minimally invasive surgery.** Minimally invasive surgery was carried out by all members of the surgical team (n = 7). Information about the mean size of the defect is not available. The patient was placed with the right side elevated by 30 degrees. A 5- to 6-cm anterolateral right thoracotomy incision was performed at the level of the fifth intercostal space (Fig. 1). The chest was entered through the third intercostal space. The pericardium was opened at least 2 cm anterior and parallel to the phrenic nerve, and a piece of it was harvested for later use as a patch. The ascending aorta was cannulated first, followed by cannulation of the inferior vena cava. A mildly-to-moderately hypothermic (30°C) cardiopulmonary bypass was instituted, and the superior vena cava was directly cannulated. Under mild general hypothermia, the ascending aorta was cross-clamped, and crystalloid cardioplegic solution was infused into the aortic root. The defect was closed through a right atriotomy. After discontinuation of the cardiopulmonary bypass, the thoracotomy was closed in a routine fashion.

The follow-up schedule after discharge was clinical and echocardiographic evaluations after one week, one month, six months and yearly thereafter.

**Midline sternotomy.** The heart was reached through a classic midline sternotomy. Mildly hypothermic cardiopulmonary bypass was instituted through aortic and bicaval cannulations. During a short period of aortic cross-clamping, transatrial defect closure was accomplished. The follow-up schedule was similar to that for minimally invasive surgery.

**Cost estimation.** Costs were calculated on an individual basis to produce a “case cost” (6), which is the sum of the variable individual direct costs (i.e., generic medical supplies like oxygen masks and intubation sets, delivery systems and devices in the case of percutaneous closure, oxygenator and bypass equipment in the case of surgery, time spent in the catheterization laboratory [operating room, intensive care unit, ward]). The costs of laboratory tests were not taken into account. Since the national health system in Italy is not comparable with a US Health Management Organization style system, we preferred avoiding calculation of the impact

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<th>Abbreviations and Acronyms</th>
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<td>ASD = atrial septal defect</td>
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<td>€ = Euro</td>
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<td>TEE = transesophageal echocardiography</td>
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Figure 1. A six-year-old child on the second postoperative day after minimally invasive surgical repair of a secundum atrial septal defect. The limited lateral right thoracotomy and the entry hole of the chest tube are clearly visible.
of the personal fees of the physicians, so they are not included in the analysis. For the same reason, we excluded fixed direct costs and indirect costs. All values are expressed using the current standard European currency (Euro).

**Statistical analysis.** Statistical analysis was performed by analysis of variance (ANOVA) and Bonferroni t test in comparison with Bartlett’s test for equal variances or the Kruskal–Wallis test in case of non-Gaussian distribution of the population (GraphPad Prism 3.0 statistical package, GraphPad Software Inc., San Diego, California). A p <0.05 was considered to be significant.

**RESULTS**

**Patient demographics.** Among 171 consecutive patients with isolated secundum ASD, 52 were evaluated as potential candidates for catheter closure of the defect but were secondarily referred to surgery because of unfavorable anatomy of the defect found at conventional TTE or TEE, while 67 were treated by primary surgical repair due to parental decision or lack of confidence of the referring cardiologist towards the percutaneous protocol.

Percutaneous closure was considered feasible in 70 children, but 18 were crossed over to the surgical groups because the defect was too large at balloon stretching (n = 17) or too close to the mitral valve (n = 1) as detected during the invasive diagnostic procedure. Cardiac catheterization and subsequent device deployment attempt was finally carried out in 52 children (median 7.0 years, median weight 23 kg) using two types of devices, the Amplatzer (AGA Medical Corporation, Golden Valley, Minnesota) (41 patients) and the Microvena Angel Wings (Microvena Corporation, Vadnais, Minnesota) (11 patients). Average ASD diameter at TEE was 12.0 ± 3.6 mm (14.6 ± 4.1 mm mean stretch diameter), and mean Qp/Qs was 1.66 ± 0.57. Mean follow-up was 41 ± 2 months for the patients receiving the Angel Wings device and 18 ± 13 months for the patients receiving the Amplatzer device.

Minimally invasive repair was accomplished from June 1996 to December 1998 in 71 patients (median age 5.1 years, median weight 20.5 kg) through a right submammary minithoracotomy by an autologous pericardial patch closure in 66 cases and direct closure in five cases. Femoral arterial cannulation was necessary in six cases (8.4%). Median follow-up time for this group was 19 months.

During the time frame considered for the study, conventional midline sternotomy repair was carried out in 50 cases (median age 5.1 years, median weight 18 kg). In 48 patients, a pericardial patch was used for repair, while in the other two, repair was accomplished by direct suture. Information about the mean size of the defects for the patients treated by surgery is not available. There were no significant differences among the three groups of patients in terms of age and weight.

**Mortality and morbidity.** There were no early or late deaths.

**Percutaneous closure.** Two patients (3.8%) experienced complications. One patient had a pericardial tamponade 6 h after the implant of an Angel Wings device, requiring emergency surgery. A perforation was found on the anterior aortic wall, probably caused by the device.

In the other patient, a premature unscrewing from the delivery system of an Amplatzer device occurred, due to a series of maneuvers aimed at reversing an occurrence of the so-called “cobra” shaping of the device. Despite several attempts, the device failed to regain a flat shape and could not be adequately positioned across the atrial septum. Due to a large residual shunt, the patient had to be operated on the same day. There were no vascular complications.

**Minimally invasive thoracotomy.** The overall rate of complications was 9.8% (7/71 patients), with four early (5.6%) and three late (4.2%) events. The short-term complications requiring a prolonged hospitalization were bleeding in one patient and transient sick sinus syndrome in three patients.

One late complication requiring readmission to the hospital consisted in patch dehiscence of the suture line with significant residual left-to-right shunt requiring reoperation (through the same minithoracotomy approach) after two weeks. Another two patients, one with postoperative pneumothorax and one with pericardial effusion, were treated conservatively and discharged after three and six days, respectively.

**Midline sternotomy.** The overall rate of complications was 12% (6/50). Only one patient (2%) had an early event (atrial fibrillation lasting for 48 h with spontaneous reversion to sinus rhythm). The other five (10%), in the days after surgery, had transient atrial arrhythmias (one case), prolonged pericardial effusions (three cases) treated with steroids or aspirin and sternal wire granuloma (one case).

**Efficacy.** No significant residual shunts were observed in this group of patients. In four cases treated with the Amplatzer device, there was a trivial to mild shunt immediately after the procedure, which disappeared after 24 h as shown by the follow-up TTE. There were no residual or recurrent shunts within the surgical groups.

**Hospital stay.** The sternotomy group required the longest hospitalization time (6.5 ± 2.1 days) followed by the minimally invasive (2.8 ± 1.0 days) and percutaneous device (2.1 ± 0.5 days) groups. The differences between the conventional and both the minimally invasive and percutaneous approaches were highly significant (p < 0.01).

**Procedure time.** The minimally invasive approach was more time consuming (196 ± 43 min) than either the device approach (118 ± 58 min, p < 0.001) or the sternotomy approach (163 ± 46 min, p < 0.01). The difference between the interventional and sternotomy groups was highly significant (p < 0.01).

**Extracorporeal circulation and cross-clamping time.** Minithoracotomy required longer extracorporeal circulation times than cases treated with sternotomy (49.9 ± 10.1 min
DISCUSSION

Minimally invasive (possibly video-assisted) repairs of ASDs (7) and other types of congenital heart defects have recently been reported but are considered highly controversial (8). The claimed advantages of minimally invasive surgical techniques are better cosmetic appearance and reduction of pain. These patients, compared with those undergoing transthoracotomy ASD closure, supposedly have a smoother postoperative course and an earlier discharge time.

On the other hand, the increasing use of percutaneous ASD closure systems has proven that selected patients may be treated with as good results as those of conventional surgery, yet implying a shorter hospital stay and no scar at all. The related economic benefits further push the current trend towards fast-track strategies for the repair of uncomplicated secundum ASDs (9). Moreover, recent studies report a subtle, but not minimal, superiority in the intellectual and psychological scores of patients treated by percutaneous device implantation compared with those treated by surgery (i.e., using extracorpore circulation) (10).

However, minimally invasive surgery may sometimes become quite challenging with complex arterial and venous cannulations and with a less-than-optimal view of the operating field, possibly implying unwarranted operating risks. Moreover, there is still some debate on whether a lateral minithoracotomy or a lower ministernotomy should be the incision sites of choice. A recent article strongly disputes the “minimal” aspect of reduced sternotomy techniques, showing similar results in terms of hospitalization, pain scores and stress indexes in a randomized trial versus conventional full-length sternotomy (11).

On the other side, percutaneous ASD closure relies on the use of prosthetic material inside the heart, needs an adequate training for the operator and presents several structural pitfalls (e.g., potential device fracture, embolization or thromboembolic accidents).

Therefore, it is still unclear whether minimally invasive surgery or device implantation will definitively provide an adequate replacement of conventional surgery as primary choice(s), especially in children. Berger and coworkers (12) recently analyzed their experience comparing a subset of patients undergoing percutaneous defect closure with another group submitted to surgery. Their study comprised adults and older children (median 12 years), and no distinction was made between lateral minithoracotomy and conventional sternotomy within the surgical group, leading to an “unfair” comparison of hospital stay and resource utilization between the percutaneously and surgically treated groups. In addition, follow-up time was very limited for both groups. Since at our institution these three techniques were distinctively and simultaneously carried out for a limited time frame, we aimed at comparing the results using efficacy and safety parameters common to all three procedures (incidence of residual shunts and complication rates) as well as parameters concerning financial and management aspects.

Morbidity. The number of complications was significantly higher in the surgical groups compared with the percutaneous group, leading to a generally longer hospital stay and a greater economical impact.

However, if one considers the severity of complications, the two serious events that occurred in the percutaneous group fairly outweigh the events that occurred in the surgical groups, making the statistical difference somewhat misleading. On the other hand, both events within the catheterization group should probably be considered as relatively rare and unlikely to recur.

It is noteworthy that the minimally invasive group had an incidence of complications similar to that of the sternotomy group (12% vs. 12.5%, p < 0.05). Again, this comparison is meaningful only with respect to economical issues (i.e., considering all the events producing a prolonged hospitalization). In fact, the patch dehiscence in one case of the minithoracotomy group should be regarded by far as the most important of all postsurgical problems, yet necessitating a re-do ASD closure. Although this case was operated on early in our experience, we acknowledge that limited surgical field, typical of lateral minithoracotomy, may have had an impact on the determination of a fractured suture line, ultimately resulting in patch dehiscence.

All things considered, stratifying complications by pure clinical impact score, conventional surgery still emerges as the safest technique (0% vs. 2.8% of minimally invasive surgery vs. 3.8% of the interventional technique).

Efficacy. All patients eventually had successful closure of their defect. Based on our data showing a 100% closure rate in the percutaneous group, we endorse the equivalence in efficacy of the three different approaches. However, we are aware that the midterm follow-up results available from the literature concerning the Amplatzer system show a 92% to 95% complete closure rate. It should be emphasized, however, that there are no established criteria yet on whether to consider “successful closure” of an ASD only a “complete closure” or whether to include among successes those cases in which there is the presence of a trivial residual shunt. In
this respect, more long-term follow-up data from larger series seem necessary.

**Hospital stay.** In our series, conventional sternotomy required a significantly longer hospitalization than the other two techniques. Whereas other groups report very short recovery periods for this kind of approach, at least three to four days were necessary for our patients to be painless and fully mobilized, as well as to regain an adequate respiratory function. In addition, many of these patients came from a long distance and we have generally preferred to prolong postoperative observation before discharging them back home. Again, in our series, minimally invasive surgery yielded similar results in length of hospitalization with respect to the percutaneous approach (despite a statistically significant difference).

**Procedure time.** We evaluated the procedure time of the three different treatments as a part of the financial assessment section of our study. Excluding the anesthesia induction time (which we assumed as being similar for all the procedures), the significantly lower procedure time of the interventional group reflects a lower degree of resource utilization. This holds even more true if one considers that 11 patients of the interventional group were treated with the Microvena Angel Wings device, which, as previously reported by our group (13), is associated with a significantly longer procedure than with the Amplatzer device.

**Extracorporeal circulation and aortic cross-clamping.** The longer extracorporeal circulation time required by the minithoracotomy approach compared with the cases treated through a sternotomy relates to a greater technical challenge in setting up a full cardiopulmonary bypass but, with increasing experience, these maneuvers have taken a progressively shorter time.

Clearly, once the aortic cross-clamp was in place, the actual exposing and closing of the defect was no more complex than it was with the sternotomy approach, as demonstrated by the similar cross-clamping times.

**Costs.** In this study, costs relate to the local health management system and should not be viewed as an absolute indication, but rather as relative economic impact, of each of the three different techniques. In our opinion, the evaluation of variable costs without the fixed component and the physician’s fees makes our evaluation applicable, even if cautiously, on a broader extent and independently from our local health and reimbursement system. Interestingly, the absolute mean cost of our cases treated by conventional midline sternotomy is not very different from that reported for patients operated on in the U.S. (14). The higher costs in the sternotomy group were largely due to the longer hospital stay. It is noteworthy that there was no significant difference in costs between the minimally invasive and catheterization groups. In fact, the high cost of percutaneous devices was counterbalanced by the need for extracorporeal circulation equipment and longer procedure time in the minithoracotomy group.

**Study limitations.** This is not a randomized study, and part of the patients submitted to catheterization procedures were selected on the basis of the anatomic features of their defects. However, while not being as reliable as a true statistic randomization, the time frame selected for data collection and the fact that there were no significant differences in age and weight among the three groups provide some support for assuming a fair comparison of results among the three approaches. On the other side, true randomization of patients for catheterization versus surgical procedures or for limited surgical access versus conventional midline sternotomy is not easily feasible, especially in the presence of determined parents denying the concept of chance while deciding the future of their children.

Another limitation of our study was the probable bias introduced by the absence of standardized guidelines for discharge of our patients after surgery. While it is true that the minimally invasive group was characterized by a significantly reduced length of hospitalization, at least some of the children in the sternotomy group were discharged from the hospital after no less than seven to eight days just for observance of old management protocols. Indeed, patients treated by minithoracotomy never had to wait for removal of the pacing wires, which were often applied instead in patients treated by sternotomy. It is, therefore, questionable whether such a long time is really required for patients treated by conventional sternotomy surgery, and this is confirmed by Laussen et al.’s (11) article showing the absence of any significant statistical difference regarding many variables, including hospital stay, in a prospective evaluation of patients randomized for ministernotomy or conventional extended sternotomy. It is interesting that a recent review on minimally invasive surgical repair of 115 patients with secundum ASD yields a median hospital stay of four days (14). Despite all hinted biases, in our opinion, a moderately shorter hospital stay of the sternotomy patients would not have severely impaired our evaluation, especially for concerns of complication rate, efficacy and surgery-related variables.

Another limitation of this study may be our preference for a minithoracotomy, an approach that has been criticized due to the risk of mammary and pectoral maldevelopment, especially if performed before the clear development of the submammary crease (15,16). We do not have short-term evidence of these kinds of problems and firmly believe that the submammary incision along the fifth intercostal space is safe in this regard.

**Conclusions.** While equally effective compared with sternotomy, the cosmetic, financial and organizational appeal of both the percutaneous and minimally invasive approaches for ASD closure must be weighed against their undoubtedly greater exposure to technical pitfalls. Therefore, adequate training and expertise must be a prerequisite if a strategy of surgical or percutaneous minimally invasive approach is selected in place of conventional midline sternotomy surgery for children with ASD.
REFERENCES