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Surgical Versus Percutaneous Occlusion of Ostium Secundum Atrial Septal Defects

Results and Cost-Effective Considerations in a Low-Income Country

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OBJECTIVES We compared the effectiveness and cost of percutaneous occlusion using an Amplatzer septal occluder (ASO) (AGA Medical Corp., Golden Valley, Minnesota) device compared with surgical closure of an ostium secundum atrial septal defect (ASD II) in Guatemala.

BACKGROUND The percutaneous occlusion of ASD II in first-world nations seems to offer better clinical results and lower cost compared with surgical closure.

METHODS We reviewed the clinical course of 111 patients referred to our institution for closure of isolated ASD II. Successful closure was assessed immediately after the procedures and at 12 months. Actual hospital costs were calculated for every patient who underwent either of the two procedures.

RESULTS Eighty-three patients with ASD II (75%) were selected for percutaneous occlusion with the ASO device, and the remaining 28 patients (25%) underwent surgical closure. In the device group, in 72 patients (86.7%) devices were successfully deployed. At immediate and 12-month follow-up, the complete closure rate was 87.5% (63 of 72 patients) and 97.2% (70 of 71 patients), respectively. In the surgical group, all patients had successful closure immediately after the procedure and at 12 months. Surgical closure offered a 27% cost savings in comparison with percutaneous occlusion (U.S. $3,329.50 ± $411.30 and U.S. $4,521.03 ± $429.71; $p < 0.001$, respectively). Cost of the device (U.S. $2,930.00) proved to be the main cause for this difference.

CONCLUSIONS We confirmed the clinical advantages of percutaneous occlusion over surgical closure of ASD II. However, percutaneous occlusion costs were higher compared with surgical closure. In Guatemala, where health care resources are limited, ASD II closure with the ASO device did not prove to be cost-effective. (J Am Coll Cardiol 2006;47:326–31) © 2006 by the American College of Cardiology Foundation

Ostium secundum atrial septal defect (ASD II) is one of the most common congenital heart defects (CHDs), occurring in 5% to 10% of children (1) and in 30% of adult patients with CHD (2,3). Surgical closure has been considered for many years the gold standard treatment for patients with an ASD II. Operative mortality is low (0% to 3%) (4–6) and long-term survival is high (25-year survival of 92%) (7).

In 1976, King et al. (8) performed the first percutaneous (transcatheter) occlusion of an ASD II in patients using a double umbrella device. Since then, the use of percutaneous occlusion has increased significantly. The successful device closure rate at 12 months' follow-up has been reported to be between 92% and 100% (9–12).

The alleged advantages of percutaneous occlusion over surgical closure include superior cosmetic results, the avoidance of cardiopulmonary bypass (CPB) and its potential adverse sequelae (13), a lower incidence of postoperative complications, and a shorter hospital stay. However, to our knowledge, published data about the outcome and safety of these intracardiac prostheses are limited to a seven-year follow-up (9–11,14). Another proposed advantage of percutaneous occlusion over surgical closure is its lower cost (between 0.7% and 36% less than surgical closure) (15–20), related in part because of a shorter hospital stay.

The research concerning cost benefits of percutaneous occlusion is based on data from high-income nations such as the U.S., Italy, United Kingdom, and Australia (15–19). To the best of our knowledge there are no data available from low-income countries, where health care resources are limited. Furthermore, these countries are especially in need of this information to derive institutional policies.

The objective of this study is to compare the effectiveness and cost of percutaneous occlusion using an Amplatzer device with surgical closure of ASD II in Guatemala.

METHODS

We reviewed the charts of 111 patients who were referred to the Unidad de Cirugía Cardiovascular de Guatemala (UNICAR) for isolated ASD II closure. Inclusion criteria were a left-to-right shunt at the atrial level with pulmonary blood flow/systemic blood flow of ≥1.5 or the presence of right ventricular volume overload. Exclusion criteria were an ostium primum and sinus venosus ASDs, including partial anomalous pulmonary venous connections, and patients with other associated CHDs requiring surgical repair.

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Abbreviations and Acronyms

ASD II = ostium secundum atrial septal defect
ASO = Amplatzer septal occluder
CHD = congenital heart disease
CPB = cardiopulmonary bypass
ICU = intensive care unit
UNICAR = Unidad de Cirugía Cardiovascular de Cardiovascular

Two techniques for ASD II closure are currently available at UNICAR: 1) percutaneous occlusion with an Amplatzer septal occluder (ASO) (AGA Medical Corp., Golden Valley, Minnesota), or 2) conventional surgical closure on CPB.

The size of the ASD II and the distance of the defect from the coronary sinus, atrioventricular valves, and right upper pulmonary vein (margins of the ASD) were preoperatively measured by transthoracic echocardiography. The size and margins of the ASD II were used as criteria to select patients either for percutaneous occlusion or surgical closure. Any ASD II ≤38 mm in diameter and with margins ≥4 mm was closed by the percutaneous approach, whereas the remaining patients underwent surgical closure.

Percutaneous occlusion was conducted under general anesthesia with endotracheal intubation. Midazolam (0.1 mg/kg dose) and ketamine (1 mg/kg dose) were used at the time of induction, and sevoflurane (0.5%) was administered for anesthesia maintenance. Vascular access was through the femoral vein. The device used was the ASO. The ASO is a self-centering device made of two flat discs of Nitinol (Mycrogroup Inc., Medway, Massachusetts) wire. A polyester mesh was added to the discs to enhance thrombogenicity. Device size was selected based on ASD II dimension, which was measured with an Amplatzer balloon-sizing catheter using the stationary balloon technique (within 2 mm of the balloon-stretched diameter); available sizes range from 4 to 40 mm.

A transesophageal echocardiogram was obtained after ASO placement to verify its correct position and to detect any residual interatrial shunts. Afterward, patients were transferred directly to the ward and analgesia was achieved with ketorolac (1 mg/kg intravenously every 8 h). A single dose of cefazolin (25 mg/kg intravenously) was used as prophylactic antibiotic therapy. Patients were discharged home within 24 h on aspirin (150 mg by mouth daily) for six months.

Surgical closure was achieved through a mid-line sternotomy by using moderate hypothermia at 30°C, CPB aortic cross-clamping, and cold crystalloid cardioplegic arrest. The ASD II was exposed though a right atriotomy and closed either directly or with a fresh autologous pericardial patch (depending on ASD size). Patients routinely were extubated in the operating room and transferred to the intensive care unit (ICU) for 24 h. Postoperative pain medications included morphine for the first 12 h (0.1 mg/kg dose) and ketorolac (1 mg/kg dose intravenously every 8 h). Cefazolin (25 g/kg intravenously every 6 h for 24 h) was used as prophylactic antibiotic therapy.

At discharge, all patients had a chest X-ray, a 12-lead electrocardiogram, and either an echocardiogram in the surgical group or a transesophageal echocardiogram in the device group (immediately after the device was placed). After 12 months, a cardiologic work-up, including an echocardiogram, was performed at UNICAR.

Complete ASD II closure was defined as no or minimal residual shunt at the interatrial level (color jet 1 to 2 mm, assessed by color Doppler echocardiogram). A residual shunt at the interatrial level was defined as the presence of a color jet width >2 mm (19,21). Complications were defined as early if they occurred while the patient was still in the hospital and late after the patient had been discharged.

Actual hospital costs were calculated for every patient who underwent either of the two procedures used for ASD II closure (22). Our cost-effective analysis compared only the direct costs (patient care related) in relation to the clinical success of the two procedures. Table 1 lists the items included for each procedure.

To estimate the total cost for each patient, we multiplied the unit cost of the various components of care by the documented use and then summed the product. Medical, nursing, and technical staff salaries were considered in the total cost of the procedure for every patient.

Results are presented as mean values and standard deviation (median and range when data not normally distributed). Differences between mean and proportions were assessed with analysis of variance if the variable was continuous or chi-square test if dichotomous (23). The Fisher exact test was used in cases in which the sample size was small. Level of significance was set at $p < 0.05$. To find a 3% difference (19) in the success rate between the percutaneous and the surgical groups (97% and 100%, respectively), with a power of 80% and alpha of 0.05, we would need a sample size of 866 patients (with continuity correction) to find this difference in percentages.

RESULTS

Eighty-three of the 111 patients with ASD II (75%) were selected for percutaneous occlusion with ASO device (device group), and the remaining 28 patients (25%) underwent

Table 1. List of Items Included in the Total Costs for Percutaneous and Surgical ASD II Closure

1. Operating room/catheterization laboratory (includes salaries of all personnel)
2. Medications and materials used during anesthesia and operation/procedure
3. Length of intensive care unit stay (days)
4. Hospitalization (days)
5. Blood products
6. Diagnostic and follow-up tests (echocardiogram, electrocardiogram, chest X-ray)
7. ASO device
8. CPB equipment

ASD II = Ostium secundum atrial septum defect; ASO = Amplatzer septal occluder; CPB = cardiopulmonary bypass.

Table 2. Demographic and Baseline Data Between Successful Device and Surgical Closure Groups

	Device Group	Surgical Group	p Value
Number of patients	83	28	
Age, yrs (SD)	18.3 (15.5)	7.14 (5.5)	0.0003
Interquartile range	6–27	3.5–10	
Female (%)	67	29	0.001
ASD II size, mm (SD)	25.5 (8.2)	20.11 (9.4)	0.04

ASD II = ostium secundum atrial septum defect.

surgical closure (surgical group). Table 2 shows the demographic characteristics of both groups.

Comparison of closure results. Of the 83 patients in the device group, 72 had devices successfully deployed (86.7%). The 10 patients in whom the ASO devices were not implanted had been erroneously considered suitable candidates based on transthoracic echocardiography. Device implantation was not attempted in these 10 patients because findings on balloon sizing of their ASD II precluded successful device implantation. The stretched diameter of the ASD II was larger than the largest available ASO device (40 mm). In the 11th patient, the device embolized into the right ventricle after deployment and required surgical removal. Of the 72 devices positioned successfully, mean size was 28.20 mm (7.29). Sixty-three of the 72 patients (87.5%) had immediate complete closure of the ASD II, whereas at 12 months' follow-up the complete closure rate was 97.2% (69 of 71 patients). Because of device displacement 20 days after deployment, one patient underwent surgical removal of ASO. This patient will be subsequently described.

In the surgical group, ASD II closure was achieved by primary suture closure in eight patients and with a fresh pericardial (autologous) patch in 20 patients. Mean CPB time was 28.08 (7.29) min and mean aortic cross-clamp time was 14.67 (9.38) min. All patients in the surgical group had a successful closure immediately after the procedure and at 12 months' follow-up (Table 3).

Three patients (4.1%) in the device group and three patients (10.7%) in the surgical groups had early complications ($p = 0.4$) (Table 3). Early complications in the device group included: 1) a device embolism after successful deployment that required surgical removal (this patient was no longer considered in the device group for further analysis); 2) an anaphylactic reaction to antibiotic; and 3) surgical removal of a defective ASO device (due to incomplete disk opening) from the femoral vein. In the latter patient, the ASD II was closed during the same hemodynamic session with a new ASO device introduced through the contralateral femoral vein. Early complications in the surgical group included a pleural effusion in two patients and a pneumothorax in one patient. All three patients required a chest tube.

Late complications occurred in two patients (2.7%) of the device group; none occurred in the surgical group (Table 3). In the device group, one patient presented with chest pain and cyanosis (transcutaneous arterial saturation of oxygen of 70%) at 20 days after occlusion. An echocardiogram revealed downward dislodgement of the ASO device, which directed the inferior vena cava blood flow into the left atrium. After a failed attempt to remove the device through a percutaneous approach, it was removed surgically, and the ASD II was closed at the same time. The other patient had chest trauma 20 months after successful placement of a 19-mm ASO device. After the trauma, an echocardiogram revealed two shunts (>4 mm) within the fossa ovalis. Two additional ASO devices (16 and 24 mm) were placed to occlude the new shunt areas. However, in one of the devices, the two disks opened incompletely and had to be removed. Subsequently, the patient underwent surgical removal of the two remaining ASO devices and surgical closure of the ASD II.

Comparison of ICU and hospital stay. In the device group, 69 patients (95.8%) were immediately transferred to the ward after device deployment (Table 3). Three patients (4.2%) were transferred to the ICU, two because of post-

Table 3. Comparison of Outcomes Between Device and Surgical Closure Groups

	Device Group	Surgical Group	p Value
Total number of patients	83	28	
Successful device deployment	72/83 (86.7%)	—	—
Residual shunts at discharge	9/72 (12.5%)	0/28 (0%)	0.06†
Residual shunts at 12 months' follow-up	2/71* (2.8%)	0/28 (0%)	0.6†
Early complications	3/72 (4.1%)	3/28 (10.7%)	0.4
Late complications	2/72 (2.7%)	0	0.9†
Blood products	2/72 (2.7%)	13/28 (46.4%)	<0.0001
Procedure time, min (SD)	180.50 (80.4)	193.67 (32.5)	0.4
Intensive care unit stay, days (SD)	0.05 (0.2)	1.75 (0.9)	<0.0001‡
Range	(0–2)	(1–2.5)	
Total hospital days (SD)	2.08 (0.6)	4.57 (1.0)	<0.0001
Cost per cure, U.S. (SD)	$4,781.88 ($429.71)	$3,329.5 ($411.30)	<0.0001
Cost of ASO device in Guatemala, U.S.	$2,930.00	—	—
Cost per case, U.S. (SD)	$4,521.03 ($429.71)	$3,329.5 ($411.30)	<0.0001

*One patient underwent surgical removal of the ASO device and subsequent ostium secundum atrial septum defect closure for device displacement 20 days after deployment. †Fisher's exact test; ‡Mann–Whitney rank-sum test.
ASO = atrial septal occluder.

procedural complications and one because of a transient hypotensive episode in the catheterization laboratory. All patients in the surgical group were transferred to the ICU (Table 3).

Blood products were administered to two patients in the device group (2.7%) and in 13 patients in the surgical group (46.4%; $p < 0.0001$) (Table 3). In the former group, blood products were used because of anemia after the procedure. In the latter group, blood products were used as part of the blood prime for CPB in three patients. The remaining 10 patients were transfused in the ICU because of a postoperative hematocrit of <24%.

Patients in the surgical group had a significantly longer hospital stay than patients in the device group ($p < 0.0001$) (Table 3). There were no hospital deaths in either of the two groups, and all patients were discharged home in stable clinical condition.

Comparison of costs. The mean cost (cost for cure) in the device group was higher compared with the cost in the surgical group ($p < 0.0001$) (Table 3). The main difference in costs between the two groups was the cost of the ASO device, despite the fact that the surgical group had longer ICU and hospital stay and required more blood transfusions ($p < 0.0001$) (Table 3).

DISCUSSION

Our data agree with previous reports of the use of the ASO device for percutaneous ASD II closure concerning safety and efficacy (14–20,24,25). There were no deaths in either device or surgical groups, and there were no statistical differences in the incidence of postprocedure complications between the two groups. Worldwide, the ASO device has been used since 1997 and, nowadays, it is an alternative to surgical treatment, offering better cosmetic results, the avoidance of CPB, and a shorter hospital stay (9–12,24,26).

The initial limitations of percutaneous occlusion of an ASD II with a device, such as a very large (>34 mm) or multiple occurrences of ASD II, or very young age of the patients, have been overcome. Hence, this procedure is considered in many centers as the treatment of choice for ASD II occlusion (10,12,27–30).

Although in our experience, patients in the surgical group were younger than in the device group, age was not considered a selection criterion for either the percutaneous occlusion or the surgical closure. The ASD II size was larger in the device group than in the surgical group, which may be due in part to the older age of patients in this group.

Percutaneous device deployment failure has been reported to be between 0% and 20% (12,14–17,19,20,24,31). Failure rate at our institution was relatively high (11 of 83 patients; 13.2%). However, improving preprocedural echocardiographic measurements of ASD II size and margins should significantly reduce this rate.

Mean CPB time and mean aortic cross-clamp time were standard for this procedure (14,24). Residual early and late atrial shunts after surgical closure were rare (32,33).

At present, there are no long-term data available about the device closure of ASD II. Midterm follow-up about the complete ASO device closure of ASD II (up to 4 years) report residual atrial shunts between 0% and 4% of patients (19,34,35).

In this study, there was a borderline statistical significant difference in the residual shunt immediately after the procedure between the device and surgical groups. 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 (our study is underpowered). Regarding 12-month procedure success, there was no statistical significant difference between the two study groups.

Data from the U.S., Europe, and Australia revealed either similar or lower costs (between 0.7% and 36% less) using the percutaneous approach in comparison with surgical closure (15–20). Difference was mainly due to avoidance of ICU stay, a lower incidence of postprocedural complications, and a shorter hospital stay (15–20).

The Transition System, Inc. accounting system (Transition System Inc., Nashville, Tennessee, 1988) is a method to estimate the average unit cost for various components of hospital care, including direct and indirect costs, and it is used in the U.S. (15,20,22). Because the national health system in Guatemala is not comparable with a U.S. health maintenance organization-style system, the Transition System Inc. system was not applicable for cost calculation in this study.

Our analysis confirmed the described clinical advantages of percutaneous occlusion of ASD II in comparison with conventional surgical closure, including the avoidance of ICU stay, a shorter hospital stay, and lower use of blood products.

However, in Guatemala, a low-income country, surgical closure of a ASD II proved 31% cheaper (cost per cure) in comparison with percutaneous occlusion (U.S. \$3,329.50 ± \$411.30 vs. U.S. \$4,781.88 ± \$429.71, respectively).

Even if we calculate the cost per case, without considering the additional cost for the initial percutaneous group of patients who underwent a catheterization but did not receive a device, or patients who received a device but then embolized requiring surgical removal, the cost of surgical closure is still 27% less than percutaneous closure (U.S. \$3,329.50 ± \$411.30 vs. U.S. \$4,521.03 ± \$429.71, respectively).

The reason for this difference is the cost of the ASO device in Guatemala, namely U.S. \$2,930.00. This cost represents 65% of the total cost of transcatheter ASD II occlusion with an ASO. The percutaneous approach without including the cost of the device is 52% less costly than the surgical procedure. We found only two other published reports (15,17) concerning the comparison of the two procedures for ASD II closure without taking into account

the cost of the device. In both there was a similar cost savings >50% in the interventional approach in comparison with the surgical closure.

According to our findings, in Guatemala, where health care resources are limited, ASD II closure with the expensive ASO device did not prove cost effective given our reduced institutional budget. Clearly, data on cost effectiveness for ASD II closure from high-income countries are not transferable to low-income countries.

Our study has several limitations. Because UNICAR does not have the information needed to calculate cost of every single medication used in the operating room and in the catheterization laboratory, we included information provided by UNICAR of 10 randomly chosen patients from each of the two groups. Assuming that the use of medications remained constant for each procedure, this estimated mean was added as a fixed cost to each patient in each group. Because this might not be always the case, costs might be underestimated (even though this would be applicable to both groups and it represents <10% of the total cost in both groups).

Nevertheless, our study provides data concerning cost effectiveness, comparing percutaneous occlusion with an ASO device versus surgical closure of ASD II in a low-income country. Given these circumstances, resources have to be judiciously allocated to the treatment that allows the largest number of patients to be effectively treated.

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