



## Device Occlusion versus Surgery for Closure of Congenital Heart Defects: Cost Issues in Iran

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Received 14 February 2008; Accepted 10 April 2008

### Abstract

**Background:** Closure of patent ductus arteriosus (PDA), ventricular septal defect (VSD) and atrial septal defect (ASD) can be done surgically or by device. This study was designed to compare the total cost of surgical or device closures of PDA, ASD or VSD for Iranian patients.

**Methods:** This is a cross-sectional study, conducted from January 1, 2005 until January 1, 2006 in two large heart centers of Tehran. The study population consisted of 91 patients with isolated PDA, ASD or VSD who underwent either surgical or device closure.

**Results:** PDA device closure either with the Amplatzer device or coil was less costly than that via surgery. VSD closure with the Amplatzer device was more costly (17.6%). Although ASD closure was also more expensive (15.4%), the difference was not statistically significant.

**Conclusion:** It can be concluded that PDA closure is cheaper than surgery in Iran. ASD and VSD device closures are more expensive, but the added cost can be affordable in view of the advantages of device closure.

*J Teh Univ Heart Ctr 3 (2008) 141-144*

**Keywords:** Cost • Patent ductus arteriosus • Atrial septal defect • Ventricular septal defect

### Introduction

Surgery was the standard treatment for patent ductus arteriosus (PDA), ostium secundum atrial septal defect (ASD) and ventricular septal defect (VSD) until the advent of transcatheter techniques. Nowadays, the transcatheter device closure of congenital cardiac defects is being used increasingly with excellent results.<sup>1</sup>

A controversial issue in pediatric cardiology during the past decades has been the comparison of the transcatheter closure of PDA, ASD and VSD with surgery. Surgical closure is reserved for patients whose families choose surgical repair

or whose lesions remain unsuitable for device closure.<sup>2</sup> The alleged advantages of percutaneous occlusion over surgery can include avoidance of cardiopulmonary bypass (CBP) and its potential adverse sequelae, fewer complications, shorter hospital stay and superior cosmetic results.<sup>3</sup>

The cost-effectiveness of PDA, ASD and VSD transcatheter closure versus surgery is still a controversial issue in many countries.<sup>4</sup>

Comparisons of costs have yielded equivocal results in different countries and at different times. Relative professional

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fees for the interventionist and cardiac surgeon, cost of the device and length of hospital stay after the procedures can be the main determinants in this regard. Comparisons in terms of hospitalization have yielded shorter durations after device closure in almost all studies reported from different parts of the world.<sup>2-11</sup>

In Iran, cost implications are an important factor for patients or parents in choosing the right procedure. The Iranian government pays subsidies for intracardiac devices (around 50% of the actual price); therefore, it can be difficult to make a comparison between the situation in Iran and that in the Western countries. To the best of our knowledge, no previous studies have compared the hospital costs of the procedures in Iran. We, therefore, sought to conduct the current study.

## Methods

We conducted a cross-sectional study of a randomized sample of 91 patients (40 patients with device closure and 51 patients with surgical closure), who were hospitalized in two large public hospitals of Tehran. We recruited patients admitted for the surgical or device closure of the ostium secundum ASD, VSD or PDA at Shaheed Rajayee Cardiovascular Center (SRCVC) and Children's Medical Center at Imam Khomeini Hospital Complex (CMC/IKHC). All the patients were hospitalized in the pediatric wards of these hospitals and were in the pediatric age group (under 18 years of age). The study period was from January 1, 2005 until January 1, 2006. The study was restricted to patients with isolated VSD (all types), ostium secundum ASD and PDA. The other inclusion criterion was Iranian citizenship as the subsidy is paid only for Iranian patients. The implanted devices included the Amplatzer Ductal Occluder (ADO), Amplatzer Septal Occluder (ASO), Amplatzer Membranous Ventricular Septal Occluder (AMVSO) (AGA Medical Corporation, Golden Valley, Minnesota, USA) and Nit-Occlude coils (pfm AG, Köln, Germany).

The number of the patients that underwent each procedure is depicted in Table 1. Of the total patients, 76 (83.5%) were hospitalized and treated in SRCVC and 15 (16.5%) in CMC/IKHC. All the VSDs were of the perimembranous type. There was no significant difference in terms of the age of the PDA or ASD patients (*p* values were 0.715, 0.415 and 0.283 for ADO, coil and ASO patients, respectively, in comparison with relevant surgical patients). The VSD patients treated surgically were significantly younger than those treated with the device ( $4.34\pm 4.77$  and  $16\pm 2.94$  years, respectively, for surgical and device closure groups, *p* value <0.001). Sex comparisons of the patients also yielded no significant differences (*p* values were 0.268, 0.637 and 0.162 for PDA, ASD and VSD patients, respectively).

Table 1. Number of patients enrolled per procedure

	Surgery	Amplatzer	Coil
PDA	20	17	9
ASD	17	10	-
VSD	14	4	-

PDA, Patent ductus arteriosus; ASD, Atrial septal defect; VSD, Ventricular septal defect

The total cost for the patients or their parents were calculated including professional fees and device price. Comparisons of the detailed costs were beyond the scope of this study. Intraoperative transesophageal echocardiography was not performed for the surgical cases. All the costs were calculated before applying insurance discounts for the insured patients. The results were calculated in Iranian Rials and then converted to US dollars (\$1=9200 Iranian Rials).

PDA and VSD device closures were successful in all the patients, but there was significant residual PDA after surgical ligation (5%) in one patient and significant residual VSD after surgery (7.1%) in another. ASD device closure was unsuccessful in one patient due to device embolization; the device was removed and the defect was repaired surgically. A similar situation occurred for a VSD device closure. Coil embolization occurred in one patient and was, subsequently, treated via repeated device occlusion. Other complications included postpericardiotomy syndrome (2 patients), apnea and cyanosis after the ADO implantation (1 patient), anemia requiring transfusion after the ADO implantation (1 patient), temporary complete heart block after VSD surgical closure (1 patient) and temporary supraventricular tachycardia after ASD surgical closure (3 patients).

Intensive care unit (ICU) stay was shorter for both PDA device closure and ASD device closure than that for surgery (*p* values were <0.001, 0.005 and 0.025 for ADO, coil and ASO closures, respectively, in comparison with the relevant surgeries); however, there was no significant difference with respect to VSD device closure (*p*=0.141). Floor bed stay was longer for all kinds of surgical closures (*p* values were 0.007, 0.038, 0.004 and 0.004 for ADO, coil, ASO and AMVSO closures, respectively, in comparison with the relevant surgeries). Comparisons of the hospitalization durations are shown in Table 2.

All the data were collected and analyzed using SPSS for Windows release 11.0.0 standard version. The independent-Samples T, Fisher Exact and Pearson Chi-Square tests were utilized, and *p* values lower than 0.05 were considered significant. Otherwise specified, data are presented as mean±standard deviation.



Table 2. Comparison of the length of hospital stays (in days) for PDA, ASD or VSD closures (surgery versus device occlusion)\*

	Surgery		Amplatzer Devices		Coil		p value			
	Floor	ICU	Floor	ICU	Floor	ICU	Floor Amp	ICU Amp	Floor Coil	ICU Coil
PDA	9.10±6.10	1.30±0.73	4.71±1.69	0.35±0.49	4.56±1.81	0.56±0.53	0.007	<0.001	0.038	0.005
ASD	12.8±8.36	3.65±3.24	4.20±2.62	1.60±0.97	-	-	0.004	0.025	-	-
VSD	12.4±8.09	3.29±2.30	4.50±2.08	1.50±1.73	-	-	0.004	0.141	-	-

\*Data are presented as mean±SD

PDA, Patent ductus arteriosus; ASD, Atrial septal defect; VSD, Ventricular septal defect; ICU, Intensive care unit; Amp, Amplatzer devices

## Results

PDA closure with the ADO and pfm coil was less expensive than that via surgery (12% and 33%, respectively, with p values of 0.18 and 0.005, respectively). PDA closure with the coil was also cheaper than that with the ADO (p=0.046). ASD device closure had a non-significant cost difference with surgery (15.4% higher, p=0.269). VSD device closure was also more expensive than surgery (17.6%) with a significant difference (p<0.001). Comparisons of the total costs for PDA, ASD and VSD closures are shown in Table 3.

Table 3. Comparison of total costs (in US dollars) for PDA, ASD or VSD closures (surgery versus device occlusion)

	Surgery	Amplatzer	Coil	p value
PDA	1697±218	1494±264	1136±440	0.018 (Amplatzer), 0.005 (Coil)
ASD	2739±615	3160±1051	-	0.269
VSD	2637±354	3102±76.7	-	<0.001

PDA, Patent ductus arteriosus; ASD, Atrial septal defect; VSD, Ventricular septal defect

## Discussion

There has been a debate over the cost-effectiveness of PDA device closure versus surgery over the past years. In 1993, Gray et al.<sup>5</sup> from the USA reported that PDA device closure (Rashkind PDA occluder) was costlier than surgical closure (\$11466 for device closure versus \$8838 for surgery). But in a later study published in 1996, Hawkins et al.<sup>6</sup> from the USA showed that the cost of PDA coil occlusion (\$7105) was almost the same as that of surgery (\$7101).

Since then, all studies comparing coil occlusion with surgery have yielded favorable results for the coil, including those of Kramer et al.<sup>12</sup> from the USA (\$4964 versus \$2941), Agnetti et al.<sup>13</sup> from Italy, Laohaprasitiporn et al.<sup>14</sup> from Thailand, Vázquez-Antona et al.<sup>4</sup> from Mexico (\$6964 versus \$4412) and Prieto et al.<sup>7</sup> from USA (\$8509 versus \$5273). Vázquez-Antona et al.<sup>4</sup> also compared Amplatzer device occlusion with surgery and found that the costs were almost the same (\$6964 for surgery versus \$6815 for device occlusion). The reason for this trend is apparently the lower cost of newer devices.

It is now accepted that PDA coil occlusion is less costly than surgery wherever it is practiced.

The relative cost of PDA occlusion with the ADO is controversial in developing countries, where the professional fees for surgery or intervention are relatively low in comparison with the device cost; the cost difference in these countries, therefore, cannot be considerable. The present study also demonstrates that PDA device closure, whether with the ADO or with the coil, is cheaper than surgery in Iran. Professional fees are relatively low in Iranian public hospitals, but what makes ADO closure more affordable is probably the subsidy that Iranian government pays for intracardiac devices (around 50% of the actual price).

As we mentioned earlier, the cost-effectiveness of ASD closure is something of an enigma: ASD device closure maybe more or less expensive than surgery in different countries even when the same device (ASO) is used at relatively the same time. The reports that are in favor of surgery include those of Durongpisitkul et al. from Thailand (Durongpisitkul K, Soongswang J, Laohaprasitiporn D, Nana A, Sriyoschati S, Ponvilawan S, Subtaweasin T, Kangkagate C. Comparison of atrial septal defect closure using Amplatzer septal occluder with surgery[Abstract]. Proceedings of the 3rd World Congress of Pediatric Cardiology and Cardiac Surgery, Toronto, Canada 2001:830.) and Vida et al.<sup>3</sup> from Guatemala (\$3330 versus \$4521). Thompson et al.<sup>8</sup> from the UK arrived at almost equal costs (£5375 for ASO versus £5412 for surgery). In contrast, there are reports in favor of device occlusion, including those of Galal et al. from Switzerland (Galal MO, von Bremen K, Sekarski N, Payot M, Bernath M, Corno A, Hurni M, von Segesser L, Fanconi S, Kappenberger L. Cost-comparison of transcatheter and surgical closure of atrial septal defect in children[Abstract]. Proceedings of the 3rd World Congress of Pediatric Cardiology and Cardiac Surgery, Toronto, Canada, 2001: 878.), Kim and Hijazi<sup>9</sup> from USA (\$25126 versus \$39351), Hughes et al.<sup>2</sup> from Australia (Aus\$11845 versus Aus\$12969) and Khelashvili et al.<sup>10</sup> from Georgia. The present study also shows statistically non-significant higher costs of ASD device closure (\$3102 versus \$2637, 15.4% higher) in Iran.

VSD device closure is the least studied device closure in terms of cost comparison. In the only other study in the existing medical literature, Xunmin et al.<sup>11</sup> found a non-significant difference between the two methods of VSD



closure, albeit Amplatzer device closure was 10% more costly (¥48521 versus ¥44058). The current study found 17.6% higher costs, which is not far from the results of the above-mentioned study.

It should be reemphasized that the Iranian government pays subsidies for the devices and the calculated costs include the discounted fees for the implanted devices. But it should be noticed that subsidy is also paid for some materials used in the operating room. Cost calculation without considering these subsidies would be difficult and only performable based on the limited number of foreign patients for whom no subsidy is granted.

Although we tried to calculate all possible payments, there may be some other charges not included in the hospital documents. In addition, the costs related to time away from work or school was not included in the study. It is deserving of note, however, that most of the other similar studies have also not included this factor due to the difficulty in assessment.

## Conclusion

PDA device closure either with the pfm Nit-Occlud coil or ADO is less costly than surgical ligation in Iran. Although ASD and VSD device closures are more expensive than their respective surgeries, the added costs can be affordable for the patients and their parents considering the benefits of device closure.

## Acknowledgment

We wish to thank the staff of the Accounting Department of Shaheed Rajayee Cardiovascular Center, and the staff of the Pediatric Cardiac Surgery Ward of Imam Khomeini Hospital Complex for their great help.

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