

# Impact of Reimbursement for the Amplatzer Septal Occluder under the National Health Insurance in Taiwan

Ming-Chih Lin,<sup>1,2,3</sup> Mei-Shu Lai,<sup>3</sup> Yun-Ching Fu<sup>1,2</sup> and Sheng-Ling Jan<sup>1,2</sup>

**Background:** Transcatheter closure of secundum-type atrial septal defect (ASD) is currently a standard procedure in medical treatment. In Taiwan, medical care is covered for most people by the National Health Insurance (NHI). The aim of this study was to investigate the change in costs, patient numbers, and the quality of care before and after reimbursement for the Amplatzer septal occluder (ASO).

**Methods:** In this retrospective time series survey, we searched the National Health Insurance Research Database (NHIRD) of Taiwan from 1996 to 2007. Files of inpatient expenditures by admissions were analyzed. The patient numbers, age, comorbidity, lengths of stay and costs were retrieved for analysis.

**Results:** After review of records from 1996 to 2007, we noted that the cases of transcatheter closure dramatically increased in 2004 after NHI began covering the fee for the ASO. However, when the cost of surgery increased 50% during the study period, the transcatheter approach had a 20% reduction of cost. The total expenditure for treating secundum-type ASD increased more than 4 times. The average length of stay decreased from 14.9 days in 1996 to 4.2 days in 2007.

**Conclusion:** In conclusion, when a new minimally invasive technology was introduced into a closed system, patient numbers surged for a short period of time because more patients with uncomplicated heart disease were willing to undergo intervention. The length of stay was dramatically shortened and costs were reduced for individual patients in a basically fee-for-service system.

**Key Words:** Amplatzer septal occluder • Atrial septal defect • Cost • Insurance

## INTRODUCTION

Transcatheter closure of secundum-type atrial septal defect (ASD) using the Amplatzer septal occluder

(ASO) (AGA Medical, Golden Valley, MN, USA) is a standard procedure as part of routine cardiac care.<sup>1-5</sup> In comparison with the traditional surgical approach, it has the advantages of minimal invasiveness, with no need for use of a heart lung machine, and shorter hospital stays.<sup>6-9</sup>

In previous reports, ASO was shown to either provide cost savings, or involve expenditure no greater than the cost of the traditional surgical approach in Western countries, with fewer complications.<sup>7-10</sup> However, in less-developed countries, ASO use is not necessarily cost effective because the fee for the device itself accounts for a large majority of the total medical fee.<sup>11</sup> However, those reports involved individual series; an actual comparison of costs between the two approaches

Received: June 29, 2011 Accepted: January 19, 2012

<sup>1</sup>Department of Pediatrics and Institute of Clinical Medicine, National Yang-Ming University, Taipei; <sup>2</sup>Division of Pediatric Cardiology, Department of Pediatrics, Taichung Veterans General Hospital, Taichung; <sup>3</sup>Institute of Epidemiology and Preventive Medicine, National Taiwan University, Taipei, Taiwan.

Address correspondence and reprint requests to: Dr. Yun-Ching Fu, Department of Pediatrics, Taichung Veterans General Hospital, No. 160, Sec. 3, Chung-Kang Road, Taichung 40705, Taiwan. Tel: 886-4-2359-2525 ext. 5900; Fax: 886-4-2374-1359; E-mail: ivanfu@vghtc.gov.tw

has never been investigated from a nationwide perspective.

In Taiwan, the National Health Insurance (NHI) has been an important social welfare program since 1995. It is a compulsory government program that provides coverage for more than 98% of the 22 million people in Taiwan.<sup>12,13</sup>

The aim of this study was to investigate the patient numbers, costs and the lengths of hospital stay before and after reimbursement for the ASO in a closed medical system.

## METHODS

This is a retrospective time series survey. Although the National Health Insurance of Taiwan was initiated in 1995, the database covering that year was incomplete. As a result, we searched the National Health Insurance Research Database (NHIRD) of Taiwan from 1996 to 2007. Files of inpatient expenditures by admissions (DD1996~DD2007 files) were the main resource for data analysis. In this claim data, patients' diagnoses were coded according to the International Classification of Diseases, 9th Revision (ICD9). All inpatients whose first or second diagnosis was ostium secundum-type atrial septal defect (ICD9 745.5) were retrieved.

If the procedure codes of the patients included repair of atrial septal defect with prosthesis, open technique (ICD9 35.51), they were identified as receiving surgical closure of ASD. On the other hand, if the procedure codes contained repair of atrial septal defect with prosthesis, closed technique (ICD9 35.52), they were identified as receiving transcatheter closure of ASD. If the patients' procedure codes were coded with both open technique (ICD9 35.51) and closed technique (ICD9 35.52), they were identified as initially device implantation, and then surgical repair after the device embolization. The patients' age, numbers, comorbidity, lengths of stay and costs were retrieved for analysis. The comorbidity were defined as: ICD9 428 for congestive heart failure; ICD9 416 for pulmonary hypertension, ICD9 427 for arrhythmia, ICD9 434 for ischemic stroke, ICD9 435 for transient ischemic attack (TIA). For patients admitted before the end of 2003, the patient-paid ASO price (New Taiwan Dollar [NTD] \$150,000) was added

to the patient's total expenditure when analyzing cost.

According to NHIRD, data which could be used to identify patients or care providers, including medical institutions and physicians, is scrambled before being sent to the National Health Research Institutes for database construction, and is further scrambled before being released to individual researchers. ([http://w3.nhri.org.tw/nhird/en/Data\\_Protection.html](http://w3.nhri.org.tw/nhird/en/Data_Protection.html)) A written agreement declaring there would be no attempt to obtain information that could potentially violate the privacy of patients or care providers was signed before the authors began data retrieval, and this analysis was conducted for research purposes only. There is no potential conflict of interest. The computer-processed personal data protection law, related regulations of the Bureau of National Health Insurance and National Health Research Institutes of Taiwan were strictly followed. The protocol was reviewed and approved by the NHRI before data release.

SAS 9.0 for Windows was applied for data retrieval and data analysis. Categorical data were analyzed by chi-square methods. When any number in a cell is less than 5, Fisher's test will be used to test the significance. A p level less than 0.05 was defined as statistically significant. Multiple logistic regression model was applied for analyzing patients' tendency to choose open or close methods, and the stepwise method was used for variable selection. The level of entry was 0.3 and the level of stay was 0.35.

## RESULTS

Covering the years 1996 to 2007, data about 26,209 admissions with a main diagnosis of ostium secundum-type atrial septal defect were retrieved. Among them, 1102 patients underwent surgical closure of atrial septal defects, and 1616 patients received transcatheter closure of ASD. There were 7 patients who underwent both transcatheter and surgical closure of ASD in the study period.

### **The trend towards use of the transcatheter method after reimbursement by NHI**

The yearly distribution of surgical and transcatheter cases is presented in Figure 1. The cases of transcatheter closure dramatically increased after NHI began covering

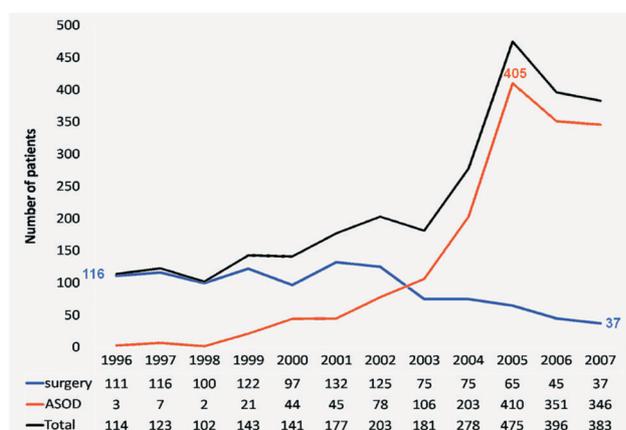


Figure 1. The yearly distribution of surgical and transcatheter cases; ASOD, Amplatzer septal occlusion device.

the cost of ASO devices in 2004, with a peak number of 401 cases in 2005. Correspondingly, the number of surgical cases decreased gradually from a peak of 116 cases annually in 1997 to a nadir of 37 cases in 2007. Overall, total cases increased significantly after reimbursement for ASO.

### The effect on cost expenditure of the National Health Insurance of Taiwan

The effect on the average cost per patient for closure

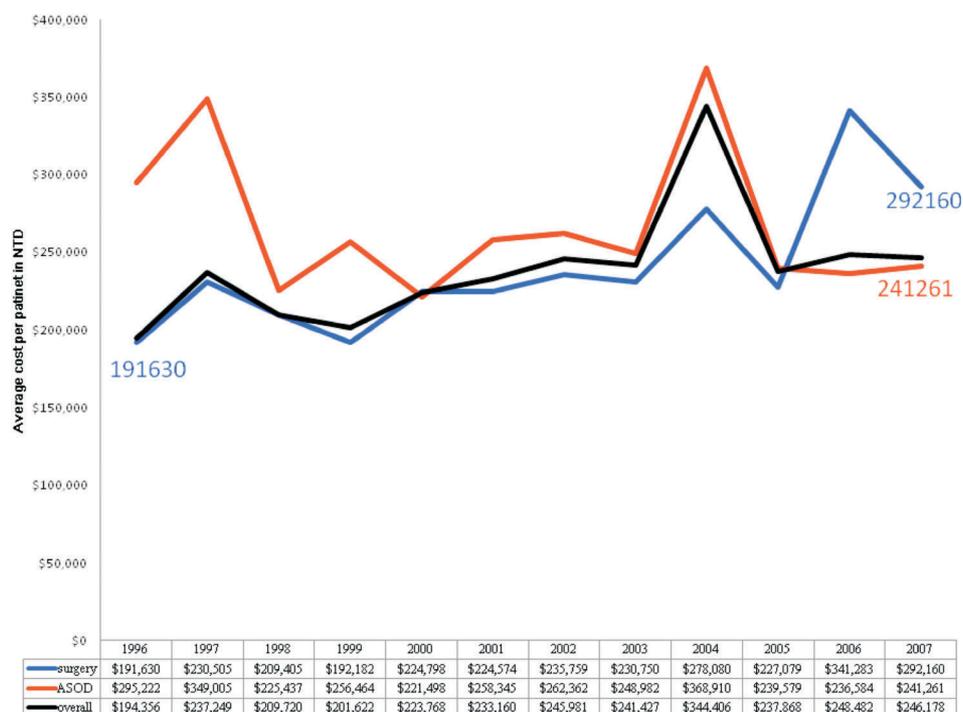


Figure 2. The effect on the average cost per patient for closure of secundum-type ASD; ASOD, Amplatzer septal occlusion device.

of secundum-type ASD is summarized in Figure 2. The cost of the surgical method increased from NTD \$191,630 to NTD \$292,160 per patient, i.e., a 52% increase in expenditure per patient for surgery during the 12-year period. The ASO was not covered by the NHI before 2004, and the cost of the device (NTD \$150,000) was added to the average cost per patient. The cost per patient declined from NTD \$349,005 in 1997 to \$241,261 in 2007.

The details of annual costs were summarized in Table 1 both in NTD and United States Dollars (USD). The largest component of the cost for the transcatheter approach was the cost of the ASO itself, which comprised approximately 60% of the total procedure cost. The operator fee for the transcatheter approach was less than that corresponding fee for the surgical approach.

The effect on the total cost per year is summarized in Figure 3. The expenditure for treating secundum-type ASD increased from 22 million NTD in 1996 to 98 million NTD in 2006. The cost for transcatheter closure rose from 26 million NTD per year in 2003 to 83 million NTD per year in 2007.

### The length of hospital stay

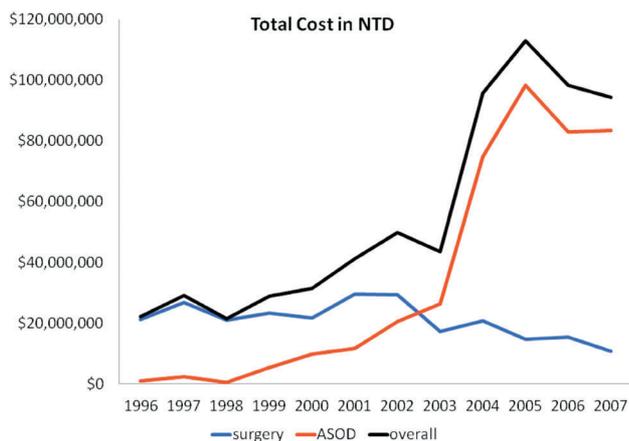
We used length of hospital stay as an index for qual-

**Table 1.** The total cost and average cost per patient annually in both New Taiwan Dollars and United States Dollars

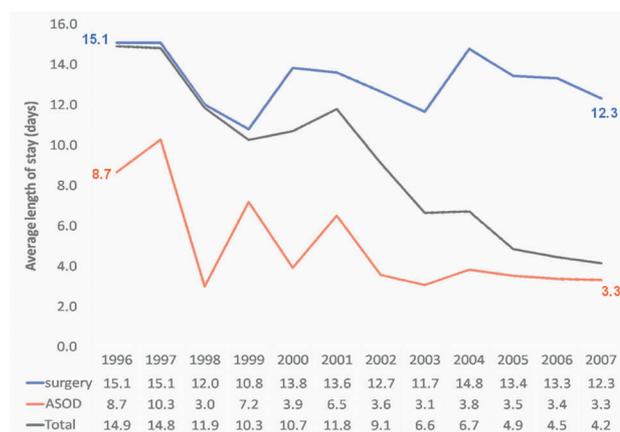
year	Surgery					ASO					Average Exchange Rate* (NTD/USD)	
	Total Cost		Average Cost		Fee for surgeon	Total Cost		Average Cost		Fee for operator		Fee for device
	NTD	USD	NTD	USD		NTD	USD	NTD	USD			
1996	21,270,904	774,682	191,630	6,979	12.7%	885,667	32,256	295,222	10,752	6.9%	50.8%	27.5
1997	26,738,612	932,902	230,505	8,042	10.5%	2,443,033	85,237	349,005	12,177	5.8%	43.0%	28.7
1998	20,940,523	626,123	209,405	6,261	11.6%	450,874	13,481	225,437	6,741	9.0%	66.5%	33.4
1999	23,446,244	726,653	192,182	5,956	12.6%	5,385,746	166,917	256,464	7,948	7.9%	58.5%	32.3
2000	21,805,375	698,326	224,798	7,199	10.8%	9,745,905	312,116	221,498	7,094	9.1%	67.7%	31.2
2001	29,643,752	877,027	224,574	6,644	10.8%	11,625,512	343,947	258,345	7,643	7.8%	58.1%	33.8
2002	29,469,904	852,342	235,759	6,819	10.3%	20,464,220	591,875	262,362	7,588	7.7%	57.2%	34.6
2003	17,306,221	502,830	230,750	6,704	10.5%	26,392,072	766,819	248,982	7,234	8.1%	60.2%	34.4
2004	20,856,021	624,024	278,080	8,320	8.7%	74,888,780	2,240,714	368,910	11,038	5.5%	40.7%	33.4
2005	14,760,160	458,859	227,079	7,059	10.7%	98,227,200	3,053,657	239,579	7,448	8.5%	62.6%	32.2
2006	15,357,726	472,090	341,283	10,491	7.1%	83,040,950	2,552,646	236,584	7,272	8.6%	63.4%	32.5
2007	10,809,917	329,151	292,160	8,896	8.3%	83,476,148	2,541,768	241,261	7,346	8.4%	62.2%	32.8

ASO, Amplatzer septal occluder; NTD, New Taiwan Dollar; USD, United States Dollar.

\* The average exchange rate data was retrieved from the central bank of Taiwan (<http://www.cbc.gov.tw/content.asp?CuItem=27029>)



**Figure 3.** The effect on the total cost paid by the National Health Insurance in Taiwan per year; ASOD, Amplatzer septal occlusion device.



**Figure 4.** The average length of stay for patients undergoing surgical or transcatheter closure of ASD; ASOD, Amplatzer septal occlusion device.

ity of care, as summarized in Figure 4. The length of stay for surgical patients decreased slightly from 15.1 days in 1996 to 12.3 days in 2007. The length of stay for the transcatheter approach was around 3 to 4 days after 2002. The average length of stay for all patients decreased from 14.9 days in 1996 to 4.2 days in 2007.

### Comorbidity of patients

The comorbidity of patients were summarized in Table 2. After the ASO was covered by NHI, slightly fewer patients (9.61% versus 6.82%) had pulmonary hypertension. If the patients were stratified by intervention types

(surgery or transcatheter), the characteristics of patients were summarized in Table 3. The parents favored transcatheter closure for children. Significantly more patients with complicated heart problems (arrhythmia, heart failure and pulmonary hypertension) chose the surgical methods. However, the most significant comorbidity was still insurance coverage (20% before to 81% after insurance coverage). When considering all of these comorbidities together in a multiple logistic regression model, the odds ratio that the transcatheter method would be chosen was 20, after adjusting congestive heart failure, pulmonary hypertension, ischemic stroke and age (Table 4).

**Table 2.** Patient characteristics before and after reimbursement by National Health Insurance

	Before reimbursement		After reimbursement		p value
	n	percent	n	percent	
Subgroups of age					0.26
0~10 years old	528	44.52%	618	40.52%	
10~20 years old	181	15.26%	262	17.18%	
20~30 years old	148	12.48%	167	10.95%	
30~40 years old	115	9.70%	158	10.36%	
40~50 years old	105	8.85%	135	8.85%	
50~60 years old	64	5.40%	111	7.28%	
60~70 years old	35	2.95%	48	3.15%	
70~80 years old	13	1.10%	24	1.57%	
> 80 years old	2	0.17%	2	0.13%	
Congestive heart failure	52	4.38%	53	3.48%	0.22
Pulmonary HT	114	9.61%	104	6.82%	0.008
Arrhythmia	44	3.71%	55	3.61%	0.89
Ischemic stroke	4	0.34%	2	0.13%	0.41
TIA	2	0.17%	0	0.00%	0.19
total	1186		1525		

HT, hypertension; TIA, transient ischemic attack.

**Table 3.** Patient characteristics for choosing open or closed technique

	Methods				p value
	Surgery		ASO		
	n	percent	n	percent	
Age < 18 years	556	50.78%	959	59.34%	< 0.001
Congestive heart failure	69	6.30%	36	2.23%	< 0.001
Pulmonary hypertension	146	13.33%	72	4.46%	< 0.001
Arrhythmia	52	4.75%	47	2.91%	0.012
Ischemic stroke	3	0.27%	3	0.19%	0.69
Transient ischemic attack	2	0.18%	0	0.00%	0.09
Period after reimbursing ASO	215	19.63%	1310	81.06%	< 0.001
Total	1095		1616		

ASO, Amplatzer septal occluder.

## DISCUSSION

In this study, we found that after the NHI began reimbursement for ASO devices in 2004, the case numbers surged. It is quite apparent that patients preferred a minimally invasive procedure to traditional surgery. However, the total cost for the procedure increased as the patient numbers grew. The surgical fee increased by 50% during the 12-year study period. However, the average cost per patient did not increase concomitantly. It was offset by the improved cost control of the transcatheter method. The quality of care viewed from the perspective

**Table 4.** Results of multiple logistic model for patients' tendency to choose transcatheter closure of atrial septal defects

	Odds ratio	95% confidence interval	p value
Age < 18 years	1.54	1.25~1.89	< 0.001
Congestive heart failure	0.30	0.18~0.50	< 0.001
Pulmonary hypertension	0.28	0.19~0.41	< 0.001
Ischemic stroke	0.64	0.38~1.07	0.09
Insurance coverage	19.90	16.20~24.45	< 0.001

of admission length was improved, in that the average admission length declined from 7 to 3 days.

Although it was suggested in previous reports that the use of ASO reduced costs,<sup>8,10,14</sup> this is not necessarily the case in all countries.<sup>9,11</sup> It can be cost-saving in a free market economy, e.g., the United States, because the cost of each day of admission and surgeon fees are high. In theory, the cost of the devices will be offset by the reduction in admission days and fewer complications.<sup>7</sup> However, in countries with national health services, the costs of surgery and device closure of ASD are about the same because expenditures regarding admission days are partially controlled by the government.<sup>9,15</sup> Thus, the reduction in fees for admission days only compensates for the extra cost of the devices themselves, and the cost is approximately similar. In developing countries, the cost of ASO is so high that the reduction in admission days and fewer surgical complications cannot compensate for the additional cost that such a financial requirement brings. Moreover, the surgeon's fee is relatively low. So, paradoxically, ASO is not cost-saving in these countries, at least according to one report.<sup>11</sup> In our report, the ASO was shown to be cost beneficial under the NHI of Taiwan. Although the overall expenditure increased about 4 times during the study period, more young adult patients with uncomplicated heart issues underwent transcatheter closure of ASD (Table 4). This signifies that the expenditure for treating long-term complications of ASD might decrease.

The average cost for the surgical patient is lower than ASO before 2006 and higher than ASO after 2006 (Table 1). The discrepancy might be attributed to the significantly decreased length of stay (from 8.7 days in 1996 to 3.3 days in 2007).<sup>16</sup> However, the increase in surgical cost in recent years is possibly caused by complications when surgical rescue of the ASO becomes necessary.

We used the length of admission as the surrogate endpoint of care quality. The length of stay for surgical patients decreased slightly from 15.1 days in 1996 to 12.3 days in 2007. The length of stay for the transcatheter approach was approximately 3-4 days after 2002. We can assume that the patients overall had a substantially improved level of satisfaction because, after the ASO was implanted, the length of hospital stay was one week shorter than that for the traditional surgical approach. It goes without saying that there are no draining tubes, surgical scars, post-operative pain and there is no

need of blood transfusion. These findings were compatible with those of other reports.<sup>7-9,15</sup>

Patients with congestive heart failure and pulmonary hypertension tended to receive treatment immediately. Therefore, in Table 2, we did not see very significant difference of proportion before and after insurance coverage of ASO. However, for young adults with uncomplicated heart disease, they may hesitate before undergoing surgical intervention that is not emergency in nature. After ASO was reimbursed by NHI, those uncomplicated patients contributed to the significant increase in patient numbers. A new technology could help doctors persuade patients to undergo treatment before complications occur. This might reduce costs in the long run, although short-term costs may appear to increase.<sup>17</sup> A longitudinal follow-up study would be needed to elucidate this issue.

During the study period, we identified 7 patients who underwent both transcatheter and surgical closure of ASD. We could not identify the exact reason for treatment decisions from the claim data. However, one possible explanation is that those patients received surgical retrieval of embolized ASOD. The average cost for these 7 patients was NTD \$300,314 (USD \$9,327), and the mean length of stay was 9.3 days. However, we thought the number of patients could be underestimated. Patients were coded as surgical closure when either the cardiologists failed to deploy the device during the procedure, or the device embolized soon after the procedure. In addition, the cost incurred due to surgical complication could not be clearly identified from the claimed data.

There are some limitations in our study. First, the patient ID number is scrambled before releasing the data to individual researchers. Thus, the claims data cannot be linked to the Taiwan government's mortality registry. However, since the mortality rates for both surgery and transcatheter closure of ASD are both quite low in Taiwan,<sup>2,5</sup> we think it can be neglected in data analysis. Second, because reimbursement is only provided for ASO when the ratio of pulmonary blood flow to the systemic flow is greater than 1.5 according to the regulations of the NHI, some patients had to pay for their own devices. As a result, the cost of transcatheter closure might be underestimated. But, we think the case number may be limited because whether small ASD should be closed is still a controversial issue.<sup>18-21</sup>

## CONCLUSION

In conclusion, when a new minimally invasive technology is introduced into a closed system, patient numbers increased substantially for a short duration because more uncomplicated patients are willing to undergo surgical intervention. Ultimately, the length of hospital stay was dramatically shortened, and medical costs were reduced for individual patients in an essentially fee-for-service system.

## ACKNOWLEDGEMENT

This study is based in part on data from the National Health Insurance Research Database provided by the Bureau of National Health Insurance, Department of Health and managed by National Health Research Institutes (Registered number 98138). The interpretation and conclusions contained herein do not represent those of Bureau of National Health Insurance, Department of Health or National Health Research Institutes.

## REFERENCES

- Butera G, De Rosa G, Chessa M, et al. Transcatheter closure of atrial septal defect in young children: results and follow-up. *J Am Coll Cardiol* 2003;42:241-5.
- Lin MC, Fu YC, Jan SL, et al. Transcatheter closure of secundum atrial septal defect using the Amplatzer Septal Occluder: initial results of a single medical center in Taiwan. *Acta Paediatrica Taiwanica* 2005;46:17-23.
- Omeish A, Hijazi ZM. Transcatheter closure of atrial septal defects in children & adults using the Amplatzer Septal Occluder. *J Interv Cardiol* 2001;14:37-44.
- Chessa M, Carminati M, Butera G, et al. Early and late complications associated with transcatheter occlusion of secundum atrial septal defect. *J Am Coll Cardiol* 2002;39:1061-5.
- Wang JK, Tsai SK, Wu MH, et al. Short- and intermediate-term results of transcatheter closure of atrial septal defect with the Amplatzer Septal Occluder. *Am Heart J* 2004;148:511-7.
- Berger F, Vogel M, Alexi-Meskishvili V, et al. Comparison of results and complications of surgical and Amplatzer device closure of atrial septal defects. *J Thorac Cardiovasc Surg* 1999; 118:674-8;discussion 8-80.
- Du ZD, Hijazi ZM, Kleinman CS, et al. Comparison between transcatheter and surgical closure of secundum atrial septal defect in children and adults: results of a multicenter nonrandomized trial. *J Am Coll Cardiol* 2002;39:1836-44.
- Hughes ML, Maskell G, Goh TH, et al. Prospective comparison of costs and short term health outcomes of surgical versus device closure of atrial septal defect in children. *Heart* 2002;88:67-70.
- Thomson JD, Aburawi EH, Watterson KG, et al. Surgical and transcatheter (Amplatzer) closure of atrial septal defects: a prospective comparison of results and cost. *Heart* 2002;87:466-9.
- Baker SS, O'Laughlin MP, Jollis JG, et al. Cost implications of closure of atrial septal defect. *Catheter Cardiovasc Interv* 2002; 55:83-7.
- Vida VL, Barnoya J, O'Connell M, et al. Surgical versus percutaneous occlusion of ostium secundum atrial septal defects: results and cost-effective considerations in a low-income country. *J Am Coll Cardiol* 2006;47:326-31.
- Wen CP, Tsai SP, Chung WS. A 10-year experience with universal health insurance in Taiwan: measuring changes in health and health disparity. *Ann Intern Med* 2008;148:258-67.
- Lin MC, Lai MS. Pediatricians' role in caring for preschool children in Taiwan under the national health insurance program. *J Formos Med Assoc* 2009;108:849-55.
- Kim JJ, Hijazi ZM. Clinical outcomes and costs of Amplatzer transcatheter closure as compared with surgical closure of ostium secundum atrial septal defects. *Med Sci Monit* 2002;8:CR787-91.
- Formigari R, Di Donato RM, Mazzera E, et al. Minimally invasive or interventional repair of atrial septal defects in children: experience in 171 cases and comparison with conventional strategies. *J Am Coll Cardiol* 2001;37:1707-12.
- Tseng YH, Wu MY, Tsai FC, et al. Costs associated with extracorporeal life support used in adults: a single-center study. *Acta Cardiol Sin* 2011;27:221-8.
- Chien SJ, Chang JP, Ko SF, et al. Long-term outcome of outlet-type ventricular septal defect: focus on congestive heart failure and aortic valve disorder. *Acta Cardiol Sin* 2011;27:197-203.
- Dowson A, Mullen MJ, Peatfield R, et al. Migraine Intervention With STARFlex Technology (MIST) trial: a prospective, multi-center, double-blind, sham-controlled trial to evaluate the effectiveness of patent foramen ovale closure with STARFlex septal repair implant to resolve refractory migraine headache. *Circulation* 2008;117:1397-404.
- Kent DM, Trikalinos TA, Thaler DE. Patent foramen ovale and cryptogenic stroke. *N Engl J Med* 2008;358:1519-20;author reply 20-1.
- Thaler DE, Kent DM. Rethinking trial strategies for stroke and patent foramen ovale. *Curr Opin Neurol* 2010;23:73-8.
- Wahl A, Praz F, Tai T, et al. Improvement of migraine headaches after percutaneous closure of patent foramen ovale for secondary prevention of paradoxical embolism. *Heart* 2010;96:967-73.