# Early Experience with Pediatric Cardiac Intervention in Songklanagarind Hospital

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**Background:** Nowadays, pediatric cardiac intervention is an effective optional treatment for congenital heart disease (CHD). Several cardiac centers have been established in different regions of Thailand and Songklanagarind Hospital is the newest of these university cardiac centers.

**Objective:** To report results and complications of transcatheter treatment for congenital cardiac defects in Songklanagarind Hospital.

*Material and Method:* The medical database was reviewed for the results and complications of different types of pediatric cardiac intervention from May, 2000 to December, 2003.

**Results:** There were 102 cases of pediatric cardiac intervention. Sixty-seven were patent ductus arteriosus (PDA), 16 were valvular pulmonary stenosis (VPS), 10 were cyanotic CHD which needed balloon atrial septostomy (BAS), 8 were abnormal aorto-pulmonary (AP) collaterals, and 1 was severe valvular aortic stenosis (VAS). Coil embolization was performed in 53 patients with PDA and 8 patients with AP-collateral vessels, 32 of PDAs (60.4%) and all AP-collateral vessels (100%) were completely obliterated within 24 hours. The Amplatzer duct occluder (ADO) was deployed in 14 PDAs with 100% completely obliteration within 24 hours. In those with VPS or VAS, percutaneous balloon valvuloplasty (PBV) was the treatment of choice. The mean peak to peak systolic pressure gradient in VPS was reduced from  $62.8 \pm 33.3$  mmHg and from 76 mmHg to 49 mmHg in VAS after the procedures. In BAS, the mean diameter of atrial communication increased from  $3.0 \pm 0.7$  mm to  $5.9 \pm 0.4$  mm. In coil embolization, 8 had distal PA embolization (15%), 1 had hemolysis (2%) and 1 had decreased dorsalis pedis pulse (2%). One (7%) of the ADO-implanted patients had a weak femoral pulse. Of the VPS cases, 1 died from intractable heart failure, and 1 developed hemiparesis, from which they completely recovered within 6 months. The patient with VAS had a femoral artery complication.

**Conclusion:** Pediatric cardiac intervention in Songklanagarind Hospital has satisfactory results with an acceptable complication rate.

Keywords: Pediatric cardiac intervention, Congenital heart disease

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Since the report of Rashkind and Miller in 1966<sup>(1)</sup>, cardiac intervention in a pediatric population has developed into a good optional treatment for congenital heart diseases (CHD). The Naradivas-rajanagarind Cardiac Center (NCC) is the first such facility in the south and the latest university cardiac center in Thailand. Here a therapeutic intervention

program was established in 2000 for closing the patent ductus arteriosus with Gianturco coils. Nowadays, several procedures are available at the NCC, for example, closure of the ductus arteriosus by Amplatzer Duct Occluder, balloon pulmonic valvuloplasty, balloon atrial septostomy and blade atrial septoplasty. The objective of the present study was to report on the initial results and complications in such procedures in this new facility.

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### **Material and Method**

The files of pediatric patients who underwent cardiac intervention from May 2000 to December 2003 were retrospectively reviewed and divided into the following different types: 1) occlusion procedures, including transcatheter closure of the patent ductus arteriosus (PDA) either with coils or Amplatzer Duct Occluder (ADO), and coil embolization of abnormal aorto-pulmonary (AP) collateral vessels. 2) dilatation procedures, including the percutaneous balloon valvuloplasty (PBV) and balloon or blade atrial septostomy (BAS).

#### **Occlusion procedures**

Right and left heart catheterization was routinely performed to evaluate hemodynamics. Heparin 50 U/kg was administered after femoral artery access had been obtained. Cloxacillin 100 mg/kg was also administered intravenously in all occlusive procedures. Chest X-ray and echocardiography were done after 24 hours to evaluate the position of the device, residual shunt, and gradient across the aortic arch and the left pulmonary artery (in a PDA occlusion procedure). In addition, a repeat echocardiogram was subsequently performed 6-12 months later to evaluate mid-term results.

In PDA coil embolization, the standard Gianturco coil (Cook Cardiology, Bloomington, IN) was the most frequently used device. The indications for transcatheter PDA closure were similar to those for surgical ligation. In general, a coil was selected with a diameter at least twice the minimum ductal diameter and less than or equal to the diameter of the aortic ampulla. Closure of the ductus was performed in retrograde fashion by using an end-hole catheter (such as a Judgkins right coronary artery catheter) across the PDA to the main pulmonary artery over a straight tip guide wire. Aortography was repeated in 10 to 15 minutes to evaluate the results. Additional coils were placed as needed if the angiogram revealed a residual shunt.

The Amplatzer Duct Occluder (AGA Medical Corporation, Golden Valley, MN), a self-expanding mushroom-shaped device, was also used for transcatheter closure in medium to large size PDA at the authors' institute. A device 2 mm larger than the smallest ductal diameter was selected to deploy via a long delivery sheath, which crossed the ductus arteriosus from the pulmonary artery side and was positioned in the descending aorta, to close the PDA. A repeat aortography was done 10 minutes later to assess the aortic arch obstruction and residual shunt.

The preparations for coil occlusion in aortopulmonary collaterals are similar to those with PDA. Collaterals were initially identified by anteroposterior projection aortography, and then selective manual injection inside the collaterals would be performed to clarify the precise position and anatomy of those vessels. Generally a coil was used 10-20% larger than the diameter of the vessel. Additional coil(s) would be used if repeated aortography demonstrated a residual shunt.

## Percutaneous Balloon Valvuloplasty

Under general anesthesia, right and left heart catheterizations were routinely obtained in all patients. In valvular pulmonary stenosis, peak to peak transvalvular gradients over 30 mmHg would be considered candidates for balloon valvuloplasty. Also, valvular aortic stenosis cases with peak to peak gradients 70 mmHg or more regardless of symptoms, or gradients of 50 mmHg or more with associated symptoms were indicative for balloon intervention. Patients with significant aortic insufficiency were not considered for the treatment. Generally, a high profile balloon with a diameter of 1.5 times larger than the pulmonic valve annulus was used for valvular pulmonary stenosis, whereas the balloon size in valvular aortic stenosis did not exceed the aortic annulus diameter. Repeated balloon inflation with dilute contrast media would be done until the stenotic valve waist diminished. Hemodynamic assessment and ventricular (RV or LV) angiogram were obtained after the procedure to ensure immediate results and detect any complications. In addition, echocardiography was also performed the day after to evaluate the degree of residual obstruction and valve incompetence.

# **Balloon Atrial Septostomy**

The indications of this procedure in the authors' institute included the following: 1) neonates with d-transposition of the great arteries, 2) patients with pulmonary atresia and intact ventricular septum (PA/IVS), and 3) patients with left or right atrioventricular valves atresia, such as tricuspid atresia. Precatheterization echocardiography was routinely performed to determine the atrial septal anatomy. BAS was usually performed in the catheterization lab using fluoroscopic and echocardiographic guidance. Right heart catheterizations were done under general anesthesia. The Rashkind balloon (Bard, Billerica, MA)

was used to create an unrestrictive atrial septal defect. The diameter of the septal defect and the mean pressure difference were measured after the procedure.

## **Bladed Atrial Septectomy**

The indications for this procedure were similar to balloon atrial septostomy. Bladed atrial septostomy was developed to overcome an unsuccessful balloon septostomy in patients with a thickened interatrial septum. A balloon septostomy was subsequently performed in the usual fashion to create unobstructed atrial communication.

# Data collection

The angiographic diameter of the defect, immediate occlusion result, 6-12 months occlusion result, and complications were recorded in transcatheter closure procedures. In PBV, the difference in peak to peak systolic pressure gradients across the valve was evaluated, as well as any complications. The types of cardiac defect, the difference in diameter of atrial septal defect (ASD) after the procedure, and complications were recorded for the BAS procedure.

#### Statistical analysis

Descriptive data are expressed as mean, range and standard deviation or number and percentage where appropriate.

#### Results

There were 102 episodes of interventional cardiac catheterization during the present study period. The median age of the patients was 60 months. (min 3 days; max 18 years). Fifty-nine (58%) were male. Sixty-seven cases (66%) were patent ductus arteriosus (PDA), 16 (16%) were valvular pulmonary stenosis (VPS), 10 (10%) were those with cyanotic congenital heart diseases in which adequate atrial communication had to be acheived before surgery, 7 (7%) were tetralogy of Fallot (TOF) with abnormal aorto-pulmonary (AP)

collateral vessels, 1 (1%) was post-total repair TOF with a residual right modified Blalock-Taussig shunt, 1 (1%) was scimitar syndrome, and 1 (1%) was severe valvular aortic stenosis (VAS).

Coil embolization (Table 1) was performed in 53 PDA and 8 AP-collateral vessels. The median diameter of the PDA was  $2.83 \pm 1.12$  mm (min 1.5 mm; max 4.5 mm). Thirty-two PDA (60%) and all of the APcollateral vessels (100%) were completely occluded within 24 hours after the procedure. 82% of the PDA were obliterated within 6 months. The complications for coil embolization were as follows: distal pulmonary artery embolization in 8 patients (15%), hemolysis in 1 patient (1.9%), and decreased dorsalis pedis pulse in 1 patient (1.9%).

Fourteen PDAs were closed with the Amplatzer Duct Occluder (Table 1). The median diameter of the ductus arteriosus in this group was  $3.72 \pm 1.18$  mm (min 2.7 mm; max 6.7 mm). Immediate aortography demonstrated complete occlusion in 29 patients (64%), increasing to a 100% obliteration rate 24 hours after the procedure, as illustrated by an echocardiogram. One patient, a 5 mm PDA with systemic PA pressure, became complicated with an iatrogenic femoral arterio-venous malformation 3 days after the procedure. She was transferred for surgical ligation of the fistula on the 5<sup>th</sup> day of admission with a satisfying postoperative result.

Percutaneous balloon valvuloplasty (PBV) was performed in 16 VPS cases and 1 VAS case (Table 2). In the VPS cases, the mean peak to peak systolic pressure gradient across the pulmonary valve prior to dilation was  $62.8 \pm 33.3$  mmHg, which reduced to  $33.33 \pm 33.33$  mmHg after the procedure. In the VAS case, the peak to peak systolic pressure gradient across the aortic valve decreased from 76.0 mmHg to 49.0 mmHg. One of the VPS cases developed right hemiparesis from which they completely recovered 6 months after the procedure. One patient with critical pulmonary valve stenosis died from reverse systemic

Table 1. Results and complications among different occlusion procedures

Type of intervention	Type of CHD	Complete occlusion	Complication(s)
	(n)	at 24 hours n (%)	n (%)
Coil embolization	PDA (53)	32 (60.4)	Distal PA embolization, 8 (15.1%) Hemolysis, 1 (1.9%) Decreased dorsalis pedis pulse,1 (1.8%)
ADO implantation	AP-C (8)	8 (100.0)	Contrast media extravasation, 1(12.5%)
	PDA (14)	14 (100.0)	Decreased dorsalis pedis pulse, 1 (7.1%)

PDA: patent ductus arteriosus; AP-C: aorto-pulmonary collateral vessels; ADO: Amplatzer duct occluder

Type of intervention	Type of CHD (n)	Pressure gradient (mmHg) (mean + SD)		Complication (s)
		Pre	Post	-
PBV	VPS(16)	62.8 <u>+</u> 33.3	33.33 ± 33.3	Dead, 1(6.2%) Hemiparesis, 1 (6.2%) Decreased dorsalis pedis pulse, 1 (6.2%)
	VAS(1)	76.0	49.0	Femoral artery occlusion,1 (100%)

Table 2. Results and complications of balloon dilation procedures

PBV: percutaneous balloon valvuloplasty; VPS: valvular pulmonary stenosis; VAS: valvular aortic stenosis

blood flow 10 hours after a successful valvuloplasty procedure. The diagnosis of this patient was critical pulmonary valve stenosis with unrestrictive patent ductus arteriosus and atrial septal defect. The cardiac catheterization revealed a small bipartite, inlet and infundibulum, right ventricle. In addition, a tiny jet of contrast media was able to pass through a thin membranous pulmonary valve, 5 mm annulus. No major coronary sinusoid was demonstrated from the right ventricle. His right ventricular systolic pressure (RVSP) was 100 mmHg, exceeding the systemic arterial pressure (70 mmHg). Balloon valvuloplasty was initially performed with a 5 mm coronary dilation balloon, and subsequently increased to a diameter of 8 mm. After the procedure, the RVSP decreased to 40 mmHg. However, moderate to severe pulmonary regurgitation and moderate tricuspid regurgitation with poor RV systolic function was demonstrated by echocardiography 1 hour after the procedure. He developed unstable hemodynamics and resisted all intravenous inotropic medications, and eventually died from cyanosis and intractable low cardiac output.

Balloon aortic valvuloplasty was performed on one valvular aortic stenosis patient. Although the peak to peak systolic pressure gradient decreased from 76 mmHg to 49 mmHg, the patient developed weakening of the right femoral pulse after the procedure and required surgical endarterectomy. Balloon atrial septostomy and blade atrial septectomy (Table 3) were used to create unobstructed atrial communication in cyanotic patients who needed adequate atrial shunt, such as an d-TGA with intact ventricular septum (TGA/IVS), and a tricuspid atresia (TA). Balloon atrial septostomy was performed in 9 patients and 1 patient underwent blade atrial septectomy. The mean diameter of the atrial septal defect (ASD) increased from  $3.0 \pm 0.7$  mm to  $5.9 \pm 0.4$  mm. All patients tolerated the procedure well without significant complications.

#### Discussion

In PDA coil embolization (Table 4), several reports<sup>(2-4)</sup> have illustrated a range of ductus diameter from 0.2 to 6.2 mm. The complete occlusion rate was approximately 56-62% within 24 hours after implantation, subsequently increasing to 81-95% 1 year later.

 Table 3. Results and complications of balloon atrial septostomy

Type of intervention (n)	ASD diameter (mm) (mean $\pm$ SD)		Complication (s)
	Pre	Post	
BAS (10)	3.0 ± 0.7	5.9 ± 0.4	None

BAS: balloon atrial septostomy; ASD: atrial septal defect

Study (n)	Size (mm)	% Complete occlusion		Complication(s) (%)	
	(min-max)	24 hr	6 mo-1 yr		
European registry, 2001 (1,291)	0.2-6.2	59	95	Distal PA embolization (3.8%) Hemolysis (0.9%)	
Khowsathit P, 1997(16)	1.0-3.7	56	81	Distal PA embolization (12.5%)	
Laohaprasittiporn D, 2002 (70)	1.4-3.7	62	88	Mild LPA stenosis (10%) Distal PA embolization (8.6%) Decrease dorsalis pedis pulse (1.4%)	
Promphan W, 2003 (53)	1.5-4.5	60	82	Distal PA embolization (15%) Hemolysis (1.8%) Decrease dorsalis pedis pulse (1.8%)	

Table 4. Results and complications of coil embolization for patent ductus arteriosus in different reports<sup>(2-4)</sup>

The authors' occlusion rate for PDA coiling was 62% immediately after implantation and 82% at 6 months follow up. Eight patients in the present series became complicated with distal PA embolization. Interestingly, the PDA diameter was much more than 3.5 mm in all of them. In the authors' experience, the suitable size for coil embolization should not exceed 3 mm, otherwise a multiple-coils embolization approach should be considered to reduce the risk of embolization and to increase the obliteration rate.

In ADO implantation procedures (Table 5), the authors experienced excellent results similar to other reports<sup>(5,6)</sup>. All patients demonstrated complete occlusion within 24 hours after the procedure. However, one with systemic PA pressure developed vascular complications after prolonged femoral arterial and venous sheaths insertion. Theoretically, ADO is suitable for a large ductus arteriosus and is usually safe to deploy in patients with pulmonary hypertension in a variety of ages. A large (6-8 Fr) long sheath is essential for device implantation, and the authors still have no experience in treating small infants with this device.

In balloon valvuloplasty (Table 6), most of the presented cases were pulmonary valve stenosis. The median pressure gradient difference in the present series was slightly lower than in other reports<sup>(7-9)</sup>. This probably resulted from a smaller initial pressure gradient across the valve than in the others. The authors experienced intractable cyanosis and shock in one infant with critical pulmonary stenosis. This may have resulted from severe acute pulmonary regurgitation causing a reverse flow condition. In conclusion, pediatric cardiac interventions in Songklanagarind Hospital have had satisfying results with an acceptable complication rate.

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Table 5. Results and complications of Amplatzer duct occluder implantation in different reports<sup>(5,6)</sup>

Study (n)	Size (mm) (min-max)	% Complete occlusion		Complication(s) (%)
		Immediate	24 hrs	
Bilkis AA, 2001(209)	1.8-12.5	44	66 (97% in 1 mo)	Device embolization (2%)
Thanopoulos BD, 2001 (69)	4.0-12	92	100	no
Promphan W, 2003 (14)	2.7-6.7	64	100	Decrease dorsalis pedis pulse (7%)

Table 6. Results and complications of percutaneous balloon valvuloplasty for valvular pulmonic stenosis in different reports<sup>(7-9)</sup>

Study (n)	Pressure gradient $(mmHg) (mean \pm SD)$		Gradient difference	Complication(s)
	Pre	Post	(mmHg)	
Echigo, 2001(172)	61 ± 27	$28 \pm 20$	33	none
Stanger, 1990 (784)	71 ± 33	$28\pm21$	43	Dead 0.2%, Tamponade 0.1% Perforation 0.1%, TR 0.2%
Khowsathit, 1997 (19)	92 ± 47	$34 \pm 25$	58	none
Promphan, 2003 (16)	63 ± 33	33 ± 33	30	Hemiparesis 1 (6%), Dead 1 (6%)

# ประสบการณ์การรักษาโรคหัวใจพิการแต่กำเนิดด้วยการใช้สายสวนหัวใจชนิดพิเศษของโรงพยาบาล สงขลานครินทร์

# วรการ พรหมพันธุ์, สมเกียรติ โสภณธรรมรักษ์, สมฤทธิ์ จันทรประทิน

**ความเป็นมา**: ปัจจุบันนี้การใช้สายสวนหัวใจชนิดพิเศษเพื่อรักษา (cardiac intervention) โรคหัวใจพิการแต่กำเนิด เป็นทางเลือกที่มีประสิทธิภาพทัดเทียมกับการผ่าตัด โรงพยาบาลสงขลานครินทร์เป็นศูนย์โรคหัวใจในสังกัด มหาวิทยาลัยแห่งล่าสุดที่เปิดให้บริการรักษาด้วยวิธีนี้

**วัตถุประสงค**์: เพื่อนำเสนอผลการรักษาตลอดจนผลข้างเคียงที่เกิดขึ้นจากการรักษาด้วยวิธีสวนหัวใจ **วัสดุและวิธีการ**: นำเวซระเบียนผู้ป่วยโรคหัวใจพิการแต่กำเนิดที่เข้ารับการรักษาตั้งแต่เดือนพฤษภาคม 2543 ถึง ธันวาคม 2546 มาศึกษารวบรวม และวิเคราะห์ผลการรักษา และอาการข้างเคียง

**ผลการศึกษา**: รายงานนี้มีผู้ป่วยจำนวน 102 ราย โดยเป็นผู้ป่วยเส้นเลือดหัวใจเกิน (patent ductus arteriosus, PDA) 67 ราย เป็นลิ้นพัลโมนารีตีบ (valvular pulmonary stenosis, VPS) 16 ราย เป็นผู้ป่วยโรคหัวใจพิการแต่กำเนิดที่ จำเป็นต้องมีผนังกั้นเอเตรียมเปิดกว้าง (adequate atrial communication) 10 ราย เป็นผู้ป่วยที่มีเส้นเลือดผิดปกติ ที่เชื่อมต่อระหว่างเอออร์ตากับเส้นเลือดพัลโมนารี (aorto-pulmonary collaterals, APC) 8 ราย และเป็นผู้ป่วย ลิ้นเอออร์ติกตีบ (valvular aortic atenosis, VAS) 1 ราย มีผู้ป่วยได้รับการอุดเส้นเลือดเกินหรือผิดปกติด้วยขดลวด (coil embolization) เป็นจำนวนทั้งสิ้น 61 ราย ในจำนวนนี้มีผู้ป่วย PDA 53 ราย ซึ่งเมื่อติดตามผู้ป่วยหลังการรักษา 24 ชั่วโมง พบว่าสามารถปิดกั้นการใหลของเลือด (complete occlusion) ในผู้ป่วย PDA ได้ร้อยละ 60.4 และผู้ป่วย APC ได้ร้อยละ 100 มีผู้ป่วย PDA จำนวน 14 ราย ได้รับการรักษาด้วยการใช้ Amplatzer duct occluder (ADO) ซึ่งพบว่าเมื่อติดตามผู้ป่วยไป 24 ชั่วโมงหลังการรักษา ผู้ป่วยทุกรายมี complete occlusion สำหรับผู้ป่วย VPS และ VAS ที่ได้รับการขยายลิ้นหัวใจด้วยบอลลูน (percutaneous balloon valvuloplasty, PBV) นั้น พบว่าความแตกต่าง ของความดัน (peak to peak systolic pressure gradient)ก่อนการรักษาลดลงจาก 62.8 ± 33.3 มิลลิเมตรปรอท เป็น 33.33 ± 33.33 มิลลิเมตรปรอท และจาก 76 มิลลิเมตรปรอท เป็น 49 มิลลิเมตรปรอท ตามลำดับ ผลการรักษา ด้วยวิธีถ่างขยายผนังกั้นเอเตรียมเพิ่มขึ้นจาก 3.0 ± 0.7 มิลลิเมตร เป็น 5.9 ± 0.4 มิลลิเมตร

ผลแทรกซ้อนจากการอุดเส้นเลือดเกินหรือผิดปกติด้วยขดลวด มีดังนี้ ผู้ป่วยร้อยละ 15 เกิดขดลวดหลุดไปสู่ เส้นเลือดแดงพัลโมนารีส่วนปลาย (distal embolization), ผู้ป่วยร้อยละ 2 เกิดภาวะเม็ดเลือดแดงแตก (hemolysis), และร้อยละ 2 มีชีพจรบริเวณปลายเท้าเบาลงกว่าปกติ ผู้ป่วยร้อยละ 7 ที่ได้รับการใส่ Amplatzer duct occluder ก็มีชีพจรบริเวณปลายเท้าเบาลงกว่าปกติเช่นกัน ผลแทรกซ้อนจากการขยายลิ้นพัลโมนารีตีบ มีดังนี้ ผู้ป่วยเสียชีวิต 1 ราย จากภาวะหัวใจลมเหลวรุนแรง (intractable heart failure) และผู้ป่วย 1 ราย มีอาการแขนขาด้านซ้ายอ่อนแรง (hemiparesis)

้**สรุป**: ผลการรักษาโรคหัวใจพิการแต่กำเนิดด้วยการสวนหัวใจของโรงพยาบาลสงขลานครินทร์เป็นที่น่าพอใจ โดยมีผลแทรกซ้อนอยู่ในเกณฑ์ที่ยอมรับได้