Percutaneous Balloon Aortic Valvuloplasty at the Queen Sirikit National Institute of Child Health: 25 Years' Experience

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Background: *Percutaneous balloon aortic valvuloplasty (BAV) is the treatment of choice in moderate and severe valvular aortic stenosis. In Thailand, the first procedure was performed at the Queen Sirikit National Institute of Child Health (QSNICH) in 1988. No previous studies have been reported regarding the outcome of these procedures at QSNICH.*
Objective: *To study the efficacy and complications of percutaneous balloon aortic valvuloplasty in the treatment of severe aortic stenosis.*
Material and Method: *A retrospective study from the medical records was performed. All patients with a diagnosis of moderate or severe valvular aortic stenosis treated with BAV from January 1988-December 2012 were recruited. Before 2008, the procedures were performed under local anesthesia with light systemic sedation. After that, most of the cases were performed under general anesthesia. The response to treatment was classified as good response, partial response or failure. The short-term complications were classified as vascular complications, arrhythmias and others.*
Results: *Sixty-eight recorded attempts on 60 patients (47 males = 71.67%) were enlisted in the study. The ages at the time of procedures ranged from 1 day to 15 years (mean 65.25, SD 53.54, median 51 months). Fourteen cases were under one year of age (20.58%). Immediate success comprised 85.29% with 65.51% classified as good response. Ten failures in nine cases all occurred before 1997. One of the cases was an attempted balloon aortic valvuloplasty with repeated failure. Three of the cases underwent open aortic valvuloplasty where one case (33.33%) survived. The other six cases refused to continue treatment and were lost to follow-up. Four deaths were reported. Repeated balloon aortic valvuloplasties were performed in eight cases. During the early phases (1988-1996), failures and mortality rates were extremely high. Experience and improved technology improved outcomes. Excluding the four dead cases, the only significant major complication occurred in a three-year-old boy with severe aortic stenosis who tore the chordae tendinae, producing severe, acute mitral regurgitation, together with ventricular tachycardia, requiring direct current cardioversion during the procedure and double valvuloplasty five years later. Other minor complications included transient cardiac arrhythmia in 12 cases, partial occlusion of femoral artery in 11 cases and groin hematoma in 8 cases.*
Conclusion: *Percutaneous balloon aortic valvuloplasty was effective and safe for the treatment of moderate and severe aortic valve stenosis in pediatric patients without significant complications.*

Keywords: *Balloon valvuloplasty, Aortic stenosis*

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Percutaneous balloon aortic valvuloplasty (BAV) is the treatment of choice in moderate and severe valvular aortic stenosis[1,2]. In Thailand, the procedure was first performed at the Queen Sirikit National Institute of Child Health (QSNICH) in 1988. The procedure is not without risks. Residual aortic stenosis (AS), recurrent AS and iatrogenic aortic regurgitation (AR) are common postprocedural problems. Many cases had significant femoral artery tear and many cases needed repeated valvuloplasty[3,4]. Until now, no study has been conducted regarding the outcome of these

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procedures at QSNICH.

Objective

To study the efficacy and complications of percutaneous balloon aortic valvuloplasty in the treatment of severe aortic stenosis.

Material and Method

The authors performed a retrospective study from the medical records of patients who with a diagnosis of moderate or severe valvular aortic stenosis treated with BAV from January 1988 to December 2012. All of the diagnoses were performed by pediatric cardiologists of the Pediatric Cardiology Unit, QSNICH. In patients with good ventricular systolic function, the classification of mild, moderate and severe stenosis is described below[5].

Mild: peak instantaneous systolic gradient <40 mmHg, mean pressure gradient <25 mmHg.

Moderate: peak instantaneous systolic gradient 40-70 mmHg, mean pressure gradient 25-40 mmHg.

Severe: peak instantaneous systolic gradient >70 mmHg, mean pressure gradient >40 mmHg.

The data collected included.

1. Epidemiologic data.

2. Hemodynamic data during the procedure.

3. Echocardiographic data after the procedure.

4. Clinical findings after the procedure.

Before 2008, the authors performed balloon aortic valvuloplasty under local anesthesia with light systemic sedation. From the year 2008, the authors introduced general anesthesia for most of the cases.

The details of the procedure are described below.

1. The procedure was started with right and left heart catheterization at the right femoral vein and artery.

2. Heparin (50-100 IU/kg) was administered at the femoral artery after femoral artery access.

3. Complete hemodynamic evaluation including left ventricular and ascending aorta pressures was performed.

4. An end-hole-catheter, e.g., pig-tailed or Gensini, was retrogradedly inserted from the femoral artery to the left ventricle.

5. Left ventricular angiogram was performed to confirm the diagnosis of valvular aortic stenosis. Aortic valve annulus was measured in antero-posterior and lateral views.

6. The exchange guide wire was inserted to the left ventricle and used to guide the balloon catheter.

7. The sizes of the balloon catheter were judged by the operator in each case with not more than 100% of aortic valve annulus.

8. After placing the catheter at the aortic valve, the balloon was inflated repeatedly until there was no waist.

9. Hemodynamic status including left ventricular and ascending aorta pressures was re-evaluated after the procedure. If the gradient across the valve was not satisfied and the patient was stable, the operator would repeat the procedure with a larger balloon catheter (but not larger than 120% of aortic valve annulus).

10. Postprocedural hemostasis was achieved and the dorsalis pedis pulses were assessed for possible occlusion. In cases of partial occlusion, continuous heparin infusion was administered and the patient was frequently re-evaluated. Progression of the occlusion or severe occlusion was an indication for open revascularization.

11. Complete medical evaluation together with echocardiogram was repeated on the day after the procedure and every six months thereafter.

The response to treatment was differentiated

Table 1. Clinical outcome of 68 attempts to perform balloon aortic valvuloplasty in 60 patients

	n (%) (n = 68)	Note
Clinical outcome		
Good	58 (85.3)	
Failure	10 (14.7)	
Complications		
Vascular	22 (32.4)	One of these had major bleeding at the puncture site
Arrhythmia	12 (17.6)	
Others	1 (1.5)	Infective endocarditis 8 years later
Death	4 (5.9)	

in three classifications.

1. Good response was defined by reduced peak to peak pressure gradient across the aortic valve to less than 50 mmHg in the cardiac catheterization laboratory and instantaneous pressure gradient across the aortic valve in the echocardiogram.

2. Partial response was defined by reduced peak to peak pressure gradient across the aortic valve but with a gradient of 50 mmHg or more in the cardiac catheterization laboratory and instantaneous pressure gradient across the aortic valve in the echocardiogram

3. Failure was defined as

3.1 Death during the procedure,

3.2 The procedure could not be performed or

3.3 No reduced peak to peak pressure gradient across the aortic valve in the cardiac catheterization laboratory and instantaneous pressure gradient across the aortic valve in the echocardiogram.

The short-term complications were classified as vascular complications, arrhythmias and others.

Results

Sixty-eight recorded attempts on 60 patients (47 males = 71.7%) were enlisted in the study. The ages at the time of procedures ranged from 1 day to 15 years (mean 65.3, SD 53.5, median 51 months). Fourteen cases were under one year of age (20.6%). The procedures performed each year are shown in Fig. 1.

Immediate success comprised 85.3% with 65.5% classified as good response. Ten failures in nine cases all occurred before 1997. One of the cases was an attempted balloon aortic valvuloplasty with repeated failure. Three of the cases underwent open aortic valvuloplasty where one case (33.3%) survived the operation. The other six cases refused to continue treatment and were lost to follow-up.

Four deaths were reported. The first two deaths were 19 and 20 months of age, moribund at the time of presentation in the year 1991. The operators could not pass the catheter through the extremely severe stenotic valves and patients were transferred to the operating room. Both died intra-operatively. A five-year-old boy died in 2006 after five months of successful balloon aortic valvuloplasties but his left ventricular systolic function did not improve. The last death was a newborn with hypoplastic left heart syndrome, who had successful balloon aortic valvuloplasty but could not survive due to neonatal sepsis.

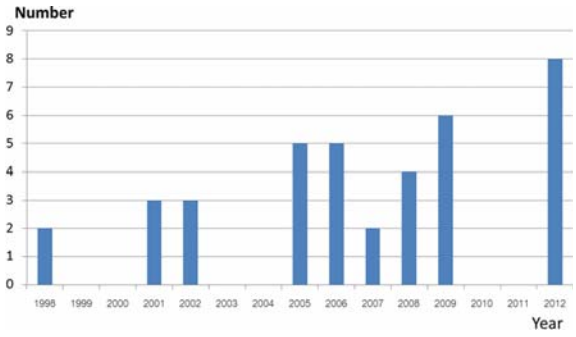

Fig. 1 Cases undergoing balloon aortic valvuloplasty from 1998 to 2012.

Balloon aortic valvuloplasties were repeated in eight cases. One of the cases failed during the first procedure because the operator could not pass the balloon through an extremely severe stenotic valve and in the second setting the result was similar. The patient underwent open aortic valvulotomy with good result. The other seven cases of repeated balloon aortic valvuloplasty had only partial responses from the first procedure and were electively set for the second valvuloplasty. All cases had successful valvuloplasty: five using balloon catheters of larger sizes and two using double-balloon technique.

Excluding the four deaths, the only significant major complication occurred in a three-year-old boy with severe aortic stenosis. During the inflation of the balloon catheter, the curve-guide wire tore the chordae tendinae producing severe, acute mitral regurgitation, together with ventricular tachycardia requiring direct current cardioversion. The patient needed mitral and aortic valvuloplasty five years later. One case had increasing aortic regurgitation following the procedure without need for intervention. One case had pericardial effusion following the procedure that resolved spontaneously without need for intervention. Other minor complications included transient cardiac arrhythmia in 12 cases, partial occlusion of the femoral artery in 11 cases and groin hematoma in 8 cases. One case in the year 1991 was successfully treated with balloon aortic valvuloplasty when the patient was one year old but eight years later presented infective endocarditis at the aortic valve requiring aortic valve replacement.

Discussion

The QSNICH is the only Thai government hospital responsible for research, training and tertiary care for children of all ages including neonates. Annually, 1,200-1,400 new cardiac cases account for one third to one fourth of all pediatric cardiac patients in Thailand. Balloon aortic valvuloplasty was performed

for the first time at this institute 25 years ago.

During the early phases (1988-1996), failure and mortality rates were extremely high. Experience and improved technology improved outcomes. The profile of balloon catheter is much smaller nowadays compared with those in the early phases. With improved technology, confidence and experience, we could perform the procedure in patients under three months of age successfully in 2005 and under one month of age in 2012. Introduction of the double-balloon technique in 2004 increased the likelihood of success and lessened vascular complications[6].

Overall success rate and complications were consistent with reports from other developed countries[7-9]. A single case of increasing aortic regurgitation forced the operator not to use too large a size of the balloon catheter. In the present study, the authors used a balloon size no larger than 120% of the aortic valve annulus. Before using the balloon size larger than 100% of the aortic valve annulus, the operator should be sure that the failure to decrease the pressure gradient exactly results from a size that is too small. Another single case of chordae tendinae injury warranted the operator to keep an eye on this rare complication.

Conclusion

Percutaneous balloon aortic valvuloplasty was effective and safe for the treatment of moderate and severe aortic valve stenosis in pediatric patients without significant complications.

Potential conflicts of interest

None.

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การรักษาลิ้นหลอดเลือดแดงใหญ่ตีบด้วยสายสวนหัวใจชนิดที่มีลูกโป่งในสถาบันสุขภาพเด็กแห่งชาติมหาราชินี: ประสบการณ์ 25 ปี

ชัยสิทธิ์ แสงทวีสิน, ธนะรัตน์ ลยางกูร, ธวัชชัย กิระวิทยา, วรการ พรหมพันธุ์, วัชระ จามจุรีรักษ์, ภารดา ทองทิพย์

ภูมิหลัง: การรักษาด้วยสายสวนหัวใจชนิดที่มีลูกโป่งเป็นทางเลือกที่ดีที่สุดในการรักษาลิ้นหลอดเลือดแดงใหญ่ตีบรุนแรงในประเทศไทย การรักษาชนิดนี้เริ่มเป็นครั้งแรกที่สถาบันสุขภาพเด็กแห่งชาติมหาราชินีเมื่อ พ.ศ. 2531 แต่ยังไม่มีการรวบรวมผลการรักษา

วัตถุประสงค์: เพื่อศึกษาผลการรักษาลิ้นหลอดเลือดแดงใหญ่ตีบด้วยสายสวนหัวใจชนิดที่มีลูกโป่งในสถาบันสุขภาพเด็กแห่งชาติมหาราชินี

วัสดุและวิธีการ: ศึกษาย้อนหลังจากเวชระเบียนผู้ป่วยลิ้นหลอดเลือดแดงใหญ่ตีบรุนแรงทุกรายที่รักษาด้วยการใช้สายสวนหัวใจชนิดที่มีลูกโป่งในสถาบันสุขภาพเด็กแห่งชาติมหาราชินี ตั้งแต่เดือนมกราคม พ.ศ. 2531 ถึง เดือนธันวาคม พ.ศ. 2555 ในระยะก่อน พ.ศ. 2551 การใช้สายสวนหัวใจทำโดยใช้ยาชาเฉพาะที่ร่วมกับให้ยานอนหลับ หลังจากนั้นจะทำโดยการดมยาเกือบทุกราย ผลการรักษาแบ่งเป็น 3 แบบ คือ ได้ผลดี ได้ผล และไม่ได้ผล ภาวะแทรกซ้อนแบ่งเป็นภาวะแทรกซ้อนที่เกี่ยวกับหลอดเลือด ภาวะหัวใจเต้นผิดปกติ และภาวะแทรกซ้อนอื่นๆ

ผลการศึกษา: ผู้ป่วยทั้งหมดที่เข้าในการศึกษามีทั้งสิ้น 60 ราย เป็นเพศชาย 47 ราย (ร้อยละ 71.67) สวนหัวใจทั้งสิ้น 68 ครั้ง อายุในขณะที่สวนหัวใจอยู่ระหว่าง 1 วัน จนถึง 15 ปี (เฉลี่ย 65.25 เดือน ส่วนเบี่ยงเบนมาตรฐาน 53.54 เดือน มัธยฐาน 51 เดือน) ผู้ป่วย 14 รายอายุต่ำกว่า 1 ปี (ร้อยละ 20.58) การรักษาได้ผลร้อยละ 85.29 โดยในจำนวนนี้จัดว่าได้ผลดีร้อยละ 65.51 การรักษาที่ไม่ได้ผลทั้งหมดเกิดก่อน พ.ศ. 2540 มีทั้งหมด 10 ครั้งในผู้ป่วย 9 ราย เป็นการรักษาที่ไม่ได้ผล 2 ครั้งในผู้ป่วย 1 ราย รายที่รักษาไม่ได้ผลนี้ 3 รายส่งรักษาต่อด้วยการผ่าตัดและรอดชีวิตรายเดียว ผู้ป่วยเสียชีวิต 4 ราย การติดตามต่อมาหลังการรักษาพบว่าต้องรักษาซ้ำ 8 ราย นอกจากรายที่เสียชีวิตแล้ว มีภาวะแทรกซ้อนรุนแรงเพียงรายเดียวในเด็กอายุ 3 ปีที่มีการฉีกขาดของ chordae tendinae และลิ้นหลอดเลือดแดงใหญ่เกิดลิ้นหัวใจรั่วและหัวใจเต้นผิดจังหวะรุนแรง ระหว่างทำต้องกระตุ้นหัวใจด้วยไฟฟ้าและต่อมาต้องผ่าตัดเปลี่ยนลิ้นหัวใจ 2 ลิ้น ภาวะแทรกซ้อนไม่รุนแรงประกอบด้วยหัวใจเต้นผิดจังหวะไม่รุนแรงระหว่างทำ 12 ราย หลอดเลือดแดงใหญ่ที่ขาหนีบตีบ 11 ราย และเกิดก้อนเลือดที่ขาหนีบ 8 ราย

สรุป: การรักษาลิ้นหลอดเลือดแดงใหญ่ตีบรุนแรงด้วยการใช้สายสวนหัวใจชนิดที่มีลูกโป่งได้ผลดี ภาวะแทรกซ้อนพบได้น้อย