Effectiveness and Safety of Percutaneous Transcatheter Implantation of Pulmonary Arterial Stent in Congenital Heart Disease

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Background and Objectives: Pulmonary arterial stenosis is a relatively common complication after corrective operation of congenital heart disease. Unilateral stenosis of pulmonary arteries could result in decrease perfusion of affected lung, pulmonary regurgitation, or elevation of right ventricular pressure. Eventually there are increasing risks of right ventricular failure, arrhythmia, or sudden death. However we have limited data of pulmonary arterial stent in paediatric population as the treatment of branch pulmonary stenosis. This study aimed at validating the effectiveness and investigating complications of pulmonary arterial stent implantation in a single institution during mid-term follow up period.

Subjects and Methods: A total of 42 patients (50 stents) were implanted for treating branch pulmonary arterial stenosis. We used cardiac catheterization for comparing diameter after stent implantation directly and lung perfusion scan indirectly. We also investigated any adverse effect relating the procedure.

Results: Percent stenosis of stenotic lesions were decreased from 54.1±10.7% to 22.8±12.5% (p<0.001) and degree of decrement in affected lung perfusion was declined from 22.7±8.0% to 10.3±9.0% (p<0.001) immediately and lasts during mid-term follow up period. Complication rate relating the procedure was 12% (6 out of 12) and there was no mortality case.

Conclusion: This series showed immediate and short term effectiveness of pulmonary arterial stent in congenital heart defects. We concluded that percutaneous transcatheter implantation of pulmonary arterial stent was safe and effective during short and mid-term follow up period. (Korean Circ J 2012;42:40-45)

KEY WORDS: Congenital heart disease; Catheterization.
ies had demonstrated a high success rate after 20 years of experience, there has not been any multicenter-randomized controlled study. This study aimed at validating the effectiveness and investigating complications of pulmonary arterial stent implantation in a single institution during midterm follow up period.

**Subjects and Methods**

Between January 1999 and May 2010, patients with unilateral or bilateral pulmonary arterial stenosis after corrective surgery for their congenital heart defects were enrolled in the Department of Pediatric Cardiology at Asan Medical Center. Only patients who were implanted with pulmonary arterial stents were included. A total of 42 patients (50 stents) were implanted. The ratio of boys to girl was 0.92. At the time of implantation the patient median age was 12 years (range 0.5-31 years), and their median weight was 22 kg (range 4.8-80.4 kg). Site of lesions were right pulmonary arteries (n=6), left pulmonary arteries (n=28), and bilateral pulmonary arteries (n=8).

Patient medical records were retrospectively reviewed for demographic data such as age, weight, and height at intervention. For assessing the effectiveness data of catheterization, lung perfusion scan, or heart computed tomography (CT) scan and echocardiography were also collected before and after the intervention. Institutional review board of Asan Medical Centre approved this study and patient consent was waived.

**Catheterization**

Pressure data and diameter of stenotic lesions were obtained before and after the implantation. Additionally, the percent stenosis (i.e., ratio of diameter at stenotic lesion to that of normal pulmonary artery at the level of helium) was calculated to compare the results. Indications of pulmonary arterial stent implantation were when lung perfusion ratio of the normal side to affected side was over 2.5 and when the right ventricular systolic pressure was over 50% of systemic systolic blood pressure.

**Percutaneous transcatheter implantation of pulmonary arterial stent**

Measurement of the diameter of the stenotic lesion and ipsilateral pulmonary artery at the first-branching site helped choose the size and length of stent from angiography of pulmonary arteries with biplane fluoroscopy. Pre-mounted or hand-mounted stent was placed accurately at the stenotic lesion and dilated by inflating the balloon. In case of a hand-mounted stent, we made a so-called shoulder of balloon to prevent slippage of the stent during catheter manipulation.

Sometimes balloon angioplasty was tried first and the proximal part of the stent was widened after implantation, making it easier to pass through the stent subsequently. Bilateral stenosis was treated simultaneously by a double wire technique to minimize displacement of the stent from the optimal site (Figs. 1 and 2). We used various type of stents, including Jostent® peripheral (Abbott, Abbott Park, IL, USA), Palmaz® stent; P**4/8/10B/14 series, XD (Johnson & Johnson-Cordis, Bridgewater, NJ, USA), Express® Vascular LD (Boston Scientific, Natick, MA, USA), and Wallflex® vascular stent (Boston Scientific).

**Lung perfusion scan**

The geometric result of lung perfusion scan before and after implantation was investigated and then the decrement of perfusion was calculated by subtracting percent of affected side from that of normal value (left : right, 45% : 55%), which was calculated only in unilateral pulmonary arterial stenosis.

**Echocardiography and heart CT scan**

The non-invasive methods of echocardiography and heart CT scan were used to supplementing the results of angiography.

**Statistical analyses**

Data was analyzed using Statistical Package for the Social Sciences (SPSS) for Windows, version 12 (SPSS Inc., Chicago, IL, USA). Descriptive data for continuous variables are presented as mean±SD. Student’s t-test was used for comparing the results before and after implantation. Pearson correlation coefficient was used to estimate correlation between percent stenosis and perfusion decrease. P<0.05 was considered statistically significant.

**Results**

Demographic data of patients are shown in Table 1. Mean diameter of the narrowest point on pulmonary arterial stenosis was 6.6 mm and mean percent stenosis was 54%. Patients with tetralogy of Fallot with or without pulmonary atresia were most common, and consisted of part truncus arteriosus and pulmonary atresia with intact ventricular septum in order.

**Validation of effectiveness**

The diameter of stenotic lesion after stent implantation increased significantly from mean 6.6 mm to mean 12.4 mm and the decrement of perfusion changed significantly from 22.7±8.0% to 10.3±9.0% (p<0.001) (Table 2). Changes of each patient in diameter and percent stenosis are presented in Fig. 3; an increase in diameter from 6.6±2.1 mm to 12.4±3.6 mm, and drop in percent stenosis from 9.0% to 10.3±8.0% (p<0.001) (Table 2).

[Table 1: Demographic data of patients]

| Parameter        | Mean ± SD | Median   |
|------------------|-----------|----------|
| Age (years)      | 12 ± 3    | 9         |
| Weight (kg)      | 22 ± 10   | 22        |
| Right Ventricular Systolic Pressure (mmHg) | 50 ± 10 | 50 |

[Table 2: Changes of diameter and percent stenosis]

| Parameter        | Mean ± SD | Median   |
|------------------|-----------|----------|
| Diameter (mm)    | 6.6 ± 2.1 | 6.0      |
| Percent Stenosis | 9.0% ± 8.0% | 10.0%    |

**Discussion**

This study demonstrated that the technical results of pulmonary arterial stenting were successful. However, complications were encountered, and we found that the most important risk factor for complications was the geometric result of lung perfusion scan before and after implantation.
54.1±10.7% to 22.8±12.5% (p<0.001) were evident. Eight patients (10 stents) had angiography for suspected re-stenosis on follow-up study. Period after first intervention was median 4.5 years, age was median 15 year-old and weight was median 38.2 kilograms. Among the eight patients, only two patients demonstrated re-stenosis to be re-dilated by balloon; the final diameter of these patients was mean 12.8 mm. Change in percent stenosis was 22.7±12.4% after the first intervention to 26.8±14.5% at the second angiography, indicative of little growth of distal pulmonary arteries after stent implantation.

**Assessment of safety**

Overall complication rate related to the procedure was 12%. There was no mortality, but there were three cases of serious complications. The first was the perforation of a pulmonary artery to be repaired by stent graft in the implanted stent (Fig. 4A). The second was a hemothorax during the access to the neck vein for the indwelling chest tube. The third was a stent migration to the right ventricle destined for surgical removal and repair due to development of ventricular tachycardia. Other complications included two cases of stent displacement re-positioned by transcatheter manipulation. One was repositioned by snaring the migrating stent and the other case positioned the first-implanted stent at the contralateral pulmonary artery because of failure to reposition and to implant another stent at the original stenotic lesion. One stent fracture was found during follow-up, requiring the implantation of another stent in the fractured stent (Fig. 4B). Additionally, balloon rupture occurred in two cases during inflation.

**Discussion**

This study showed that short-term result of pulmonary arterial stent implantation was effective in increasing the diameter and flow of treated pulmonary arteries. Although the long-term result

**Table 1. Patient characteristics**

| Age at first intervention (years, range) | 6.5 | 0.5-31 |
| Weight at first intervention (kg, range) | 21.8 | 4.8-80.4 |
| Male (n, %) | 23 | 54.8 |
| PA stenosis (n, %) | | |
| Left PA | 28 | 67 |
| Right PA | 6 | 14 |
| Both PAs | 8 | 19 |
| Diagnosis (n, %) | | |
| TOF without pulmonary atresia | 19 | 45.2 |
| TOF with pulmonary atresia | 9 | 21.4 |
| Truncus arteriosus | 3 | 7.1 |
| PAIVS | 2 | 4.7 |
| Others | 9 | 21.4 |

PA: pulmonary arteries, TOF: tetralogy of Fallot, PAIVS: pulmonary atresia with intact ventricular septum

**Table 2. Effect of stent implantation**

| | Pre-stent | Post-stent | p |
|---|---|---|---|
| Minimal PA diameter (mm) | 6.6±2.1 | 12.4±3.6 | <0.001 |
| Percent stenosis (%) | 54.1±10.7 | 22.8±12.5 | <0.001 |
| Percent of decreased lung perfusion scan results (%) | 22.7±8.0 | 10.3±9.0 | <0.001 |

PA: pulmonary arteries

**Fig. 1.** Double wire technique in stenosis of both pulmonary arteries. This still frame image shows that two wires were located at both sides of pulmonary arteries for simultaneous ballooning of the stents. A: sit-up view. B: lateral view.
still needs to be clarified, follow-up catheterization showed that rate of re-stenosis and percent stenosis remained relatively low after intervention. However, dilatation over 14 mm, the normal typical pulmonary artery size of an adult, is potentially harmful to the vessel when using over a 12 Fr sheath for delivering a bulky stent such as the Palmaz® genesis stent (Johnson & Johnson-Cordis, Bridgewater, NJ, USA). Presently, there was no instance of mortality and the rate of com-

Fig. 2. Extra-balloon widening of proximal stent for easy-approach. This image showed ballooning (A) of proximal part of stent after implantation first, which made it easier and safer to access distal pulmonary artery next time. Wide opened stent is shown (B).

Fig. 3. Changes in diameter of pulmonary arterial stenosis and in percent stenosis. This represents increase of diameter in stenotic lesion and decrease of percent stenosis after stent implantation significantly among almost patients.

Fig. 4. Complications of implantation of pulmonary artery stent. A: after implanting stent vascular leakage was noted (left) then it was repaired by Jostent® Graft Master. After graft implantation within stent, no leakage was found on angiography (right). B: this showed that stent fracture at proximal part of stent was found during follow-up catheterization for evaluating re-stenosis of left pulmonary artery.
plications association with implantation was 12%, similar to the long-term reports of other studies.\textsuperscript{9,13,14,16-17} One study reported their long-term result of pulmonary stent experiencing 9.1% of complication rate (six out of 55 stents) including one death related to procedure. The complication rate has decreased with the refinement/development of equipments and skills.\textsuperscript{9,13,14,16-17}

After more than 20 years of pediatric stent implantation, this use of stents has not received Food and Drug Administration approval, which has necessitated the use of peripheral stents intended for adult patients (Jostent\textsuperscript{®}, Genesis\textsuperscript{®}, Wallflex\textsuperscript{®}, and Express\textsuperscript{®} stents). Additionally, Mega\textsuperscript{®} LD or Maxi\textsuperscript{®} LD stents, which prevent jailing vessel, Double stent\textsuperscript{®} LD stent, which increases flexibility, and custom-built Cheatham-Platinum\textsuperscript{®} (C-P) stent have been used in other countries.\textsuperscript{18} The maximal diameter of a stent is usually larger than recommended in spite of variable shortening in length. For example, the maximal diameter of the Express\textsuperscript{®} stent is 12 mm and that of the Palmaz genesis\textsuperscript{®} stent is over 20 mm.

The BIB\textsuperscript{®} stent, which is not available in Korea, consists of an inner and outer balloon. This stent is useful for severe stenotic lesions of the large pulmonary artery, a location in which the usual balloon cannot resolve the stenosis, necessitating the implantation of a butterfly stent. BIB\textsuperscript{®} has a two-step inflation process in which an inner small balloon relieves severe stenotic lesion first to avoid wrinkling of the stent, which could be a fixed stenosis.\textsuperscript{19}

Since we were unable to reach consensus on indication of stent implantation among centers, there are two considerations for the procedure: policy for jailed vessel and treatment time for patient age and physical condition. Treatment timing is changing to reflect device improvements and jailing vessel from stent implantation is contraindicated in our institution. Furthermore, accessibility and diversity of suitable stents is limited in many centers.\textsuperscript{19}

Methods for detecting re-stenosis after stent implantation should be effective and safe. This study used a non-invasive method, lung perfusion scan, which showed a relationship between perfusion decrease and percent stenosis. However, patients having follow-up catheterization had decreased perfusion ratio but percent stenosis was not appreciably increased. This could be postulated to be due to the persistent increase of pulmonary resistance or diffuse stenosis of distal pulmonary artery without growth after stent implantation. Follow-up modalities used in other studies were mostly catheterization, and cardiac MRI. Lung perfusion scan lacks the ability to detect patency of a jailed vessel. However, we did not perform an implant when an adjacent vessel could be jailed if the stent was implanted.

This series showed immediate and short-term effectiveness of pulmonary arterial stent in congenital heart defects, which had a comparable result to surgical correction. However, we were limited in validating the result of lung perfusion scan compared to data from catheterization because we performed only a limited number of cardiac catheterizations.

We conclude that transcatheter percutaneous implantation of pulmonary artery stent is safe and effective during short- and mid-term follow-up.

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