# Cheatham-Platinum stent implantation for pulmonary artery stenosis in children and adolescents: immediate and mid-term outcome

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***Background:*** **NuMED Cheatham-Platinum (CP) stent implantation for pulmonary artery stenosis in children and adolescents has been rarely reported. This study aimed to evaluate the immediate and mid-term results of CP stent implantation for the treatment of pulmonary artery stenosis associated with congenital heart disease (CHD) in children and adolescents.**

***Methods:*** **From August 2005 to May 2007, four consecutive pediatric patients with pulmonary artery stenosis associated with CHD underwent CP stent implantation. They were followed up, and transthoracic echocardiography was done for outcome evaluation.**

***Results:*** **In the four patients, 5 stent placement procedures were performed and 7 CP stents were implanted (8-zig, 22-39 mm in length). All stents except one were successfully placed in the target lesions without displacement during the procedures. After the procedure, the systolic pressure gradient across the stenosis decreased from 36.67±20.08 to 3.67±3.20 mmHg (*P*=0.005), and the narrowest diameter of the stenotic segment increased from 6.97±2.22 to 13.40±4.40 mm (*P*=0.013). Two stents implanted in the left and right pulmonary arteries in patient 4 developed intrastent restenosis 6 months after the procedure, and the distal end of the main pulmonary artery also developed restenosis 26 months later. The results of the remaining stents have been stable without complications during a median follow-up of 34 months (range, 26-48 months).**

***Conclusions:*** **Our experience indicates that CP stent implantation is suitable for the treatment of pulmonary artery stenosis in children and adolescents with CHD. The immediate and mid-term results are encouraging, but long-term results demand further follow-up in more cases.**

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**Cheatham-Platinum stent;**
**congenital heart disease;**
**pulmonary artery stenosis;**
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## Introduction

Branch pulmonary artery stenosis accounts for 2%-3% of patients with congenital heart disease (CHD).[1,2] It causes underperfusion of the lung supplied by the stenotic vessel and pulmonary hypertension in the contralateral pulmonary artery. Unrelieved stenosis imposes pressure overload on the right ventricle and results in right ventricular hypertension, arrhythmia, dysfunction, and even sudden death.[3,4]

For many years, congenital or acquired pulmonary artery stenosis has remained one of the most challenging lesions to manage clinically. Compared with surgery and balloon angioplasty, endovascular balloon-expandable stents are the most effective modalities in the treatment of branch pulmonary artery stenosis in children and adults.[5] Over the past 10 years, NuMED Cheatham-Platinum (CP) stent, which is specifically designed to treat vascular obstructions associated with CHD, has increasingly attracted the interest of interventional cardiologists.[6-9] However, the application of this new stent in the pediatric population is relatively uncommon,

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especially in those with pulmonary artery stenosis. In addition, previous follow-up of CP stents for pulmonary artery stenosis was limited, including a 12-month (range, 1-30 months) follow-up reported by Ewert et al.[8] Furthermore, CP stent implantation for pulmonary artery stenosis has not been reported in China so far.

This article presents our initial experience in CP stent implantation for the treatment of pulmonary artery stenosis associated with CHD in 4 consecutive pediatric patients, with an emphasis on the immediate and mid-term results.



## Methods

### Patients

From August 2005 to May 2007, four consecutive patients (2 boys and 2 girls) with pulmonary artery stenosis associated with CHD were treated with CP stent implantation at our institution. Their median age and weight were 10.5 years (range, 4-15 years) and 22.5 kg (range, 20-42 kg), respectively. Before stent implantation, all patients were evaluated by transthoracic echocardiography, and the pulmonary artery flow to the affected lung was measured by magnetic resonance imaging (MRI) in two cases of unilateral branch pulmonary artery stenosis. Detailed characteristics of the patients are listed in Table 1.

### Definition

Stent implantation was indicated by at least one of the following criteria: systolic pressure gradient across the stenosis ≥20 mmHg,[8] right ventricle systolic pressure ≥50% of the aortic systolic pressure in bilateral branch pulmonary artery stenosis, and pulmonary artery flow to the ipsilateral lung ≤20% of the total lung blood flow in unilateral branch pulmonary artery stenosis.[10] Successful outcome after stent implantation was defined by at least one of the following:[4,5,11] an increase in vessel diameter by ≥50%, an increase in pulmonary blood flow to the ipsilateral lung by ≥20%, a decrease in right ventricular to aortic systolic pressure ratio by ≥20%, and a decrease in pressure gradient by ≥50%.

### Stent

In this study bare CP stents we used are made of 90% platinum and 10% iridium metal alloy, with 0.013-inch metal wire arranged in a "zig" pattern.[6,7]

### Stent implantation techniques

Informed written consent was obtained from the parents of the patients before the procedure. General anesthesia was given in all patients with the femoral vein or right internal jugular vein as the access site. Diagnostic catheterizations were performed to determine the site and length of the stenotic segment, the narrowest-, distal- and proximal-diameter of stenotic segment, and the systolic pressure gradient. CP stent (NuMED Inc., Hopkinton, NY, USA or NuMED Canada Inc., Cornwall, ON, Canada) and balloon-in-balloon (BIB) catheter (Numed Inc., Hopkinton, NY, USA) were selected according to the results of digital subtracted angiography measurement. A stiff exchange guidewire was placed across the stenotic area, then a long sheath was advanced across the lesion over the guidewire. The CP stent was crimped onto an appropriate BIB balloon and advanced to stenotic vessel through the sheath. After the correct position of the lesion was confirmed by angiography, the inner balloon and outer balloon were inflated sequentially to expand the stent to a desired diameter. Immediate results were evaluated by repeat angiography and hemodynamic measurements. Cefradine (50-100 mg/kg) was given to all patients at the beginning of the procedure and continued for 24 hours. Intravenous heparin (100 IU/kg) was administered routinely throughout the procedure, and hemostasis was achieved by manual compression. All patients were instructed to take aspirin at a dose of 3-5 mg/kg once a day for 6 months after the procedure. Pulmonary artery flow to the affected lung was remeasured by MRI in 2 cases of unilateral branch pulmonary artery stenosis.

### Follow-up protocol

Transthoracic echocardiographic evaluation was scheduled at 1, 3, 6, and 12 months after the procedure, and yearly thereafter.

**Table 1.** Patient characteristics

| Patient | Gender | Age (y) | Body weight (kg) | Diagnosis |
|---|---|---|---|---|
| 1 | Female | 15 | 42 | Bilateral branch pulmonary artery stenosis after surgery for TOF |
| 2 | Male | 4 | 20 | Right pulmonary artery stenosis after BT shunt for PA/IVS, PDA, and ASD |
| 3 | Female | 9 | 21 | Left pulmonary artery stenosis after surgery for TOF |
| 4 | Male | 12 | 24 | Pulmonary artery bifurcation stenosis, with involvement of the distal end of the main pulmonary artery and the origins of the left and right pulmonary artery after surgery for AP window |

TOF: tetralogy of Fallot; BT shunt: Blalock-Taussig shunt; PA/IVS: pulmonary atresia with intact ventricular septum; PDA: patent ductus arteriosus; ASD: atrial septal defect; AP window: aortopulmonary window.

### Statistical analysis

Systolic pressure gradient and minimal vessel diameter before and after the procedure were expressed as means ± SD. Their changes were compared using the paired, 2-tailed Student's *t* test. Statistical analysis was performed by the SPSS 11.5 software for Windows. *P* values less than 0.05 were considered statistically significant.

## Results

### Immediate results

Totally 5 stent placement procedures were performed and 7 stents were implanted in the 4 patients (Table 2). All stents used were 8-zig CP stents from 22 to 39 mm in length (Fig.). One stent was displaced during the procedure in patient 2. It was placed in the pulmonary trunk, without affecting pulmonary blood flow evidenced by selective pulmonary arteriography. This patient was recatheterized, and a second CP stent (8-zig, 34 mm) was successfully reimplanted 11 months later. Other stents were successfully placed in the target lesions without complications during the procedure. After the procedure, the systolic pressure gradient across the stenosis decreased from 36.67±20.08 to 3.67±3.20 mmHg ($t$=4.692, $P$=0.005), and the narrowest diameter of the stenotic segment increased from 6.97±2.22 to 13.40±4.40 mm ($t$=-3.742, $P$=0.013). The percentage of pulmonary artery flow to the ipsilateral lung increased from 11.0% and 13.0% to 52.2% and 47.5% after the procedure in two cases of unilateral branch pulmonary artery stenosis, respectively. The ratio of right ventricular to aortic systolic pressure decreased from 62.3% (76/122 mmHg) and 72.2% (65/90 mmHg) to 27.0% (33/122 mmHg) and 33.3% (30/90 mmHg) in two cases of bilateral branch pulmonary artery stenosis, respectively.

### Follow-up results

During a median follow-up of 34 months (range, 26-48 months), all CP stents but two were stable, with no evidence of artery dissection, aneurysm formation, restenosis, embolization, stent fracture or displacement. In patient 4, two CP stents developed intrastent restenosis 6 months after the procedure. Systolic pressure gradients across the stents implanted in the left and right pulmonary arteries were 34.0 and 34.0-41.0 mmHg determined by transthoracic echocardiography, respectively. Twenty-six months later, the distal end of





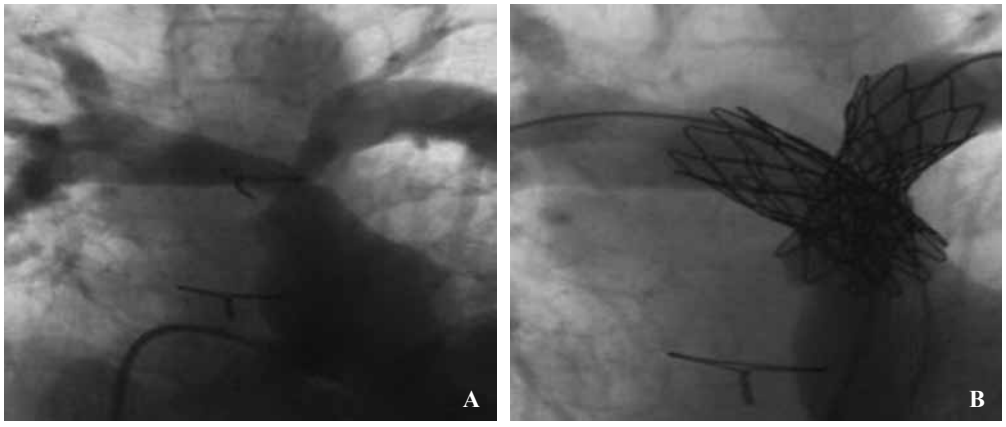


**Fig.** CP stent implantation for pulmonary artery stenosis (cranial 40º). **A:** Before implantation: pulmonary artery bifurcation stenosis with extension into the left and right branch pulmonary artery of a 12-year-old boy (patient 4); **B:** After implantation: two 39-mm length 8-zig CP stents were implanted in the proximal left and right pulmonary artery, and the stenotic segment improved significantly.

**Table 2.** Data of 4 patients treated with seven 8-zig CP stents

| Patient | Implantation site | Stenotic segment (mm) | | | Minimal diameter (mm) | | Pressure gradient (mmHg) | | CP stent length (mm) | Sheath size (F) |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Proximal diameter | Distal diameter | Length | Before SI | After SI | Before SI | After SI | | |
| 1 | Proximal LPA | 6.3 | 8.3 | 12.5 | 3.3 | 13.6 | 54 | 4 | 39 | 12 |
| | Proximal RPA | 11.6 | 17.0 | 14.2 | 8.1 | 19.1 | 42 | 4 | 39 | 12 |
| 2 | Middle segment of RPA | 18.0 | 17.4 | 17.4 | 8.8 | 18.2 | 14 | 0 | 22/34* | 12 |
| 3 | Proximal LPA | NA | 11.4 | 3.1 | 5.8 | 9.1 | 9 | 0 | 34 | 12 |
| 4 | Proximal LPA | NA | 14.9 | 11.5 | 6.6 | 9.1 | 54 | 8 | 39 | 12 |
| | Proximal RPA | NA | 12.3 | 9.3 | 9.2 | 11.3 | 47 | 6 | 39 | 12 |

NA: not available; LPA: left pulmonary artery; RPA: right pulmonary artery; SI: stent implantation; *: Stent displaced during the procedure, and a second CP stent (34 mm in length) was reimplanted successfully 11 months later.

the main pulmonary artery also developed restenosis, and the systolic pressure gradients across the distal end of the main pulmonary artery, left and right pulmonary artery were 55.7, 33.6 and 22.3 mmHg, respectively.

## Discussion

Traditionally, surgical repair is the initial treatment option for pulmonary artery stenosis, but the results are quite unsatisfactory.[1,2,5] Since the introduction of balloon angioplasty for pulmonary artery stenosis in the early 1980s,[12] balloon pulmonary arterioplasty has been considered for most of these cases of stenosis lesions.[1] Nevertheless, the acute success rate of balloon pulmonary arterioplasty in children is as low as 50% to 60%.[13,14] Even with the use of high-pressure balloon, the success rate reaches only 75%.[1] In addition, there are other limitations of balloon dilation for pulmonary artery stenosis, such as restenosis secondary to vessel recoil and unexpected complications.[4] Stent implantation for pulmonary artery stenosis, first successfully introduced for clinical use by O'Laughlin and colleagues in 1991,[15] has become a new therapeutic modality because of the increasing success rate to over 90% and avoiding complications associated with balloon angioplasty.[1,2,4] For many years balloon-expandable stainless steel Palmaz stent has been used routinely by pediatric cardiologists. The disadvantages of this device lie in its limited expanded diameters and lengths, and the rigid, sharp edges. Therefore, Palmaz stent treatment for vessel stenosis associated with CHD in children is restricted.[6,7]

The balloon-expandable CP stent, designed by Cheatham and NuMED Company, is used specifically to treat vascular obstructions associated with CHD. Compared to Palmaz stent, the advantages of CP stent are the wider range of expanded diameters from 8 to 24 mm allowing for somatic growth, wider selection of stent lengths to meet the variable target lesions, less potential trauma to the delivery balloon and target vessel, minimal foreshortening after full expansion (≤20%), and more flexible and stronger, and superior radiopacity.[6,7] Catheters we used were BIB balloon, which is designed specifically for stent delivery in the pediatric/congenital population, and particularly for the placement of stents expanded to diameters greater than 12 mm at the initial implantation.[16] The BIB balloon consisted of an inner balloon and an outer balloon. The inner balloon expands to half the outer balloon diameter (range, 8-24 mm), while the length is 1 cm shorter than the outer balloon. Before inflation of the outer balloon, the stent can be repositioned precisely if needed, so BIB balloon catheter is superior to single balloon delivery catheter.[6,7]

Palmaz stent implantation for pulmonary artery stenosis has often been reported.[3,17-21] However, CP stent implantation for pulmonary artery stenosis in children and adolescents has been rarely reported. Ewert et al[8] successfully treated 13 patients with native or postsurgical pulmonary artery stenosis after implantation of 17 CP stents (8-zig). Of these stents, 7 stents of 16-34 mm in length were placed in 5 children (6-16 years, weighing 18-44 kg). The stents were in good position without complications during the procedure and within 12 months of follow-up.

In the present study, we selected CP stent and BIB balloon according to the results of digital subtracted angiography. The BIB outer balloon size for any particular lesion must be individualized according to the particular anatomy and the etiology of stenosis. The diameter of the outer balloon for dilation of a postoperative branch pulmonary artery stenosis should be 50%-75% larger than that of the proximal and distal segments of the stenosis, or alternatively, three to four times that of the narrowest segment. For the native branch pulmonary artery stenosis, the diameter of the outer balloon should be no more 10%-15% larger than that of the adjacent "normal" vessel or no more than three times the diameter of the narrowing.[16] When the BIB balloon was in the ideal position, we inflated the inner and outer balloons not exceeding the maximum inflation pressures of 4-6 atmospheres using a pressure-controlled inflation device.[16]

Complications occurred in two patients during the procedure or in the period of follow-up. In patient 2, the stent displaced during the procedure, then it was placed in the pulmonary trunk. Eleven months later, the procedure was repeated, and a second CP stent was successfully reimplanted. Although BIB balloon can control stent deployment, the stent dislocation is unavoidable during the procedure. We believe that increased experience of operators will reduce the risk of this complication. Patient 4 with stent restenosis has prepared to receive redilation of the stents. Stent restenosis in this patient may be due to neointimal proliferation within the stent. Previous studies have suggested that overdilation, minimal overlap, and sharp angulation of the stent to the vessel wall are risk factors for in-stent neointimal hyperplasia.[17,18] Usually stents are covered by a thin layer of neointima within six months after placement. Neointima within 2 mm is considered normal. However, greater neointimal proliferation may result in restenosis characterized by significantly reduced lumen size, and such a condition is indicated for stent redilation.[17] Relative stenosis at the site of stent implantation due to somatic growth is another indication for stent redilation.[17] Although Palmaz stent redilation is safe and efficacious for stenosis of the branch pulmonary artery,[17] it is limited to older children and adults. Expanded diameters suggest that CP stent can be further redilated many years later.[9] Hence CP stent in growing children is capable of being redilated

up to an adult size. Relative stenosis due to somatic growth was not seen in our patients, but long-term follow-up is mandatory, especially in younger children with early CP stent placement.

Our study has some limitations. First, there are only 4 patients included in this study. A larger series of patients with a longer follow-up are required to determine the results of CP stent implantation for pulmonary artery stenosis associated with CHD in children and adolescents. Second, the pulmonary artery flow to the affected lung has not been remeasured by MRI during the follow-up period.

In conclusion, our experience indicates that CP stent implantation is suitable for the treatment of pulmonary artery stenosis associated with CHD in children and adolescents. The immediate and mid-term results of this implantation are encouraging, but long-term outcomes in more cases remain to be studied.

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