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Cheatham-Platinum 10-zig stents for transcatheter treatment of congenital heart diseases: A new tool to widen the spectrum of treatable conditions

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ABSTRACT

Objectives: To report our experience using the 10-zig C-P stents in children and adults with congenital heart disease.

Background: The use of stents in congenital heart disease has become widespread since the 1990s and a large range of stents has been designed for a variety of indications. In many situations there is a need for stents that can be dilated to large diameters without excessive shortening. Cheatham-Platinum (10-zig C-P) (NuMED, Hopkinton, NY, USA.) stents may fulfil this requirement.

Methods: Between January 2015 and January 2020, 17 patients with congenital heart disease were treated using a 10-zig C-P stent at our center. (6 Females 13 males; (median age 33 years (range 10–69 years); median weight 85 kgs (range 25–119 kg). Indications for use of the 10-zig stents were right ventricular outflow tract (RVOT) interventions in 8 subjects and aortic coarctation in 9 patients.

Results: 1) Right ventricular outflow tract stenting. Ten right ventricular outflow tract stents (2 also had implantation of transcatheter valves in the same procedure) were implanted in 8 patients. All the RVOT interventions were in preparation for a transcatheter pulmonary valve. Median fluoroscopy and procedure times were 41 min (range 31–131 min) and 164 min (range 152–361 min), respectively. One patient had distal perforation of a pulmonary artery due to guide-wire injury and required blood products. Two subjects showed stent fracture during follow-up needing further stent implantation. **2) Aortic Coarctation.** Nine stents were implanted in 9 patients. The median fluoroscopy and procedure times were 36 min (range 11–75 min) and 164 min (range 95–225 min), respectively. The median peak systolic gradient reduced from 33 mmHg (range 15–60 mmHg) to 3 mmHg (range 0–4 mmHg) ($p < 0.001$).

Conclusions: Our experience shows that the 10-zig Cheatham-Platinum stents can be used successfully and safely in congenital heart diseases.

Introduction

The use of stents in congenital heart disease has become widespread since the 1990s [1–4] and a large range of stents has been designed for a variety of indications. Their use in paediatric cardiac interventions is limited by access vessel size, which limits the maximum size of introducer sheath that can be used. Subsequent stent redilation may be required to keep pace with somatic growth and, so there is a need for stents that can be dilated to large diameters without excessive shortening. Cheatham-Platinum (10-zig C-P) (NuMED, Hopkinton, NY, USA.) stents may fulfil this requirement. We have previously published data on successful percutaneous closure of sinus venosus atrial septal defects [5] using custom-made 10-zig covered C-P stents. Subsequently, the 5 and 6 cm long 10-zig C-P stents have received 'CE' marking and are available for routine use. We report our experience using the 10-zig covered C-P stents in children and adults with congenital heart disease (CHD).

Patients and methods

Between January 2015 and January 2020 (with the majority n = 12, in 2019), 17 patients with congenital heart disease were treated using a 10-zig C-P stent at our center. (6 Females 13 males; (median age 33 years

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Table 1
RVOT stent implantation.

PT NUMBER	Diagnosis (Cardiac)	Diagnosis (Non Cardiac)	Previous Procedures and age at procedures
#1	Pulmonary atresia/VSD/MAPCAs; Severe calcific homograft stenosis and distal branch PA stenosis	None	- 1 year Full repair with unifocalisation/MAPCA ligation, VSD closure, RV-PA conduit with 17 mm pulmonary homograft - 2 years Balloon dilatation LPA
#2	Severe PS, CoA, AS, RPA stenosis	None	- 3 weeks: CoA repair - 3 weeks: balloon dilation AS - 1 year: Ross and arch repair - 5 and 6 years RPA stent - 7 years replacement of pulmonary homograft and removal of RPA stents
#3	ToF MAPCAs, PR (severe)	Balanced Robertsonian translocation (ch 14 and 15)	- 8 months: TOF repair and MAPCAs ligation
#4	Bicuspid AoV; AS, Moderate pulmonary homograft obstruction and regurgitation	None	- 47 years: Ross Procedure - 49 years: Melody valve implantation abandoned- coronary artery compression
#5	ToF, right aortic arch, RVOTO (conduit stenosis)	None	- 4 months: Right BTS & ligation of azygos vein, Ligation of thoracic duct for chylothorax - 13 months: ToF repair and BTS removal - 4 years: PV replacement, 19 mm Matrix P pericardial conduit and RVOT resection
#6	AS (presumed bicuspid AoV), AF, PV stenosis, PR	none	16 years: Ross procedure (27 mm pulmonary homograft, Presumed balloon dilatation AoV
#7	ToF; PR and RV dilation	22Q11 deletion; Cerebral palsy, developmental delay	- 1 day: Emergency transannular patch - 1 year: RVOT aneurysm repair and tetralogy of Fallot correction
#8	Tetralogy of Fallot, LPA stenosis	Depression	6 years: Tetralogy of Fallot repair 24 years: Stent (18 mm) placement in LPA

Table legend: AF atrial fibrillation; AS aortic stenosis; AoV aortic valve; BTS BT shunt; CoA coarctation of the aorta; LPA left pulmonary artery; MAPCAs major aortopulmonary collateral vessels; PA pulmonary artery; PR pulmonary regurgitation; PS pulmonary stenosis; PV pulmonary valve; RPA right pulmonary artery; RV right ventricle; RVOT right ventricular outflow tract; RVOTO right ventricular outflow tract obstruction; ToF Tetralogy of Fallot; VSD ventriculoseptal defect.

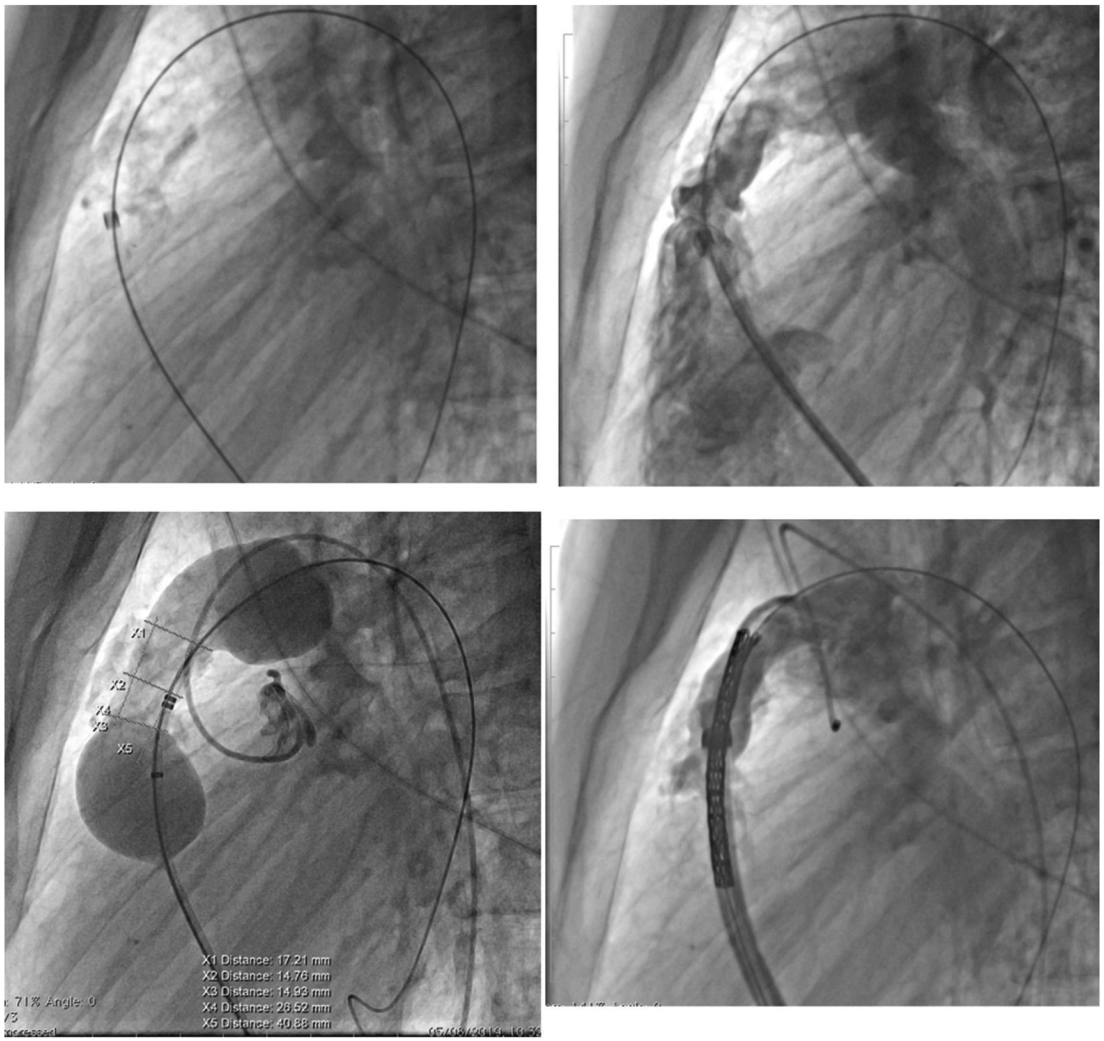

Fig. 1. Lateral fluoroscopic and angiographic views showing significant calcifications of the conduit (left and right upper); balloon sizing of the landing zone (left bottom); test angiography with 10 zig CP stent ready to be implanted (right bottom).

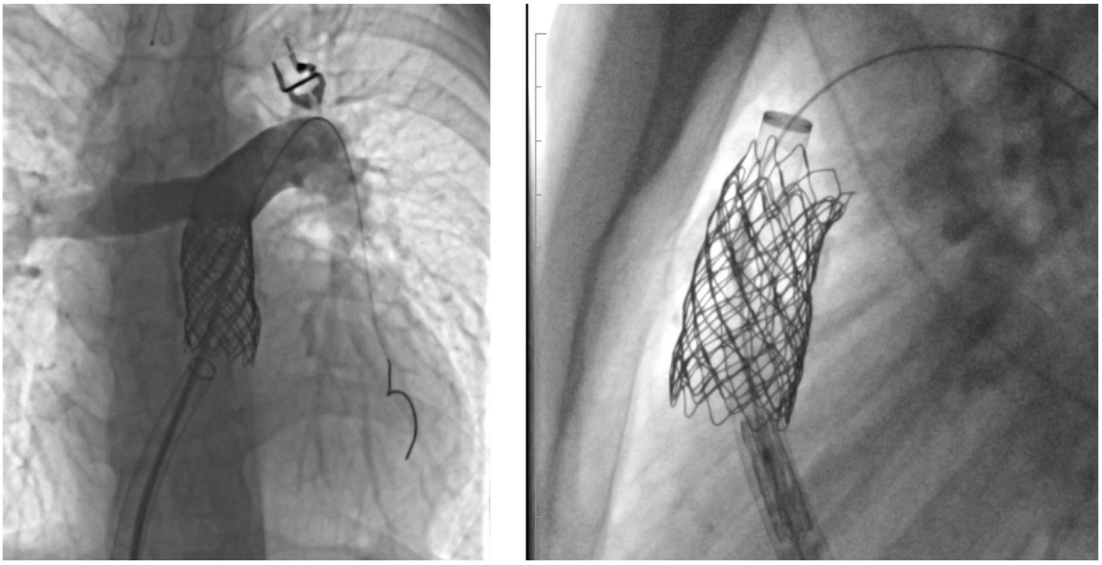

Fig. 2. Angiography in pulmonary arteries in anteroposterior view with cranial angulation after implantation of 10-zig CP stents (left); Lateral fluoroscopy showing the 23 mm Sapien valve ready to be implanted in the landing zone prepared with 10 zig-CP stents.

(range 10–69 years); median weight 85 kgs (range 25–119 kg). Indications for use of the 10-zig stents were as follows; right ventricular outflow tract (RVOT) interventions (n = 10 procedures in 8 patients) (4 females, 4 males, median age 27 years [range 10–69 years], median weight 84 kg [range 25–112 kgs]); stenting of aortic coarctation in 9 patients (1 female, 8 male, median age 44 years [range 22–61years], weight 88 kg [range 71–119 kgs). All patients were evaluated with detailed pre-procedural cross-sectional imaging of the lesion with multidisciplinary team consensus that intervention was indicated. Pre-procedural imaging was reviewed to determine the length of the stent, the final diameters and the delivery systems (sheath, guide wires and balloons) required. Vascular access, angiographic planes and additional imaging were also agreed pre-procedure.

Medicines and Healthcare products Regulatory Agency (MHRA) approval was required for the use of the 5 and 6 cm 10-zig stents during the period before their CE mark and for the 7 cm stent used in one patient. All patients or their legal guardians provided written informed consent prior to the procedures, in line with hospital governance policy.

The stent

The covered C-P stent (NuMED Inc, Hopkinton, NY, USA) is composed of 0.013" platinum-iridium wire arranged in either an 8-zig or 10-zig pattern, that is laser welded at each joint and then over brazed with 24 K gold. The stent is then covered with a sleeve of expanded polytetrafluoroethylene (ePTFE). The 8-zig configuration is expandable from 12 to 24 mm in diameter and is available in lengths of 1.6–6.0 cm, whilst the 10-zig configuration is expandable up to 30 mm in diameter and is available in lengths of 3.9–6.0 cm. The covered C-P stent is licensed for use in aortic coarctation and right ventricle to pulmonary artery conduits

Table 2
Aortic coarctation.

Pt number	Diagnosis (Cardiac)	Diagnosis (Non Cardiac)	Previous Procedures and age at procedure	Medications
# 9	CoA (native)	Anaemia	None	Indapamide, Amlodipine, Losartan, Atenolol
# 10	CoA (native)	None	None	Bendroflumethiazide, Ramipril
# 11	CoA (native)	None	None	Lisinopril, Amlodipine Bisoprolol
# 12	CoA (native)	Fragile X, CVA	30 years RTA– right thoracotomy	Amlodipine, Bisoprolol, Clopidogrel
# 13	Bicuspid AoV, CoA, Aortic dissection (Type A)	None	23 years: Emergency repair dissection (28 mm Gelweave interposition graft and 18 mm Gelweave tube graft) and aortic valve replacement (25 mm ATS Bileaflet mechanical valve)	Warfarin, Bisoprolol Losartan
# 14	CoA native, AF cardiomyopathy	None		Amlodipine, Clonidine, Indapamide, Perindopril, Bisoprolol, Apixaban, Atorvastatin
# 15	CoA (native), bicuspid aortic valve, aortic root and ascending aorta aneurysm	Monoclonal Gammopathy of uncertain significance, hypertension, lumbar microdiscectomy, osteoarthritis (knees) and impaired renal function.		Lercanidipine, Atenolol Lisinopril, Pravastatin Oxycontin, OxyNorm, Cetirizine.
# 16	CoA native, bicuspid aortic valve	Hyperlipdaemia, Hyperthyroidism	None	Aspirin, Bisoprolol, Ramipril, Felodipine, Doxazosin, Betahistidine and Levothyroxine
# 17	CoA native, Bicuspid aortic valve	Ulcerative colitis	None	Ramipril, Spironolactone, Amlodipine, Bendroflumethiazide, Balsalazide, Aspirin

AF atrial fibrillation; CoA coarctation of the aorta; CVA cerebrovascular accident; RTA road traffic accident; ToF Tetralogy of Fallot; VSD ventriculoseptal defect.

and for procedures in preparation for a transcatheter pulmonary valve implantation.

Procedure

All the procedures were performed under general anaesthesia with oro-tracheal intubation and fluoroscopic control. All the patients received 100 IU/kg of heparin and antibiotics intravenously as per institutional protocol. Vascular access was achieved through femoral artery or vein. Perclose ProGlide vascular closure devices (Abbott, Illinois, USA) were used for large-bore arterial access. Angiography of the vessel to be stented was performed in two orthogonal planes. None of the lesions were predilated with a balloon. Standard procedural steps were used, which have been described previously [1–4]. Following the procedure, all patients had check echocardiography and chest x-rays in both postero-anterior and lateral projections. All patients received antiplatelet medications (aspirin 5 mg/kg, max 75 mg daily lifelong±clopidogrel 1 mg/kg, max 75 mg for 6 months). First follow up in the outpatient clinic was typically between 6 and 12 weeks for clinical review and repeat imaging (CXR/echocardiogram and review of interval CT or MRI). All data were collected retrospectively from the electronic paper records.

Results

1) Right ventricular outflow tract stenting

Ten right ventricular outflow tract stents (2 also had implantation of transcatheter valves in the same procedure) were implanted in 8 patients (Table 1). Indications included pulmonary homograft stenosis/incompetence after a Ross operation (n = 4), repair of pulmonary atresia with ventricular septal defect (PA/VSD) (n = 1), or repair of tetralogy of Fallot (n = 5) (Table 1). Patients had their last operation a median of 10 years (range 2–20 years) prior to the stent implantation procedure. All the RVOT interventions were in preparation for a transcatheter pulmonary valve (Figs. 1 and 2). Stent lengths were implanted using Mullins long sheaths (Cook Medical, Bloomington, USA) or Gore DrySeal (Gore, Flagstaff, USA). Median sheath size was 20 Fr (range 16–26 Fr). Median stent diameter at the end of the procedure was 20 mm (range 16–29 mm). Median fluoroscopy and procedure times were 41 min (range 31–131 min) and 164 min (range 152–361 min), respectively. After deployment, six cases required further stent dilation with an Atlas Balloon (Bard Medical, New Jersey, USA) (16–26 mm), Coda balloon (9 Fr) (Cook Medical, Bloomington, USA) or using the outer balloon of the balloon-in-balloon (BiB (NuMED Inc, Hopkinton, NY, USA). With the exception of one patient with a stent fracture

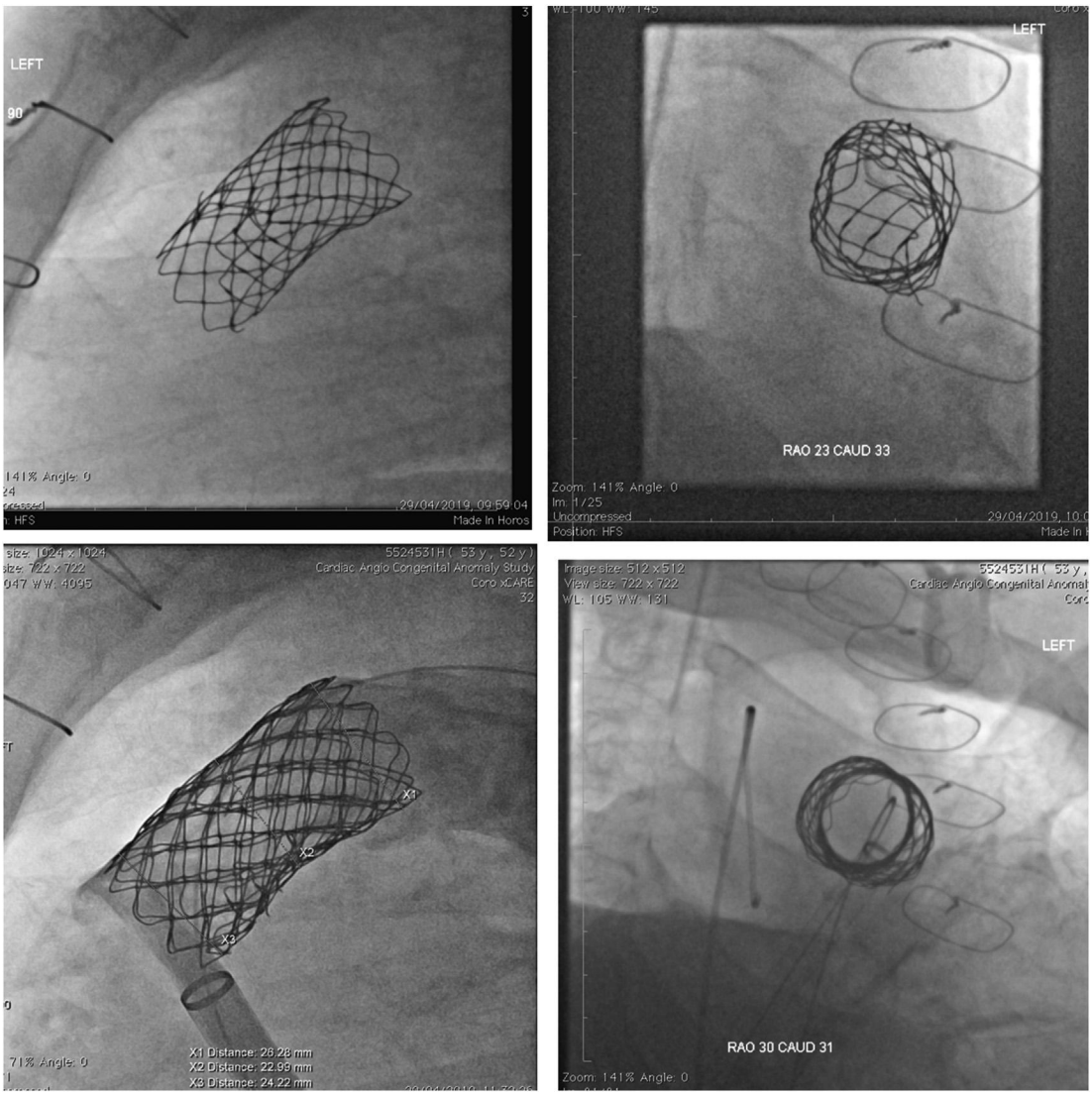

Fig. 3. Lateral (left upper) and down-the barrel view (right upper) showing significant fracture of the proximal end of the stent; Lateral (left bottom) and down-the barrel view (right bottom) after stents implantation.

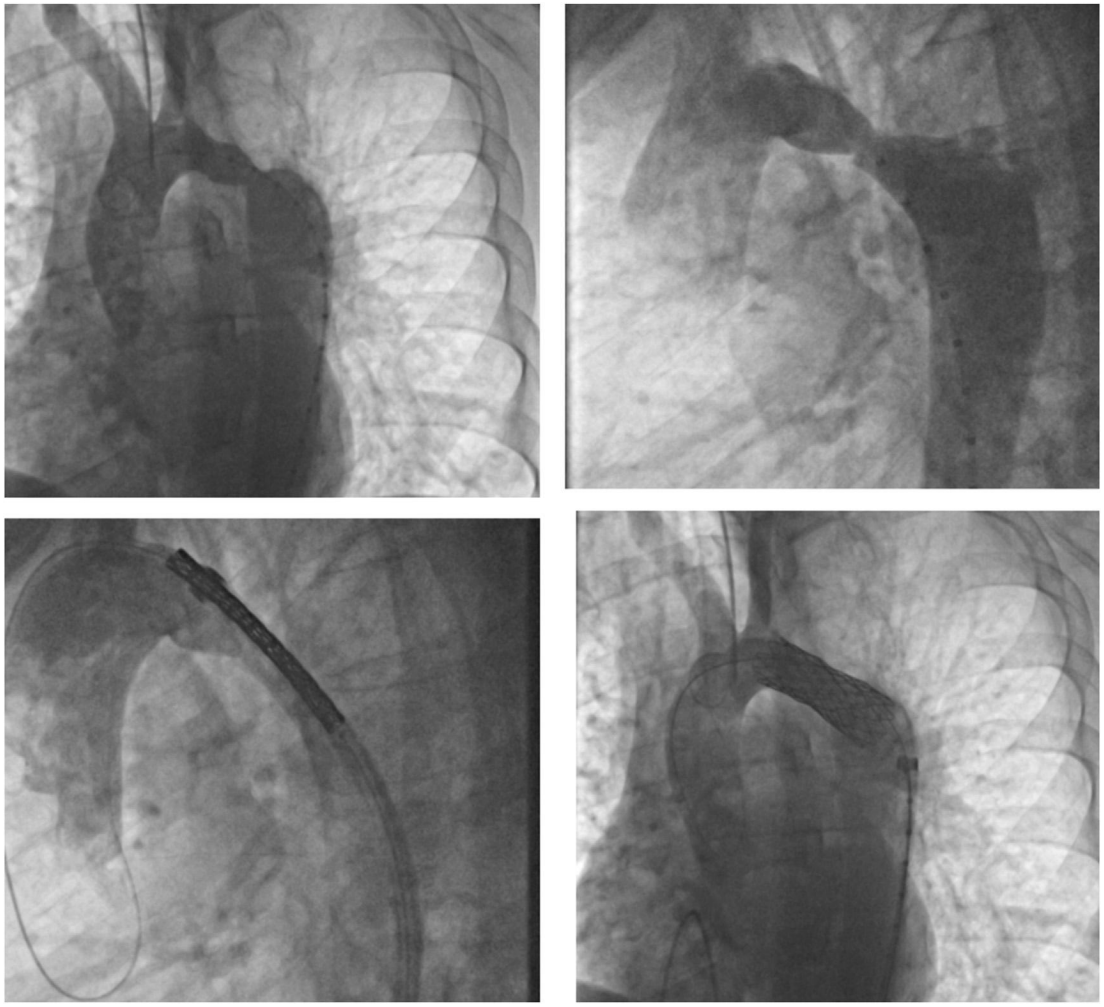

Fig. 4. Left anterior oblique views of the aortic arch. Complex and long aortic arch coarctation is shown (left and right upper; A 10 zig CP stent is ready to be implanted in the lower bottom panel. Final result is demonstrated in the right bottom panel.

found at follow up, there was no haemodynamically significant increase in right ventricular outflow tract Doppler velocity (median 1.8 m/s post procedure). With regard to complications, there were 2 stent fractures (pt #4 and pt #8) and 1 femoral vein intimal injury managed conservatively (pt 8#).

One of the stent fractures (patient # 4, Table 1) was an incidental finding in clinic follow up with an increased right ventricular outflow tract velocity of 4.3 m/s on Doppler echocardiography. This was managed by expediting the planned Sapien valve implantation. The other stent fracture was a proximal fracture of a previous stent (patient #8, Table 2) noticed during a subsequent diagnostic catheter. This was managed with an Atlas (16 × 20 mm) balloon dilation of the existing proximal and distal part of the stent, before delivering another 10-zig stent in the right ventricular outflow tract (Fig. 3).

One patient had distal perforation of a pulmonary artery due to guidewire injury and required blood products (Patient #1, Table 1). He had heavy calcification of the conduit and left pulmonary artery, therefore was technically challenging to enter and cross with the wire. The same patient developed a broad complex tachycardia during the procedure requiring cardioversion. All patients were followed up with CXR and either CT or MRI. There were no late complications. The median duration of follow up was 15 months (range 6–60 months).

2) Aortic Coarctation (Fig. 4)

Nine stents were implanted in 9 patients (Table 2). The indications included native coarctation ($n = 8$) and homograft/re-coarctation ($n = 1$). The stent lengths were between 5 and 7 cm and were implanted by using BIB balloons (NuMED Inc, Hopkinton, NY, USA). Mullins long sheaths were used (Cook Medical, Bloomington, USA) or Gore DrySeal (Gore, Flagstaff, USA). Median sheath size was 20 Fr (range 16–20 Fr). The median final stent diameter was 21 mm (range 14–25 mm). The median fluoroscopy and procedure times were 36 min (range 11–75 min) and 164 min (range 95–225 min), respectively. The median systolic BP reduced from 160 mmHg (range 110–180 mmHg) to 132 mmHg (range 114–140 mmHg) ($p < 0.001$). The median peak systolic gradient reduced from 33 mmHg (range 15–60 mmHg) to 3 mmHg (range 0–4 mmHg) ($p < 0.001$). Six patients required flaring or further dilation at the time of the procedure using an Atlas balloon (16–18 mm) (Bard Medical, New Jersey, USA) in three and with a Coda (9Fr) balloon (Cook Medical, Bloomington, USA) in the remaining three patients. With regard to complications, there was one femoral artery access site spasm in patient #17 treated with IV glyceryl trinitrate. At a median follow up of 14 months (range 6–50 months), there have been no late complications. The maximum echocardiographic Doppler flow velocity across the aortic stent at follow up was 2.5 m/s.

Discussion

Paediatric and adult congenital cardiac catheterisation is evolving rapidly. Avoiding an invasive surgical procedure and cardiopulmonary bypass is of benefit to many patients. There is an increasing trend for the

percutaneous pulmonary valve implantation as an alternative to surgery [6]; both the Melody and the Edwards Sapien valves have been used with a favourable safety and efficacy profile [7]. Pre-stenting of the RVOT to create a landing zone for the percutaneous valve is often performed before valve implantation [8]. Many patients undergo interventions in adulthood and there is the need for large stents that do not change their characteristics and in particular, shortening, when expanded to larger diameters. The 10-zig CP stents largely fit this need. In our experience, 10-zig CP stents prepare a safe and effective landing zone for percutaneous valve implantation or for treatment of RVOT homograft stenosis. It is worth noting however, that there were 2 stent fractures in this group and one patient required a further stent implantation due to elastic recoil. This is not a low risk of fracture, therefore changes in stent characteristics or strength could be warranted. However, these are known risks for all implanted stents. There was also a lung parenchymal injury in a technically challenging case that required blood transfusion. The higher complication rates in the RVOT group reflect the greater technical challenges in treating these substrates. The percutaneous treatment of aortic arch stenosis by transcatheter placement of bare-metal or covered stents in adult patients is at least as effective as surgery [9]. Treatment of congenital stenosis in children is limited by the requirement for large sheaths to deliver larger stents. Smaller stents require multiple re-dilations as the child grows with questions over their long-term durability and little is known about the long-term fatigue resistance of small stents expanded over their limits [10]. Furthermore, most native or congenital vascular stenosis involves intimal and medial tears with a significant recoil effect necessitating the need for a more durable stent [2]. Taking these factors into account the median age (44 years) of our CoA cohort is not surprising. Our data suggest that the 10-zig Cheatham-Platinum stents are safe and effective in treating native and post-surgical coarctation The most significant complication was femoral artery spasm managed with intravenous GTN. A median clinical reduction of 30-mmHg systolic blood pressure at follow-up enabled many of our patients to reduce their antihypertensive drugs. Interestingly, there have been no stent fractures to date in this group and the maximum flow velocity at the site of coarctation was 2.5 m/s or less in our cohort. Our experience shows the extended range of application of the 10-zig covered stents, in addition to our previously published work on the transcatheter closure of sinus venosus ASDs [5]. To our knowledge this is the only published data for the use of 10-zig stents for these indications. The data demonstrate the use of these stents in both paediatric and adult patients with low procedural and follow-up complication rates.

Conclusion

These data are the largest case series documenting evolving experience in a tertiary centre with an extended range of applications for the 10-zig Cheatham-Platinum stents in congenital heart disease and demonstrate their successful use in both paediatric and adult population with low complication rates.

Disclosure

Prof Shakeel A. Qureshi is consultant for NuMED Med.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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