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PEDIATRIC AND CONGENITAL HEART DISEASE

Original Studies

Covered Cheatham-Platinum Stents for Serial Dilation of Severe Native Aortic Coarctation

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Objectives: To report on the early results of treatment of native coarctation of the aorta by implantation and serial dilations of covered stents. Background: Transcatheter dilation of native coarctation of the aorta carries a risk of aneurysm or rupture. Covered stent implantation requires a large delivery system with the risk of vascular damage. Methods: Covered stents on balloons of diameter sufficient to anchor the stent in the coarctation were implanted using the smallest delivery system possible. Dilation with larger diameter balloons was performed until the pressure gradient was <20 mm Hg and the stent was opposed to the aortic wall. Results: Twenty-two patients with native coarctation underwent stent implantation. Coarctation diameter increased from 3.6 ± 1.9 to 12.6 ± 1.9 mm ($P < 0.001$). Peak pressure gradient decreased from 29.4 ± 8.5 to 6.7 ± 5.7 mm Hg ($P < 0.001$). Nine patients underwent further dilation on average 5 months later. Residual pressure gradient decreased from 12.3 ± 5.8 to 2.1 ± 2.9 mm Hg ($P = 0.002$). The stent achieved the diameter of the transverse arch in all cases. Complications included a small tear at further dilation treated with a second stent and a femoral pseudoaneurysm. At short-term follow-up of 18.5 months all patients are alive and well with no evidence of recoarctation or aneurysm. Conclusions: These initial results show that serial dilation of covered Cheatham-Platinum stents is feasible, safe, and an effective percutaneous method for the treatment of native coarctation of the aorta. However, long-term follow up is required.

Key words: heart defects; congenital; catheterization; radiology interventional

INTRODUCTION

Bare stent dilation of native and recurrent aortic coarctation has become a recognized therapeutic modality providing an alternative to surgical repair [1–7]. However, native narrowings of the aorta, especially in the older patient, often require the unprotected coarcted area to be dilated to a large diameter, or are tortuous, and this carries a risk of aneurysm or rupture, especially when cystic medial necrosis may be present [8–11]. The covered Cheatham-Platinum (CP) stent, since it is covered by polytetrafluoroethylene (PTFE), and is balloon expandable from 8 to 24 mm, provides a solution for both dilation and protection of the narrowed area. Covered stents require relatively large delivery systems and therefore their use is limited, especially in the pediatric population. We report our acute procedural experience with the covered CP stent for severe native coarctation of the aorta using an initially small balloon to reduce the size of the delivery system required followed by serial dilations of the implanted stent.

MATERIALS AND METHODS

Patient Population

All patients with a diagnosis of coarctation of the aorta who underwent transcatheter PTFE covered stent

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Conflict of interest: None.

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implantation at Schneider Children's Medical Center Israel were identified from the cardiac catheterization database. Patient characteristics, procedural characteristics, hemodynamic and angiographic findings, and clinical status were recorded from the patient records. The study was approved by the Institutional Review Board. Informed, written consent was obtained from all patients prior to the procedure.

CP Stent

The covered CP stent (NuMED, Hopkinton, NY) has been described previously [8,12–14]. In brief, the stent is made of a laser-welded framework of platinum iridium wire with gold soldering at the weld points. The stent is covered with PTFE which stretches over the stent when expanded from 8 to 24 mm in diameter. The stent design reduces shortening during expansion to <20% of the original length. The stent is available in various lengths and in our laboratory we use lengths from 28 to 45 mm. The covered stent typically requires a delivery sheath at least 3 Fr larger than the introducer required for the balloon on to which it is crimped.

Implantation Technique

Following general anesthesia, percutaneous access to the femoral vessels with 6 Fr sheaths was attained by Seldinger technique. A hand injection of contrast media was performed through the arterial sheath to evaluate it's adequacy for a larger delivery sheath. This was determined by measuring an arterial diameter at least 1.7 times the 6 Fr sheath that was implanted. If too small or stenotic, a 6 Fr sheath was placed in the other femoral artery and this was similarly assessed. Following heparinization (100 IU/kg) a hemodynamic and biplane angiographic evaluation were performed. A high-flow marker pigtail catheter (Merritt Medical, Cleveland, OH) was advanced to immediately below the coarctation and during angiography usually a small amount of contrast media outlined the narrowing. A 4 Fr angled visceral catheter (Berenstein or cobra, Merritt Medical) was then advanced over a 0.038″ guidewire (Terumo, Somerset, NJ) and advanced to the transverse aortic arch. The wire and catheter were exchanged for the marker pigtail catheter and, following pressure measurements, angiography was performed in the ascending aorta and transverse arch. Exact measurements of the diameters of the coarcted segment, transverse aortic arch at the left subclavian artery and length of the lesion were made. The length of the stent was chosen, when possible, to reach from the beginning of the tapering of the aorta, through the coarctation and beyond the ''bell shape'' of the poststenotic dilation. To minimize the size of the delivery sheath (Brite Tip, Cordis, Miami, FL or Mullins, Cook, Bloomington, IN), low-profile high-pressure balloons (Powerflex, Cordis) were used. The initial balloon diameter was chosen to suffice in anchoring the stent in the coarctation and oppose it to walls of the aorta immediately adjacent to the coarcted segment.

A CP covered stent was hand crimped on to the balloon. To protect the PTFE from perforation during crimping, a wet umbilical tape was wrapped with increasing tension around the stent from distal to proximal ends and this was repeated until the stent was uniformly crimped and could be passed through a cut 10 Fr introducer. While in the sheath a blunt edged clamp was used to crimp the stent further while protecting the balloon shaft lumen with a wire. The mounted stent was then inserted into a cut 9–10 Fr introducer that acted as a protective sleeve when pushing the stent through the hemostatic valve into the delivery sheath.

A 0.035″ Rosen wire (Cook) was advanced through the pigtail catheter to the right subclavian artery. The delivery sheath was advanced beyond the coarctation and the introducer removed and replaced by the balloon catheter, which was advanced to the site of implantation. To position the stent correctly, a hand injection of contrast media was performed through the sidearm of the delivery sheath. Once positioned, the sheath was withdrawn and the stent dilated using an indeflator syringe. The balloon was removed while advancing the sheath over it to avoid traction and dislodgement of the stent. A hand injection of contrast was performed though the sheath and a second balloon of diameter up to 4 mm larger than the initial balloon was advanced into the stent and dilated with an indeflator syringe. The balloon was removed and the pigtail catheter advanced to measure pressures and to perform angiography. If the pressure gradient was <20 mm Hg and the stent was opposed to the walls of the aorta proximal to the coarcted segment the procedure was stopped (Fig. 1). Hemostasis was achieved by manual compression.

Further Dilation

Patients, in whom the final stent diameter was less than that of the transverse arch at the left subclavian artery, were referred for further dilation 4–6 months later. In the second catheterization, a 7 Fr introducer was percutaneously placed in the femoral artery that was not used for stent implantation so as to minimize vessel damage. An XXL balloon (Boston Scientific, Natick, MA) of diameter similar to that of the transverse arch was advanced into the stent and maximally dilated (Fig. 1). The balloon was removed and the pigtail catheter advanced to measure pressures and to perform angiography.

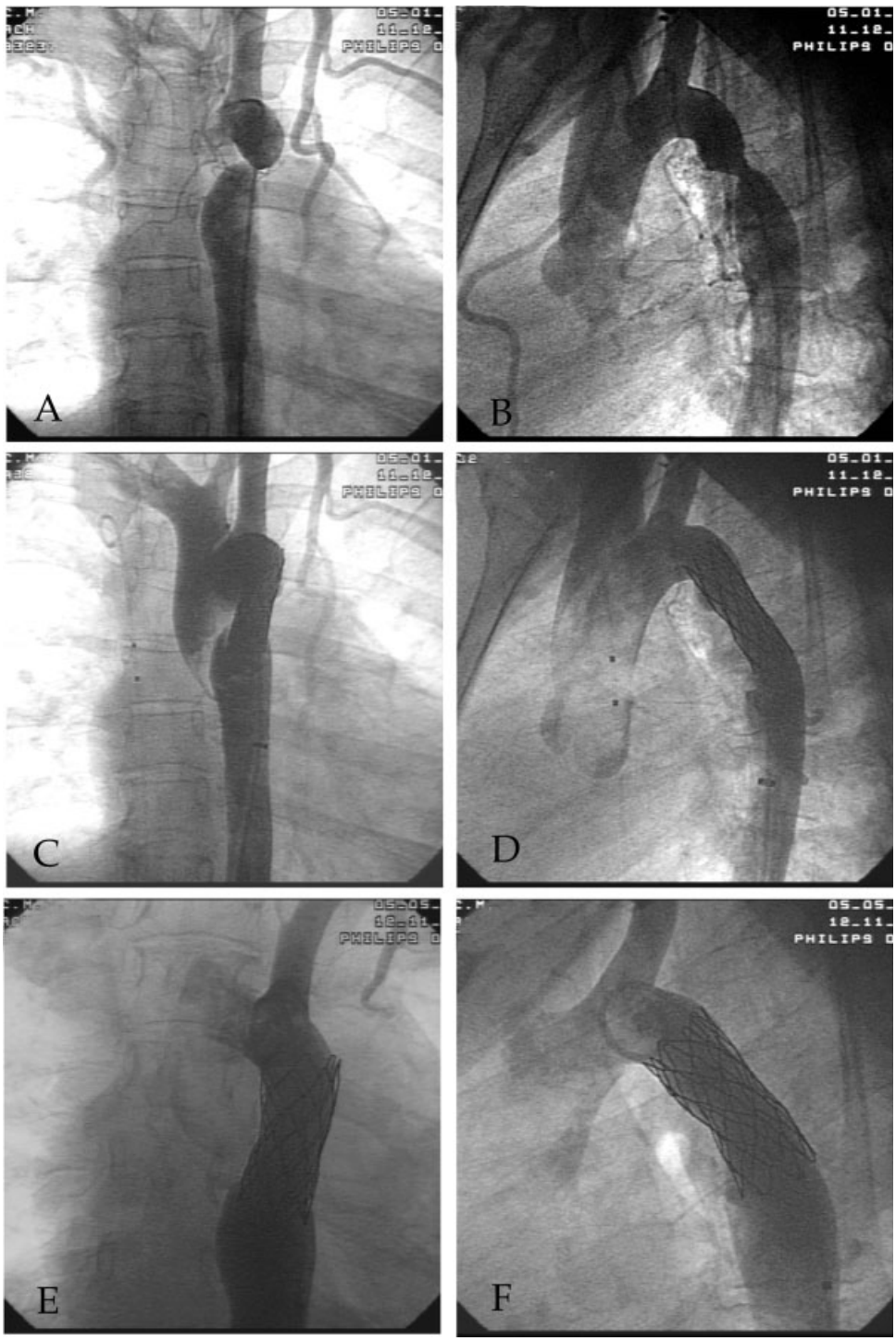

Fig. 1. A, B: Anteroposterior and lateral angiograms of the aorta in a 38-year-old woman with severe discrete native coarctation of the aorta. C, D: AP and lateral angiograms following implantation of a covered CP stent and dilation to 12 mm. The stent diameter is less than that of the arch. E, F: Angiograms in the same patient 4 months later following stent dilation to 18 mm to match the diameter of the transverse arch distal to the left subclavian artery.

Special Considerations

In cases in which the left subclavian artery was at risk for occlusion by the covered stent, the right vertebral artery was identified and selective angiography was performed to establish antegrade flow. In cases when the coarctation was $\leq$2 mm in diameter, a 4–5 mm high pressure balloon was used to dilate the coarctation to afford passage of the delivery sheath. In one

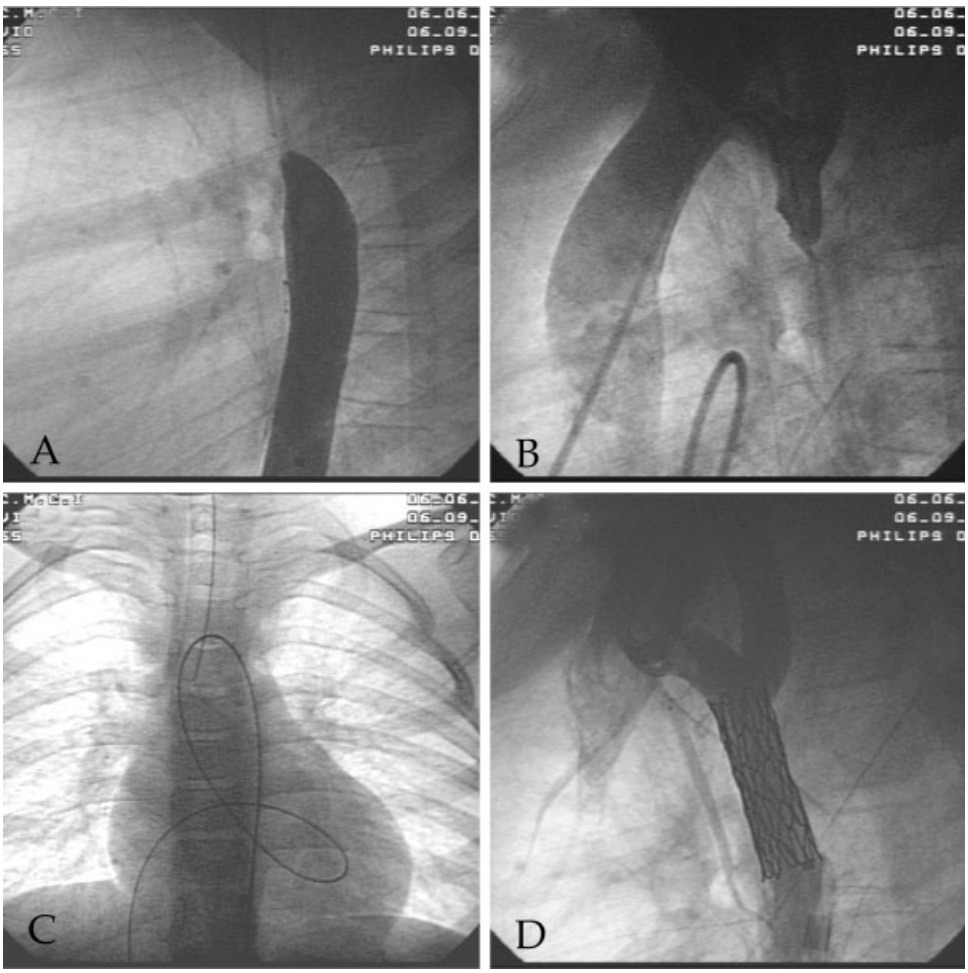

Fig. 2. A: Lateral angiogram of the descending aorta in a 7-year-old boy with near-atresia of the aorta. B: Lateral angiogram of the ascending aorta and transverse arch performed with a pigtail catheter advanced trans-septally. C: AP fluoroscopic image of the arteriovenous wire loop from the IVC to the left atrium and ventricle and then to the ascending and descending aorta. D: Lateral angiogram of the descending aorta following implantation of a covered CP stent and dilation to 8 mm. The stent diameter is a little larger than that of the arch and has been expanded into the base of the left subclavian artery.

case of extreme coarctation, in which a wire could not be advanced retrogradely to the ascending aorta, a trans-septal approach was taken and a wire advanced from the ascending aorta and snared in the descending aorta and exteriorized (Fig. 2). The remainder of the case was as described above.

RESULTS

Between November 2004 and December 2007, 42 patients underwent cardiac catheterization with implantation of a covered CP stent in the aorta. Of these patients, 22 (14 M, 8 F) had native coarctation of the aorta. Their median age was 15.5 years (7.8–38.6) and median weight was 57.0 kg (21.0–100.0). The femoral artery was adequate for a 9–10 Fr sheath in all patients. All 22 initial implantations were successful with one stent implanted in each patient. The initial coarctation diameter was 3.6 ± 1.9 mm, transverse arch distal to the left subclavian artery was 13.7 ± 2.6 mm and the initial balloon diameter was 10 ± 2 mm, with a balloon:coarctation ratio of 3.4 ± 1.3 and balloon:transverse arch ratio of 0.7 ± 0.1.

In 21 patients, a second balloon dilation of the stent was performed during the same catheterization to approximate the stent to the walls of the aorta proximal to the coarctation. There was significant angiographic improvement with the final coarctation diameter increasing to 12.6 ± 1.9 mm ($P < 0.001$). The final balloon:coarctation ratio was 4.3 ± 1.7 and final balloon:transverse arch ratio was 0.9 ± 0.1. There was a significant reduction in the peak pressure gradient from

29.4 ± 8.5 to 6.7 ± 5.7 mm Hg ($P < 0.001$). There were no immediate complications, in particular, no stent dislodgement and no dissection or aneurysm.

Nine patients in whom the stent had not been dilated to the diameter of the transverse arch underwent further dilation of the stent at a second procedure on average 5 months later. There was reduction in the residual pressure gradient from 12.3 ± 5.8 mm Hg to 2.1 ± 2.9 mm Hg ($P = 0.002$). There was angiographic improvement with the stent achieving the diameter of the transverse arch with no residual angiographic narrowing in all cases.

Complications

One patient with a long segment coarctation had a small tear at the distal stent edge during a further dilation 4 months after initial implantation. The distal edge of the stent was immediately adjacent to the coarctation and this was successfully treated with a second CCPS telescoped into the first stent. One patient had a femoral pseudoaneurysm after the second procedure which spontaneously resolved.

Follow-Up

At median short-term follow up of 18.5 months (1.6–31.4) all patients are alive and well. Of the 22 patients, nine have undergone repeat angiography at a period of 4–6 months after initial stent implantation. In these patients, the stent remains in position with no fracture. There is no recurrence of narrowing and no evidence of dissection or aneurysm.

All patients were hypertensive to some degree prior to stent implantation with four of the older patients on antihypertensive medications. Following stent implantation the previously untreated patients are normotensive and the others continue on medications due to long-standing hypertension.

DISCUSSION

Percutaneous transcatheter interventions for aortic disorders in the adolescent and adult may be advantageous over surgery by obviating the need for the often, difficult, dissection and repair and cross clamping with its inherent dangers [15]. However, these procedures can be limited by the necessity for very large delivery systems that preclude a percutaneous approach. In this study, we report on the initial results in a series of patients with native coarctation who were treated by implantation of a covered CP stent. These implantations were performed with the smallest delivery system possible and then serially dilated to achieve the required diameter. This systematic approach in a series of patients has not been previously reported.

Transcatheter techniques for treatment of native coarctation of the aorta have been reported for over 20 years [16–18]. Balloon angioplasty has been, in the main, initially successful but significant rates of recoarctation and aneurysm formation have called in to question the use of this technique [18]. The use of bare stents in native coarctation has become more common since the technique provides support to the arterial wall by holding the torn intima in place and reduces recoil and recoarctation [1,12,19–21]. The most commonly used stents have been the larger stainless steel Palmaz and Genesis LD stents (Cordis), which can reach maximal diameters of 18 mm or 24 mm and usually require delivery systems of 8–10 Fr or 11–13 Fr, respectively. Aneurysm formation has been reported [7,19] and is more likely to occur, as has been our experience, in cases of severe native narrowings or when calcification is present [19,20]. The requirement for large delivery systems has limited their use to older children and adults and vascular damage to the femoral artery is not uncommon [19]. Further dilation of stents has been achieved to match the growth of the aorta along with the somatic growth of the patient [1,22,23].

Although there are only a few published series of the use of covered stents for coarctation [8,13,14], and there has been no long-term follow-up, this modality could present the best solution. The covered CP stent is a balloon-expandable stent graft which can be dilated to a diameter of 24 mm and thereby provides for the advantages of stent implantation while adding safety by protecting the dilated area with PTFE. The successful use of the covered CP stent has been reported for the treatment of previously treated coarctations with aneurysm and complex native coarctation. A recent series [8] of patients with aortic disease treated with a covered CP stent included 14 patients who had native coarctation. The patients required a 10–16 Fr delivery system and the smallest patient was 28 kg. The procedures were successful and four patients had a second procedure 6 months later.

By employing the approach we described above, with serial dilations with low-profile balloons, stent implantation and initial dilation was often achieved through a 9 Fr sheath, with the smallest patient weighing only 21 kg. The possibility to implant balloon expandable stent grafts through smaller delivery systems is encouraging and in our series there were no instances of femoral arterial damage at stent implantation.

The approach adopted of serially dilating the stent during the implantation procedure and, in nine cases,

further dilation at a second procedure, was employed to prevent excessive dilation of the coarctation in one step. The tissue in the coarcted area is unpredictable in its response to dilation and we felt that a graded approach may prevent acute or chronic vascular damage, and so far this appears to be the case. The effect of serial dilations on the integrity of the PTFE after it has been incorporated in the human aortic wall is not known. Using a small initial balloon diameter may lead to stent slippage at implantation. As mentioned above, the initial balloon diameter was chosen to suffice in anchoring the stent in the coarctation and oppose it to walls of the aorta immediately adjacent to the coarcted segment. The initial balloon diameter was ~3.5 times the diameter of the coarctation and this proved adequate for anchoring and there were no incidences of stent slippage. This was aided by advancing the sheath over the collapsed balloon prior to pulling the balloon out of the stent.

In addition to protecting the dilated narrowing, the stent can also protect the vessel wall in the area of poststenotic dilation, which is a site for aneurysm formation due to the presence of cystic medial necrosis. Therefore, the length of the stent chosen was such that the distal end would reach beyond the narrowing into the area of poststenotic dilatation and this served two purposes. As mentioned above, the covered stent protects the poststenotic area by directing the flow away from the dilated areas and more centrally into the descending aortic lumen. Second, this approach prevents the edge of the stent being in contact with the newly dilated area that may lead to dissection of the aortic wall. This occurred in one patient with long segment coarctation from the mid-transverse arch, involving the origin of the left subclavian artery, to the descending aorta. The edge of the 4.5 cm stent reached just to the most distal edge of the narrowing. During further dilation a small dissection of the wall became apparent and a second covered CP stent was implanted with complete resolution of the coarctation and the dissection. In this patient the left subclavian artery was occluded and flow in the artery was maintained via retrograde flow in the left vertebral artery. Of interest, was that this ''steal'' phenomenon was present on angiography prior to stent implantation. The patient had been asymptomatic prior to stent implantation and remained so after stent implantation.

These initial results show that serial dilation of covered CP stents is a feasible, safe and an effective percutaneous method for the immediate treatment of native coarctation of the aorta. However, further studies and long-term follow-up with imaging are required to determine the effect on the incidence of recoarctation and aneurysm formation.

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