USE OF COVERED CHEATHAM-PLATINUM STENT IN THE TREATMENT FOR COARCTATION OF THE AORTA

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ABSTRACT

Objective: To share our institutional experience of cCP stent (Covered Cheatham-Platinum stent) implantation in children and adults with native and Re-COA (Coarctation of Aorta).
Study Design: A retrospective cross sectional study.
Place and Duration of Study: This study was conducted at Armed Forces Institute of Cardiology/National Institute of Heart Diseases (AFIC/NIHD) Rawalpindi Pakistan, from Jan 2016 to Oct 2018.
Materials and Methods: Retrospective analysis of all consecutive patients who underwent cCP stent implantation for COA was carried out to assess its immediate, short and intermediate term efficacy and safety.
Results: A total of 25 individuals diagnosed with significant COA (native and re COA) with a median age of 18years were enrolled. About 15 were male (M: F, 1.5: 1). 23 pt's had native coarctation and 2 had re coarctation. Mean follow up duration was 14.8 months (range 1 to 29 months). Immediate success was achieved in 100% by significant reduction of pre vs post stenting mean peak systolic pressure gradient (68 mmHg vs 12 mmHg, $p<0.001$) and increase in the mean minimum aortic diameter (3.5 mm vs 12.8 mm, $p<0.001$). Mean systolic and diastolic BP was significantly reduced after the procedure in 18 (72%). Complications occurred in 18 (72%), which included transient pulse loss in 16 (64%) and restenosis in 2 (8%).
Conclusion: Percutaneous CP stent implantation is a very effective and safe intervention for both native and re coarctation in reducing the coarctation gradient and increasing the lesion diameter.

Keywords: Covered cheatham platinum stent, Coarctation, Re-coarctation.

INTRODUCTION

Aortic coarctation is defined as a narrowed aortic segment, most commonly located near the ligamentum arteriosum adjacent to the left subclavian artery[1]. It occurs in 4 of 10,000 live births and represents 5-8% of all congenital cardiac lesions[2] and is the fourth most common lesion requiring surgical or catheter intervention during infancy[3].

COA (Coarctation of Aorta) has a 2:1 male predominance[4]. If left untreated CoA mean survival is 34 years and is associated with high morbidity and mortality[5]. Treatment options include balloon angioplasty, endovascular stenting or surgery[6].

The first successful repair of aortic coarctation was at the Mayo Clinic in 1946 by Dr Crafoord and Nylin[7] which is still a preferred option in neonates or younger children, but recurrent obstruction, aneurysm formation, late hypertension and premature death is always a risk[8].

Balloon dilatation introduced in 1982[9] may produce good results in around 60–75% of the patients but has resulted in high aneurysm rates (7% to 20%) and residual or re-coarctation of aorta[10].

Use of endovascular stents was started in mid 1980's for CHD'S[11] followed few years later by use of balloon-expandable stents in COA[12]. In 1999, the first covered stent was used to treat coexistent CoA and aneurysm of the aorta in a young man[13].

In this study, we aimed to present immediate, short and intermediate term results of our

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experience with covered CP stents in children and adults both in native and reCoA.

MATERIAL AND METHODS

In this retrospective analysis 25 patients (23 native and 2 re-coarctation)underwent stent implantation. CoA was defined as the presence of systemic hypertension with an upper to lower-limb systolic blood pressure (BP) difference >20 mm Hg, which was confirmed by echocardiography, computed tomography (CT) angiography or aortography. Patients with long segmental coarctation, hypoplasia of aortic arch, patients under 10 years of age or those with a body weights <30 kg were excluded from the study. Hypoplastic Transverse aortic arch (TAA) was termed hypoplastic if ratio of TAA (mm) and descending aorta at the level of the diaphragm (mm) is <0.6.

Patients data (demographic, echocardiographic and angiographic) before and after the procedure was analysed retrospectively. Study protocol was approved by the Ethics Committee of AFIC/NIHD.

Procedure / Stent Implantation Technique

Informed written consent prior to the procedure was obtained from the patients or parents. This was performed by at least 2 experienced paediatric cardiologists under general anaesthesia in 10 pt's and under conscious sedation with local anaesthesia in 15 pt's (with anaesthesia back up) under fluoroscopic guidance in the cardiac cath lab.

In all procedures covered Cheatham-Platinum stents (cCP) (NuMed, Hopkinton, New York) was used but choice of balloon varied depending upon severity of coarctation segment and availability. Length of the stent was based on the distance between the left subclavian artery and at least 15 mm distal to the coarctation site. Balloon was selected according to transverse arch diameter but not exceeding descending aorta diameter at level of diaphragm.

Heparin 100IU/kg body weight (maximum 5000 IU) and one dose of prophylactic antibiotic was administered before introducing delivery sheath.

Femoral artery access was used in all except one pt in whom left carotid approach was required to cross the stenotic segment but continued via the femoral approach after snaring the wire. Coarctated aortic segment was crossed with MPA 2 or Judkins right coronary catheter (Cordis Corporation, Miami, Florida) over 0.035 inch straight tip terumo exchange wire. Pre and post coarctation aortic pressures were recorded. Aortography in left oblique projection (LAO 30-lateral (LAO 90) and anteroposterior projections was performed with pigtail catheter to profile the lesion.

Balloon-expandable cCP stent was 1st hand crimped onto the balloon between two already set black markers and further augmented by looping silk thread. Final deployment was done over amplatzer super stiff exchange wire already parked in the ascending aorta or the right subclavian artery by inflation of the balloon catheter up to recommended maximum pressure as shown in the figure. In few pt'scCP stent was manually uncovered partially before crimping on balloon to avoid left subclavian artery obstruction.

Procedure was declared successful if post procedure pressure gradient across stented segment was <20 mmHg and the narrowest diameter increased to at least >50% of the normal adjacent aortic arch vessel in the absence of stent migration or aortic dissection. Manual compression was done to secure haemostasis.

Pt was given IV heparin (50 IU/kg) 6 hrly for 24 hrs and discharged on dual antiplatelet for 6months post procedure. Anti-hypertensive drug treatment usually was continued for 1 to 4 months even if the BP normalized, with restriction for competitive sport or strenuous exercise. Follow-up at 1, 3, 6, and 12 months and yearly thereafter was done. During follow-up, complete physical examination including BP was recorded and echocardiography was done. CXR was done in case of suspected stent migration

and CT Scan was performed only if there was suspicion of re-coarctation or aneurysm on TTE.

Our primary endpoint was re coarctation (arm-leg BP difference >20 mm Hg and >20 mm Hg PG across the stented segment on TTE or invasive gradient measurements by cardiac catheterizatiion and >10% of the stent lumen obstruction within the stent on CT angio).

Secondary endpoints were mortality, pseudoaneurysm, obstruction of left subclavianartery, dissection of aorta, stent migration and post-CoA syndrome.

Satistical Analysis

Descriptive statistics was used to describe data such as mean (SD), median and n (%). Wilcoxon test was used for pre and post stent placement comparison of pressure gradients and diameters. $p<0.05$ was considered statistically significant. Statistical analysis was performed using SPSS 13.0 (SPSS Inc., USA).

RESULTS

Our pt's mean age was 20 ± 7.94 years (range 10 to 48 years) and their mean weight was 49.31 ± 13.22 kg (range 35 to 90 kg). 15 (60%) were males, 13 (52%) were 18 years or below and one pt was >40 years old (48 years). 11 (44%) had near atretic coarctation (3mm or less dia). Of those with aortic re-coarctation, one had primary surgical repair with subclavian flap aortoplasty before stenting and the other had stent restenosis. None of our pt's had PDA or was syndromic (Turner, Marfan).

Overall we managed to increase COA diameter from 3.54 ±1.65 mm to 12.8 ± 2.19 mm ($p<0.001$) and pressure gradient across the CoA site decreased from 68.77 ± 28.55 mm Hg to 11.83 ± 7.60 mm Hg ($p<0.001$). Mean procedural time was 50.63 ± 13.40 mins, Mean fluoroscopy time 14.1456 ± 5.74 mins. Mean balloon size used was 14.280 ± 2.26 mm (Range 12 to 18 mm) and Mean stent size used was 35 mm (Range 28 to 45 mm) via mean delivery sheath size of 11.5mm (Range 9 to 14 mm). Osypka VACS III balloon was used in 14 pt's (56%) and BIB in 8 pt's (32%) depending on availability. In 3 (12%) younger pt's (10-12 years) a relatively softer balloon, Osypka VACSII balloon was preferred.

The procedures were successful in 100% of patients. The only procedure related complication encountered was transient pulse loss noted in 16 pt's (64%). Heparin IV infusion was needed in only 4 pts (16%). We were able to discharge 22 pt's(88%) after 24 hrs and 3 pt's (12%) after 36-48 hrs of hospital stay. Mean follow up duration was 14.8 months (range 1 to 29 months).

Systolic and diastolic mean BP was significantly reduced after the procedure in 18 pt's (72%) and then at 1and 3 months at the end of follow-up from values before intervention ($p<0.001$). Seven pt's (28%) were able to reduce their medication dose and 11(44%) discontinued it as their BP remained persistently within normal range. 5 pt's out of 11 (45.4%) with near atretic coarctation continued on anti-hypertensives as compared to 5 (35.7%) who had coarctation diameter >3mm before stenting. Seven pt's (53.8%) in 18 years or below group were off medications after stenting as compared to 6 (50%) in above 18 years group. 6 (60%) female needed anti hypertensives as compared to 8 (53.3%) males after coarctation stenting.

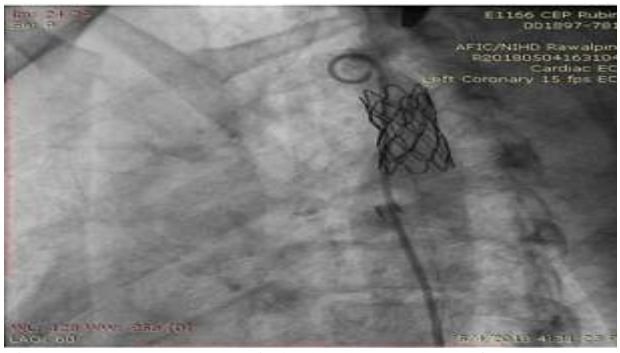

Figure: Post successful deployment of cCP stent with some residual waist. PG across the stent being checked with PG catheter.

During followup re coarctation was seen only in 2 pt's (8%), between 24 to 30 months after stent implantation confirmed on CT angio to be secondary to stent stenosis because of intimal hyperplasia and currently planned for balloon-

ing. Both were <18 years old and had balloon: coarctation ratio >3.5. One pt had near atreticcoarcted segment and had prior surgery done before stenting. Two pt's who had PG >20 mmHg still need anti hypertensive medications but their CT angio showed patent stent with no evidence of intimal hyperplasia.

None of our pt's has yet experienced any other complications like aortic rupture, dissection, bleeding, haematoma, stent migration/ embolisation,stent fracture, aneurysm, pseudoaneurysm formation, post coarctation syndrome, cerebrovascular accident or death during the procedure or follow up period.

DISCUSSION

Both covered and uncovered stents have been in use for aortic coarctation inpaediatric and adult age group. Covered stents are usually reserved for those considered to be high risk, pt's with post ballooning or bare metal stent aortic wall injury or physician preference[14,15]. Balloon-to-coarctation ratio >3.5 and prior balloon dilatation are the most important known factors leading to aneurysm formation[15,16].

The most widely used covered stent is the Covered Cheatham- Platinum stent (cCPS) (Numed - Hopkinton, USA) which is 90% platinum and 10% iridium. It's e-PTFE membrane covering prevent acute AWI[17].

In our series, cCP stent was used electively in all patients. BP reduction was a major aim as hypertension can lead to significant morbidity and mortality[5]. Post coarctation stenting antihypertensive medications can be reduced or even discontinued in 18% to 88%[18,19] which was also seen in our pt's as continued antihyper-tensive treatment in unchanged dose was required in only 7 (28%). Decrease of BP was not associated with balloon coarctation ratio or percentage of improvement in diameter of coarctation segment. Our results are comparable with experience of several others. Chang *et al* has reported normotension in 84%[20]. In our study normotensive population increased to 72% leading to reduction or discontinuation of medications as compared to Tzifa *et al* who saw this increase from 43 to 70%[18], Sohrabi *et al*[21] from 14 to 77.2%[21] and Chamie *et al* from 21.4 to 57.1%[22]. Our data also confirms that COA is a systemic cardiovascular disease rather than just narrowing of an aortic segment because innate morphological and functional changes in the arterial wall can result in a more rigid or less complaint arterial wall leading to persistence of hypertension even after successful stenting of coarctation[23,24].

Bare-metal stent has resulted in AWI (rupture, dissection) in 1.0% and 4.1% which is significantly lower than balloon angioplasty or surgery 16 25 26 27 28. Aortic wall dissection or rupture following cCP stent is reported in 3.3% by Sohrabi *et al*[21] and by others as well 15 29 30. Late aneurysm after covered stents was seen in two patients (14.2%) by Chamie *et al*[22] because of strut fracture which usually occurs after enthusiastic manipulation of terumo wire but none by Chang *et al* 20, COAST II trial 27 28 and Tzifa *et al*[18].

In our study we used cCP stents electively very successfully without encountering any cases of acute AWI or pseudo aneurysm in the followup so far, although our mean Balloon/ COA ratio was 4 (±SD 1.36) but none of our pt underwent pre stent angioplasty. This was also experienced by Chang *et al*, in whom series the post procedure to pre procedure coarctation diameter ratio was 7.0 (median 4.2).

Serial stent dilatation is also suggested by some but in our experience single session maximum dilatation is very effective like Sohrabi and colleagues[21].

Complications like malposition, migration and embolization of stent is usually due to larger balloons (>2 mm than proximal aorta diameter), under sized balloon catheter, or rupture of balloon[31,32].

Covered stent migration can result in occlusion of side branches (e.g., spinal, celiac, superior mesenteric, renal arteries, innominate or left common carotid artery) which can result in severe complications[18-20,28] although accidental covering

of left subclavian artery in the presence of intact vertebrobasilar system and absence of carotid or vertebral artery stenosis is tolerated well[33]. Spinal artery occlusion although rare (1-4%)[34] because in >90% it arises below ninth thoracic vertebra but can result in significant functional deficit[35].

In our series we didn't experience any side branches occlusion this is in accordance with finding of Chamie *et al*[22], Sohrabi *et al*[21], Chang *et al*[20], COAST II trial[27,28], Tzifa *et al*[18]. Use of BIB balloon also played a role because its stability and easy control during the procedure[31-36,37].

Restenosis after stent placement is less frequent (2.7-14.9%)[16,38] than after balloon angioplasty alone (13-31%)[39] resulting from neointimal pro- liferation, stent fracture, stent recoil and growth. In our experience 2 of our pt's (8%) had re-coarctation, one had primary surgery done for COA before initial stenting and the second had near atretic coarctate segment currently planned for balloon dilatation of covered stents as surgery is technically more difficult and risky in re coarctation cases[40].

Post stenting cerebral vascular accidents are rare (<1%)[32]. None of our pt had CV accidents in the acute or later FU.

Femoral access and use of larger sheaths[41] can lead to haematoma formation or limb ischaemia. Vascular closure devices can reduce its risk. Arterial access injuries were the most important acute complications seen in COAST II trail. We had low incidence of vascular access complications as transient pulse loss noted in 64%[16] but IV heparin infusion was needed only in only 16%[4].

We didn't experience any procedure related mortality in our study although death is reported in 0% to 1.4% after bare metal stenting[42].

CONCLUSION

Elective implantation of cCP stent for native and re-coarctation is very safe and effective for both adolescents and adults. Use of CCPS hasnot only a technical edge but is associated with reduced risk of significant complications. A longer follow up will define its efficacy and potential complications in a much better way. Re dilation of covered stents remains an area to ponder upon needing further studies to encourage their elective use in children.

LIMITATION OF STUDY

Our limitations were a cohort of small no of patients with a medium term followup, non availabilityof BPholter monitoring and failure to check BP response during exercise after coarctation stenting.

CONFLICT OF INTEREST

This study has no conflict of interst to be declared by any author.

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