Is the Coast Clear for Stent Angioplasty of Coarctation?

**Running title:** Khambadkone; Stenting of coarctation

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Coarctation and re-coarctation of aorta have been treated successfully with endovascular therapy including balloon angioplasty or stent angioplasty for over three decades.\(^1\),\(^2\),\(^3\),\(^4\) After successful surgical repair reported by Craafoord,\(^5\) the concept of angioplasty in the coronary arteries by Gruntzig\(^6\), opened up a new strategy of treatment of native and recoarctation.

Balloon angioplasty was successful in relieving the obstruction but the long term results were disappointing with the recurrence of obstruction and incidence of aneurysm formation in the earlier studies\(^7\),\(^8\). This was soon abandoned in infants and young children to make way for improved acute and intermediate outcomes from surgery that included techniques such as end – to – end anastomosis, extended end to end anastomosis, subclavian flap repair, patch angioplasty and interposition grafts for complex coarctation\(^9\).

The basic principle of disruption of the aortic wall with a tear in the intima extending to the media remains the mechanism of relief of coarctation.\(^10\) Over time, stent angioplasty became a natural progression of an endovascular interventional strategy. The stent apart from reducing the risk of recoarctation, also arguably, reduces the risk of aneurysm formation by apposing the disrupted intima at the site of the coarctation.\(^11\) With the advent of stent angioplasty, the material properties and stent designs and their advantages and disadvantages became an important topic for discussions, publications and research. The balloon expandable stainless steel slotted tube stents were first to be used as off label devices in aorta, when primarily designed for renal and peripheral interventions.\(^12\) Although the acute hemodynamic results were acceptable, the risk of aortic aneurysm formation, early or late, aortic disruption or rupture remained a major risk.

Also, at larger diameters these stents shorten to greater than 20 %. The double strut design was then considered to be a better design that would not shorten and be flexible to go around curves. The strength of this design however was not good enough to withstand the
compressive stresses.

The Cheatham-Platinum (CP) stent has a unique design with platinum-iridium wires welded together rather than slotted stainless steel tubes. The rounded edges of these wires are less traumatic to the edges of the vessel that is stented. It was designed to be used in large vessels such as the aorta and to allow for dilatation to larger dimensions with limited shortening.\textsuperscript{11}

Against this background, the accompanying report by Meadows and colleagues\textsuperscript{13} in this issue of Circulation describes intermediate outcomes for the COAST trial patients. In the previous iteration, the investigators reported the acute hemodynamic results after use of a CP stent for native and re-coarctation.\textsuperscript{14} There was the expected improvement in the diameter of the aorta, gradient across the coarctation, and upper and lower extremity blood pressure gradient. The complication rates as defined as adverse events were higher probably due to prospective nature of the trial compared to a previous study by the Congenital Cardiovascular Interventional Study Consortium (CCISC).\textsuperscript{15} However, the procedure related events are acceptably low. The occurrence of aneurysms or tears described as aortic wall injury (AWI) is interesting considering that a compliance testing with a low pressure balloon (2 – 4 atm) led to this injury and exclusion and transfer to the COAST II trial with covered CP stent.\textsuperscript{13}

The intermediate outcome over a period of 2 years with 86 % follow-up shows sustained improvement of upper and lower extremity gradients. At 1 year follow-up, 19% remained hypertensive and 28% continued to receive antihypertension medications, that remained unchanged at 2 years. For a median age of 16 years and a wide range of ages within the cohort, it is difficult to draw any conclusions on the risk of persistent hypertension and the use of medications. One of the commonest late sequelae of coarctation itself rather than its treatment strategy is systemic hypertension. Unless a selected group of patients is followed-up
meticulously for a long term, we may never have an answer to whether surgery or catheter intervention provides better relief from late systemic hypertension.

The fact that four patients who were thought to have minor vascular injuries, that were further confirmed as so by the core laboratory, ended up having a covered CP stent further highlights the low thresholds that operators have, to use covered stents to prevent the progression of such a lesion. The current practice in most European centers to use a covered stent for interventional treatment of coarctation in patients more than 30 kg also emphasizes this concern. With such low incidence of major aortic wall injury with the use of bare metal stent, it will be difficult to show a clear superiority of the covered CP stent, in the current era of stent angioplasty of coarctation.

Indeed this was clearly shown in the recent study by Bahrami and colleagues who randomized 120 patients with native coarctation to receive a bare or covered CP stent with successful relief of obstruction in all patients. There was a small increased risk of recurrent obstruction in the bare CP stent group and paradoxically the only patient who had aortic wall injury was in the covered CP stent group. Although CT scan was used to look for aortic wall injury 6 months after the procedure, they did not look for incidence and severity of stent fractures. Various other reports of stent angioplasty for coarctation that include the use of CP stents covered and bare, show very good relief of obstruction and low incidence of aortic wall injury. Similarly, in the accompanying report, it remains to be seen whether a covered stent would be necessary for all coarctations, nevertheless, the report serves the purpose for showing the safety and outcome of the CP stent for angioplasty.

One of the concerns of end to end anastomosis type repair is the growth of the transverse arch. Although earlier papers reported adequate growth after relief of coarctation, long term
follow-up is disappointing.\textsuperscript{17,18} Furthermore, the incidence of hypertension in patients with mild to moderate hypoplasia of the transverse arch is a cause for concern.\textsuperscript{19} Stent angioplasty of coarctation in principle deals with the discrete obstruction in the proximal descending aorta. The transverse arch being a hypoplastic arterial segment between the two carotids is tiger territory for interventional cardiologists. Also, late presenting native coarctations have variable underdevelopment of the transverse arch related to the asymmetric collateral development from the subclavian arterial systems. This would remain one of the greatest limitations of stent angioplasty as a treatment option of coarctation in older children and adults.

Whether a more aggressive strategy of transverse arch augmentation during neonatal surgical intervention would improve the transverse arch in the long term remains to be seen. Also, the potential calcification or stiffening of the material used to enlarge the arch and its impact on aortic wall properties needs to be borne in mind. Similarly, the impact of a stent in an aortic segment may also contribute to altered aortic wall properties.

The safety and efficacy of stent angioplasty for native and re-coarctation is well documented in various clinical studies of different designs. The important questions about the best strategy to reduce the life time burden of systemic arterial hypertension and its consequent sequelae will need meticulous long term follow-up data. Sadly, in the field of congenital cardiology, this remains one more area where we have hastened to draw conclusions from relatively short term data for a disease that has life time manifestations with a major impact on survival.

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References:


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