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Editorial

Stents in the Management of Heart Disease in Children

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The editorials in previous issues of this Journal [1,2] addressed balloon valvuloplasty and angioplasty in pediatric practice and percutaneous occlusion of cardiac defects nchildren. In this editorial, the use of stents in the management of heart disease in children will be reviewed.

Percutaneous, transluminal angioplasty while effective in relieving vascular obstructive lesions in most cases, it does have limitations in that elastic recoil of vessel wall and intimal dissection may produce ineffective relief of obstruction. Stents exert radial forces to prevent elastic recoil of the vessel wall and may also compress dissection flaps against vessel wall, thus producing more effective relief of obstruction. Stents may also be helpful in keeping open naturally occurring lesions (for example ductus arteriosus or foramen ovale) or surgically created connections (for example Blalock-Taussig shunt).

Although the concept of stents was introduced by Dotter and his colleagues in 1960s, it is not until introduction of stainless steel mesh stents by Palmaz in 1980s did the stent technology became a reality. Clinical studies in late 1980s and early 1990s demonstrated that the stents are useful in the management obstructive lesions of coronary, iliac and renal arteries in adults. Application of the stent technology to pediatric patients followed [3].

Stents are classified based on the delivery mechanism, composition and configuration of the stent. Balloon-expandable and self-expandable types are available; balloon-expandable stents, mounted on balloons may be positioned across the site of obstruction and implanted by inflating the balloon. The diameter of the balloon determines the expanded diameter of the stent. This is the most commonly used stent in children because these stents may be further expanded to meet the needs of a growing child. Self-expandable stents on the other hand are restrained within a covering sheath and after positioning the stent in the desired location, withdrawal of the sheath uncovers the stent; the stent then assumes its original shape. Because of anticipated growth in children, self-expandable stents are used in a very limited manner in children. Stainless steel (316L) is the most common metal utilized in stents although platinum-iridium, Nitinol, cobalt-based alloys, titanium and tantalum have also been used. Because of lack of growth of stented segments, biodegradable materials may offer advantage. However, these are not currently available for pediatric patients. While several varieties of stent designs have been used, including slotted tube, mesh, coil-loop and ring; the slotted tube design or its variations are used in the majority of stents in clinical practice.

The usefulness of stents in treating obstructive lesions of the branch pulmonary arteries [4,5], systemic [6,7] and pulmonary [8] veins, aorta [9] and right ventricular outflow conduits [10] and maintaining the patency of ductus arteriosus [11-13], stenotic aorto-pulmonary collateral vessels [14,15] or surgically created but obstructed shunts [15,16] has been demonstrated. Extensive review of the techniques and results may be found in our previous publications on this subject [17-22].

Obstructive Lesions

Branch pulmonary artery stenosis

Because of poor results associated with surgical and balloon

angioplasty of stenotic pulmonary arteries (PAs), balloon expandable stents introduced by Palmaz et al. [23], have been rapidly adopted [3,4,17,22,24-26] in their management. The indication for intervention [19,26] in unilateral obstructions is ipsilateral lung perfusion \leq 35% on quantitative pulmonary perfusion scans and in bilateral obstructive lesions a right ventricular peak systolic pressure equal to or greater than 50% aortic systolic pressure. These criteria may be relaxed in the presence of pulmonary insufficiency. Long-segment lesions and older children are preferred for stenting whereas infants and younger children and discrete lesions may be dealt with balloon angioplasty alone.

Reduction in peak systolic pressure gradient across the branch PA sites, improvement in vessel diameter and better perfusion to ipsilateral lung were seen have following stent placement. Results from initial experience with stents in branch PAs is tabulated elsewhere [19] for the interested reader. Advances in the technique over the past two decades helped in reducing the profile of stent delivery sheaths and reduced the complication rate. Follow-up results are usually good, and re-dilation of the stent can be performed if restenosis occurs. Reduction in right ventricular (RV) to aortic pressure ratio in patients with biventricular circulation and increase in quantitative pulmonary perfusion by lung scans in unilateral branch PA stenosis are good indicators of success. Implantation of stents to relieve branch PAs is feasible, safe and effective. Currently intravascular stents are the chief mode of treatment for branch PAs inmost pediatric cardiology programs.

Coarctation of the aorta

Problems associated with surgical and balloon therapy of aortic coarctation promptedacceptance of stent therapy over the last two decades [9,19,22,26-49]. The indications for use stents are: 1) long segment coarctation, 2) associated hypoplasia of the isthmus or aortic arch, 3) tortuous coarctation with misalignment of proximal with distal aortic segment and 4) recurrent aortic coarctation or an aneurysm following prior surgical or balloon therapy [19]. Because the stents do not grow as children grow, most cardiologists limit use of stents to adolescents and adults. However, some cardiologists [50-53] advocate stents at early age. However, Ipersonally do not advocate use of stents in young children with aortic coarctation [21,54].

Reduction of peak systolic pressure gradient and increase in the diameter of the coarcted segment are seen following stent deployment. In the initial series of 10 patients reported by Suarez de Lezo in 1995 [9], the peak systolic pressure gradient across the coarctation site

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decreased (43 \pm 12 vs. 2 \pm 3 mmHg: p<0.001) and the ratio of isthmus/ descending a orta improved from 0.65 \pm 0.14 to 1 \pm 0.08 following the stent procedure. Similar results have been reported later by other investigators [9,19,22,26-49]; results from initial series aretabulated elsewhere [19] for the interested reader. Stentdeployment was found effective in native coarctation as well as post-surgical and post-balloon recoarctation.Complications such as vessel disruption, displacement of stent, balloon rupture, loss of pulse, bleeding from puncture site and aneurysms have been reported, but are uncommon. The follow-up was incomplete in that it involved a limited number of patients and the duration of follow-up was short in most studies. Nevertheless, in some studies [33,35,37,48] the results of more than 20 patients at a mean follow-up of 2 years or longer were scrutinized. The systolic pressure gradients across the coarctation site remained low and systemic hypertension improved both in frequency and magnitude with resultant decrease in antihypertensive medication use. No evidence for significant rate of recoarctation, aneurysmal formation or stent fracture/ displacement was observed, although no systematic or complete followup was achieved in the most studies. Residual or recurrent obstruction was present in a few patients and re-dilatation with larger balloons was successful.Suarez de Lezo et al. [33] performed detailed angiographic studies which revealed no detectable neointimal proliferation in 75% patients. In the other patients focal neointimal ridge formation was observed at ends of the stent causing mild restenosis. Segmental analysis of the aorta [33] revealed increase in non-stented portions of the aorta suggestive of normal growth.

Stent therapy is emerging as an attractive technique for management of native coarctation, post-surgical recurrent coarctation or aneurysm formation followingsurgical or balloon treatment as well as for long segment hypoplasia; this is particularly applicable for the adolescent and adult. Use of balloon-in-balloon (BIB) catheters to implant the stents is likely to reduce the complications. That the obstruction can be relieved both acutely and at follow-up is well shown in several published studies. The rate of recoarctation at follow-up is low and if that happens, re-expansion of the stent to address residual or recoarctation and growth related narrowing, appears feasible, safe and effective. Based on the currently available data, stent therapy foraortic coarctation is a preferred alternative to surgical or balloon treatment in the adolescent and young adult.Covered stents may have utility in highly selected patients with aortic coarctation, but are not currently approved in the US for addressing aortic coarctation.

Right ventricular outflow conduits

Obstruction may develop in bioprosthetic RV-to-PA conduits and this is thought to be secondary to calcific degeneration. This may necessitate surgical replacement of the conduit [55]. Balloon dilation may produce some improvement with nominal extension of the life span of the conduit, as reviewed elsewhere [55]. Therefore, several groups of cardiologists advocate use of stents to relieve these obstructions [10,24,56-61]. Potential for obstruction of the coronary arteries [62,63] during stent placement should be recognized and avoided. The indications for stent deployment that we use are elevated right ventricular systolic pressure >50% of systemic systolic pressure and/ or right ventricular dysfunction. We continue to use balloon dilatation [55] in infants and young children initially and if not successful, stent may be implanted. The reason for this type of palliation is to postpone surgical replacement of the conduit.

Fall in peak systolic gradient, increase in conduit stenosis diameter

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and prolongation of conduit life span for varying time periods has been observed by most investigators [10,24.56-61]. It would appear that stent therapy is useful in prolonging the life of the RV/PA conduits and should be undertaken in an attempt reduce total number surgical replacement of the conduits.

Stent therapy to open up: 1. native right ventricular outflow tracts of tetralogy of Fallot patients in the premature babies and young children as a bridge to later corrective surgery [64-66] and 2. Sano shunt obstructions in hypoplastic left heart syndrome babies [67-69] may accrue benefit to these infants. However, the practice with such interventions is limited. I will not address trans-catheter delivered pulmonary valve replacement [70-72] in this editorial.

Other lesions

While the experience is limited the stents have been utilized to address several other cardiac anomalies: 1. obstructed systemic veins after surgery such as atrial switch (Mustard or Senning) procedures for transposition of the great arteries, classical or bi-directional Glenn anastomosis, correction of partial anomalous pulmonary venous connection and cardiac transplantation or those that develop after trans-venous pacing leads or prolonged use of indwelling catheters and those that occur secondary to malignancy and radiation, 2. congenital pulmonary vein stenosis or pulmonary venous stenosis that develop after cardiac surgery such as Mustard or Senning procedures for transposition of the great arteries or repair of total anomalous pulmonary venous connection and 3. obstruction of ilio-femoral venous system.

Patency of Natural or Surgically Created Shunts

Stents have been found to be useful in maintaining patency of naturally occurring structures or surgically created but obstructed shunts. The ductus may be kept patent in the neonate with reduced pulmonary blood flow such as pulmonary atresia with intact ventricular septum, critical pulmonary stenosis and other complex heart defects withdeceased pulmonary blood flow [11,12,73]. The ductus may also be kept open in hypoplastic left heart syndrome patients either as a bridge to transplantation [13] or as a part of hybrid procedure as an alternative of Stage I Norwood procedure [74]. Similarly a markedly restrictive foramen ovalemay be kept patent in hypoplastic left heart syndrome or mitral atresia cases. Creation of an atrial septal defect by stenting the atrial septum in severe pulmonary hypertension cases, again as a bridge to transplantation may be useful. The pulmonary blood flow may be augmented by stenting stenotic aortopulmonary collateral vessels in patients with tetralogy of Fallot with multiple aorto-pulmonary collateral arteries and severe pulmonary oligemia [14,15]. Stenotic or completely occluded surgically created aorto-pulmonary shunts [16] such as Blalock-Taussig or Sano shunt may be re-opened by implanting stents into them.

Future Directions

Use of stents in infants and young children with aortic coarctation is not advisable because of growth issues. Development of biodegradable stents [75] which dissolve with time or growth stents [76] that can be re-expanded is likely be beneficial in addressing optimal treatment of infant coarctation and should be investigated in future studies.

Implantation of stents in pulmonary venous stenotic lesions is fraught with problems because of development of stenosis of stents and therefore use of drug-eluding stents/balloons (impregnated with drugs such as paclitaxel) may impede neo-intimal proliferation [77,78]. Studies to test this concept should be undertaken.

Finally, hybrid procedures to use of ductal stents along with surgical bilateral branch pulmonary artery banding in the palliation of hypoplastic left heart syndrome [74] and staged surgical-catheter approach [79,80] to accomplish staged Fontan need further study.

Conclusions

The efficacy of stents in the management of vascular obstructive lesions not responsive to balloon angioplasty is well accepted. The feasibility, safety and effectiveness in successfully addressing branch pulmonary artery stenosis, aortic coarctation, right ventricular outflow tract conduits and systemic venous obstructive lesions have been validated. Stents may be useful in maintaining patency ofductus arteriosus and foramen ovale and surgically created aortopulmonary shunts.Newer generations of stents and simplified technique of implantation of stents have reduced complications. Stent therapy for pulmonary venous obstructive lesions,addressing growth related issues in children with biodegradable and growth stents and role of stents in hybrid procedures need further investigation.

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