

Transcatheter Stent Therapy in Children: An Update

Raj Sahu¹ and P. Syamasundar Rao^{1*}

Department of Pediatrics, Division of Pediatric Cardiology, The University of Texas-Houston Medical School/Children's Memorial Hermann Hospital, Houston, TX, USA

Abstract

To address elastic recoil of vessel wall and intimal dissection that can follow balloon angioplasty, stents have been designed and these appear to produce more effective relief of obstruction. Of the two types of stents, namely, balloon expandable and self expandable, balloon expandable stents are most commonly used in children. The usefulness of stents in the management of vascular obstructive lesions not amenable to balloon angioplasty is well established and has been successfully used to treat branch pulmonary artery stenosis, coarctation of the aorta, stenotic right ventricular outflow tract conduits, obstructive lesions of the systemic and pulmonary veins and others. The techniques of implantation, indications, immediate and follow-up results and complications were reviewed. The stents have also been effectively used in keeping open naturally occurring or artificially created inter-circulatory connections and as adjuncts in hybrid procedures, but these have not been discussed in this review. Future directions include investigative work on biodegradable stents and growth stents to address issues related to increase in vessel size in infants and children, use of drug eluting stents to prevent neo-intimal proliferation to avoid pulmonary vein restenosis and refinement of stent technology in hybrid procedures such as neonatal palliation of hypoplastic left heart syndrome and transcatheter completion of Fontan procedure. The feasibility, safety and effectiveness stents in the pediatric population are demonstrated, although scrutiny of results of larger experience with longer follow-up is important.

Introduction

Percutaneous balloon angioplasty has been proven effective [1]; however, elastic recoil of vessel wall and intimal dissection can result in ineffective relief of obstruction in some cases. Stents, by exerting radial forces, prevent elastic recoil and compress dissection flaps against the vessel wall, thereby produce more effective relief of obstruction.

Dotter and Judkins [2] while exploring balloon angioplasty in the 1960s introduced the concept of stents. Later that decade, Dotter [3] implanted a spiral, coil-spring prosthesis to expand experimental vascular stenotic lesions. The stent concept remained dormant until early 1980s when self-expanding double helical spiral stents were implanted in animal models [4]. In the mid-1980s, Palmaz et al. [5] designed stainless steel stents to address atherosclerotic lesions in rabbits. Subsequent clinical studies showed the stents to be successful in subjects with obstructive lesions of coronary, iliac and renal arteries [6-9]. Mullins, O'Laughlin et al. [10,11] introduced endovascular stents into pediatric practice. Stents were used to treat obstructions in pulmonary arteries, systemic and pulmonary veins, aorta and right ventricular outflow tract (RVOT) conduits [12-18]. They were also utilized to maintain patency of ductus arteriosus in pulmonary atresia and hypoplastic left heart syndrome [19-21], stenosed aorto-pulmonary collaterals [22,23] and surgically created but obstructed shunts [23,24]. Furthermore, stents are particularly helpful in accessing places inaccessible in conventional surgery.

In this report we will review the types of stents used in clinical practice, techniques of implantation, and results of stent use in selected congenital heart defects as well as future directions in stent therapy.

Types of Stents

Stents are categorized depending on the mechanism of delivery, the material used to construct the stent (composition), and its configuration.

Delivery mechanism

Two types of stent delivery options, namely balloon expandable (Figure 1) and self expandable (Figure 2) are currently available. In the balloon expandable version, the stents are mounted on balloons

either by the manufacturer (premounted) or by the interventionalist, immediately prior to implantation. Once the stent/balloon assembly is positioned across the obstructive lesion, inflating the balloon results in implantation of the stent. The balloon diameter over which the stent is mounted determines the diameter of the implanted stent. The first available stent for use in children was the balloon expandable Palmaz stent [10,11]. A number of other types of stents have since become available and include, Bridge [25], Cheatham-Platinum [26], IntraStent DoubleStrut [27,28], Corinthian [28,29] and others [28,29]. Today the most commonly used stents include Genesis XD, premounted Genesis, Mega LD, Max LD and ev3 LD. Although the early versions of the Palmaz stent and the DoubleStrut stents are still available, they have

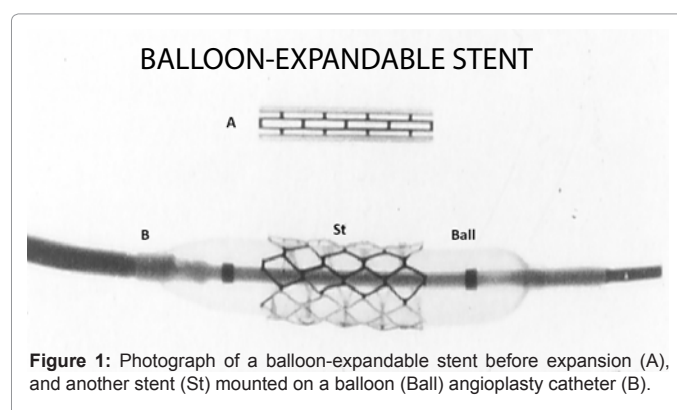


Figure 1: Photograph of a balloon-expandable stent before expansion (A), and another stent (St) mounted on a balloon (Ball) angioplasty catheter (B).

***Corresponding author:** P. Syamasundar Rao, MD, Professor and Emeritus Chief of Pediatric Cardiology, University of Texas-Houston Medical School, 6410 Fannin Street, UTPB Suite # 425, Houston, TX 77030, USA, Tel: 713-500-5738; Fax: 713-500-5751; E-mail: P.Syamasundar.Rao@uth.tmc.edu

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mostly been replaced by the Genesis, Mega LD and Max LD stents. Balloon expandable stents are the most commonly used stents to date, especially in children. These balloon expandable stents can be further dilated at a later date, however self expandable stents cannot be.

In contrast, self expandable stents [18,30] are constrained by a covering sheath (Figure 2) and after positioning and withdrawal of the covering sheath, the stent assumes its original shape. Once in place, further expansion of the size of the stent is not possible. Because children grow, self expandable stents have limited use in pediatric practice. In addition, there is evidence that there is a greater degree of intimal proliferation in self expandable stents [31,32]. For these reasons, self expandable stents are not usually selected for use in children.

Composition

The stents are mostly made of metals that impart radial strength. Stainless steel is the most common metal utilized in most stents. Other materials such as tantalum, platinum, titanium, as well as alloys (cobalt-based and nickel-titanium) are also used to construct the stents. Stents made of these metals remain within the vessel wall and get incorporated into the wall and do not have the potential to grow. Biodegradable stents [33-35] may address these concerns. Characteristics of ideal biodegradable stents would be: 1) offer sufficient radial strength to prevent vessel recoil, 2) do not induce inflammatory or thrombotic response, 3) reabsorbed within weeks to months and 4) breakdown products are not toxic. Several types of biodegradable stents have been used in animal models and adult subjects, but there is limited use in children [36].

Configuration

A number of stent designs have been used to date. Slotted tube designs or their variations are used in the majority of stents in clinical practice although mesh, coil-loop, and ring designs are used in the some stents.

Comments

Virtually all currently used stents in children have not been approved for vascular lesions in children and consequently their use is often on an off-label basis. Choice of stent depends on the age and size of patient, expected adult dimensions of the vascular structure, morphology of the lesion, future surgical procedures as well as previous procedures.

An ideal stent, in our opinion, should have the following characteristics: 1) low profile to be delivered through small delivery sheaths, 2) easily crimped, or available pre-mounted, 3) rounded, atraumatic edges, 4) high degree of flexibility for placement around curved structures, 5) low degree of stent shortening during expansion, 6) high radial force to keep tight and scarred lesions open, 7) probability for re-expansion to adult size, 8) open cell design, 9) MRI compatible, 10) low risk of neo-intimal proliferation and 11) biodegradable material to minimize tissue reaction and maximize tissue remodeling. Unfortunately all these features do not exist in any currently available stents.

Method of implantation

Many of the stents employed are of off-label use, thus informed consent of the patient/parent, as appropriate is of paramount importance. The procedure can be performed under conscious sedation or general anesthesia, but this is usually institutional dependent. Cardiac catheterization along with selective cineangiography is performed first to confirm clinical and echocardiographic diagnosis, and to exclude other defects. Pressure gradients across the obstructive lesion and angiograms in multiple projections are performed. Measurements made include the following: diameter of the stenotic lesion, diameter of the vessel proximal and distal to the obstruction, diameter of the contra-lateral branch pulmonary artery in branch pulmonary artery stenosis (BPAS) and “stentable” length of the vessel; all measurement are made in two orthogonal views.

Heparin (100 units/kg) is given before the intervention and activated clotting times (ACTs) are maintained between 200-250 seconds and heparin dose adjusted accordingly. An end-hole catheter (multipurpose or balloon wedge) is placed across the stenotic lesion. If necessary, a 0.035” Bentsen guide wire or a similar soft-tipped wire is used to guide the catheter across the lesion. After the catheter is positioned distal to the obstruction, the wire is removed and exchanged for a 0.035” extra stiff (super stiff is preferable in some situations, particularly branch pulmonary artery stenosis) Amplatz guide wire. Next a blue Cook or a similar sheath with a multipurpose curve is inserted over the guide wire and positioned across the stenotic lesion. Once the tip of the sheath is positioned distal to intended site, the dilator is removed. The guide wire is left in place and the sheath flushed.

The selection of the sheath size is dependent on the sheath size necessary for stent deployment. Attempts are made to introduce the smallest size sheath necessary to deploy the stent successfully. Initially stents required large sheaths (11-French); however, recently profile stent-delivery systems have become smaller allowing stent deployment through as small as 6-French sheaths. When using a balloon-in-balloon (BIB) catheter, a sheath size 1-French larger than that required by the BIB catheter is used.

The selected stent is mounted on a BIB catheter; we usually perform crimping with fingers and then use an umbilical tape to finish crimping on the balloon. The balloon/stent assembly is introduced through the valve of the sheath either with the help of tubular tools that is supplied with some of the stents or slowly ease the stent across the sheath, to prevent inadvertent dislodgement of the stent from the balloon. The balloon/stent assembly is advanced over the stiff wire, but within the sheath and positioned across the obstructive lesion based on the bony landmarks. The sheath is withdrawn gently while holding the stent in

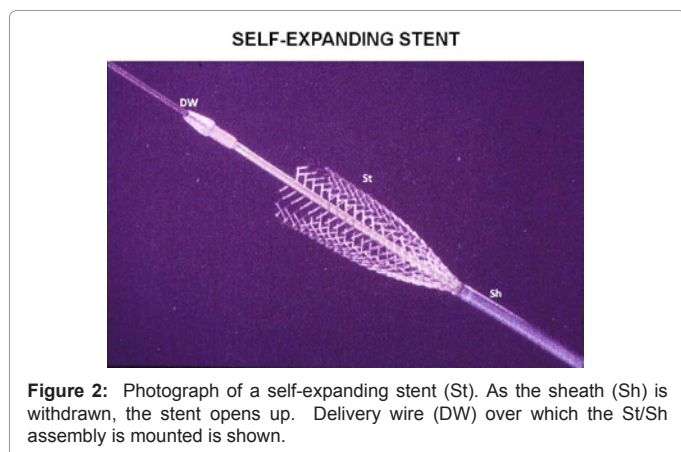


Figure 2: Photograph of a self-expanding stent (St). As the sheath (Sh) is withdrawn, the stent opens up. Delivery wire (DW) over which the St/Sh assembly is mounted is shown.

place, thus uncovering the stent. Once the tip of the sheath is proximal to the stent, contrast is injected via the side-arm of the Cook sheath and the stent position adjusted accordingly. When the BIB catheter is used, the inner balloon is inflated, a test angiogram is repeated and the stent position adjusted if necessary. Then the outer balloon is inflated thus implanting the stent. The balloon catheter is then positioned across the proximal/distal portion of the stent and the outer balloon is re-inflated. The balloon is repositioned across the other end of the stent and the outer balloon is re-inflated. These maneuvers will ensure apposition of the stent against the vessel wall. If needed, a larger diameter balloon may be used to reach the optimal size; we try to avoid this step by initially selecting the outer balloon diameter of the BIB catheter to be equal to the intended diameter of the stent.

During the removal of the balloon catheter, the tip of the sheath is advanced over the deflated balloon (into stent) and the balloon catheter is slowly withdrawn into the sheath to prevent inadvertent displacement of the stent, a maneuver initially described by Recto et al. [37] A multi-track catheter [38] is positioned over the wire and pressure pullback and angiograms are performed to assess the success of the stent implantation.

In young children, we usually employ premounted stents without a long delivery sheath. In such cases test angiography to verify the position of the stent is not feasible and we carefully select and use multiple bony and soft tissue landmarks.

Cefazolin (25mg/kg) is given in the catheterization laboratory and repeated two more times every 6-8 hours. Aspirin is started at doses of 5-10mg/kg/day for the next 6 weeks. Heparin, Coumadin, or other anti-platelet drugs have been used in the past, but data suggests that aspirin is sufficient. However in Fontan circulation, more aggressive anticoagulation may be advisable. The next morning chest x-ray and echocardiogram are performed to assess the results of the intervention, as well as quantitative lung perfusion scans (in BPAS cases). Follow-up evaluation 1, 6, and 12 months after intervention and yearly thereafter is recommended. If necessary, cardiac catheterization is repeated in 1 to 2 years to re-dilate the stent, especially in a growing child.

Branch Pulmonary Artery Stenosis

Pericardial or prosthetic patch repair of stenotic branch pulmonary arteries [39,40] was used in the past to address BPAS. Because of poor surgical results and relatively inaccessible distal branch pulmonary arteries, balloon angioplasty, once described [41,42], was readily accepted as an alternative treatment of BPAS [43-46]. The initial enthusiasm was high but the low success rate resulted in introduction of high pressure balloons [47]. Even with this technical improvement, success rate remained low, complication (ruptured pulmonary artery, hemoptysis, pulmonary edema, pulmonary artery aneurysm) rate was high, and recurrence rate was significant [43-46]. Consequently balloon expandable stents, first introduced by Palmaz et al. [7], have been adopted for management of BPAS [11,16,17,48-50]

Technique

The implantation of stents is as described in the preceding section; however, the following technical aspects are specific to branch pulmonary artery stents. A 0.035" super stiff Amplatz guide wire with a short soft tip (Meditech) is used to position the stent delivery sheath. We almost always use BIB catheters to achieve precise delivery. The

exception is infants and young children in whom premounted stents are utilized. Pre-dilation of the stenotic lesion by balloon angioplasty, advocated by some workers in the field, is not recommended by the senior author. Instead, the elastic recoil of the stenotic pulmonary arterial segment is considered to be important in holding the stent in place before endothelialization sets in.

Indications

The indications for stent implantation [50,51] are: a) right ventricular peak systolic pressure >50% systemic systolic pressure in patients with bilateral BPAS or b) less than 35% perfusion to the ipsilateral lung (by quantitative pulmonary perfusion scan) in unilateral pulmonary artery stenosis. These criteria are not as strict in the face of pulmonary valve insufficiency. Stents are preferred in long-segment

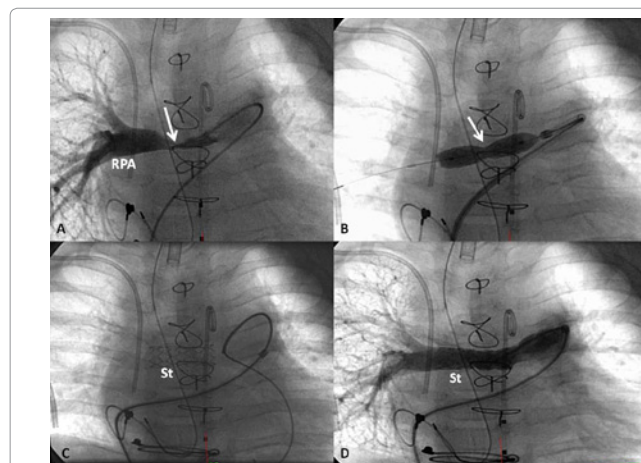


Figure 3: Selected cineangiographic frames from pulmonary artery cineangiogram demonstrating severe narrowing (solid arrow in A) in the right pulmonary artery (RPA). During implantation of the stent (B) a waist of the balloon was seen (solid arrow in B) which was completely abolished following further inflation of the balloon. Following the removal of the balloon, the stent (St) is seen and is widely open (C). Follow-up angiogram shows wide open St in the RPA (D). Multiple radio-opaque structures such as catheters, sternal wires, pacemaker wires and endo-tracheal tube are seen and are not germane for the stent implantation result.

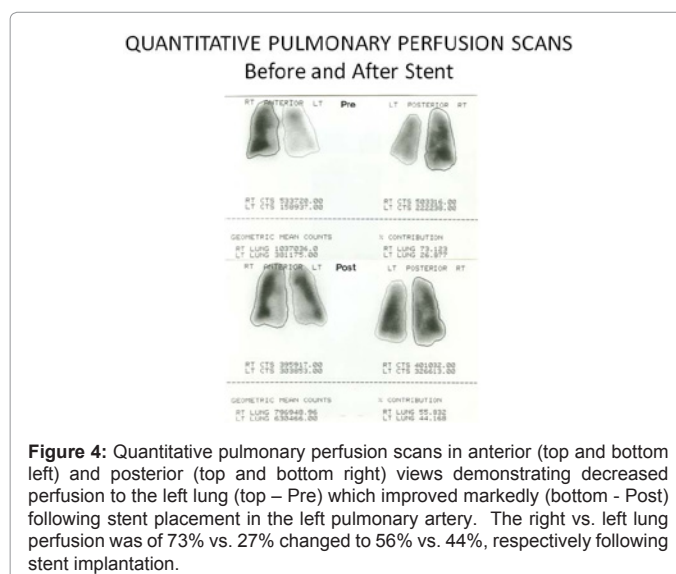


Figure 4: Quantitative pulmonary perfusion scans in anterior (top and bottom left) and posterior (top and bottom right) views demonstrating decreased perfusion to the left lung (top - Pre) which improved markedly (bottom - Post) following stent placement in the left pulmonary artery. The right vs. left lung perfusion was of 73% vs. 27% changed to 56% vs. 44%, respectively following stent implantation.

lesions and in older children, whereas young children and infants may be managed, at least initially, with balloon angioplasty alone.

Immediate results

Decrease in peak systolic pressure gradient across the stenotic lesion, increase in vessel diameter (Figure 3) and improved perfusion to the ipsilateral lung (Figures 4 and 5) have been seen after stent placement. In the first series of BPAS stents, O'Laughlin et al. [11] reported their results with 35 stents in 23 patients. They found that the peak pressure gradients decreased (51 +/- 24 vs. 16 +/- 13 mmHg; $p < 0.01$) and the vessel diameter increased (5 +/- 3 vs. 11 +/- 4 mm; $p < 0.01$). Subsequent studies [16,17,48-50,52-57], including our own [25,50] documented similar results. The results are similar in both post-operative and native BPAS lesions [17].

Complications

Reported complications [17] associated with stent implantation in BPAS include rupture of the balloon (2%), migration of the stent (2%), hemoptysis (2%), retroperitoneal hemorrhage (1.5%), and death (1%). Pulmonary edema of the under-perfused lung and stent thrombosis can occur, but the incidence is low. With increasing experience and development of new technology, the complication rates have been decreasing. Meticulous attention to details of the procedure is mandatory to reduce complication rate.

Follow-up results

There are several publications on the immediate and short term results, but long term follow-up studies are scant [17,48,49,58,59]. Follow-up studies [17,59,60] of the cohort reported by O'Laughlin et al. [48] revealed minimal loss of stent diameter, mild increase in gradient with true stenosis in only 7% of stents. However, 30 of the 31 stents required re-dilatation either due to development of severe stenosis (7%), residual waist (33%) or limited dilatation at the time of initial stent implantation (60%). Re-dilatation of the stents resulted in increase in diameter of the stenotic region and decrease of pressure gradient across the stenotic lesion [58,59] Also, the right ventricular (RV) to aortic systolic pressure ratio fell [58]. Similar results were reported from a different institution [49]. The follow up results from these and other studies were generally good with some neo-intimal covering of the stent, but without obstruction; true re-stenosis was infrequent. When stenosis is present it is usually at location of initial stenosis or at the ends of the stent. Similar results at follow-up with regard to residual pressure gradients and need for re-expansion (either by repeat balloon dilatation or surgical revision) in bifurcating BPAS stents [60] and stents that were implanted intra-operatively [61]. Risk factors for re-intervention included initial age <2 years, post-intervention diameter of <10 mm and diagnoses of tetralogy of Fallot and truncus arteriosus.

Comments

The placement of stents to relieve BPAS is feasible, safe and effective. Technical advances over the past 20 years have brought down the profile of stent delivery sheaths and decreased the complication rate [62]. Balloon expandable stents are preferred to self-expanding stents, and flexible stents are preferred over rigid stents [28]. Follow-up results are generally good, and re-dilatation of the stent if necessary has been shown to be effective when restenosis is present.

In patients with biventricular circulation, a reduction in RV to systemic pressure ratio is a good indicator of a successful outcome. In

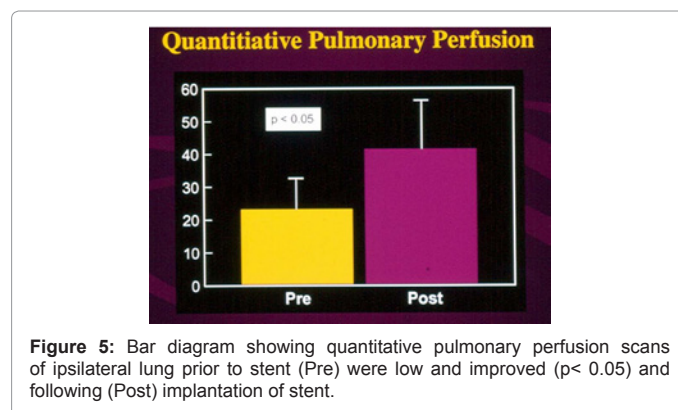


Figure 5: Bar diagram showing quantitative pulmonary perfusion scans of ipsilateral lung prior to stent (Pre) were low and improved ($p < 0.05$) and following (Post) implantation of stent.

unilateral branch pulmonary artery stenosis, pressure gradients are less meaningful as significant stenosis can be associated with surprisingly low pressure gradients. In these cases, percentage of improvement of angiographic diameter of the stenotic sites is a good outcome parameter. In addition demonstration of improvement in quantitative pulmonary perfusion by lung scans (Figure 5) is useful. Results of stents have been very good in regards to elimination of gradient and restoring vessels to their normal diameter. Unlike in balloon angioplasty, over-dilation of vessel is not required when stents are used. For these and other reasons, intravascular stents are now the primary mode of therapy for BPAS at most institutions.

Coarctation of the Aorta

Following the introduction of surgical therapy by Crafoord, Gross and their colleagues [63,64] in the mid 1940s, surgery has become therapy of first option in the management of aortic coarctation. However, after adapting Gruntzig's angioplasty technique [65] to aortic coarctation [66-68], it has been used to treat aortic coarctation [69,70]. Despite initial controversy, reviewed elsewhere [71,72], balloon angioplasty was in time adopted [71-73] as the treatment of choice for both native and post-operative coarctation in children, adolescents and adults. Its use in neonates remains controversial. Despite reasonably good short and long term results [74], some issues, such as restenosis, inability to address long, tubular coarctations, vessel rupture, and aneurysm formation, still remain. In addition, experimental work in animal models (75-81) has demonstrated feasibility and utility of stents in the management of coarctation. Consequently, stent therapy of coarctation has gained acceptance over the last two decades [15,50,82-109].

Technique

The technique is as described above. The lesion is visualized and measurements made in lateral and left anterior oblique views. Intravascular ultrasound is used by some interventionalists to assess coarctation segment as well as visualize results after therapy; we do not routinely use intravascular ultrasound for coarctation stents. The tip of the guide wire is placed in the right subclavian artery instead of ascending aorta as is used for balloon angioplasty; this is to keep the stent straight and avoid balloon rupture. Predilatation of coarcted segment by balloon angioplasty prior to stenting is not performed or recommended by our group. When selecting the size of the stents, it is important that only stents that can be dilated up to adult size are used. If larger maximum diameter is required, Max LD, Cheatham-Platinum

and the older Palmaz XL stents may be employed. If the head and neck vessels must be crossed, open cell design stents like Mega or Max LD should be used. In that situation we carefully traverse the stent cells with a soft guide wire followed by a multi-A2 catheter. That stent cell is then dilated with an angioplasty balloon to the size equal to the left subclavian artery. If performed appropriately, uncompromised flow can be expected in these patients. Alternatively, dual wire technique [110] may be used. Should the left common carotid artery be involved, stent implantation should be avoided.

Indications

The indications for employing stents include: 1) long segment coarctation, 2) hypoplasia of the isthmus or aortic arch, 3) tortuous coarctation with malalignment of the proximal and distal aortic segment and 4) recurrent aortic coarctation or aneurysm following prior surgery or balloon angioplasty. The goal of the procedure is to achieve gradient <10 mmHg or $>90\%$ relief of obstruction by angiography. In the older child, adolescent and adult, primary stent therapy is advised both for native aortic coarctation and post-surgical recoarctation. Because of issues related to growth and the need for large sheaths for implantation, most cardiologists limit stent usage to adolescents and adults, although some workers [15,105,111-114] advocate stents in infants and young children. We do not advocate routine use of stents in neonates, infants and young children [106,115].

Immediate results

O' Laughlin et al. [11] were the first to report the use of stents for the treatment of aortic coarctation, although the results in a 12 year old child were marginal. In the first series of stents in 10 patients, Suarez de Lezo et al. [15] showed that peak systolic pressure gradient decreased from 43 ± 12 to 2 ± 3 mmHg and the ratio of isthmus/descending aortic diameter improved from 0.65 ± 0.14 to 1 ± 0.08 following stent procedure. Similar results have been found in subsequent studies [82-109] including those involving series with a larger number of patients than reported by Suarez de Lezo et al. [89]. Increase in the diameter of the coarcted segment (Figure 6) and reduction in peak systolic pressure gradient across the coarctation site have been demonstrated after stent placement. Stents has been found to be effective in post-surgical and post-balloon angioplasty recoarctation as well as native coarctation. Improvements of the size of hypoplastic isthmus or transverse arch, and exclusion of aneurysms have also been documented.

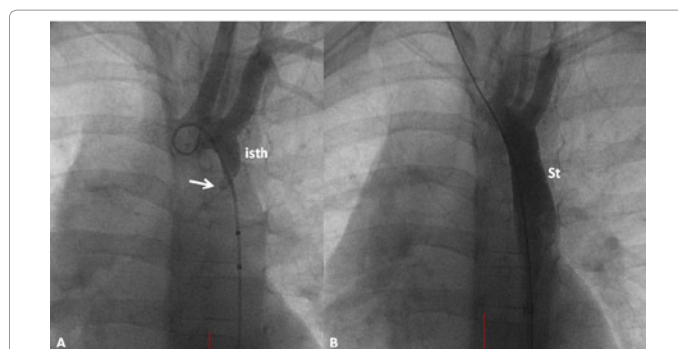


Figure 6: Selected cine frames from aortogram demonstrating severe coarctation (white arrow) with isthmus hypoplasia (isth) in an adolescent (A) which improved (B) following the deployment of stent (St).

Complications

Vessel rupture, displacement of the stent, and aneurysm may occur but are infrequent. Balloon rupture [91,93] may be prevented by avoiding curvature of the balloon/stent and use of newer stents with less injurious ends and by the use of BIB catheters. Because of the large sheath size, loss of pulse and bleeding from the puncture site has been reported. Using vascular closure devices may help circumvent this problem. Rarely reported complications include myocardial infarction and retroperitoneal hemorrhage [91,93] In a large series from the Congenital Cardiovascular Interventional Study Consortium (CCICS) database [100], reporting successful stenting of coarctation in 580 out of 588 (98.6%) cases, the complication rate was 11.7%. The complications include aneurysms in 2.2%, aortic dissection in 1.5%, stroke in 1% and death in 0.3%. Complications related to femoral vessel access occurred in 2.6% of patients. The authors conclude that balloon-expandable stents are safe and effective in the treatment of a subset of patients with aortic coarctation.

Follow-up results

In most studies there is only short term or incomplete follow-up. However a few investigators [89,91,93,108] followed more than 20 patients for more than a mean follow-up period of 2 years. In these studies the pressure gradients across the coarctation site remained low and systemic hypertension decreased in frequency and degree with consequent decrease in antihypertensive medication use. Although follow-up was not complete, minimal incidence of recoarctation, aneurysms, or stent fracture/ displacement occurred. Residual or recurrent obstruction was observed in a few patients, and in those cases successful redilatation of the stents was accomplished with larger balloons. Re-dilatation of the stents is frequently related to deliberately under-dilating stents during the initial stent placement [108]. There is conflicting data on the effectiveness of re-dilatation. Some studies [116] indicate that much of the re-expansion was necessary simply to restore the original lumen size and other studies [108,113] suggest that re-dilation is feasible, safe, and successful. In the few patients who developed aneurysms, they were obliterated by coil placement [89]. Angiographic studies by Suarez de Lezo et al. [89] revealed no detectable neo-intimal proliferation in $\frac{3}{4}$ patients. In the remaining patients, a ridge was noticed at the ends of the stent, causing only minimal restenosis. Segmental analysis of the aorta revealed increase in non-stented segments consistent with normal growth. As a whole, the follow-up results are encouraging.

Comments

Stent therapy appears to be a suitable method for the management of recurrent coarctation or aneurysm formation after previous surgical or balloon angioplasty as well as native aortic coarctation with long segment hypoplasia. Although most cardiologists use stents for adolescents and adults, some advocate their use in infants and younger children. The types of stents and deployment catheters continue to evolve. Use of BIB catheters for stent deployment appears to avoid balloon rupture and help appropriate placement of the stent. The role of covered stents will be discussed in the next section. Selected stent diameter should be at least twice the diameter of the narrowest segment to prevent stent migration during implantation. The jailing of brachio-cephalic vessels still needs to be addressed. Relief of obstruction at implantation and follow up has been demonstrated in several studies.

Recoarctation rates appear to be low. Re-expansion of narrowed stents appears feasible, safe and effective, although this is questioned by some investigators. Longer-term follow-up studies are needed to confirm long-term utility of stents in aortic coarctation. Based on the available data, stenting of aortic coarctation appears to have emerged as the preferred treatment of aortic coarctation in the adolescent and young adult.

Covered stents

Covered stents have been used successfully in the management of aortic coarctation and a number of reports document this experience [117-136]. A variety of covered stents have been utilized and these include Jostent grafts (Jomed International, Helsingborg, Sweden), Cheatham-Platinum stents (NuMed Inc, Hopkinton, NY), AneuRx (Medtronic, Watford, UK), Advanta V12 (Atrium Medical, Hudson, NH) and others. While these stents are available outside the United States, they are not approved by the US Food and Drug Administration (FDA) for clinical use. However, off-label use of available endoluminal grafts by customizing to patients needs is feasible [137], but such use is cumbersome.

Indications

The indications for use of covered stents include post-angioplasty or post-surgical aneurysm, tortuous aortic arch and isthmus, associated patent ductus arteriosus [138,139], prior surgical conduit, Takayasu arteritis, and extremely narrow (subaortic) coarcted segment. When the risk for development of aneurysm or dissection is assessed to be high, a covered stent should be used. Aortic rupture is an important but an infrequent complication after primary (bare metal) stenting for aortic coarctation. Therefore covered stents have been used to reduce this risk. However, aortic rupture has been reported even with covered stents [140].

Results

The results thus far reported with covered stents generally appear to be good with excellent relief of obstruction. However, some of the stents can be expanded only to an 18-mm diameter size and may not be suitable for all fully grown adults. In addition, the stent shortens when expanded to larger diameters. Use of covered stents has another disadvantage in that the vessels that arise from the aorta are blocked. Re-narrowing of covered stents has been reported; however, limited available data suggest covered stents can be re-dilated [141].

Comments

Our opinion is that the current data would indicate that the covered stents may be useful in highly selected patients with aortic coarctation. Reduction in the size of the stent delivery sheath and approval by appropriate authority will further enhance the utility of the covered stents.

Other Stenotic Lesions

Stents have been used to treat other cardiac abnormalities and will be briefly reviewed here.

Right ventricular outflow conduits

Calcific degeneration and development of obstruction in bioprosthetic right ventricular-to-pulmonary artery (RV/PA) conduits is well documented, necessitating repeat surgery to replace the conduit

[142]. Balloon dilation of these valves has produced some improvement with nominal extension of the life span of the conduit, as reviewed elsewhere [142]. Therefore, use of stents to relieve the obstruction has been advocated [13,52,143-149].

The method of implantation is similar to that described previously, although inability to implant and balloon rupture occur more frequently than seen with other locations. It is important to ensure that no distal obstruction exists, and if present, it should be addressed as necessary. Distal obstructions are likely to increase pulmonary regurgitation and therefore should be relieved at the same sitting. One should recognize the potential for obstruction of the coronary arteries [150,151] during stent deployment and the appropriate steps to avoid this complication should be taken.

The indications for stent deployment are not well defined. Most interventionalists use elevated right ventricular systolic pressure >50% of left ventricular systolic pressure and/or right ventricular dysfunction. In infants and young children, we continue to use balloon dilatation as the initial step and if that is not successful, stents are used. The major reason for the palliative intervention is to avoid immediate surgical replacement of the conduit.

In one report, involving 44 patients, conduit stenting resulted in reduction of peak systolic pressure gradient from a mean of 61 to 30 mmHg ($p < 0.01$), increase in conduit stenotic region from 9.3 to 12.3 mm and freedom from conduit replacement in 65% patients at 30 months after stent deployment [144]. An example from our experience is shown in figure 7. Most reports cited [13,52,143-149] demonstrate decrease of peak systolic gradient, improvement in conduit stenosis diameter and prolongation of life span of the conduit for varying time periods. However, fractures of the stent have been seen at follow-up. Nonetheless, implantation of stents in the RV/PA conduits appears to be a good palliative procedure resulting in reduction of right ventricular pressures and successful in postponing surgical replacement of the conduit for the majority of patients.

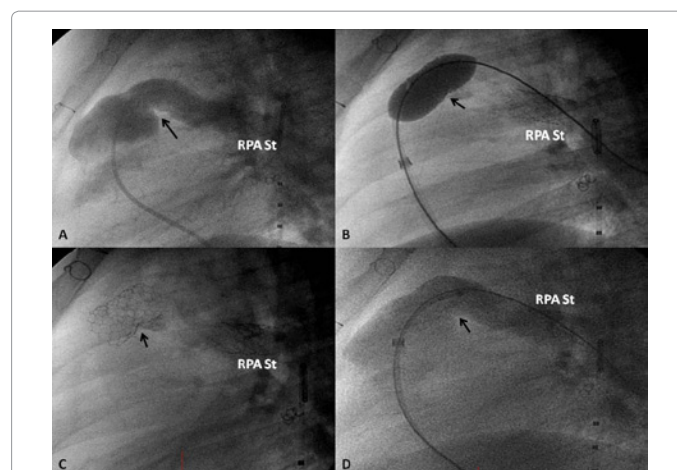


Figure 7: Selected frames from lateral view of a right ventricular outflow tract cineangiogram (A) demonstrating narrowed outflow tract (arrow). The position of the stent mounted balloon during stent implantation with residual waist (arrow) is shown in B. Following the removal of the balloon, the stent (C) is seen with residual indentation (arrow). Follow-up angiogram (D) shows wide open stent. Right pulmonary artery stent (RPA St) that was implanted at a prior catheterization is seen in each of the frames.

Stents have also been used in native RV outflow tracts of tetralogy of Fallot patients in the premature and young infants to relieve symptoms and as a bridge to later surgery [152-154] and to relieve Sano conduit obstructions in hypoplastic left heart syndrome patients following Norwood procedure [155-157]. These interventions appear to accrue benefit to the patients, although the experience with such procedures is limited. Trans-catheter delivered pulmonary valve replacement [158-160] will not be included in this review.

Systemic veins

Obstruction of the systemic veins may occur following: 1) surgical procedures such as the atrial switch (Mustard or Senning), unidirectional or bidirectional Glenn procedure, correction of total or partial anomalous pulmonary venous return, and cardiac transplantation, 2) transvenous pacing lead placement, 3) prolonged use of indwelling catheters and 4) malignancy and radiation [51,161]. Balloon angioplasty of stenosed systemic veins is often successful [162,163]; however, long-segment obstructions would require stents.

The method of stent placement is similar to that of the preceding section although the method needs to be tailored to the given location. The diameter of the stent selected should be the average of the venous channel proximal and distal to the obstruction. Because of potential injury to the aorta [164,165], use of rigid stents with sharp edges should be avoided.

The indications for intervention are the presence of clinical signs of venous obstruction with angiographically demonstrated stenotic lesion. However, signs of obstruction may not be apparent because of development of collateral circulation. It is not clear whether stent or balloon angioplasty is the best choice in a given situation. We use balloon angioplasty in infants and young children, and stent therapy in older children and adolescents and for those with long-segment stenosis. While the conventional thinking supports use of catheter interventions several weeks after surgery, their use even in freshly operated areas [166] appears to be well tolerated.

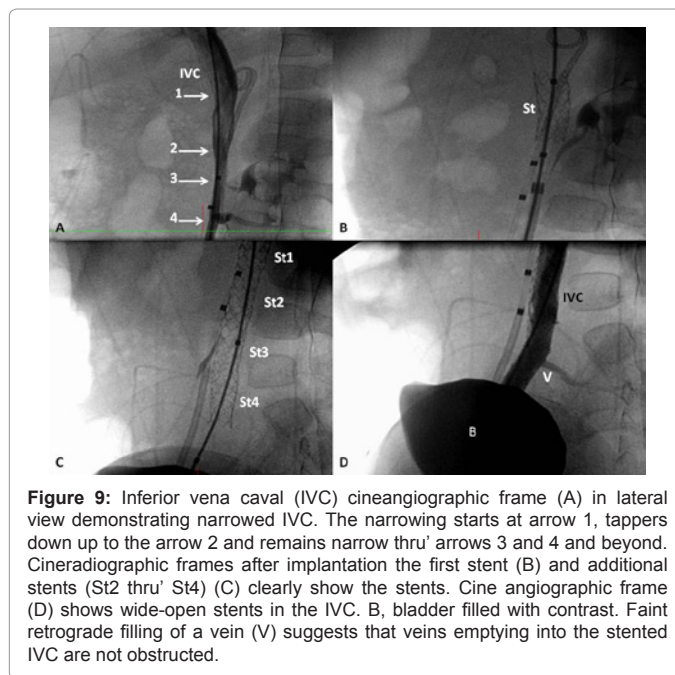


Figure 9: Inferior vena caval (IVC) cineangiographic frame (A) in lateral view demonstrating narrowed IVC. The narrowing starts at arrow 1, tapers down up to the arrow 2 and remains narrow thru' arrows 3 and 4 and beyond. Cineangiographic frames after implantation the first stent (B) and additional stents (St2 thru' St4) (C) clearly show the stents. Cine angiographic frame (D) shows wide-open stents in the IVC. B, bladder filled with contrast. Faint retrograde filling of a vein (V) suggests that veins emptying into the stented IVC are not obstructed.

Relief of obstruction and clinical improvement has been observed in most studies [11,12,18,25,51,167-169]. A few examples from our personal experience with superior and inferior vena caval stenting are shown in figures 8 and 9, respectively.

Complete obstruction of iliofemoral venous system may occur secondary to multiple catheterizations, surgical procedures and/or prolonged use of indwelling catheters. Collateral flow through the paravertebral and other veins is usually excellent and these patients rarely show signs of venous obstruction. However, it is problematic for future catheterizations and catheter interventions. In such cases stenting of the iliofemoral veins up to the inferior vena cava is possible and the procedure has been described by Ing and associates [170,171]. Immediate and follow-up results look satisfactory [172] as documented in one study; 70 systemic venous stents were placed in 33 patients and a significant increase in vessel diameter was observed. At a mean follow-up of 4.1 years, 41% of the 17 patients who had re-catheterization required re-intervention. Stenting of occluded iliofemoral veins provides access to proceed with catheterization and catheter interventional procedures which are required in many of these patients.

Pulmonary veins

Pulmonary vein stenosis may be congenital in origin, or more often occur after prior cardiac surgery such as the Mustard or Senning procedure and repair of total anomalous pulmonary venous return [161]. Surgical and transcatheter therapy for congenital and post-surgical pulmonary vein stenosis have had notoriously poor long-term outcome. Both congenital [161,173] and post-surgical [161,162,174-176] pulmonary venous stenoses may be treated by balloon angioplasty, but results are relatively poor. Cutting balloon angioplasty [177] was attempted which did not accrue additional benefit compared to conventional balloon angioplasty. Given these disappointing results, stenting the pulmonary vein was thought to be more effective.

Intraoperative and transcatheter stenting has been attempted [14,177-184]. Immediate relief of pulmonary vein obstruction is

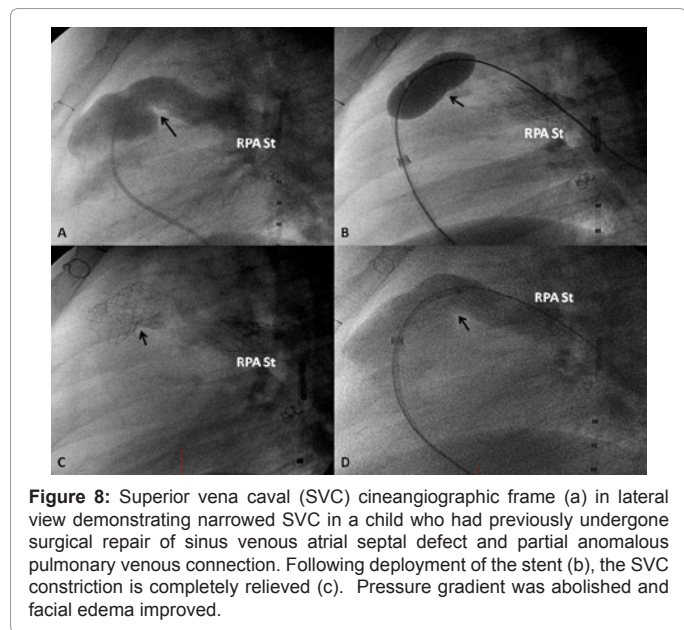


Figure 8: Superior vena caval (SVC) cineangiographic frame (a) in lateral view demonstrating narrowed SVC in a child who had previously undergone surgical repair of sinus venous atrial septal defect and partial anomalous pulmonary venous connection. Following deployment of the stent (b), the SVC constriction is completely relieved (c). Pressure gradient was abolished and facial edema improved.

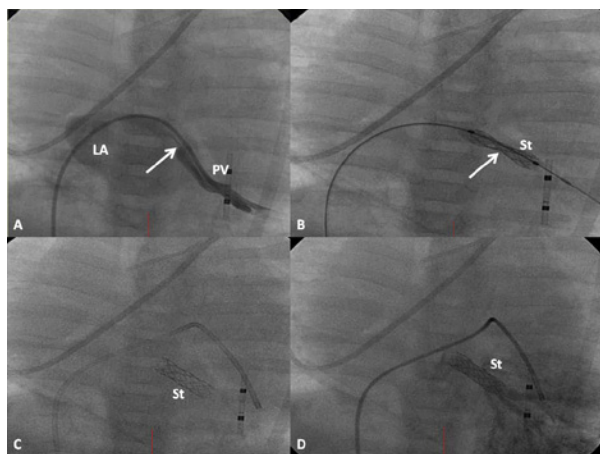


Figure 10: Selected frame from pulmonary vein (PV) cineangiogram demonstrating narrow jet of contrast (arrow) suggestive of severely stenotic PV (A). During implantation of stent, waist of the balloon/stent (St) assembly (arrow) is seen (B); this waist disappeared with further inflation of the balloon (C). Levophase of left pulmonary artery cineangiogram filling of the stent with contrast is seen in D. LA, left atrium.

demonstrated in one of our patients (Figure 10). In one of the largest series reported [184], 74 stents were implanted in stenotic pulmonary veins in 47 patients, and there was immediate relief of obstruction in all veins. At a mean follow-up of 3.1 years, 21 (45%) patients died and 32 (59%) of the 54 re-studied stents (veins) required re-intervention. Because of poor results, stenting of stenotic pulmonary veins may be thought of as palliative procedure at best and may serve as a bridge to lung transplantation [185].

Recently a drug-eluting stent was used to prevent neo-intimal proliferation; Dragulescu et al. [186] described a patient with congenital pulmonary vein stenosis and single ventricle physiology who was bridged to transplantation (for >182 days) after relieving recurrent pulmonary vein stenosis with a paclitaxel eluting stent. Similarly, Mueller et al. [187] used paclitaxel-coated balloon to relieve neonatal pulmonary vein restenosis and conclude that drug eluting stents/balloons may be able to prevent neo-intimal proliferation after pulmonary vein stenting. Further investigation of this methodology may provide a new hope in this disease with an invariably grim prognosis.

Other Use of Stents

Stents have been found to be useful in many other situations: 1) to maintain ductal patency in the neonate with reduced pulmonary blood flow such as pulmonary atresia with intact ventricular septum, right ventricular hypoplasia and other complex heart defects with decreased pulmonary blood flow, 2) to keep the ductus arteriosus open in ductal dependent systemic blood flow such as hypoplastic left heart syndrome either as a bridge to transplantation or as a part of hybrid procedure as an alternative of Stage I Norwood procedure, 3) to keep the patent foramen ovale open in hypoplastic left heart syndrome or mitral atresia cases, 4) to create an atrial septal defect in severe pulmonary hypertension cases, again as a bridge to transplantation, 5) to augment pulmonary blood flow by stenting aortopulmonary collateral vessels, 6) to open up stenosed or completely occluded surgically created aortopulmonary shunts and 7) to close fenestrations of the inferior vena cava to pulmonary artery conduit with a covered stent, as a part non-

surgical Fontan completion. Because of the limitation of space, these stent applications will not be discussed in this review.

Future Directions

Stents in aortic coarctation

Recoarctation can occur both after surgery [188-190] and following balloon angioplasty [74,191,192]. Development of post-surgical recoarctation does not depend on the type of surgical repair, but the age at surgery [188,189], hypoplasia of the aortic arch [190] and short body length [190] were shown to be risk factors for recoarctation. Factors predictive of post-balloon angioplasty re-stenosis are young age and severely narrowed isthmus and coarcted segment [74,191-193], very similar to those after surgery. Investigation of biophysical characteristics suggested reduced recoil of the coarcted aortic segment, indicating that the elastic properties of the aortic wall are not preserved [194]. This may be related to cystic medial necrosis [195,196] or to extension of the ductal tissue into the aortic wall [197,198]. However, true cellular pathophysiologic mechanisms responsible for recoarctation have not been clarified. Once they are known, suitable treatment algorithms to address the pathophysiology, in order to prevent recoarctation may be developed. For that reason, keeping coarcted segments open mechanically with stents is an attractive option. However, the stents, which are metallic, do not grow with the child and cannot be used routinely in neonates and infants. Re-dilatation of the stents, while possible, may not achieve adult size [116]. Alternative solutions include development of biodegradable and growth stents [106,115,199].

Biodegradable stents

Biodegradable stents [32-36,200,201] may offer a solution. These stents, composed of polyesters, polycarbonates, bacterial-derived polymers, or corrodible metals, initially keep the coarcted aortic segment open and dissolve over a period of months to years. By that time, hopefully, the ratio of the normal aortic tissue to abnormal tissue may be in favor of the infant, thus preventing recurrence of significant narrowing. However, this concept should be tested in appropriate animal models followed by clinical trials to test the feasibility, safety and efficacy. Successful use of a bioabsorbable metal stent in a neonate with for critical recoarctation [36] is encouraging. However, as stated above, orderly clinical trials in large groups of young patients are needed. Issues related to mechanical stability and inflammation should be resolved. Stent delivery systems should also be miniaturized so that they can be used in neonates and young infants.

Growth stents

Alteration of the stent by making an "open-ring" stent and implanting in swine and then over-dilate the stent was shown to be feasible [202,203]. Ewert et al. [204], Sigler et al. [205] and their colleagues extended this concept and demonstrated feasibility, effectiveness, and biocompatibility in animal models. Clinical application of this concept was reported by Ewert et al. [206]; immediate relief of obstruction was shown and re-dilatation to a larger diameter was successful. However, the overall results, requiring multiple interventions may not be satisfactory. Larger clinical trials of this type of modification of stents in young children are needed to demonstrate the usefulness of this technique and to confirm the utility of this concept.

Stents in pulmonary veins

As reviewed in a previous section of this paper, implantation of stents in pulmonary venous stenotic lesions, while produced immediate

relief of obstruction, the follow-up results are uniformly poor. Limited number of reports [186,187] suggested that drug-eluting stents/balloons (impregnated with drugs such as paclitaxel) may thwart neo-intimal proliferation, thus prevent pulmonary vein restenosis. Further studies to test this concept (paclitaxel and other drug eluting stents/balloons) on larger groups of patients are warranted.

Stents in hybrid procedures

Hybrid use of ductal stent along with surgical bilateral branch pulmonary artery banding in the palliation of hypoplastic left heart syndrome [207] has been reported with encouraging results. Multi-institutional studies are needed to determine whether this type of approach is superior to the conventional staged (Norwood/bidirectional Glenn/Fontan conversion) management currently in vogue [208].

Staged surgical-catheter approach for Fontan procedure was proposed by Konertz et al. [209] Initially a modified hemi-Fontan performed and is later completed by transcatheter method [209-211]. This approach reduces the total number of operations required. This approach was used in a limited number of patients, and preliminary data suggest that the usual post-Fontan complications, such as pleural effusion and ascites, have not occurred with this approach [212]. Examination of results of larger experience and longer-term follow-up and ready availability of covered stents are necessary for routine application of this innovative approach.

Conclusions

The utility of stents in the treatment of vascular obstructive lesions not amenable to balloon angioplasty is well recognized. While the stents have been shown to be useful in maintaining patency of natural and artificially created inter-circulatory connections, these stent applications were not reviewed in this paper. With newer generations of stents, the technique of implantation is simplified and complications reduced. The feasibility, safety and effectiveness in the management of branch pulmonary artery stenosis, aortic coarctation, right ventricular outflow tract conduits and systemic venous obstructive lesions have been demonstrated. However, stent therapy for pulmonary venous obstructive lesions has not been effective. Issues related to growing vascular structures in children have not been resolved. Research regarding biodegradable and growth stents, drug-eluting stents and hybrid procedures that use stents is warranted.

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