Stent angioplasty of narrowed right ventricular outflow conduits and pulmonary arteries consistently reduces right ventricular systolic pressures and delays subsequent surgeries

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ABSTRACT

Objectives: Narrowed right ventricular (RV) outflow conduits and pulmonary arteries (PA) increase RV pressures and warrant interventions. Stent angioplasty is an alternative to more morbid redo-surgery in developing countries. We evaluate the efficacy and safety of stenting and assess need for redo-surgical reinterventions on midterm follow-up after stent angioplasty.

Methods: Patients who underwent conduit, main PA and bilateral branch PA stenting for elevated RV pressures were analyzed retrospectively. Success was defined as 20% reduction in RV pressures or RV-aortic pressure ratio; 50% reduction in gradients or 50% increase of luminal diameter. Procedural results, complications and need for redo surgeries on follow-up were assessed.

Results: Among 60 patients aged 1–46 years, 57 were post-operative patients, who needed stenting at a median period of 48 months after surgery. Stenting succeeded in 98% and reduced RV pressures from 105.42 ± 28.39 mmHg to 54.46 ± 16.89 mmHg. Direct major procedural complications in five (8%) patients included procedural failure in one, stent migration in three and lung hemorrhage in one. None of the stented conduits needed a surgical change on a follow-up ranging 3–120 months. Following bilateral PA stenting in twenty-four patients, only two needed a repeat open-heart surgery during follow-up ranging 3–108 months. Catheter reinterventions on follow-up included elective percutaneous pulmonary valve implantation in nine patients and stent redirection in seven patients.

Conclusions: Stent angioplasty was safe and effective. Surgery was postponed in all stenosed conduits. Elective redirection of stents after bilateral PA stenting may be needed for somatic growth; but open-heart repeat surgeries can be avoided in a majority.

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1. Introduction

Right ventricle (RV) compensates by adaptive hypertrophy to pressure overload initially but fails later due to progressive contractile dysfunction. In the child who undergoes transplantation. In comparison to volume overload, RV adapts poorly to pressure overload. Right ventricle fails earlier than left ventricle in increased afterload due to differences in ventricular geometry, embryological ontogeny, type of myosin heavy chains, reduced blood supply and increased fibrosis. Surgical techniques using conduits from RV to pulmonary arteries (PA) and pericardial or synthetic patch enlargement of branch PA aim at early normalization of RV systolic pressures. When conduits degenerate and pericardial or synthetic PA patches fibrose, they result in recurrence of outflow narrowing. Distal conduit and branch PA narrowing aggravate pulmonary regurgitation and hasten the need for surgical pulmonary valve implantation. If RV pressures are less than 50% of systemic pressures, RV function is maintained well for long duration. When surgery is planned for conduit stenosis or branch PA stenosis, the morbidity and economic issues of redo surgery in a developing economy have to be considered.

Catheter interventions for narrowed conduits and PA carries certain advantages. Conduit stenting delays their surgical replacement. Stenting provides sustained luminal widening with significant recoil compared to balloon angioplasty. Stenting remains a safe option in post-hilar branches. Low-profile stents, improved techniques and operator experience have facilitated safe stenting even in infants. Morbid surgery can be avoided if stenting
offers a consistent reduction in RV pressures. A longer freedom from repeated re-interventions is always desirable.

A periodical planned stent re-expansions may be needed in a young child after conduit and PA stenting to accommodate for the somatic growth. Outgrowing the stent is a more common cause of re-elevation of RV pressures than in-stent ingrowth. This study aims to evaluate the safety and efficacy of conduit and PA stenting in reducing the elevated RV pressures in patients with obstructed outflow tracts and to analyze the need, frequency and indications for surgical reinterventions in their midterm follow-up.

2. Materials and methods

Hospital records of patients who underwent conduit, main PA and bilateral branch PA stenting in a tertiary care cardiac center by a single operator over a nine-year period from 2008 were included in this retrospective observational analysis after approval from Institutional review boards. An informed consent was obtained in all patients before the intervention.

2.1. Patient groups and indications

The patients were categorized into two groups. Patients with conduit or main PA stenosis formed Group A and those with obstruction of bilateral PA branches formed Group B. Indications for stenting were: 1. Symptomatic patient, 2. RV systolic pressures more than two-thirds systemic pressures. 3. Systemic venous congestion due to RV dysfunction, 4. Distal conduit or PA stenosis associated with dilatation of proximal conduit or RV outflow tract, with attendant risk of increasing pulmonary regurgitation.

2.2. Preprocedural imaging

When echocardiographic images were not optimal, a contrast computed tomographic study was done and post-processed using multiplanar reformattting. The extent of calcification, metallic clips near the stenosis and proximity of the conduit to the coronary arteries was also analyzed on computed tomography. As unilateral PA narrowing was not part of this study, lung perfusion scans were not performed.

2.3. Vascular access and hemodynamics

Stenting was usually done under conscious sedation. General anesthesia was restricted to young infants, hemodynamically compromised patients, acute post-operative interventions, requirement of unusual vascular access, need for apnea for rotational angiography or failure of conscious sedation. Jugular and transhepatic access were obtained in patients with occluded femoral veins. Two separate femoral or jugular venous access were used for simultaneous kissing Y stents in bilateral branch PAs. In case of transhepatic access, a single 6F sheath was advanced initially, through which two superstiff guidewires were advanced. These guidewires were then used to get two separate braided sheaths into respective PAs for bilateral PA stenting. Full heparinisation, hemodynamic recording, measuring lesion length and diameter, assessing pulmonary regurgitation and coronary interrogation were routinely followed.

2.4. Stent angioplasty

A braided Flexor sheath (Cook Medical, Bloomington, IN) was placed over an exchange length stiff guidewire across the lesion. Advancing the stent-balloon assembly without a sheath was often avoided. If lesion tortuosity precluded sheath placement, front-loading techniques were adopted. The stent length and diameter was chosen based on the reference diameter of the normal segment of the pulmonary arteries or the conduit diameter. Large diameter bare stents that can be post-dilated beyond 14 mm were chosen in the majority. In the latter part of the study, few premounted dilatable stents were used.

2.5. Predilatation

Direct stenting was the procedure of choice. Predilation was done in the following patients: (i) markedly stenotic conduits to facilitate sheath passage, (ii) check compliance in densely calcified lesions to avoid balloon rupture during stent deployment and (iii) coronary interrogation before stenting of proximal conduits.

2.6. Outcome measures

Acute procedural success was defined as either more than 20% reduction of the RV systolic pressures or right ventricular to aortic systolic pressure ratio or more than 50% reduction in peak systolic gradients or more than 50% improvement in luminal diameter. Lumen diameter was difficult to measure in densely calcified conduits, where pressure data was primarily used for defining success. The endpoints on follow-up included the need for and frequencies of redo surgeries and repeat interventions.

2.7. Complications

All complications ranging from catastrophic events like death or emergent surgery to trivial hemodynamic events were analyzed. Vessel rupture, emergent surgery, hemodynamic collapse, hemothorax, major perfusion lung bleeds, need for blood transfusions, stent embolization, procedural failure, sustained arrhythmias and tricuspid valve injury were named as major complications. Contrast extravasation, stent malposition, stent fracture, balloon rupture, transient arrhythmias, vascular access complications, side branch jailing and self-limiting hemoptysis were minor complications.

2.8. Follow up

Patient symptoms and freedom from reinterventions were assessed on follow-up. Catheter reinterventions included planned stent re-expansions in a growing child and restenting for in-stent ingrowth. Echocardiography was used to assess stent patency and gradients, RV function and systemic venous congestion. If echocardiography was inadequate, computed tomography was utilized. A telephonic contact was made in patients who could not come for follow-up.

2.9. Reinterventions

Need and timing of all surgical and transcatheter reinterventions were noted. Planned catheter reinterventions included stent redilations in growing children and percutaneous pulmonary valve implantation (PPVI) in stented conduits. When young infants and children undergo stenting, an elective cardiac catheterization is planned after 3–4 years to study the gradients, stent diameter and the luminal diameter. A high-pressure balloon is used to redilate these stents to larger diameter proportionate to the somatic growth of the patient, if the gradients are more than 20 mmHg. PPVI would ideally be indicated for free pulmonary regurgitation in a stented conduit after RV dilatation, but was electively planned in few selected patients even before they met the criteria.
2.10. Statistical analysis

Descriptive statistics were presented as mean ± standard deviation or median with range. Bivariate comparisons of right ventricular systolic pressures, right ventricular to aortic pressure ratio and gradients across the lesion, comparisons of means and proportions between stenosis diameters were performed with the paired t test. Analysis of time-dependent occurrences was analyzed graphically with Kaplan-Meier plots.

3. Results

The study cohort comprised of 60 patients aged 1-46 years (median 7 years) and weighing 7-82 kg (median 22 kg) who underwent conduit and PA stenting using a total of 103 stents. The mean RV systolic to aortic pressure ratio reduced significantly from 0.88 ± 0.25 to 0.44 ± 0.14 after the procedure. The mean RV systolic pressure also significantly decreased from 105.4 ± 28.4 mmHg to 54.5 ± 16.9 mmHg after the stenting. (Fig. 1)

3.1. Etiology of stenosis

Among the fifty-seven postsurgical patients, the elevated RV systolic pressures warranted stenting at a median period of 48 months (3 days - 206 months) after the initial surgery. Prior surgeries included tetralogy repair (17), Rastelli repair (22), truncus repair (5), arterial switch operation (5), Ross procedure (6), conduit repair for corrected transposition (1) and pulmonary thromboendarterectomy (1). The remaining three-denovo patients were syndromic (William, Noonan and cutis laxa in one each) and had bilateral PA stenosis.

3.2. Vessel involved

The conduits stented in 31 patients included 17 homografts, 11 xenografts and 3 hand-sewn pericardial conduits. Main PA was stented in five patients. Stenting involved bilateral mediastinal PA in 22 patients and post hilar lobar PA branches in two patients.

3.2.1. Group A: conduit or MPA stenting

This group consisted of thirty one patients with conduit narrowing and five with main PA stenosis (Table 1). Conduit stenting was done at a median period of 8 years (range 0.5-19 years) following initial surgery. One patient was excluded after balloon interrogation showed coronary compression before stenting. A total of 51 stents used in conduits and main PA included Palmaz and Genesis XD (Cordis Incorporated, Miami Lakes, FL), Cheatham platinum stents (Numed, Hopkinton, NY), Andistent (Andra Medical, Reutlinger, Germany), Intrastent (Medtronic endovascular, Minneapolis, MN), Advanta V12 (Maquet, Rastatt, Germany) and Formula (Cook Medical, Limerick, Ireland). Main PA was narrowed after arterial switch in three and tetralogy repair in two patients.

3.2.2. Group A: hemodynamic results

The mean RV pressure reduced significantly from 107.2 ± 25.9 mmHg to 56.2 ± 14.8 mmHg following the procedure. The right ventricle systolic to aortic pressure ratio also significantly reduced from 0.9 ± 0.24 to 0.46 ± 0.16. Stenosis diameter could not be precisely measured in densely calcified conduits. The conduits were dilated to a median final diameter of 20 mm (12-24 mm). Additional interventions included six branch PA stenting and one device closure of atrial septal defect.

3.2.3. Group A: outcome and follow-up

All except one had procedural success. Procedure failed due to stent migration in an infant with supravalvar main PA stenosis diagnosed six months after tetralogy repair. He was re-operated after two weeks. None of the patients with stented conduits needed surgical replacement on follow-up. Two patients had stent redilatations. A planned PPVI was done as a transcatheter procedure in eight and hybrid off-pump percutaneous procedure in one patient. A two-year-old child had successful conduit stenting within one year after Ross Konno operation. On a further two-year follow-up, left ventricular subvalvar outflow obstruction progressed but conduit gradients were stable. One patient was lost to follow up. One stent distally migrated and was lodged in mediastinal PA. One immunosuppressed patient with lupus

Fig. 1. Changes in right ventricular systolic pressure, right ventricle to aortic pressure ratio and pulmonary artery diameters following the stenting.
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TOF PA – Tetalogy of fallot pulmonary atresia; DORV – Double outlet right ventricle; RVSP – right ventricular systolic pressure; ICR – intracardiac repair; ASD – arterial switch operation; DSO – double switch operation; APV – absent pulmonary valve; CTGA – corrected transposition of great arteries; AS – aortic stenosis; PPVI – percutaneous pulmonary valve implantation; LPA – left pulmonary artery; LV – left ventricle; mmHg – millimetres of mercury.

nephritis died of Candida endocarditis, unrelated to procedure. On a follow-up of 1–10 years, all the other patients were free of symptoms and reinterventions. None required a redo surgery for conduit replacement.

### 3.2.4. Group B: bilateral PA stenting (Table 2)

Twenty-four patients had stenting of both pulmonary arteries using 52 different types of stents. Stenting in two patients with occluded femoral veins were done through jugular and hepatic
veins. (Figs 2 and 3) Three syndromic patients had denovo bilateral PA stenosis and one patient with secundum atrial septal defect had thromboembolic postbranch PA stenosis. The other twenty patients had a previous cardiac surgery at a median period of 37 months (3 days–206 months) before the stenting procedure. Four patients needed additional interventions; device closure of multiple atrial septal defects in one and residual ventricular septal defect in three.

3.2.5. Group B: hemodynamic results

The mean RV pressure showed significant reduction from 98.56 ± 27.19 mmHg to 50.65 ± 15.1 mmHg following the procedure. The right ventricle to aortic pressure ratio also significantly reduced from 0.86 ± 0.25 to 0.41 ± 0.12. The diameter of the stenosed pulmonary arteries showed a significant increase from a mean of 5.19 ± 1.89 millimetres to 11.25 ± 2.07 millimetres for right PA and from 5.02 ± 2.08 millimetres to 10.91 ± 2.35 millimetres for left PA. (Fig. 1)

3.2.6. Group B: outcome and follow-up

Stenting was successful in all the 22 patients. One patient underwent successful postoperative bilateral PA stenting within three days after surgery, but died four days later due to sepsis and multiorgan dysfunction. Hyperperfusion lung bleed in a patient with cutis laxa was successfully managed by antifibrotic placement of double lumen endotracheal tube. Stent migration in two patients needed multiple overlapping stents. On a median follow-up of 6 years (0.5–9 years), two patients needed surgery later. Surgical conduit replacement with bilateral stent removal was performed five years later in one patient. The other patient underwent tricuspid valve repair and supravalvar aortic surgery six years later; but stented PA were widely patent. Five patients needed reimplantation for outgrowing stents with increasing gradients. One patient was treated for enterococcal endocarditis. Two patients were lost to follow-up after successful procedure.

3.3. Freedom from reinterventions

Surgical reinterventions were done in three and transcatheter reinterventions in sixteen patients on a median follow-up of 4 years (0.5–10 years) in the entire cohort (Fig. 4). The three surgeries included redo surgery in one patient with failed main PA stenting after two weeks, conduit replacement and repair of the stented pulmonary arteries in the second patient and supravalvar aortic surgery (without any interventions on the stented pulmonary arteries) in the third patient. Elective PVR was done in nine patients after conduit stenting and seven patients required stent redilatation. Hemodynamic status of three patients who were lost to follow-up was unknown.

4. Discussion

When surgical conduits degenerate or reconstructed pulmonary arteries narrow, elevated RV pressures might warrant a redo surgery. Repeated surgeries pose a higher risk than the initial surgery and have economic impact on scarce resources. We aimed to see if stenting would avoid or postpone a repeat surgery. This study aimed to study the safety and efficacy of stent angioplasty to reduce the elevated RV pressures. The need for and frequency of catheter reinterventions in medium term follow-up and freedom from redo open-heart surgeries was analyzed.

Surgical patch repair of PA stenosis or balloon angioplasty fail to provide permanent relief due to recoil and scarring. Stents provide sustained relief, support vessel wall and avoid recoil in PA and conduits. Neointimal hyperplasia of stents protects against thrombosis. The procedure was successful in all (98%)
4.1. Conduit stenting

Conduits narrow either due to progressive fibrosis, calcific degeneration or anastomotic scarring. Increased RV pressures lead to hypertrophy, fibrosis and ventricular failure. The initial conduit lasted for 0.5-19 years after the initial surgery and was less than eight years in half of the patients. Frequent conduit changes carry the risk of redo sternotomy and cardiopulmonary bypass. Stenting significantly lowered the RV pressures and served to delay conduit replacement in all patients. In none of these patients, there was a need for conduit change at a follow-up of 3-120 months. Even though nine patients had elective PPVI, freedom from open-heart surgery was 100%.

4.2. Main PA stenting

Supravalvar main PA stenosis occurred after arterial switch in three patients and tetralogy repair in two, 6 months to 6 years after surgery. While the stenting succeeded in four patients (80%) who were beyond infancy, it failed in an infant after tetralogy repair due to proximal stent migration and inadequate gradient relief. Main PA stents need to be short to avoid trapping the valve leaflets and post-dilatable to cope for somatic growth. Stenting is superior to balloon angioplasty after arterial switch surgery.

4.3. Bilateral PA stenting

Simultaneous stenting was safe and effective in reducing RV pressures in bilateral PA stenosis in all patients. Acute postoperative stenting was safely completed three days after tetralogy repair, but the child died later of other reasons. Unilateral hyperperfusion lung bleed in one patient with cutis laxa was
managed by ventilator strategies. Simultaneous stenting should be done to avoid such unilateral hyperperfusion injury.\textsuperscript{18}Bifurcation kissing Y stenting strategy also needs simultaneous approach. Half of our patients had Y stenting. If femoral veins are occluded, femoro-femoral cardiopulmonary bypass is not feasible making redo surgery risky.\textsuperscript{6} Stenting was effective in patients with occluded femoral veins through jugular or hepatic veins. Stent migration in two patients needed placement of additional anchoring stents. Even though a repeat surgery was needed in two patients on follow-up, only one needed PA repair near the implanted stents and the other had widely patent stents.

4.4. Complications

Young age is often associated with complications following PA stenting.\textsuperscript{29} Complications were seen in 12\% patients aged under five years in our group. It included procedural failure in an infant with main PA stenosis needing redo surgery two weeks later and stent migration in another managed with overlapping stents. Even though fresh suture lines are another known risk factor, acute postoperative stenting was safe in our patient due to avoidance of overdilation and simultaneous deployment of bilateral stents.\textsuperscript{29} Complications like stent migration, balloon rupture, vessel dissection, pulmonary edema, arrhythmia, or thrombosis have been reported in 17\% of stenting procedures.\textsuperscript{30} Bilateral stenting has been reported to have high incidence of restenosis (32\%) and complications (6\%).\textsuperscript{18} The results were better in our cohort. Major complications were noted only in 4 patients (8\%) in our group and it included procedural failure in one, migration in two and lung hemorrhage in one.

4.5. Redilation of stents

Serial planned stent redilation are needed to keep pace with somatic growth and to treat in-stent restenosis especially in young patients.\textsuperscript{29,30} A few recent premounted post-dilatable stent designs have made stenting feasible even in small infants. Stent redilatations were done in four patients including one with occluded groin veins.

4.6. Study limitations

No comparisons were made between stenting and plain balloon angioplasty. During the study period, a small number of patients with narrowed PA and conduits underwent surgery when they had additional residual defects or valvar regurgitations. So the stented and surgical groups were not comparable. Procedural costs between surgery and stenting were not compared. While clinical and echocardiographic follow-up was complete in 94\% of patients, hemodynamic assessment or advanced imaging was performed on follow-up.

5. Conclusions

Stent angioplasty of stenosed conduits was safe; effective in relieving gradients, provided sustained relief and avoided surgical conduit change on medium term follow-up. They served as a landing zone for PPVI in a third of the patients. Stenting was equally safe and effective in bilateral pulmonary artery stenosis and often avoided repeat surgeries. It was feasible even when femoral veins were occluded. Complications were uncommon and often manageable in the catheterization laboratory. Elective
transcatheter redilatations in younger patients who outgrow their stents might offer an even longer freedom from a repeat surgery.

Financial support

None.

Ethical standards

All procedures comply with the ethical standards of the Helsinki declaration and are approved by institutional ethical committee.

Conflicts of interest

None.

Acknowledgements

None.

References