Is Stent Placement Effective for Palliation of Right Ventricle to Pulmonary Artery Conduit Stenosis?

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Objectives
This study was designed to evaluate the outcome of stent placement (SP) for conduit discrete stenosis using predefined criteria.

Background
Right ventricle (RV) to pulmonary artery (PA) conduits are often associated with complications, such as stenosis, requiring multiple surgical replacements.

Methods
Patients who underwent primary or repeat SP were included. Indications for SP were clinical symptoms and/or RV to systolic blood pressure (SBP) ratio (RV:SBP) > 0.65 by echocardiography. Our definition of success was a decrease in RV:SBP by > 20%, a final RV:SBP ratio of < 0.65, or resolution of symptoms.

Results
Stents were placed successfully in 28 of 31 patients (90%), including 3 patients who underwent the procedure solely for symptoms. The RV:SBP ratio decreased (0.75 ± 0.17 vs. 0.52 ± 0.12, p < 0.001), and the conduit diameter increased (postero-anterior 9.1 ± 2.9 vs. 12.0 ± 2.8 mm, lateral 8.3 ± 2.2 vs. 11.6 ± 2.4 mm, p < 0.001). In the 28 patients with successful SP, 8 (29%) remained free from second intervention. In the remaining patients, the median time to re-intervention was 16 months (range 6 to 44 months). Second transcatheter interventions (4 SP, 4 balloon dilation) were successful in 8 of 13 patients. Complications included balloon rupture (n = 4), stent fracture (n = 2), and pseudoaneurysm formation (n = 1).

Conclusions
Initial SP has excellent intermediate outcomes, successfully postponing surgical intervention for the majority of patients. Conduit restenosis may be successfully treated with a second transcatheter intervention. On the basis of these data, SP is likely the procedure of choice for patients with a discrete stenosis of the RV to PA conduit. (J Am Coll Cardiol 2007;49:480–4) © 2007 by the American College of Cardiology Foundation

Surgical placement of a right ventricle (RV) to pulmonary artery (PA) conduit is the procedure of choice for palliation of RV outflow tract obstruction in many forms of complex congenital heart disease. Conduit placement is limited by the need for surgical replacement owing to progressive conduit obstruction, valve dysfunction, or patient growth (1,2). Conduit replacement is associated with high morbidity in patients with multiple previous cardiac procedures (3).

The most common reason for surgical conduit replacement is stenosis (4). Because of surgical morbidity, transcatheter balloon angioplasty was initially used in an attempt to relieve conduit stenosis with poor results (5–7). Subsequently, endovascular stent placement has emerged as a therapeutic option to prolong the survival of RV-PA conduits, with improved results (3,8–10). Although these studies reported hemodynamic improvement after stent placement, a strict definition of success was not used to determine immediate and intermediate outcomes. The present study examines: 1) our experience with stent placement as treatment of RV-PA conduit discrete stenosis using strict, predefined criteria for procedural success, and 2) our intermediate results of transcatheter intervention for the postponement of surgical conduit replacement.

Methods
Approval from the Human Investigation Committee of Wayne State University was secured for access to patients’ charts for this retrospective review. The catheterization laboratory database from January 1993 to December 2003 was reviewed for patients who underwent stent placement in RV-PA conduits. Patients in whom additional pulmonary artery interventions were performed were excluded from the study. The technique for stent implantation has been previously described (11,12). The indications for stent placement were clinical symptoms (e.g., exercise intolerance, fatigue, or increasing cyanosis) and/or an RV to systolic blood pressure (SBP) ratio (RV:SBP) of ≥ 0.65 by...
echocardiography. During the period of the study, every patient who met these criteria and had a discrete stenosis on catheterization underwent stent placement. However, if the stenosis was diffuse or the patient had simply outgrown the conduit, there was no attempt to place the stent.

The criteria used for defining procedural success were: 1) a decrease in the RV:SBP ratio by >20%, and 2) a final RV:SBP of <0.65, or 3) a resolution of symptoms following stent placement. These criteria were selected because a RV:SBP ratio of more than 0.65 is a widely accepted threshold for intervention, and a drop in RV:SBP by at least 20% limited the chance that small variations in hemodynamics were interpreted as significant changes.

Patient records from clinic visits, surgical procedures, echocardiograms, and cardiac catheterization were reviewed retrospectively. For each patient, demographic data including age, weight, gender, diagnosis, size and type of conduit, number of previous surgical replacements, and date of last surgery were recorded. Catheterization data included directly measured RV:SBP and the peak systolic pressure difference across the conduit before and immediately after stent placement. Angiographically, the site of conduit stenosis was defined as proximal (below the conduit valve), mid-portion (at or near the conduit valve), or distal (at the conduit-pulmonary artery anastomosis). The narrowest conduit diameter was measured on the postero-anterior and lateral projections before and after transcatheter intervention using the Siemens Cathcor system with online measurement capability (Siemens Medical Solutions, Nuremberg, Germany). If the site of obstruction did not involve the valve, only the stenotic proximal or distal segment of the conduit was covered. The valve leaflets were preserved when possible.

A rigid protocol for follow-up was observed in our center. Echocardiograms were obtained on the day of stent placement, between 3 and 6 months after the procedure, and yearly thereafter. Additional echocardiograms were performed in case of symptoms. Echocardiographic data included before and after stent placement and most recent follow-up RV systolic pressure estimate from tricuspid regurgitation, RV:SBP, and the peak systolic pressure difference across the conduit. Study end points included surgical conduit replacement or the most recent follow-up data.

Statistical analysis. Statistical analyses were performed using SPSS software, version 11.5 (SPSS Inc., Chicago, Illinois). Patient demographic, hemodynamic, and angiographic data are described as frequency, median (range), and mean ± SD as appropriate. The paired, 2-tailed Student t test was used for analyzing hemodynamic and angiographic data before and after stent placement. Kaplan-Meier curves were used to plot freedom from re-intervention. The Cox proportional hazard regression model was used to compare multivariate relationships among patient characteristics, conduit and stent types, and other procedural characteristics with freedom from re-intervention. Univariate relationships among patient demographics, hemodynamics, and outcomes were evaluated by linear regression, 1-way ANOVA, and 2-sample Student t tests when appropriate. A p value of <0.05 was used for statistical significance.

**Results**

**Patient characteristics.** A total of 31 patients (14 men and 17 women) underwent 38 stent placement procedures for treatment of RV-PA conduit stenosis. In 6 of 31 patients, a second (n = 5) or third (n = 1) stent was placed during separate catheterization procedures. During the same time period, 28 patients did not qualify for stent placement and underwent surgical replacement of the RV-PA conduit. The median age at initial stent placement was 12 years (range 1.5 to 25.6 years), and the median weight was 39 kg (range 7.9 to 89.4 kg). In our cohort, 7 of 31 patients (23%) were symptomatic, and 4 of them had RV:SBP ratios >0.65. Three patients underwent stent placement solely because of symptoms. The primary diagnoses included tetrology of Fallot with (n = 4) or without (n = 10) pulmonary atresia, truncus arteriosus (n = 8), transposition of great arteries with pulmonary stenosis (n = 8), and aortic stenosis status after the Ross procedure (n = 1). The number of surgical conduit revisions performed before stent placement were none (n = 16), 3 (n = 9), 2 (n = 5), and 1 (n = 1). The RV-PA conduits were cryopreserved pulmonary (n = 14) or aortic (n = 8) homografts or Dacron tubes (n = 8); 1 conduit type was unknown. There were 25 valved and 6 nonvalved conduits. The median original conduit diameter was 17 mm (range 7 to 27 mm). Mild to moderate pulmonary insufficiency was recorded on echocardiogram in all except 2 patients who had severe stenosis with a gradient of 80 to 90 mm Hg across the conduit.

**Initial stent placement.** The site of conduit obstruction was proximal (n = 7), mid-portion (n = 17), or distal (n = 7). Stent type was Palmaz (n = 21; Cordis Corp., Warren, New Jersey), Large Diameter (n = 4; eV3, Minneapolis, Minnesota), Genesis-XD (n = 4; Cordis Corp.), and Cheatham-Platinum (n = 2; NuMED, Inc., Hopkinton, New York). The choice of stent was based on availability and size. Palmaz stents were used for size <18 mm and Large Diameter or Cheatham-Platinum for size >8 mm. Since the Genesis XD stent became available in 2000, it has been preferred for conduits >18 mm. The RV pressure, conduit gradient, RV:SBP ratio, and conduit diameter at the site of stenosis improved significantly immediately after stent placement (Table 1).

Echocardiographic estimates of RV pressure and RV:SBP ratio were similarly improved after stent placement (Table 2).
Our definition of success was met in 28 of 31 (90%) initial stent procedures, including the 3 whose symptoms resolved following the procedure. In 1 unsuccessful procedure, RV:SBP decreased by 44% but did not fall below 0.65 (1.26 before vs. 0.71 after stent). No significant change in RV:SBP was found in the 2 remaining procedures. Univariate analysis showed that a higher before-stent, directly measured RV systolic pressure (91.7 ± 42.1 mm Hg vs. 68.5 ± 15.3 mm Hg) and a higher estimated echocardiographic conduit gradient (75 ± 30.8 mm Hg vs. 63.4 ± 11.2 mm Hg) were significantly associated with failure. Success was not significantly associated with patient age at the time of conduit or stent placement, weight, gender, diagnosis, conduit size, type of stent, or location of stenosis.

**Follow-up.** Of the 28 patients with successful procedures, 8 (29%) continued to have a RV:SBP of <0.65 (0.53 ± 0.7) by echocardiography at latest follow-up (median 36 months, range 10 to 74 months). The RV systolic pressure estimate was 61.3 ± 12.4 mm Hg. Of the remaining 20 patients with initial success, 13 underwent transcatheter re-intervention, 5 underwent surgical conduit replacement, and 2 were lost to follow-up. The median time to re-intervention was 16 months (range 6 to 44 months). The freedom from re-intervention, based on Kaplan–Meier analysis, was noted in 67% of patients at 1 year, 50% at 2 years, and 33% at 3 years (Fig. 1). The criteria for re-intervention were the same as for initial intervention.

Of the 3 patients with unsuccessful initial procedures, 1 had a dramatic decrease in RV:SBP from 1.26 to 0.71 but did not meet our criteria for success. At a repeat catheterization 12 months after the initial procedure, a stent fracture was noted. A second stent was placed over the fractured stent, but the procedure did not improve the RV:SBP ratio, and the patient underwent surgical conduit replacement.

Balloon dilation of a previously placed stent was performed in another patient. In a third patient with tetralogy of Fallot, pulmonary atresia, and a residual ventricular septal defect, peripheral arterial saturation increased after stent placement, although the procedure did not meet our definition of success.

**Repeat transcatheter intervention after initial success.** Repeat stent placement was performed in 5 patients. The indications were stenosis at a different site within the conduit (n = 4) and stent fracture (n = 1). Palmaz stents were used in all 5 patients. Of the 3 patients who met our criteria for success after the second stent procedure, all were re-intervention-free at follow-up (median 42 months, range 27 to 56 months). Of the 2 failures, one patient could not undergo stent placement because of non-availability of an appropriately sized balloon. He subsequently underwent a successful stent placement procedure. The other failure underwent surgical replacement of the conduit.

Transcatheter balloon dilation of the previously placed stent was performed in 8 patients. Before the year 2000, the Opti-Pro balloon (Cordis Corp.) was used for stent sizes <12 mm and the Blue Max balloon for sizes >15 mm. Given the propensity of these balloons to rupture, since 2000, we have used the Cordis Powerflex for stent sizes <12 mm, Cordis Max for stents 12 to 15 mm, and the Bib balloon for stents >15 mm. It is important to use high-pressure balloons with the largest possible diameter. Of the 4 patients who met our criteria for success after balloon angioplasty, 2 are re-intervention-free, and 2 required surgical conduit replacement at follow-up (median 49 months, range 15 to 55 months).

Overall, repeat transcatheter intervention was successful in 7 of 13 (53.8%) patients. Surgery was ultimately delayed by a median of 42 months (range 15 to 56 months).

![Figure 1](image.png)

**Table 1** Catheterization Data Before and After Initial Stent Placement

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Before Stent (Mean ± SD)</th>
<th>After Stent (Mean ± SD)</th>
<th>p Value (n = 31)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Right ventricular pressure (mm Hg)</td>
<td>70.7 ± 19.4</td>
<td>54.7 ± 13.2</td>
<td>≤0.001</td>
</tr>
<tr>
<td>RV:SBP ratio</td>
<td>0.75 ± 0.17</td>
<td>0.52 ± 0.12</td>
<td>≤0.001</td>
</tr>
<tr>
<td>Conduit diameter, postero-anterior view (mm)</td>
<td>9.1 ± 2.9</td>
<td>12 ± 2.8</td>
<td>≤0.001</td>
</tr>
<tr>
<td>Conduit diameter, lateral view (mm)</td>
<td>8.3 ± 2.2</td>
<td>11.6 ± 2.4</td>
<td>≤0.001</td>
</tr>
</tbody>
</table>

RV:SBP = right ventricular to systolic blood pressure ratio.

**Table 2** Echocardiographic Data Before and After Initial Stent Placement

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Pre-Cath (Mean ± SD)</th>
<th>Post-Cath (Mean ± SD)</th>
<th>p Value (n = 38)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Right ventricular pressure (mm Hg)</td>
<td>83 ± 13.3</td>
<td>56 ± 12.5</td>
<td>0.001</td>
</tr>
<tr>
<td>RV:SBP ratio</td>
<td>0.79 ± 0.12</td>
<td>0.52 ± 0.11</td>
<td>0.01</td>
</tr>
</tbody>
</table>

Abbreviations as in Table 1.
Surgery. By the end of the study period, 17 patients had undergone surgical conduit replacement. No technical difficulties were encountered secondary to the previously placed stents. The methodology employed was to cut open the conduits from end to end with the stents in situ.

Complications. Complications were encountered in 9 of 38 procedures (24%), including balloon rupture (n = 4), stent fracture (n = 2), stent malposition after balloon rupture requiring deployment of the stent in the inferior vena cava (n = 1), partial occlusion of the proximal left pulmonary artery (n = 1), and pseudoaneurysm formation (n = 1). The pseudoaneurysm and stent fractures were noted at subsequent cardiac catheterizations. A certain degree of calcification was present in all cases; when severe, balloon dilation was performed at the site of stenosis before stent placement. All complications were encountered in the first 5 years of our experience, and none required emergent surgical intervention. There were no deaths.

Discussion

For the past 3 decades, surgical placement of conduits from the right (sub-pulmonary) ventricle to the pulmonary arteries has been used for palliation of RV outflow tract obstruction associated with complex congenital heart defects (13–15). Although advances in surgical technique and availability of newer types of conduits have improved outcome, more than 50% of conduits require replacement within 10 years.

Conduit stenosis is the most common reason for reintervention (4,14). Surgical conduit replacement is associated with high morbidity owing to multiple ventriculotomies and cardioplegia/caridiopulmonary bypass (3). Repeat midline sternotomies are frequently technically difficult because of fibrosis and adherence of the conduit to the sternum. Furthermore, subsequent (replaced) homograft conduits have a shorter lifespan (14). Therefore, nonsurgical, less invasive methods to prolong conduit lifespan are important to the clinical care of patients with congenital heart disease.

Transcatheter balloon angioplasty of conduit stenosis is associated with limited success owing to rapid recoil of the conduit wall (5,7). More recently, stent placement for conduit stenosis was first performed on baboons and subsequently on humans with a significant decrease in the RV:SBP ratio after stent placement (3,8–10,12,16). Unfortunately, none of these previous studies used a strict definition of success, so that institutional bias may be present in reporting. Furthermore, there are limited follow-up data on whether conduit stent placement results in a meaningful delay of surgical replacement in patients with conduit stenosis.

Using our strict criteria for success, conduit lifespan was prolonged for >1 year in 67% of patients and for at least 36 months in 33% of patients after stent placement. Each of these patients would otherwise have been a candidate for surgical intervention. Furthermore, repeat conduit intervention for conduit restenosis was successful in 54% of patients without significant complications. Therefore, with 2 transcatheter interventions, conduit lifespan was extended for a median of 42 months in this study. Complications in our study were infrequent and occurred in the first few years. This could be attributed to multiple reasons, including a learning curve and improvement in skills in the operator; availability of high-pressure, more compliant balloons; improved stent design; and availability of bigger stents. The effect of stent placement on later surgical procedures, specifically the bypass times in comparison to children with conduits without stents, needs to be evaluated in future prospective studies.

Worsening of pulmonary insufficiency with stent placement across a valved conduit is reported in published data and may be aggravated by distal obstruction in pulmonary arteries. The extent and evolution of the deleterious effect of valvular regurgitation on RV function is not clearly known. However, there is a serious concern that progressive pulmonary valve regurgitation may increase susceptibility to arrhythmias and cause sudden death and RV dysfunction, which may be irreversible in some cases (17,18). Even in the presence of pulmonary valve regurgitation, stent placement could be a useful short-term solution to prolong the life of the stenosed conduit and avoid multiple surgical replacements and cardiopulmonary bypass. This may enable placement of bigger conduits after a period of somatic growth. Besides, if stenosis coexists with insufficiency, stent placement may alleviate the pressure overload on the RV.

Recently, there has been increasing experience with and interest in the percutaneous placement of bovine valves within a balloon expandable stent. The advantage of this technique is that it relieves conduit obstruction without causing pulmonary valve insufficiency. The data are currently limited to patients who weigh more than 20 kg, long-term outcomes are scarce, and the technique is not available in the U.S. (19,20). A single case report in a 10-month-old demonstrates the technical feasibility of the procedure in smaller patients (21). In the future, with improvement in technology, this procedure is likely to become a nonsurgical therapeutic option.

The issue of possible compression of the proximal coronary artery during stent placement is a concern in patients with tetralogy of Fallot who have undergone conduit placement because of an anomalous coronary artery (22). In our series, 2 patients with tetralogy of Fallot had conduit stent placement without any coronary artery complications. It is imperative that this patient population has a coronary artery evaluation before and after stent placement. If necessary, an angioplasty balloon may be inflated during simultaneous coronary angiography.

Study limitations. This is a retrospective analysis of data. Complications may be underestimated, as there was no routine surveillance of patients other than by clinical findings and echocardiograms. Information on RV dimensions
and sensitive functional analysis, such as exercise testing, over the duration of follow-up was not available from our retrospective analysis.

**Conclusions.** Stent placement as the initial treatment for conduit stenosis is safe, effective, and has excellent intermediate outcomes. Surgical conduit replacement is delayed after stent placement in the majority of patients. Conduit restenosis may be successfully treated with a second transcatheter intervention, including balloon angioplasty of the previously placed stent and/or placement of an additional stent. On the basis of these data, stent placement appears to be the procedure of choice for patients with a discrete stenosis of the RV to pulmonary artery conduit.

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**REFERENCES**


