Transcatheter Occlusion of the Persistently Patent Ductus Arteriosus
Forty-Month Follow-up and Prevalence of Residual Shunting

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Background. Percutaneous closure of the persistently patent ductus arteriosus with the Rashkind prosthesis is an established effective therapeutic modality, although some patients are left with residual shunting. To evaluate this, a retrospective study of the prevalence of persistent shunting over a 40-month period in the first 190 patients was undertaken.

Methods and Results. All patients (male 45, female 145; mean age, 3.9±3.6 years; range, 5 months to 20 years) had serial clinical and color-flow echocardiographic follow-up at 6–12-month intervals (range, 6–40 months). Four patients required surgical removal of an embolized device, leaving a cohort of 186 patients in whom 196 procedures were performed, resulting in successful placement of 195 devices (43 17-mm [22%] and 152 12-mm [78%]). Complications occurred in seven of 195 procedures (3.6%). Nine of 10 attempted reocclusions (all with 12-mm devices) were successful. The prevalence of residual shunting was 38% at 1 year, 18% at 2 years, and 8% at 40 months. Patients with ductus measuring less than 4 mm had a higher success of initial occlusion. Thirty-four patients were left with residual shunting determined by color-flow Doppler study, but no anatomic or echocardiographic features were found predictive for residual shunting. All remain asymptomatic with 26 (76%) having no detectable murmur, two (6%) a continuous murmur, and six (18%) a systolic murmur.

Conclusions. Catheter occlusion will obviate the need for surgery in the majority of patients presenting with persistently patent ductus arteriosus. Reocclusion has been found feasible in those with continuous murmurs (nine of nine) and should be offered early because it is unlikely for spontaneous closure to occur in this group. It appears prudent to follow those with residual shunting because further spontaneous closure can occur. (Circulation 1991;84:2313–2317)

Percutaneous closure of the persistently patent ductus arteriosus with the Rashkind prosthesis (USCI Angiographics, Tewksbury, Mass.) has been established as an effective management modality with low morbidity and no mortality.1–6 However, some patients are left with small residual left-to-right shunts identified by Doppler echocardiography. Few patients outside the neonatal period undergo closure for relief of symptoms caused by left ventricle failure. In the vast majority, ductus occlusion is an elective procedure to eliminate endarteritis risk. Thus, the effectiveness of catheter occlusion requires review with particular regard to the natural history of these residual shunts. The time course for

shunt disappearance through 1 year postimplantation has been examined by Musewe et al,7 who report a residual shunt in 38% of patients at 24 hours falling to 19.7% 1 year postprocedure. Spontaneous closure and secondary reocclusion will further influence the final prevalence of residual shunting. To these ends,

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this study addresses shunt prevalence from our first 200 ductal occlusion procedures on 190 patients over 3½ years of follow-up.

Methods

Patient Population

Between February 1986 and June 1990, 190 patients (male 45, female 145) underwent elective patent ductus arteriosus occlusion with the Rashkind ductal occluder at the Hospital for Sick Children, Toronto. Mean age was 3.9±3.6 years (range, 5 months to 20 years). Ninety-six percent (n=182) had isolated ductus, two patients an associated pulmo-
nary valve stenosis (both having concurrent balloon valvotomies), and one each an atrioventricular septal defect and complex univentricular connection after an atroipulmonary connection. Two patients each had an isolated small perimembranous ventricular septal defect and left pulmonary artery stenosis and two had previous attempted surgical ligations. For consideration for occlusion, patients were required to weigh more than 6 kg and have normal atrial isomcrism and no arch anomalies.

Four of the 190 patients reviewed required surgical ligation as a result of device embolization; these patients are not included in the analysis. Therefore, the study cohort consisted of 186 patients having 196 procedures with 195 devices placed (see “Results”). In follow-up, all patients had routine clinical examinations and color-flow Doppler echocardiographic study at least 6 months after device implant (range, 6–40 months) and serially during the follow-up period.

**Occlusion Technique**

All procedures were performed on patients over 6 kg in weight under general anesthesia from the right femoral vein by using either an 8- or 11-F sheath and by following previously described techniques. For the ductus measuring less than 4 mm in internal diameter, a 12-mm device was used, and the ductus measuring 4 mm or greater but less than 8 mm were occluded with 17-mm devices. A retrograde arterial approach with a femoral artery–femoral vein wire loop technique was required in three patients after unsuccessful attempts at ductus cannulation from the venous approach. Balloon dilatation (4-mm diameter, Cook Inc., Bloomington, Ill.) of the ductus was required in 17 patients (one patient during reocclusion) in whom the 8-F sheath (9-F O.D., 3 mm) could not be passed.

**Doppler and Echocardiographic Examination**

All patients had imaging by color-flow Doppler examination within 24 hours of occlusion and serially during follow-up (at 6–12-month intervals). Studies were performed using previously described techniques on an ATL Mark 9, Hewlett Packard 77020A or SONOS 1000 system, using either 3.5- or 5.0-MHz transducers. Residual shunts were best visualized with the low-frequency transducer. The transducer was maneuvered through multiple sagittal and axial planes to ensure that small or eccentric jets were not missed. Particular attention was paid to the detection of residual shunt patterns, device position, and left pulmonary artery stenosis or distortion. The prevalence of residual shunting was solely based on color-flow Doppler evidence of left-to-right shunting.

**Statistical Analysis**

Results are expressed as mean±1 SD. Comparison of parameters between groups was performed with a χ² or unpaired two-tailed Student’s t test. The prevalence of residual ductal shunting was evaluated using a Kaplan-Meier product-limit analysis technique.

**Results**

**Ductal Occlusions**

A total of 196 occlusion procedures were attempted on ductus measured at the pulmonary artery insertion averaging 2.7±0.7 mm (range, 0.5–8 mm). Nine of 10 attempted reocclusions were successful, all with the use of 12-mm devices. Of the 195 devices placed, including second reocclusions, there were 43 17-mm (22%) and 152 12-mm (78%).

**Complications**

In the four patients with device embolizations, three were to the right and one was to the left pulmonary arteries (three of four embolizations occurred in the initial 25 patients). Three patients required surgical retrieval, and in one, the device was removed with an intravascular retrieval catheter. In one patient, the device became entangled in the tricuspid valve during catheter retrieval and required surgical removal. There were two instances of transient mild hemolysis, presumably caused by passage of blood under high pressure through the foam, and one patient was treated successfully for active bacteremia postimplantation without device removal.

**Prevalence of Residual Ductal Shunting**

The prevalence of residual shunting for patients undergoing a single-occlusion procedure (n=177) from day 1 through 40 months of follow-up using a Kaplan-Meier product-limit analysis is shown in Figure 1. Residual shunting fell from 53% on day 1 to 34% at 1 year, 19% at 2 years, and 11% at 40 months. The results of all patients with persistently patent ductus arteriosus managed by catheter occlusion (n=1/6), including those patients who received a second device (n=9), demonstrated a prevalence of ductal shunting of 38% at 1 year, 18% at 2 years, and 8% at 40 months.
Table 1. Comparison of Variables Between Patients With and Without Residual Shunt at Final Follow-up

<table>
<thead>
<tr>
<th></th>
<th>Residual shunt (n=34)</th>
<th>No residual shunt (n=152)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at occlusion (yr)</td>
<td>4.3±4.05</td>
<td>3.8±3.6</td>
<td>NS</td>
</tr>
<tr>
<td>Weight at occlusion (kg)</td>
<td>16.1±10.8</td>
<td>15.7±10.3</td>
<td>NS</td>
</tr>
<tr>
<td>Ductus lumin (mm)</td>
<td>2.9±1.2</td>
<td>2.3±1.0</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Ductus occluder size (mm)</td>
<td>12 mm</td>
<td>22</td>
<td>130*</td>
</tr>
<tr>
<td></td>
<td>17 mm</td>
<td>12</td>
<td>31</td>
</tr>
</tbody>
</table>

*Nine as second device.

From our initial cohort of 77 patients,7 excluding those who underwent a second occlusion, the prevalence of residual shunting at 40 months of follow-up was 18%. Three patients previously reported to have residual shunt at the time of initial analysis have subsequently undergone spontaneous closure at periods of 13 months to 25 months after occlusion. Five patients have undergone further second occlusion, leaving a final prevalence within this initial group of 13%.

All nine patients who underwent a second occlusion procedure had successful uncomplicated placement with no color-flow Doppler evidence of residual left-to-right shunting.

Comparative Data on Patients With and Without Residual Shunts

Ductal size (p<0.05) and consequently the use of 17-mm devices (p<0.01) were greater in those with residual shunts with other parameters being similar (Table 1). One-year follow-up of 74 patients with color-flow Doppler evidence of complete occlusion has demonstrated no incidence of recanalization to date.

Clinical and Echocardiographic Findings of Residual Ductal Shunting

Thirty-four patients are left with color-flow Doppler evidence of residual shunting. All remain asymptomatic with 26 (76%) having no detectable murmur, two (6%) a continuous murmur, and six (18%) a soft systolic murmur. No patient with a continuous murmur on clinical examination went on to spontaneous closure and no echocardiographic or angiographic features were found characteristic of those with continuous versus systolic or no murmur. A single discrete color-flow jet coursing over the superior aspect of the device along the anterior wall of main pulmonary artery was seen in 24 of these patients. In four patients, the shunt base was broader with a more turbulent flow pattern. Three patients had multiple discrete jets through the device, whereas in three, the jet was inferior. Those few patients with significant left ventricular volume loading all had resolution of symptoms.

Discussion

Catheter occlusion of the persistently patent ductus arteriosus with the Rashkind ductal occluder is a management alternative for those patients weighing more than 6 kg and having a ductus of less than 8 mm. Early reports have concentrated on the degree and effectiveness of immediate closure and resolution of symptoms in patients with significant left-to-right shunting, with studies (up to 2 years of follow-up) suggesting a residual shunt prevalence of 0–30%.

Color-flow Doppler examination sensitive to the presence of small residual shunts was not used for the duration of each study. In this regard, the time course for disappearance of these small residual shunts has not been assessed in medium-term follow-up. Musewe et al7 followed an initial cohort of 77 patients through 1 year with color-flow studies and found a residual shunt rate of 19%. Speculation at that time was that further spontaneous occlusion might occur. The role of second occlusion was only briefly examined, with five patients having a second device placed with a successful outcome.

The data from this study demonstrate an 8% residual shunt at 40 months of follow-up for 186 patients treated with catheter ablation for patent ductus arteriosus. To examine the efficacy of a single-occlusion procedure in complete resolution of ductal flow, the nine patients with a second device placement were excluded from the analysis, resulting in an 11% residual shunt rate. An initial day-1 success (53%) followed by a steady decline over the next 2 years is demonstrated. These results compare favorably with those initially published5–6 and greatly extend the follow-up period.

Serial echocardiographic follow-up of surgical ligation has been infrequent, although residual shunt rates of 6%7 and 23%11 have been reported. Our data demonstrate that even though catheter occlusion can be a successful management option, it is apparent that there is an initial high day 1 prevalence of residual shunting compared with surgical procedures assessed by color-flow imaging. Residual shunting is more frequent with the use of a 17-mm device, although ductal morphology has not been found predictive of shunt persistence.12

Concern has been expressed regarding possible encroachment of the occluder arms into the left pulmonary artery leading to stenosis. A review of 94 patients in the study cohort13 has demonstrated angiographic evidence of mild narrowing in half of the patients. There was no relation, however, between the degree of angiographic narrowing and pulsed Doppler–estimated branch obstruction, which was mild. The long-term significance of persistent mild turbulent flow on the integrity of the left pulmonary artery and potential for development of stenosis is not known. Mild left pulmonary artery
narrowing after surgical or spontaneous closure of the patent ductus is known, however.

The safety of ductal occlusion has been demonstrated by this and other studies. In this cohort, four device embolizations occurred within the first 25 occlusion procedures. During this time, the occluder release was modified from a knuckle-eye to pin-pin attachment mechanism. However, this modification was associated with two of four emboli in quick succession, and as a result the knuckle-eye mechanism was reintroduced.

When considering the therapeutic option of a second occlusion for residual shunting, the timing for this procedure had been arbitrarily set at approximately 1 year. However, follow-up data from our initial cohort has demonstrated that spontaneous occlusion may occur up to 2 years after device placement. Whether these late occlusions are a result of further fibrous deposition or alterations of device spatial geometry as a result of growth is purely speculative. There are no anatomic or echocardiographic features predictive of spontaneous closure after implantation. Irrespective of the optimal timing of second occlusion, attempted repeat occlusion in nine cases has resulted in complete resolution of their shunts. Of note, a continuous murmur was consistently present in those who have undergone successful second occluder placement. In the patient with only a short soft systolic murmur, the size and or contour of the residual communication precluded even successful wire cannulation. It appears that although a few residual communications can potentially be occluded with a second device, the majority may be left with a residual shunt that is not likely to be amenable to further catheter interventions at this time. In this regard, it seems reasonable, therefore, to offer any patient with a continuous murmur early recooclusion.

The existence of shunting in the absence of physical signs in both ductal occlusion patients and in patients undergoing echocardiographic studies for nonducal occlusion has recently been reported. The clinical management of such patients with a "silent ductus," that is, a patient (in the absence of pulmonary hypertension) who has either no murmur or a systolic murmur of vibratory quality and echocardiographic findings of ductal flow remains problematical. On review of the literature to date, there are no reports of subacute bacterial endarteritis in patients who were not known to previously have a continuous murmur. Apart from the single case of postimplant sepsis in a patient who did not receive prophylactic antibiotics, no further cases of endarteritis or sepsis have occurred. We are unaware from the multicenter trial of any patients acquiring endarteritis postimplantation who received proper acute antibiotic prophylaxis.

Recognizing that catheter occlusion will probably fail to give 100% success and thus leave a small group of patients at an unknown risk of endarteritis, is catheter occlusion a justified management option for the asymptomatic child? To answer this question, the prevalence of color-flow Doppler shunting after surgical ligation must be more completely addressed, as well as the risk of endarteritis. It would appear that the former situation is not uncommon when flow patterns are assessed by color Doppler technologies and endarteritis has not been found to be a clinical problem in this population, although follow-up is relatively short. The potential for late development of left pulmonary artery stenosis needs further study. Additional benefits of the procedure offered on an outpatient program, the avoidance of potential surgical complications relative to a left thoracotomy, and the financial impact for the patient need to be factored into the total assessment.

Our data suggest that successful catheter occlusion will obviate the need for surgery in up to 92% of patients presenting with persistently patent ductus arteriosus. As a consequence, we believe that catheter occlusion is an appropriate initial line of therapy. It appears prudent to continue antibiotic prophylaxis and follow expectantly those patients with residual shunts, especially because spontaneous closure may still occur. Despite the success of the Rashkind prosthesis, the role of surgical ligation for the small remaining number of patients ultimately may need to be considered.

References
13. Smythe J, Benson LN, Musewe N, Freedom RM: Left pulmonary artery morphology following occlusion of the patent


KEY WORDS  •  pediatric  •  Rashkind  •  follow-up  •  patent ductus arteriosus
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