

# Factors influencing the persistence of shunting within 24 hours of catheter occlusion of the ductus arteriosus

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## Abstract

**Catheter occlusion of the persistent ductus arteriosus recently became clinically available with a Rashkind (USCI Bellerica, Massachusetts, USA) umbrella occluder system. A few patients, however, had residual left to right shunting after the procedure. The impact of soaking the foam of the device in a thrombin solution to enhance clotting and of using a device with a diameter of 12 or 17 mm was assessed in 117 consecutive patients undergoing catheter closure. The frequency of residual shunting detected by colour flow Doppler 24 hours after the procedure was the same whether or not thrombin was used.**

Several reports have shown the clinical safety and efficacy of transcutaneous occlusion of the persistently patent ductus arteriosus by the Rashkind prosthesis (USCI Angiographics, Bellerica, Massachusetts, USA).<sup>1-3</sup> Successful closure was reported in 0-35% of attempted occlusions.<sup>4-6</sup> The wide difference is attributable to: (a) different methods of assessing shunting (auscultation and pulsed or colour Doppler echocardiography), and (b) the interval between occlusion and assessment. A recently completed study suggested some technical modifications intended to enhance the rate of complete occlusion.<sup>5</sup> Our study attempts to define those factors or interventions that may influence ductal shunting after placement of the device. To control for those haemodynamic and vascular variables that with time may influence occlusion we choose as our end point evidence of shunting 24 hours after implantation.

## Patients and methods

One hundred and seventeen patients (mean (SD) age 4.0 (3.7) years; weight 15.8 (9.5) kg) had a ductal occluder successfully implanted between February 1986 and June 1989. They were divided into two groups: group 1 with residual ductal shunting and group 2 without residual shunting as determined by pulsed or colour flow Doppler echocardiography, or both, 24 hours after implantation.<sup>7</sup> Details of the procedure have been given before.<sup>3-5</sup> No heparin was administered. Transvenous placement was accomplished in all study group patients.<sup>2</sup> Ductal morphology and the smallest diameter at the junction with the pulmonary artery were determined from the

lateral projection of an arteriogram of the descending aorta obtained by injection of contrast into the transductal catheter; arterial catheterisation was not performed.<sup>8</sup> All the ducts occluded were haemodynamically restrictive. A 12 mm occluder was used if the ductus was <3.5 mm and a 17 mm occluder was implanted if the ductus was larger, up to a diameter of 9 mm. For the first 62 patients the device was immersed in physiological saline before being loaded on to the delivery catheter. In the remaining 55 patients the occluders were soaked in a solution of topical thrombin (250 IU/ml) for 10 minutes as suggested by Wessel *et al.*<sup>5</sup> We carefully flushed the lumen of the delivery catheter with the thrombin solution to avoid it being diluted on the foam. In the later series, four patients had Doppler evidence of residual shunting within the first 10 minutes after implantation and in these patients an 8 French balloon tipped angiocatheter was inflated in the main pulmonary artery and placed against the pulmonary artery arms of the occluder. We stiffened the catheter with the firm end of a 0.035 inch guide wire (Cook, Bloomington, Illinois) which was inserted to the tip of the catheter but not beyond.<sup>5</sup> Pressure was applied for 10 minutes, and it was monitored by colour Doppler echocardiography to ensure absence of flow. Doppler echocardiographic studies were repeated after we retracted the balloon. We used pulsed and/or colour Doppler echocardiography to assess residual left to right shunting 24 hours after implantation. Groups 1 and 2 were compared by Student's *t*,  $\chi^2$ , and the Fisher's exact tests as appropriate.

## Results

Thirty nine (33%) (group 1) of the 117 patients had residual shunting one day after the procedure. In 16 of these patients the ductus was closed with a 17 mm occluder and in 23 with a 12 mm occluder. In the 78 patients without residual shunting (group 2) 64 patients had a 12 mm device and 14 a 17 mm device. The use of the 17 mm occluder was significantly associated with the presence of a residual shunt a day after the procedure ( $p = 0.007$ ) and, as was expected, with the presence of a larger ductus: 3.3 (1.1) mm in group 1 *v* 2.7 (0.8) mm in group 2 ( $p < 0.01$ ).

There were 17 instances of residual shunting in the last 55 patients in the series, in whom topical thrombin was used. In the group in which thrombin was not used 22 patients had residual shunting and 40 patients

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did not. Residual shunting was no less common after the occluder had been soaked in thrombin solution, however ( $p = 0.522$ ). The size of the occluder did not influence the effectiveness of the thrombin ( $p = 1.0$  for the 12 mm and  $p = 0.4$  for the 17 mm devices). In four patients we attempted balloon tamponade of the residual flow but shunting persisted when the balloon was withdrawn. Finally, there were no significant associations between ductal morphology, patient age, or weight and persistent shunting.

### Discussion

We detected a residual shunt by colour Doppler echocardiography one day after the procedure in a third of our patients; in most only a soft systolic murmur was audible.<sup>7</sup> Though long term studies that used colour Doppler echocardiography to assess the success of the procedure detected residual shunts in 10% of patients 1–2 years later, it is not clear which factors influence closure of the duct and could be modified. Because several uncontrolled variables (for example, haemodynamic effects and cellular or vessel ingrowth) may lead to occlusion in the medium and long term, our study attempted to define those variables that may influence closure rates in the first day. It seems that patient selection by age or weight alone has no impact.

Wessel *et al* suggested that soaking the umbrella foam in a solution containing thrombin might increase the rate of successful transcatheter closure.<sup>5</sup> Our data do not support this assertion; we found no improvement in initial closure rates in the group in which we used thrombin. Nor did occluder size influence shunting rates. In a few patients we used a balloon-tipped catheter to stop blood flow through or over the device. Though the balloon catheter stopped flow past the occluder, the shunt persisted, unmodified after

the balloon was withdrawn. There is no evidence that the device can be repositioned by this technique, but halting flow through the foam to allow blood stasis and clotting may have some advantages and deserves further study.

We found that implantation of the 17 mm occluder and the size of the ductus were associated with residual shunting. The problem may be intrinsic to a larger ductus or to the way the prosthesis sits within it. The surface area of the foam available to the 17 mm device may not be sufficient to occlude the larger ductal communications, though the diameter of the device arms appears adequate for safe placement.

The Rashkind system is a safe and successful method of eliminating shunts.<sup>5–7</sup> Subtle design changes may further increase both the short and long term success rates. There is enough clinical experience with the procedure for it to be regarded as the first choice for treating patients in whom a ductus arteriosus persists.

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