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TRANSCATHETER CLOSURE OF THE DUCTUS ARTERIOSUS IN CHILDREN AND YOUNG ADULTS*

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SUMMARY: Aydoğan Ü, Dindar A, Cantez T, Ertuğrul T, Tanman B, Ayhan Yİ, Alpay T. (Cardiology Unit, Department of Pediatrics, İstanbul University Faculty of Medicine, Çapa-İstanbul, Turkey). Transcatheter closure of the ductus arteriosus in children and young adults. Turk J Pediatr 1995; 37: 103-109.

Transcatheter occlusion of persistent patent ductus arteriosus (PDA) was attempted in 32 patients (22 female and 10 male, mean age 5.12 ± 3.98 years, range 9 months to 19.2 years) using Rashkind's occluder device (USCI). Implantation of a second occluder device was attempted in three of the patients. Device embolization to a pulmonary artery occurred in three patients, all with the 12 mm occluder device; two of these devices were retrieved by grabber catheter and the last with thoracotomy without adverse sequelae. Embolization to the right atrium occurred in another patient during a second device implantation attempt because of fluoroscopy problems; this patient required open-heart surgery with sequala of 2 (+) tricuspid insufficiency. In another patient with a significant shunt after the implantation of a 17 mm occluder device, mechanical hemolysis developed, but surgical intervention was not required. The overall complication rate was five out of 35 implantation procedures (14.3%). Besides these, sublingual nifedipine was required for two patients whose systolic blood pressure exceeded 160 mmHg just after the implantation procedure.

Sixteen 12 mm and fifteen 17 mm occluder devices were successfully and uneventfully implanted in the first procedure, except for two patients in whom a 17 mm occluder device was implanted after retrieval of an embolized 12 mm occluder. Overall early and mid-term complete occlusion was achieved in 24 patients (75%). Complete occlusion of PDA in the first days after the procedure was achieved in all patients, with the narrowest ductal diameter of less-than 3 mm with the 12 mm occluder device, and less than 6 mm with the 17 mm occluder device. Catheter occlusion of the PDA using Rashkind's umbrella appears to be a safe and effective method of nonsurgical management. However, good fluoroscopy, an experienced team, careful monitoring of systemic blood pressure, a good patient selection and a preference for the 17 mm occluder device when possible is highly recommended. *Key words: interventional cardiology, patent ductus arteriosus congenital heart disease.*

Successful transcatheter occlusion of persistent patent ductus arteriosus (PDA) offers a number of advantages over surgical intervention. It avoids general anesthesia, thoracotomy pain, a chest scar, extended hospitalization, a prolonged

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convalescence period, psychological trauma, the possible need for blood products and injury to the recurrent laryngeal nerve. The early transarterial approaches suffered from a relatively high rate of complications[1], but the development of the double umbrella occlusion device and the application of a transvenous technique for its placement have stimulated renewed interest in transcatheter occlusion[2,3]. We outline our 2.5 year experience with 32 patients who underwent occlusion procedures using the Rashkind device.

Material and Methods

Patients: Between August 1991 and March 1994, parents of patients diagnosed clinically by two-dimensional and color Doppler examination to have persistent patent ductus arteriosus appropriate for a transcatheter occlusion procedure were offered the options of surgical division or transcatheter occlusion with the Rashking PDA occlusion device. Patients whose parents preferred the surgical approach underwent elective division of the PDA without a preceding cardiac catheterization. Others were admitted electively for diagnostic cardiac catheterization in order to identify the ductal anatomy and to measure the narrowest diameter of the ductus.

Thirty-two patients, 22 female and 10 male, ages nine months to 19.2 years (median 4.44 years, mean ± standard deviation 5.12 ± 3.98 years) with weights of 8.6 to 46.0 kilograms (median 14.7 kg, mean ± standard deviation 16.24 ± 8.04 kg) participated in the study. One of the patients had Down's syndrome, while another had a bicuspid aorta with moderate aortic regurgitation as the associated anomalies.

Occlusion Technique: All patients were sedated one hour before the intervention with the combination of chlorpromazine 0.3 mg/kg, pheniramine 0.5 mg/kg and pethidine 1 mg/kg. Ketamine 0.5-1.0 mg/kg was also given intravenously before the start of the implantation procedure when it was needed. The procedure was performed from the right femoral vein by using 8 or 11-F sheath (for the 12 mm and 17 mm occlusion devices, respectively) and by following previously described techniques[3-5]. Of note, for the arterial approach, a 4-F pig tail catheter was introduced through a 5-F sheath in patients weighing more than 12.0 kg in order to facilitate continuous monitoring of arterial pressure from the side port during the implantation procedure. In patients weighing less than 12.0 kg a 4-F sheath and pig tail catheter were used; thus, pressure monitoring was interrupted during the implantation procedure.

Echocardiographic-Doppler Examination: All patients underwent a complete two-dimensional echocardiogram and color-flow Doppler examination within the first three days of occlusion and at six-month intervals during follow-up. Studies were performed using previously described techniques[6] on a Hewlett-Packard SONOS 1000 system, using either a 3.5 or 5.0 MHz transducer.

Results

12 mm Occluder Device: The 12 mm occluder device was used in 19 patients (60%) with the narrowest diameters ranging from 1.5 to 5.0 mm. The patients' ages ranged from nine months to 10.3 years (median 4.56 years, mean ± 2.4 years), and their weights ranged from 8.6 to 22.0 kg (median 14.4 kg, mean ± standard deviation 14.44 ± 4.33 kg). Successful implantation of the occluder device without any complication was achieved on the first attempt in 15 patients (79%). Of these, an anterograde approach with a femoral vein-femoral artery wire loop technique was required in the two patients with the narrowest diameters < 2 mm[7].

In the remaining four patients, the proximal arms of the occluder device did not open completely although all of them were in the appropriate position and gentle traction had been maintained on the safety wire with advancement of the sheath against the proximal legs after the prosthesis was extruded from the sheath. As a result, the tip of the safety wire became entangled in the foam covering after release. Dislodgement was successful in one of these four patients by performing the technique described above[4]. Embolization of the occluder device to the pulmonary artery occurred in the remaining three patients during the trial of dislodgement procedure, two to the right and one to the left. In the first two patients it was retrieved uneventfully from the pulmonary artery with the use of a grabber catheter (multipurpose grasping forceps; Microvasive, Boston Scientific Corp., Watertown, Mass) and was withdrawn into a larger sheath in the pulmonary artery; the sheath was then withdrawn. One of these patients received another 17 mm device during the same procedure, and the other at a later date.

In the third patient, weighing 8.6 kg, the occluder device embolized to the proximal left pulmonary artery, This patient required surgical PDA division and retrieval of the device by thoracotomy; surgery was uneventful.

As a result, solely the 12 mm occluder device implantation was used in 17 patients (50.3%) with the narrowest ductal diameters ranging from 1.5 to 5.0 mm. Among them, one patient (6.25%) required surgical PDA ligation and retrieval of the embolization device by thoracotomy. In the remaining 16 patients, the narrowest duct diameter was less than 3 mm in five, 3 mm in five, 4 mm in four, and 5 mm in two patients. Among these, complete occlusion of the ductus in the first three days of the post-occlusion period was achieved in all patients, with the narrowest duct diameter being less than 3 mm. In the patients with 4 mm ductal diameter, complete occlusion in the early post-occlusion period was observed in one patient and during follow-up in another. Residual leakage with only systolic murmur still persisted in the other two patients at one and 12 months follow-up, respectively. In both of the 5 mm ductal diameter patients, residual shunting persisted in the early post-occlusion period. Complete occlusion

occurred in one during follow-up, but a second 12 mm occluder device with a femoral vein-femoral artery loop technique was required for the second patient six months later to achieve complete occlusion.

17 mm Occluder Device : A 17 mm occluder device was used in the remaining 15 patients, including the two patients in whom the 12 mm occluder embolized to the right pulmonary artery (40.67% + 6.25% = 46.92%) with the narrowest ductal diameters ranging from 4 to 11 mm; the patients' ages ranged from 1.24 to 19.24 years (median 3.0 years, mean + standard deviation 5.68 ± 5.28 years), and their weights ranged from 9.3 to 46.0 kg (median 12.0 kg, mean ± standard deviation 17.71 ± 10.85 kg). Three patients weighed less than 10.0 kg, and eight weighed less than 12.0 kg. Successful implantation of the occluder device was achieved without any complication in all of the patients in the initial procedure.

Then narrowest duct diameter in these patients was 4 and 5 mm in three each 6, 7 and 8 mm in two each; and 9, 10 and 11 mm in one each, respectively. Among these, complete occlusion of the PDA in the first three days of the post-occlusion period was achieved in all patients whose narrowest ductal diameter less than 6 mm, and in another patient whose narrowest ductal diameter was 7 mm. The remaining six patients (40%) had residual leakages or significant shunts after the initial implantation procedure.

The patient with a 9 mm duct needed a second 12 mm occluder in order to achieve complete occlusion. In another patient with a ductal diameter of 10 mm, a second 17 mm occluder device implantation was also attempted; however, fluoroscopic visualization of the landmarks and occluder was inadequate to ensure proper placement, so retrieval of the occluder device was attempted after both the distal and proximal arms of the occluder were opened. Withdrawing it into the Mullins sheath was unsuccessful, and it became entangled in the chordae of the tricuspid valve and required open-heart surgical removal. A 2 (+) tricuspid insufficiency was found on color Doppler examination during follow-up of this patient.

In another patient whose narrowest ductal diameter was 11 mm, significant mechanical hemolysis developed eight hours after the implantation and continued for 26 days, requiring six blood transfusions. This patient did not come for follow-up after discharge. The remaining three patients in the 17 mm occluder device group still have leakages rather than a significant shunt and are followed by color Doppler examinations.

Overall Results : The number of completely occluded patients in the first three days after the transcatheter PDA occlusion procedure with a single device implantation, including the two patients in whom a 17 mm occluder was implanted after the retrieval of the 12 mm occluder device, was 20/32 (62.5%).

This number increased to 24 (75%) with the addition of two patients in whom complete occlusion had occurred during mid-term follow-up and another two with a second occluder device implantation.

Occluder device embolizations occurred in four patients (12.5%, three with 12 mm occluder and one with a second 17 mm occluder). Transcatheter retrieval was uneventful in two; but one of the others needed uneventful thoracotomy and the last open-heart surgery with a sequala of 2 (+) tricuspid insufficiency. In another patient, significant mechanical hemolysis developed after the implantation procedure. The overall complication rate was five in 35 implantations (14.3%).

Besides the above-mentioned complications, sublingual nifedipine administration was needed for two completely occluded patients just after the implantation procedure due to systolic blood pressure increases to 176 and 161 mmHg.

Discussion

Rashkind et al[2] recommended the 12 mm occluder for PDA of less than 5 mm in diameter. The overall incidence of residual shunting was 8 percent in their group. However, they did not specify in their study whether this result was from the first day or from later follow-up. On the other hand, the incidence of residual shunting was reported to be 32% percent on the day of the procedure in another study in which the 12 mm occluder was utilized for PDA up to 5 mm[6]. The incidence of ductal shunting was also high in the series in which an upper limit of 4 mm ductal diameter had been selected for the 12 mm occluder[4,8]. On the contrary, Latson[8] and Wessel[4] in two separate series with the upper limit of 3 mm, reported residual shunting of 16 and 4 percent, respectively. Complete occlusion also was unsuccessful in our two patients in whom the 12 mm occluder device was implanted with a 4 mm ductal diameter. In these two patients, residual leakage persisted after mid-term follow-up. Although it has been shown that ductal shunting may disappear as late as 40 months after the occlusion procedure[6], we recommend the 17 mm occluder device for PDA larger than 3 mm if the weight of the patient is permissible (> 10 kg). As a general rule, after inserting an 8-F catheter through the ductus, if aortography shows a significant left-to-right shunt around the catheter, then a 17 mm occluder should be selected for the occlusion. On the other hand, the 17 mm occluder device has relatively stronger springs on the proximal arms and is more stable, so that the arms can open widely after the occluder is extruded from the sheath and entanglement of the safety wire in the foam covering after release may be avoided.

We could not accomplish complete occlusion in any PDA larger than 7 mm with a single 17 mm Rashkind occluder. This result supports Hosking's[6] findings that one may risk residual shunting and require a second occluder implant if an attempt

is made to occlude a PDA larger than 7 mm with the Rashkind device. The report of the European Registry on transcatheter occlusion of persistent arterial duct[10] and Hosking's[6] study showed a higher proportion of patients with residual flow when the larger device (17 mm) was used. This finding may be related to the relatively stronger springs on the arms of the occluder device that may change the shape of the long, tubular ductus, or the ductus with a long, narrow aortic end other than to the size of the duct as the authors of the European Registry[10] emphasized. Besides these, changing the rectangular configuration of the 17 mm occluder device to a cricle or polygon may be of further benefit in complete occlusion of the larger ducts.

Mechanical hemolysis in incompletely occluded patients is an uncommon complication of transcatheter PDA occlusion. Ladusans et al.[11] performed surgical intervention for such a complication, and Grifka et al.12 developed a technique for retrieving the leaking occluder. In our series, it was speculated that progressive clot formation around the device would eventually cover the rough surface of the occluder and surgical intervention could be avoided. The rate of hemolysis did decrease by the fifth day after the procedure and completely ceased by the twenty-sixth day. However, multiple transfusions were required. Multiple blood transfusions are associated with some major risks such as contamination with hepatitis-B, AIDS and other infections, and precise serological controls are necessary.

Systemic hypertension crisis just after the occlusion procedure may be the natural result of abrupt cessation of vacsular failure related to left-to-right shunting through PDA and still circulating, high levels of angiotensin[13] other than volume overload and ketamine anesthesia. The case of the patient who developed transient hemiparesis during surgical PDA ligation without ketamine anesthesia in O'LAughin et al'.s report[14] supports this hypothesis.

We conclude that transcatheter PDA occlusion with the Rashking occluder device is a safe and effective method of nonsurgical management, but good fluoroscopy, an experienced team, careful monitoring of systemic blood pressure, good patient selection and a preference for the 17 mm occluder device when possible will result in favorable results.

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