Patent Ductus Arteriosus Closure Using a New Device: The Nit-Occlud Device

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Between May 2003 and July 2006, we carried out percutaneous patent ductus arteriosus closure using a Nit-Occlud device in 28 patients, who had a median age of 1.8 years (range 0.5-21 years) and a median weight of 10.9 kg (range 5.9-64 kg). The ductus arteriosus had several different morphologic forms, and there was one postsurgical recanalization of the ductus arteriosus. The median minimum ductal diameter was 1.8 mm and the median maximum aortic ampulla diameter was 6.5 mm. The occlusion rate immediately after intervention was 53.5%, which increased to 95.2% by 12 months and to 100% by 18 months. The median follow-up time was 20.5 months. The Nit-Occlud device provided an effective and safe means of patent ductus arteriosus closure, irrespective of ductus morphology.

Key words: *Cardiac catheterization. Ductus arteriosus. Nit-Occlud device. Pediatrics.*

Cierre del ductus arterioso permeable con un nuevo tipo de dispositivo: Nit-Occlud

Entre mayo de 2003 y julio de 2006, efectuamos cierre ductal con dispositivo Nit-Occlud en 28 pacientes con edades de 0,5-21 años (mediana, 1,8 años) y peso de 5,9-64 kg (mediana, 10,9 kg). Los conductos tuvieron una variada morfología, e incluían una recanalización posquirúrgica. Las medias del diámetro ductal mínimo y el extremo aórtico fueron de 1,8 y 6,5 mm, respectivamente. La tasa de oclusión inmediata fue del 53,5%, y llegó al 95,2% al año y al 100% a los 18 meses. La media de seguimiento fue de 20,5 meses. El Nit-Occlud resultó útil y seguro para el cierre ductal, independientemente de su tipo morfológico.

Palabras clave: *Cateterismo cardiaco. Ductus arterioso. Nit-Occlud. Pediatría.*

INTRODUCTION

Porstmann et al were the first to report the percutaneous closure of a patent ductus arteriosus (PDA).[1] During the 1960s, Rashkind designed the "double umbrella" device, which was later used extensively.[2-5] In the 1990s Gianturco coils were used[6] and then Jackson coils with a controlled release system.[7]

Later on, devices appeared with different anchoring and release systems, such as the Sideris button,[8] the Grifka bag[9] and the Amplatzer device.[10] Another recent device is the Nit-Occlud (NOc), which has undergone several modifications in material, release system and configuration since it was first designed,[11,12] with the latest version being in use since 2001. We report our experience with this device.

METHODS

From May 2003 to July 2006 we undertook percutaneous closure with the NOc in 28 patients (13 male) who had a clinical and echocardiographic diagnosis of isolated PDA (one involving post-surgical recanalization).

The ages of the patients ranged from 0.5 to 21 years (median, 1.8 years), and their weight ranged from 5.9 to 64 kg (median, 10.9 kg). The patients were managed clinically, radiologically and by echocardiography.

The device is composed of a coil of nitinol with no thrombogenic material which, on implantation, acquires a double cone structure like an hourglass. The pulmonary end adopts a reverse form, endowing it with a safer anchoring. The device is premounted on a controlled release system, which can be used with 4 to 6 Fr sheaths.

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The device is compatible with magnetic resonance imaging studies.[13]

The statistical analysis was done with the program SPSS, version 12.0.

Procedure

Under general anesthesia, the right femoral vessels were approached by the Desilets-Hoffman method, using 3 or 4 Fr in the artery and 4 to 6 Fr sheaths in the vein. Heparin was administered at a dose of 100 U/kg. After the hemodynamic study, aortography was performed to define the ductal morphology and measure its ends.

Due to the difficulty to catheterize the PDA from the pulmonary end in four patients (14.2%), a guide wire was advanced via the arterial end, creating an arteriovenous loop. The device was advanced from the femoral vein in all cases. The correct position of the occluder was verified by aortography and, if necessary, it was repositioned, as the device allows this to be done. A post-implant control aortography was done 10 min after its release (Figure). Prophylactic cefazoline was given.

RESULTS

Implant of the NOc device was possible in all cases; its size was chosen in accordance with the nomogram indicated by the manufacturer.

The mean pulmonary artery pressure ranged from 13 to 28 mm Hg (mean, 17.6 mm Hg). The pulmonary and the aortic ampulla diameters were between 0.7 and 4 mm (mean, 1.8 mm) and between 2.8 and 12.1 mm (mean, 6.5 mm), respectively (Table 1).

All types of ductal forms according to the classification of Krichenko et al[14] were found. The immediate residual shunt was classified as follows: trace, if the contrast was slightly opaque at the ductal pulmonary end; mild, if the pulmonary artery was stained without outlining its valve; moderate, if the whole valvular plane was outlined.[13] The rates of immediate residual shunt were: absent in 53.5%, trace in 10.7%, mild in 17.8%, and moderate in 17.8%. The patient admission time was 24 h in all cases.

No association was found between the magnitude of the initial residual shunt and the occlusion of the PDA at 24 h, as in some patients with a moderate immediate residual shunt, it had closed by the following day and in

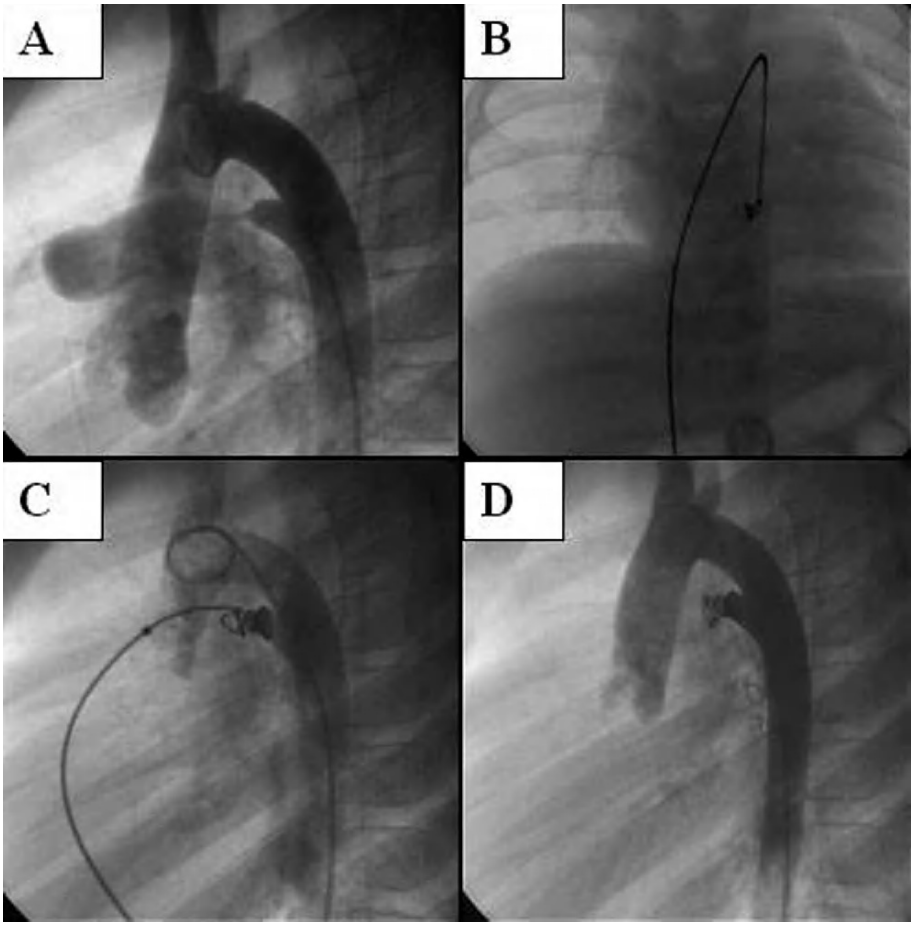

Figure. Angiographic sequence of the implantation of the Nit-Occlud device in patent ductus arteriosus.
A. Lateral arteriography showing the ductal morphology. B and C. Presenting and positioning of the device. D. Implanted device, with no immediate residual shunt.

TABLE 1. **Data Related With the Implantation of the Nit-Occlud Device for Patent Ductus Arteriosus***

N	Sex	Age	Weight, kg	Type of PDA (Krichenko)	Diameter PDA (mm) Aorta× Artery Pulmonary	Immediate Residual Shunt	1 Day	6 Months	12 Months	Post-Procedure Time
1	M	4 years 5 months	15.7	A	62×6	Mi	RS	C	C	38 months
2	F	4 years	16.4	A	4.7×1.2	C	C	C	C	33 months
3	M	7 years	20	A	5.2×2	Trace	C	C	C	33 months
4	M	1 year 8 months	9.2	A	4.7×1.2	Mi	RS	RS	RS	32 months
5	M	1 year 5 months	9.7	D	4.8×1.8	Mi	RS	C	C	31 months
6	M	2 years 1 month	9.7	E	8.0×1.7	C	C	C	C	29 months
7	F	11 months	7.6	B	2.8×1.7	Mod	C	C	C	29 months
8	F	2 years	11.2	PS	5.0×0.9	C	C	C	C	28 months
9	F	3 years 2 months	11	A	11.3×3.2	C	C	C	C	26 months
10	M	1 year 5 months	10.4	E	9.0×1.7	Trace	C	C	C	24 months
11	M	21 years	64	E	9.0×2.5	C	C	C	C	23 months
12	F	3 years 4 months	14.2	A	8.0×1.6	Mi	C	C	C	23 months
13	M	6 months	6.6	A	3.5×1.3	Mod	C	C	C	23 months
14	M	13 years 5 months	37	A	12×1.98	C	C	C	C	21 months
15	M	1 year	10.3	A	5.8×1.1	C	C	C	C	20 months
16	F	4 years 1 month	19	E	9.3×2.5	C	C	C	C	20 months
17	M	1 year 5 months	10.8	A	6.6×1	C	C	C	C	20 months
18	F	10 months	7	C	4.0×2.5	C	C	C	C	19 months
19	F	1 year 4 months	10	A	5.0×1	C	C	C	C	19 months
20	F	1 year 4 months	8.1	A	3.8×0.7	Trace	C	C	C	14 months
21	M	1 year 9 months	11.9	A	6.0×1.2	C	C	C	C	12 months
22	F	1 year	11.7	D	6.5×1	C	C	C		9 months
23	F	8 months	5.9	E	9×4	Mod	RS	RS		8 months
24	F	2 years	9.3	E	9.5×2.2	Mod	RS			2 months
25	F	6 years	21	D	5×2	Mod	RS			2 months
26	M	10 years	46	C	5.4×2.1	C	C			1 month
27	F	1 year	9.1	A	5×2	L	C			1 month
28	F	1 year	11	E	5×1	C	C			0.5 month

*C indicates closed; PDA, patent ductus arteriosus; RS, residual shunt; F, female; Mi, mild; M, male; Mod, moderate; PS, post-surgical.

other patients with a mild residual shunt it remained patent.

The rate of post-implant occlusion of the NOc is shown in Table 2. Five patients underwent the procedure less than six months before the time of writing and three of them have no residual shunt. The follow-up of the patients ranged from 0.5 to 38 months (median, 20.5 months). No complications were recorded during the procedure or the follow-up.

DISCUSSION

The reduction in the profile of the implanting system has enabled treatment of smaller patients with a lower rate of complications during the vascular access or positioning maneuvers. Accordingly, as the NOc permits sheaths of 4-6 Fr, it is especially useful in children younger than one year of age, as well as proving versatile with different ductal morphologies, as it can be withdrawn and repositioned.

The manufacturer does not recommend its use in PDA with a minimum diameter in excess of 6 mm. This disadvantage does not apply to the Amplatzer device.[15] The largest pulmonary diameter in our series of patients was 4 mm, with a moderate immediate residual shunt that was mild at the six-monthly control.

As with other groups,[13,16] we had a considerable rate of immediate residual shunt, which was markedly reduced at 24 h. Its persistence had no hemodynamic repercussion in any patient.

In conclusion, in our experience the NOc proved useful for the percutaneous closure of PDA, independently of

TABLE 2. **Rate of Occlusion of Patent Ductus Arteriosus After Implantation of the Nit-Occlud Device**

Time of Control	Occlusion, %	Occluded/Total Patients
Immediate	53.5	15/28
24 hours	78.6	22/28
1 month	83.3	20/24
6 months	91.3	21/23
12 months	95.2	20/21
18 months	100	19/19

its morphology. The rate of effectiveness was comparable to that reported with other devices used with the same aim.[17-20] Our results show that, using the adequate device for the size of the PDA, the magnitude of the immediate residual shunt was not an adverse indicator of later occlusion.

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