NIT-OCCLUD® PDA
Coil System for PDA Closure
CLINICAL STUDIES

CLINICAL STUDIES

Study description

A prospective, non-randomized, multi-center, single-arm study and a continuing access study were performed using the same protocols at 15 centers in the United States of America to assess the safety and effectiveness of the Flex and Medium Nit-Occlud® PDA coil for occlusion of Patent Ductus Arteriosus (PDA) with minimum angiographic diameter of less than 4 mm. The primary effectiveness endpoints were echocardiographic and clinical closure rates at 12 months. The primary safety endpoint was the serious adverse event rate at 12 months. The endpoint rates were compared to an Objective Performance Criteria as follows:

- Echocardiographic closure (absence of detectable residual PDA flow on echocardiogram) greater than 85% at 12 months
- Clinical closure (absence of heart murmur) greater than 95% at 12 months
- Serious adverse event rate of less than 1% at 12 months

The following criteria were considered for their inclusion:

Inclusion criteria	Exclusion criteria
• PDA with 4 mm or smaller minimum diameter by color Doppler • Patent weight ≥ 5 kg • Age 6 months to 21 years (Patients older than 21 years may have device implanted and be included in a study registry.) • Previous treatment by surgery or Nit-Occlud device with residual PDA noted at least 6 months after the procedure	• Associated cardiac anomalies requiring surgery • Known bleeding or blood clotting disorders • Ongoing febrile illness • Pregnancy • Pulmonary hypertension/increased pulmonary vascular resistance (>5 Wood Units) • Known hypersensitivity to contrast medium

Table 1 Inclusion/Exclusion Criteria

Study results

A total of 378 patients were enrolled and 357 patients were evaluated for safety and effectiveness. The patient´s mean age was 4.26 years (range 0.5 to 21.9 years); the mean weight was 18.1 kg (range 4.7 to 109.0 kg), a total of 68.1% of the enrolled patients were female. Of the 357 evaluable patients, 347 had successful implantation of the device (technical success).

Principal safety and effectiveness results are presented in Table 2 below:

	OPC Rates	Nit-Occlud Patients	Percent	95% Lower Bound	95% Upper Bound
Technical Success at Implantation	95%[2]	347/357	97.2%	95.6%	N/A
Clinical Closure at 12 Month Follow up	95%[1]	308/314	98.1%	96.7%	N/A
Echocardiographic Closure at 12 Month Follow-Up	85%[1]	299/309	96.8%	95.0%	N/A
Mortality at 12 Months	0%[1]	0	0.0%	N/A	0.95%
Serious Adverse Events at 12 Months	1%[1]	0	0%	N/A	0.95%
Total Device and Procedure Related Adverse Events at 12 Months	6%	15/316*	4.7%	N/A	7.21%
		14/316**	4.4%	93.0%	6.84%
Composite Success at 12 Months	80%[3]	N/A	N/A	N/A	N/A

Table 2 Principal Safety and Effectiveness Results

1 Objective Performance Criteria (OPC) specified by the Multiorganization Advisory Panel to (FDA) Appendix (XII)

2 Inferred from technical success rate of Gianturco coil technical success cited in Multiorganization Advisory Panel to FDA report (Appendix XII)

3 Defined in IDE protocol but not defined by the Multiorganization Advisory Panel report

* Numerator is number of events; denominator is number with 12 mos fu + 2 with AE before 12 months

** Numerator is number of patients; denominator is number with 12 mos fu + 2 with AE before 12 months

Procedural success, effectiveness and safety results were comparable to or better than predefined Objective Performance Criteria.

Refer to Table 3 for procedural and fluoroscopy times by device size and type.

Catalog #	Device Size Distal x Proximal Diameter	Device Type	Number of Implants	Mean Procedure Duration [min.]	Median Procedure Duration [min.]	Mean Fluoroscopy Time [min.]	Median Fluoroscopy Time [min.]
145044	4 x 4mm	Flex	38	68.6	66.0	17.2	14.0
145054	5 x 4mm	Flex	27	77.8	72.0	19.6	17.0
145065	6 x 5mm	Flex	57	91.5	82.0	19.8	18.5
145076	7 x 6mm	Medium	110	83.3	73.5	17.0	15.0
145096	9 x 6mm	Medium	97	92.0	79.0	18.8	16.0
145116	11 x 6mm	Medium	26	93.0	85.0	25.5	23.5

Table 3 Procedural and Fluoroscopy Times by Device Size and Type

Differing Technical Failure Rates were observed based on Angiographic Classification of the PDA on the lateral aortogram and are summarized in the Table 4 below:

Classification N (% of Total)	Technical Failure Rate n/N (%)
Conical (A) 267 (74.8%)	4/267 (1.5%)
Short (B) 17 (4.8%)	3/17 (17.6%)
Tubular (C) 5 (1.4%)	1/5 (20%)
Complex (D) 18 (5.0%)	1/18 (5.6%)
Elongated (E) 50 (14.0%)	1/50 (2.0%)
TOTAL 357 (100%)	10/357 (2.8%)

Table 4 Technical Failure rate by Angiographic Classification

The 15 Adverse Events are further described in Table 5 below:

DSMB Adjudication	Category	No of Events
Major Device Related	Device embolization Device Retrieval/Removal Obstruction of descending aorta	2 2 1
Minor Device Related	Possible Thrombus	1
Major Procedure Related	Decreased Pulse in Right Foot Reaction to anesthesia	1 2
Minor Procedure Related	Reaction to anesthesia	1
Major Device Related	Vascular access site complication Other Adverse Event Nausea Fever	1 2 1 1

Table 5 Adverse Events

Study Adverse events were defined as follows:

SERIOUS ADVERSE EVENTS:

- Procedural or device related events which were life-threatening, required surgery to correct, resulted in hospitalization or prolonged hospital stay, caused long-term disability, or resulted in genetic damage or birth defect.

MAJOR ADVERSE EVENTS:

- Procedural or device related events which were not life-threatening, required interventional (catheter based) and /or medical treatment to correct up to one year follow-up evaluation but were resolved without surgical intervention.

MINOR ADVERSE EVENTS:

- Procedural or device related events which were not life-threatening, and were resolved without intervention or with a brief specific non-surgical intervention up to one year follow-up evaluation.

THE COMBINED STUDIES SAFETY RESULTS WERE THE FOLLOWING:

- Mortality at 12 months: 0.0% (0/314)
- Serious Adverse Events at 12 months (device related): 0.0% (0/314)
- Serious Adverse Events at 12 months (procedure related): 0.0% (0/314)
- Total AEs (Serious, Major, and Minor) at 12 months or last follow up (related to the procedure or the device): 4.7% (15/316*)
  *Patients with 12 month follow up and those with an adverse event at any time

Indications for Use:
The Nit-Occlud® PDA coil is a permanently implanted prosthesis indicated for percutaneous, transcatheter closure of small to moderate size patent ductus arteriosus with a minimum angiographic diameter less than 4mm.

Refer to the Nit-Occlud® PDA Instructions for Use for relevant warnings, precautions, complications and contraindications.

Rx only

CV2015-12/13

pfmmedical

Manufacturer:
pfm medical, ag
Wankelstraße 60
50996 Köln, Germany
T +49 (0)2236 9641-10
F +49 (0)2236 9641-20

B|BRAUN Interventional Systems

Distributed by:
B. Braun Interventional Systems Inc.
824 Twelfth Avenue
Bethlehem, PA 18018 USA
Tel: 1-877-VENA CAV (836-2228) (USA)
Fax: 1-610-849-1334
www.bisusa.org