Catheterization and Cardiovascular Interventions 84:464–470 (2014)

Immediate and Short-Term Outcomes After Percutaneous Atrial Septal Defect Closure Using the New Nit-Occlud ASD-R Device

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Objectives: To evaluate the feasibility, safety, and efficacy of implantation of the new Nit Occlud ASD-R® (NOASD-R) device for percutaneous closure of ostium secundum atrial septal defects (ASD-OS). **Background:** Device catheter implantation has become the method of choice for most patients with ASD-OS. No single device has proven to be ideal for this type of procedure. The NOASD-R has a distinct design that may help to overcome limitations of other devices. **Methods:** A prospective, single arm, observational study including all consecutive patients receiving the NOASD-R device for ASD-OS closure between October 2011 and September 2013 was performed. Patient selection, device design, deployment technique, complications, and procedural outcomes were evaluated. **Results:** Seventy-four patients underwent attempted transcatheter ASD-OS closure using the NOASD-R device. Implantation of the occluder was successful in 73 patients (98.6%). The majority of patients were female (79.5%) with a median age of 17.2 years (range: 2–74). A 2-D transthoracic color-Doppler echocardiogram (TTE) obtained at the 3 or 6 month follow-up visit showed complete occlusion of the ASD-OS in 72/73 patients (98.6%). At a mean follow-up interval of 11.4 ± 6.8 months there have been no episodes of late device embolization, cardiac perforation or erosion, endocarditis, thromboembolism, wire fracture, embolic neurologic events, or death. **Conclusions:** We report the first worldwide clinical experience using the NOASD-R device for ASD-OS closure. The procedure was feasible, with a high rate of successful implantations, and safe. High ASD-OS closure rates and no complications were encountered during short-term follow-up.

Key words: atrial septal defect; device closure; Nit-Occlud ASD-R; outcomes

INTRODUCTION

In the last 10–20 years, percutaneous device implantation has emerged as an attractive, safe, and effective alternative to surgical treatment in the management of the ostium secundum atrial septal defect (ASD-OS) closure [1]. With current devices, the success rate of the procedure has improved, resulting in an expansion

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Additional Supporting Information may be found in the online version of this article.

Conflict of interest: Drs Alejandro Peirone and Carlos Pedra are proctors for PFM and receive honoraria for proctoring sessions.

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Received 13 November 2013; Revision accepted 8 February 2014

DOI: 10.1002/ccd.25434
Published online 12 February 2014 in Wiley Online Library (wileyonlinelibrary.com)

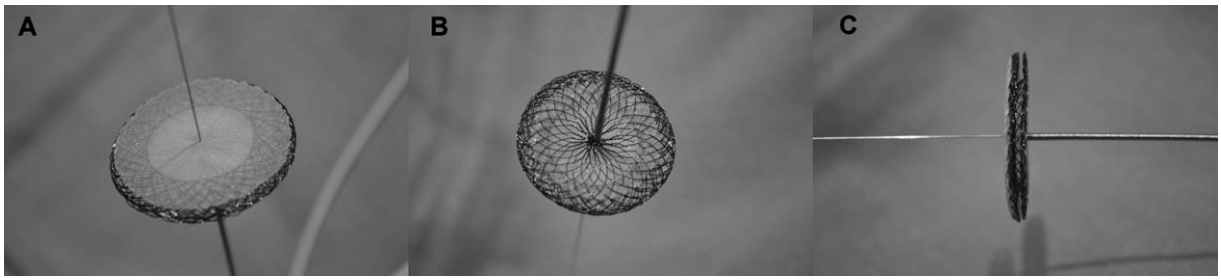

Fig. 1. The Nit Occlud ASD-R device. The premounted device is shown with its left atrial disc (A), right atrial disc (B), and lateral appearance (C). The release mechanism constituted by the "locking wire" crossing the entire device and the proximal "pusher" are visualized.

of the indications of the technique for more complex cases [2,3]. It has been estimated that more than 85–90% of all ASD-OS are amenable to transcatheter closure, including fenestrated defects (associated or not with an aneurysm of the interatrial septum), multiple distant defects, and large ASD-OS [4–6]. The procedure is not only safe but also results in high closure rates and a rapid improvement in right ventricular dilatation [2,7]. Moreover, the overall outcomes of the percutaneous technique have compared favorably with those of surgical repair [8,9].

Although most of the available devices for use are generally safe and effective, some drawbacks still persist, including device malformation [10,11], device fracture [12,13], thrombus formation [14], and occurrence of erosion [15,16]. The Nit Occlud ASD-R® (NOASD-R) (pfm Medical, Cologne, Germany) is a new device with a distinct design that may help to overcome some of these limitations. We report the initial clinical experience and the immediate- and short-term outcomes after the utilization of this device in two large-volume centers in South America.

MATERIALS AND METHODS

The Device

The NOASD-R device has been described in detail elsewhere [17]. Briefly, it is a double-umbrella, self-expandable, self-centering, and premounted device knitted from a single nitinol wire without any soldering or protruding clamps or screws in either side of the occluder. It consists of two circular retaining discs linked together by a short connecting waist (Fig. 1). The device comes pre-mounted on and connected to a flexible and low profile delivery catheter. Although the device nitinol frame work and loading, delivery and deployment techniques are similar to other self-expandable devices, the NOASD-R distinct design is based on two aspects:

"Reverse configuration" of the single-nitinol-layer that forms the rims of the left atrial disc (hence the ASD-R terminology) (Supporting Information Video 1). Most of the circular area of the left disc is composed by a polyester membrane sutured to the nitinol rims. Both discs have the same diameter and an additional polyester membrane is sewn onto the right atrial disc to improve the device closure rate. Two platinum markers are applied to the wire ends of the left atrial disc for radiological guidance during implantation.

"Snare-like" release mechanism which includes a central "locking wire" that crosses the device entirely and a "pusher" with a distal wire noose ("eyelet"). The locking wire is attached to the right atrial side of the implant by four accessory wires connected to the pusher which is covered by a "blue catheter." For release, a distal "security seal" is removed and the locking wire is retracted, disengaging the noose and freeing the implant.

The NOASD-R is available in 12 different sizes related to the connecting waist ranging from 8 to 30 mm with 2 mm increments. Eight to 14 Fr long sheaths are required for delivery. The device is approved for clinical use by ANMAT and ANVISA (regulatory agencies for medical devices use in Argentina and Brazil, respectively).

Patient Selection

Inclusion criteria included patients with isolated or multiple ASD-OS, evidence of clinical and echocardiographic findings of an hemodynamically significant defect with increased right ventricular end diastolic dimensions on transthoracic or transesophageal echocardiography, and a maximum stretched diameter measured by the "stop-flow technique" <28 mm at the time of the procedure.

Exclusion criteria included a weight less than 8 kg, pulmonary vascular resistance (PVR) greater than 8 Woods units, active infection (or within 1 month prior the procedure), associated cardiac anomalies that would require cardiac surgery, malignancy with life expectancy < 2 years, intracardiac thrombi, inability to obtain

informed consent, and contraindications to aspirin or other antiplatelet agents.

Procedure

Informed consent was obtained from patients or their guardians. Under general endotracheal anesthesia and continuous transesophageal echocardiography (TEE) monitoring (2 and 3-dimensional in some cases), the femoral vein was cannulated and heparin sulfate given (100 IU/kg). After a complete standard right heart catheterization was performed, the defect was crossed with an end-hole catheter and an extra-stiff guide wire was positioned in the left upper pulmonary vein. Device selection was mostly based on the stretched diameter of the defect using a sizing balloon (PTS® balloon; Numed; Cornwall, Canada) and the so-called "stop-flow technique." The selected device was the same size or up to 2 mm larger than the stretched diameter. With accumulation of experience, balloon sizing was not performed in some patients with smaller ASDs and thick surrounding rims. In such cases, a device with a waist 20% larger than the largest diameter of the defect (measured by TEE) was selected for implantation.

A long Mullins-type sheath was positioned over the guide wire in the left upper pulmonary vein and the selected device was advanced through the long sheath. The distal reverse disc was carefully opened in the left atrial body (alternatively opened in the right upper or left upper pulmonary veins) and the whole system pulled back as a unit so that the distal reverse disc abutted the interatrial septum. While keeping some tension on the pusher, the sheath was retracted in order to deploy the waist followed by the right atrial disc. While the device was still attached to the delivery system, a gentle push–pull maneuver was performed for confirmation of proper device stability. The device was then released by pulling the thin inner-wire completely out of the device ("snare mechanism") (Fig. 2). Patients received three doses of cephalosporin (50 mg/kg; max, 1 g) and were observed overnight and discharged home the following day if there were no complications.

Closure and Follow-Up Protocol

A 2-D transthoracic color-Doppler echocardiogram (TTE) was performed the following day prior to discharge. Clinical visits were scheduled at 1 week and 1, 3, 6, and 12 months after the procedure during follow-up. Electrocardiogram (ECG) and serial TTEs were reviewed at the scheduled visits with special attention given to possible residual interatrial flow, presence of pericardial effusion, and arrhythmias. A Holter monitor was also indicated at the 3 month clinical visit in the majority of patients. All patients were instructed about infective endocarditis prophylaxis for a total of six months after the intervention and aspirin 3–5 mg/kg/day was initiated a couple of days before closure and continued for six months after.

Patients were considered to have a successful ASD-OS closure if they had the device stable in place and no, trivial (<1-mm color jet width) or small (color jet width 1 to 2 mm), residual shunt as assessed by color Doppler echocardiography during follow-up. Patients with moderate (color jet width >2–4 mm) or large (color jet width >4 mm) residual shunts were considered to have a suboptimal outcome.

Data Collection and Statistical Analysis

Demographic, clinical, procedural, and echocardiographic data were prospectively collected. Patients who did not come for their follow-up visit were contacted by phone to perform their examinations. Results are expressed as mean ± standard deviation or median and range as appropriate. Statistical analysis was performed using the SPSS 12.0 (SPSS Institute, Inc.).

RESULTS

Between October 2011 and September 2013, a total of 74 patients who fulfilled the inclusion criteria to undergo an attempt of transcatheter ASD-OS closure using the NOASD-R device were taken to the catheterization laboratory. Most of patients were female (79.5%) with a median age of 17.2 years (range: 2–74) and a median weight of 40.2 kg (range: 9–97). The mean ASD-OS diameter was 12.6 ± 3.3 mm (range: 7–22) and 14.9 ± 3.8 mm (range: 7–26) measured by TTE and TEE, respectively. The mean systolic pulmonary artery pressure was 21.2 ± 6.2 mm Hg (range: 12–34). Multi-fenestrated defects were observed in six patients (8.1%). One patient had a residual moderate size ASD-OS following surgical repair of a sinus venosus type ASD, and another patient had an associated patent ductus arteriosus, which was percutaneously occluded during the same procedure using a coil. An additional patient presented with severe scoliosis without previous interventions. The stretched diameter by balloon sizing was a mean of 18.6 ± 3.5 mm (range: 12–28). In 12 patients (16.2%), the defect was not balloon-sized.

Implantation of the occluder was successful in 73 patients (98.6%). The single failure occurred in a 4 ½ year old girl weighing 14.6 kg in whom a 16 mm device was implanted in a 14.7 mm ASD. Before device release, progression from a 2nd degree atrioventricular (AV) block to complete heart block was noted on the monitor prompting device removal, which resulted in

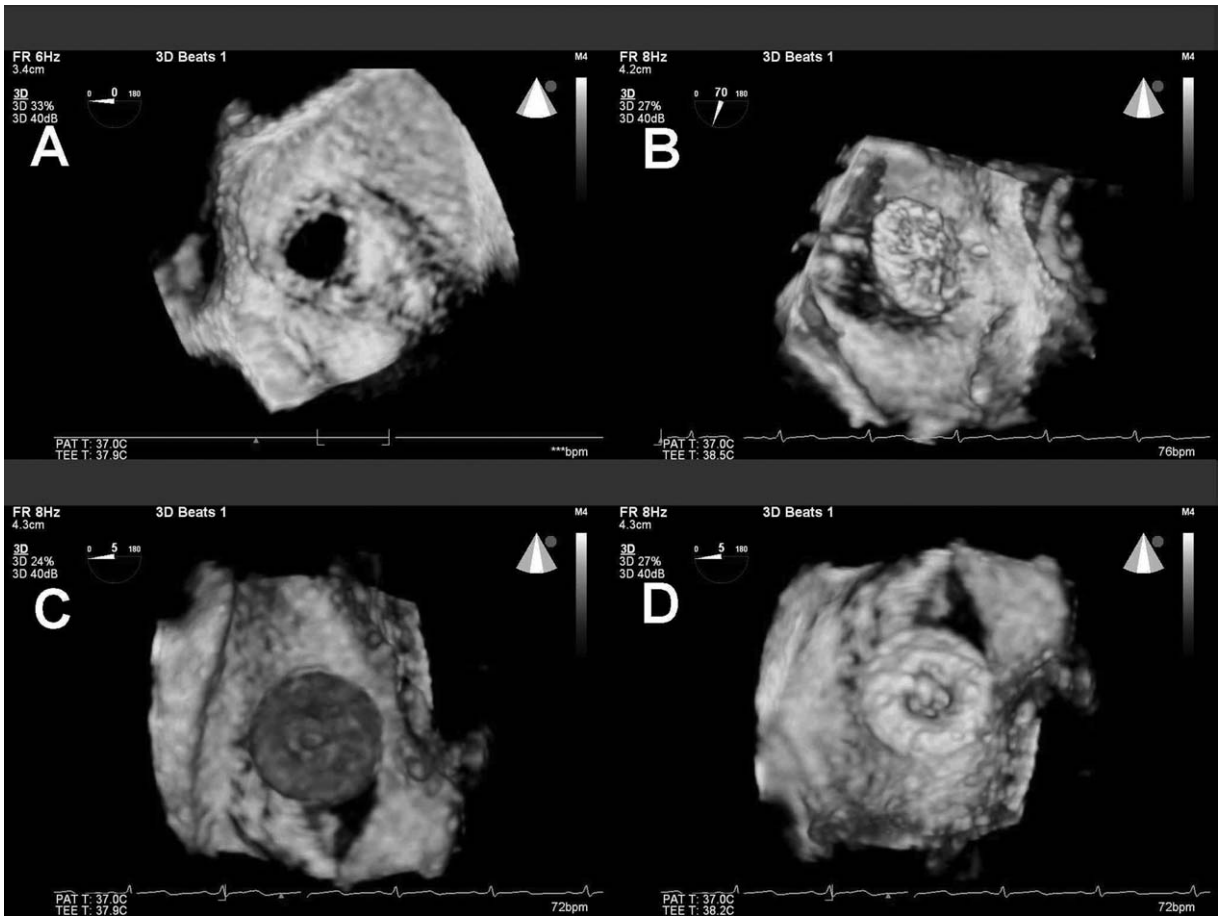

Fig. 2. Three-dimensional TEE during the procedure. (Same patients as in 2D echocardiography). View from the left atrial side. The secundum atrial septal defect is relatively circular with good rims all around (A). Left atrial disc fully opened seen from the left atrial perspective. Note the rims of the left atrial disc formed by the reversed nitinol wire frame and the central portion of the disc composed by the thin polyester membrane. The central wire that crosses the device can also be appreciated in the picture (B). Right atrial disc of the Nit Occlud ASD-R viewed from the right atrium before release. The surface of the disc is smooth and the central portion of the disc is still attached to the delivery cable (C). Left atrial disc of the Nit Occlud ASD-R viewed from the left atrium after release. Note the rims formed by the reversed nitinol wire frame and the central portion of the disc composed by the thin polyester membrane (D).

complete recovery and normal sinus rhythm. The procedure was subsequently abandoned. There was one episode of device embolization in a 22-year-old girl weighing 52 kg. TEE showed a 10 mm ASD-OS with a floppy posterior rim. Stretched diameter was 12 mm. A 12 mm NOASD-R device was implanted but immediately embolized to the descending aorta without causing obstruction to flow. Retrieval with a bioptome and a regular snare was unsuccessful. The device started to unravel using the bioptome and it did not fold into an 18 Fr sheath using a regular snare. Therefore, a hand-made snare using a 0.014″ wire was used to secure the device and bring it to the right femoral artery where it was finally taken out with the aid of a surgical tool. The stretched diameter was measured again and it was 18 mm. A 20 mm device was placed uneventfully with complete closure of the defect. The patient had an uneventful recovery and was discharged home after 3 days on low molecular weight heparin with normal distal pulses. A 74-year-old woman with a past history of atrial fibrillation had a relapse of the arrhythmia during balloon interrogation of the defect. Amiodarone I.V was administered and the defect was successfully closed using a 28-mm device. Sinus rhythm was resumed 2 hr after the procedure and no recurrent arrhythmia was detected during follow-up. Another patient who suffered from chronic atrial fibrillation still persisted with the arrhythmia after closure and has been maintained on oral anticoagulation.

The mean device size implanted was 18.9 ± 4.5 mm (range: 10–30), similar to the stretched diameter obtained for the entire cohort ($P = \text{NS}$). Of note, except

TABLE I. Demographics and Outcomes

Age mean ± SD (range)	17.2 ± 17.9 years (2–74)
Weight mean ± SD (range)	40.2 ± 22.2 kg (9–97)
Sex F/M	79.5%/20.5%
ASD-OS TTE size mean ± SD (range)	12.6 ± 3.3 mm (7–22)
ASD-OS TEE size ± SD (range)	14.9 ± 3.8 mm (7–26)
ASD-OS balloon sizing size mean ± SD (range)	18.6 ± 3.5 mm (12–28)
Median pulmonary artery pressure mean ± SD (range)	21.2 ± 6.2 mm Hg (12–34)
Successful interventions	98.6%
Device size mean ± SD (range)	18.9 ± 4.5 mm (10–30)
Fluoroscopy time mean ± SD (range)	10.1 ± 3.3 min (4–20.8)
Follow up time mean ± SD (range)	11.4 ± 6.8 months (1–24)
Closure 7 days–1 months	97.2%
Closure 3–6 months	98.6%
Hospital admission time mean ± SD (range)	24.9 ± 6.2 h (24–72)

for the patient that suffered from the embolization, there were no instances of changing device sizes after the initial selection. Median fluoroscopy time was 10.1 min (range: 4–20.8). Most patients had slow velocity central leaks through the polyester membrane of the left atrial disc on TEE immediately after implantation. There was no change in the device position on TTE before discharge. The median hospital stay was 1 day ranging from 1 to 3 days.

Serial TTEs obtained at the 1 week or 1 month follow-up visit showed complete occlusion in 71 of the 73 patients (97.2%). One patient had a 1 mm leak in the posterior aspect of the device. The other had multiple defects and a decision was made not to close an additional and distant small posterior ASD (1.8 mm) at the time of the intervention. At the 3- or 6-month follow-up visit, only the patient with multiple defects continued to show a residual flow through the additional ASD on TTE. Therefore, the closure rate of the entire cohort was 98.6%.

At a mean follow-up interval of 11.4 ± 6.8 months (range: 1–24), there have been no episodes of late device embolization, cardiac perforation or erosion, endocarditis, thromboembolism, wire fracture, embolic neurologic events, or death. Serial ECGs showed no new arrhythmias. Also, a routine Holter monitor obtained in 52 patients at 3 months follow-up ruled-out the presence of new arrhythmias. Table I summarizes demographics and outcomes.

DISCUSSION

Attempts at catheter closure of the ASD-OS began over 3 decades ago. With evolving device technology, the procedure has proven to be safe and effective in extensive clinical trials and become the standard treatment for most patients with this type of congenital heart defect. By and large, the Amplatzer® Septal Occluder (St. Jude Medical, St Paul) is the most popular utilized device because it has a low profile, is easy to use, retrievable, recapturable, highly effective, and safe. However, recent reports on the occurrence of erosion [15,16] have raised some concerns about the widespread use of this device. To address this issue, the FDA recently demanded a post-market study to determine the real incidence of this complication and its impact on clinical care. Also, thrombus formation on the left sided disc has been described, albeit being a rare occurrence [14]. Therefore, continuous and careful clinical assessment of other devices available for closure is warranted.

To the best of our knowledge, this is the first report to describe the clinical performance of the NOASD-R for transcatheter closure of the ASD-OS. In this small cohort of patients with small-to-moderate ASDs, the use of this new device was feasible, safe, and effective resulting in excellent immediate and short-term outcomes. Although immediate central residual shunt is the rule after implantation, which is mainly related to the left atrial disc design, final occlusion rates are optimal at follow-up as demonstrated in this experience. Just a single patient had a small residual shunt during follow-up through a previously detected additional defect.

Similar to other nitinol devices used for percutaneous closure, the NOASD-R is a double-disc, self-expandable, self-centering and low profile device, easy to position with a simple locking mechanism that allows for recapturing and repositioning several times before release. The implantation technique is similar to those employed for other self-expandable devices and the visualization both on echocardiography and fluoroscopy is optimal. The delivery catheter is flexible, minimizing the tension on the device before final release, which is accomplished in a simple and predictable way due to its snare-like and tension-free mechanism.

There are some advantageous characteristics of this device. The peculiar "reverse configuration" of the left atrial disc tightly fixes the implant to the left atrial aspect of the interatrial septum offering a secure anchoring mechanism, minimizing the risk of "pulling-through" during implantation or inadvertent embolization after release. On the other hand, careful reverse distal disc opening is advised in order to prevent any left atrial wall injury. In this regard, positioning the sheath in the left upper pulmonary vein avoids opening the device inside the left atrial appendage. If opening the device is required in either the left or the right pulmonary veins to attain a better alignment with the plane of the interatrial septum, we have safely

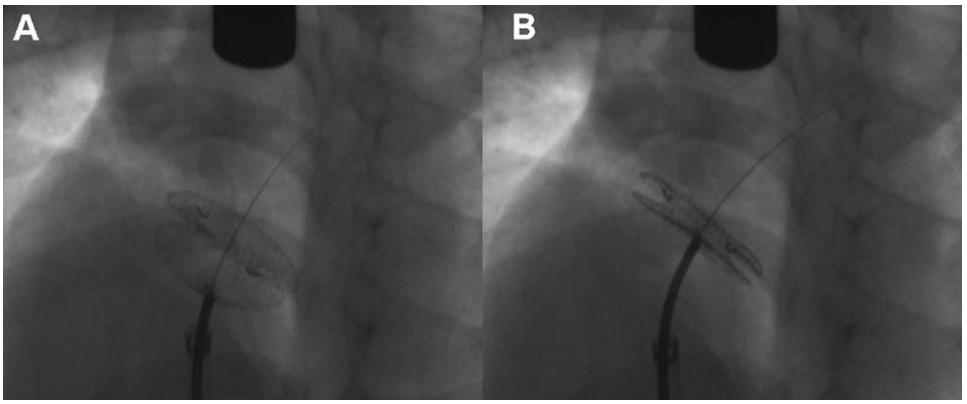

Fig. 3. Fluoroscopic appearance of the device in situ. Of note, after initial device deployment (A), in order to obtain the lowest device profile, a gentle "push maneuver" should be performed until a "concave shape" is seen on the right atrial disc (B).

accomplished the maneuver with partial deployment within the vein itself reaching a complete final reconfiguration once the device is pulled into the left atrial body. Additionally, the fact that the left atrial disc is mainly composed by the thin polyester membrane without any pins or screws attached to the device results in less amount of metal on the left atrial side, which potentially promotes faster endothelialization and mitigates the incidence of thrombosis. The right atrial disc also has no screw/pin.

Oversizing should be avoided with this new device. Selecting a device >2 mm larger than the stretched diameter may result in an excessive bulging of the right atrial disc and suboptimal final configuration. If the selected device size is correct, the final appearance even before release is of a flat and a very low profile occluder embracing the interatrial septum. To help to attain this low profile configuration, the operator should employ a gentle "push maneuver" during deployment of the right atrial disc until a "concave shape" is seen on the right disc (Fig. 3). Some rotational movements of the delivery catheter may also be required to optimize coaxialization and profile. Finally, due to the characteristics of release mechanism, we have experienced no significant movements or rotation of the device after it is disengaged from the delivery catheter.

Complications were observed in two patients in this initial experience. One child had AV block after device deployment, which prompted device removal. Children who undergo transcatheter closure of the ASD-OS may be more susceptible to AV block than adult counterparts, probably due to the relative larger dimensions of the device with regards to the dimensions of the interatrial septum [18]. Embolization occurred in one patient probably due to inappropriate device selection in an undersized defect associated to a floppy posterior rim. Retrieving the device was more laborious due to the lack of screws and pins on either disc. However, securing the device with a manually made snare followed by careful withdraw directly out of the body without recapturing inside a sheath proved to be the best approach, especially considering the increased flexibility of the device wire mesh. In this regard, focused research protocols trying to define the best technique to retrieve an embolized device are underway.

As of now, the NOASD-R device is not applicable to defects larger than 28 mm in diameter. The largest device size commercially available is 30 mm waist diameter. In addition, with the current device design it may be too soft to be implanted in larger ASDs ($>$ 28–30 mm), which require bulkier devices to achieve proper stability within the septum. It is also worth mentioning that the long sheaths recommended to deliver the NOASD-R are approximately 1–2 Fr larger compared to the ones used for the ASO, albeit similar to those used for other self-expandable nitinol devices such as the Cera® (Lifetech Scientific, Shenzhen, China) and Figulla Flex II® (Occlutech, Helsingborg, Sweden). Nevertheless, trauma to the femoral vein was not a problem in the age group and weight range presented herein.

There are some limitations in the present study. This is a prospective, single arm, observational study with no comparisons with other available devices. The selection of the NOASD-R was performed arbitrarily according to the operator preference. Although follow-up time was short, the vast majority of potential complications for this type of procedures occur immediately or during the short-term period after the intervention. Therefore our findings probably represent a fair preliminary report on the device performance. Finally, chronic mechanical stress upon the device and possible metal fatigue need to be elucidated in further trials with longer follow-up.

CONCLUSIONS

In this initial clinical experience with transcatheter closure of the ASD-OS using the new NOASD-R device, the procedure was feasible, safe, and effective. Technical success and closure rate were high, and there were no instances of immediate- or short-term complications such as arrhythmias, cardiac perforation, erosion, or death. Larger number of patients and longer follow-up time are required to assess its ultimate clinical performance.

ACKNOWLEDGMENT

The authors wish to thank Mrs. María Elena Cardillo for helping in gathering the follow-up data on the patients.

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