Frequent Oversizing during Amplatzer Device Deployment for Percutaneous PDA Closures

A. Fatehi MD*, M. Maadani MD**, S. Abdi MD*** and J. Norouzi MD****

Abstract

Background- Transcatheter closure of small to moderate patent ductus arteriosus (PDA) has been well established during this last decade. The Amplatzer device occluder (ADO) is a self-expandable device with ease of delivery and a rapid learning curve. The aim of the study was to access the optimum sizing of ADO in regard to maximum efficacy with respect to shunt occlusion without oversizing and reducing bulk and potential protrusions.

Methods- From April 2007 to July 2008, a total of twenty-four adult PDA closures were reviewed. Occlusion was achieved via antegrade venous approach. Our primary objective was an evaluation of optimum ADO sizing for PDA closures. We retrospectively compared the patients with a theoretical optimum size as regards complications and residual shunts.

Results- PDA size determination was based on the smallest diameter at pulmonary artery (PA) side. Based on specific criteria, undersizing was not observed in our cases, while oversizing was noted in 42% of cases. Oversizing did not lead to a decrease in residual shunts (37.5% vs. 36%, *p*=NS). Although no short-term complications were observed in the oversized group, oversizing resulted in a characteristic mushroom deformity due to unnecessary tension applied to our device. The Chinese device also performed well in terms of deployment and short-term complications with no significant difference in comparison to its American counterpart (*p*=NS).

Conclusion- An acceptable rate of acute complications was obtained; nonetheless, we were frequently oversizing, leading to mild device deformation and protrusion. Although not previously described in the literature, the terminal ballooning of the ADO should alert us of such a complication ***(Iranian Heart Journal 2009; 10 (4):14 -18).***

Key words: patent ductus arteriosus ■ Amplatzer device occluder ■ transcatheter device closure

The Amplatzer device occluder (ADO), apart from having a range of sizes to close large PDAs, has a number of salutary features, namely retrievability up to the point of deployment and ease of delivery using small 5-7 F long sheaths.[1,2] In recent years, it has become the choice for closing PDAs more than 5 mm in diameter.

In a critical reprisal of our previous deployment and sizing techniques, we estimated the optimum size ADO and the deployed device and looked for discrepancies.

Methods

From April 2007 to July 2008, twenty-four adults underwent PDA closure. Six cases were closed with PFM coils, one patient had the PDA closed with a muscular VSD Amplatzer, and the rest had their PDAs closed with an Amplatzer device.

Received May 12 , 2008; Accepted for publication Jan. 19, 2009

Associate Professor of Cardiology, ****Assistant Professor of Cardiology, Firouzgar Hospital, Tehran; **Assistant Professor of Cardiology and Department of Interventional Cardiology, Shaheed Rajaie Cardiovascular Medical and Research Center, Tehran, ****Cardiologist, Milad Hospital, Tehran, Iran.

Correspondence to: Mohsen Maadani, Shaheed Rajaie Cardiovascular Medical and Research Center, Tehran, Iran
Tel: 098 21 23922133, Fax: 098 21 22055594 Email: mohsenmaadani@ rhc.ac.ir.

After catheterization and diagnosis, a 90-degree LAO injection with a pigtail catheter patients' PDA according to the Krichenko classification. We assessed the optimum size of the ADO devices by carefully measuring the smallest PDA dimension (pulmonary side) with QCA software. Based on the assumption that an ideal ADO size was: two millimeters plus the smallest diameter of our PDA (pulmonary side), we classified the patients into optimum sized, oversized, and undersized. An arbitrary cut-off level was allowed adequate visualization of the PDA size and anatomy, enabling us to classify the defined in a sense that oversizing was considered when the ADO device was $\geq$ 3 mm bigger than the smallest PDA diameter. We assessed the device shape post-deployment in LAO projections to visualize any deformities in shape and residual shunts. Transcatheter closure was performed under local anesthesia and has been described previously.

PDA Demoraphic Data

ID	Sex	Age	PDA Type	PDA Aortic	PDA Pulmonary	Systolic PAP	Diastolic PAP	Krichenko Type	Qp/Qs	Associated Defects	Amplatzer	Amplatzer Size	Mismatch
1	femal	14	DeNovo Lesion	14	5	25	8	D	2	Small ASD	AGA Medica	8+10	£
2	female	15	DeNovo Lesion	7	4	40	10	A2	18	VSD. Skeletal defects	None		£
3	Male	15	Residual Shunt		4	30	12	A2	1.6	Corrected TF	None		£
4	Male	24	DeNovo Lesion		7	22	10	B1	1.8		Chinese	Nonstandard	☑
5	Male	27	Residual Shunt		6	55	10	A2	2	Mod Al, Severe PI, RV Failure	Chinese	10*12	☑
6	Female	12	DeNovo Lesion	4	2	35	10	A1	17	valvualr AS	None		£
7	Female	36	DeNovo Lesion		4	25	10	A3	1.9		Chinese	6*8	£
8	Female	12	DeNovo Lesion	8	4	55	20	A2	3	Preductal Coarctation	Chinese	8*10	☑
9	Female	23	DeNovo Lesion		7	35	10	A1	2		AGA Medical	8*10	£
10	Male	22	DeNovo Lesion	7	5	40	15	A2	2		AGA Medical	10*12	☑
11	Female	13	DeNovo Lesion	6	3	15	6	A3	1.9	VSD	None		£
12	Female	24	DeNovo Lesion	7	4	30	12	B2	2		Chinese	8*10	£
13	Female	50	DeNovo Lesion	7	4	40	20	A1	1.4		AGA Medical	10*12	☑
14	Male	26	DeNovo Lesion		3	30		A1	1.8		AGA Medical	8*10	☑
15	Female	29	DeNovo Lesion	9	5	40		E	2.33		AGA Medical	6*8	£
16	Female	31	DeNovo Lesion		4	30	12	A2	1.3		Chinese	6*8	£
17	Female	25	DeNovo Lesion		6	20	10	Unclass ified	2		Chinese	8*10	£
18	Male	59	DeNovo Lesion	4	3	35	15	B2	1.4	Post CABG	AGA Medical	8*10	☑
19	Female	24	DeNovo Lesion	10	8	35	12	B3	2.6		VSD Nonstandard Amplatzer		£
20	Female	27	DeNovo Lesion		3	25	10	C	1.8		None		£
21	Female	24	DeNovo Lesion	8	6	30	15	A2	2	Reduced EF	Chinese	8*10	£
22	Female	14	DeNovo Lesion	6	3	25	10	A2	1.8		AGA Medica	l 8*10	☑
23	Female	18	DeNovo Lesion		3	45	20	A1	1.3	Valvular PS	None		£
24	Female	22	DeNovo Lesion		4	25	10	A1	1.8		AGA Medical	4*6	£

The ADO (Aga Medical Corporation, Golden Valley, Minnesota, USA) is a cone-shaped device, 7 mm in length, made of a 0.004 inch nitinol wire mesh. A 2-mm retention skirt extends radially around the distal part of the device, offering secure fixation in the mouth of the PDA. Prostheses are available in sizes ranging from 6–4 to 14–12 mm at increments of 2 mm. The larger measurement is at the aortic site and the smaller is at the pulmonary end.

The quantitative data were analyzed by Student's t-test. A *p*-value of 0.05 or less was considered significant. Statistical analysis was done with SPSS 16.0 software.

Results

Our patient's demographic data are reviewed below.

We retrospectively studied the 16 cases of ASO closure in terms of "Goodness of Fit" to determine whether our devices were appropriate for this size PDA. We reviewed our 90-degree LAO shots, measured the smallest size of the PDA canal, calculated the optimum size ASO, and compared them with the size we utilized.

According to our data and based on the Krichenko [5] classification, our patients were A1 (25%), A2 (31%), A3 (7%), B1 (5%), B2 (7%), B3 (5%), C (5%), D (5%), E (5%), and unclassifiable (5%).The F/M ratio was 3 and the mean size of pulmonary insertion was 4.5±1.5 mm. Mean age of our patients was 24±11 years, mean shunt size was 1.86±0.38, and mean systolic PAP was 32±10 mmHg. The majority of the cases were closed with a 8*10 device (38%).We used the AGA Medical PDA ADO device in 9 cases, while the Chinese counterpart was utilized in 8 of our cases and in 1 case due to anatomic considerations an AGA Medical muscular VSD ADO was used.

Based upon this assumption that the ideal size of our PDA should be the smallest PDA dimension plus two millimeters, we were oversizing the devices in 42% of cases, while no cases of undersizing were observed. The oversized devices were in 80% of cases 1 size above the estimated size while in 20% of cases it was 2 sizes above the optimum size. By oversizing we had not decreased residual shunts in our cases. Comparison of residual shunts between the optimum group and the oversized group showed no significant decrease in residual shunts (37.5% vs. 36% P=NS). There was also no significant difference in terms of short-term complications between the two groups (P=NS). In cases that were classified as a mismatch in size, we noted a characteristic mushrooming or ballooning of the retention skirt, which was probably due to the fact that this part was under excessive tension. In the small PDA devices, it was due to the slipping of the device into the canal; and in the large devices due to our possible excessive tension applied to fit the large bulk into the ampulla, presumably causing the retention skirt to being dragged into the canal.

Discussion

Follow-up studies following ADO deployment have confirmed occlusion rates of >99% within 6 months of device deployment, with minimal complication rates. The majority of occlusions can be confirmed within 24 hours, prior to discharge from hospital. Protrusion of the retention disc into the descending aorta, producing aortic obstruction is a rare complication, and may necessitate removal of the device. By transcatheter techniques and the duct **occluded using a new device.** A modification of the ADO has been described to avoid this complication, in which the aortic retention disc is angulated at approximately 32^{o} to the body of the device and is concave towards the aorta, and may be indicated in special instances[6]. Device protrusion into the left pulmonary artery is also infrequently seen when compared with the Rashkind device or following the use of multiple coils, as the device has a low profile on the pulmonary

side [8, 9]. To avoid this potential complication, aortography is always recommended after device deployment, prior to release, and following the release of the device.

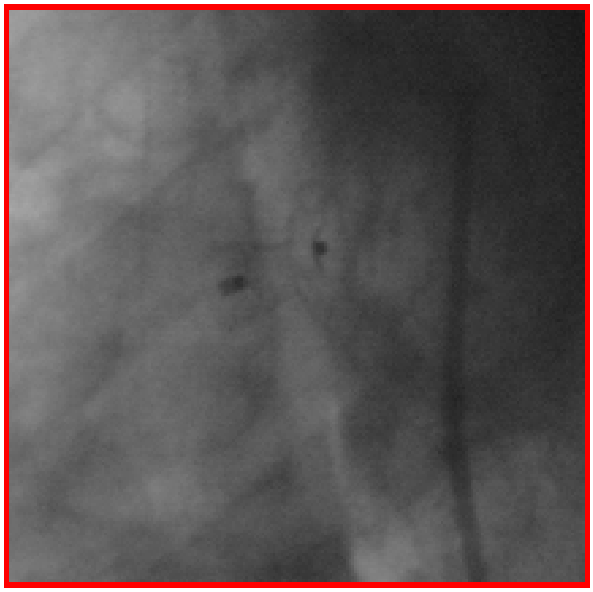

Fig. 1. Optimum sizing with flat plug-shaped device and retention skirt

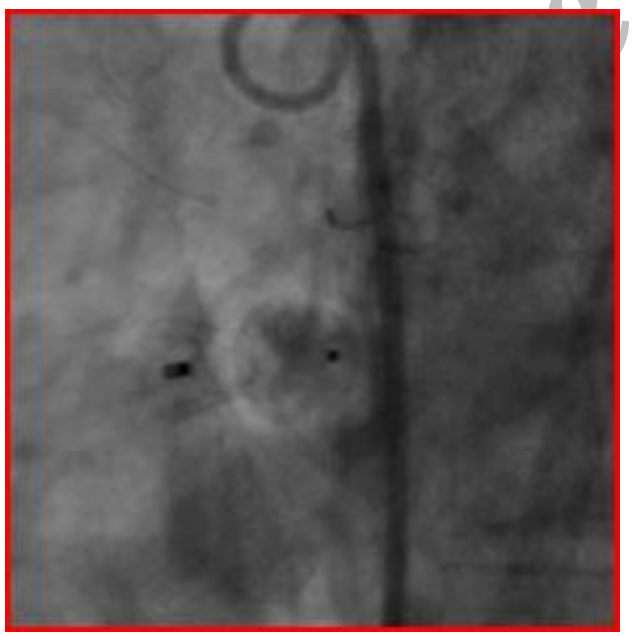

Fig. 2. Deformed mushroom-shaped retention skirt

Even after the device has been released, it can be retrieved. Late device embolization into the pulmonary arteries, occurring up to 24 hours following implant, was reported in the early series, and was probably due to the use of a smaller than optimal device. This may be avoided by confirming that no part of the retention disc has prolapsed into the body of the duct, prior to release. There has to date been a single procedure-related death with use of the ADO. In that patient, the device which was probably too small for the duct in question embolized into the descending aorta and was not retrieved until 4 hours later, resulting in mesenteric vascular complications and sepsis.[7] Device embolization into the aorta would constitute a medical emergency, necessitating immediate transcatheter or surgical retrieval of the embolized device.

We strived to critically review the best fit for our PDA devices. Although we had obtained zero percent short-term major complications, it was obvious that this could not be a foundation for long-term results. We noticed that in cases that were oversized, the tension applied to the device to pull it into the ampulla would cause a rather characteristic deformity causing the retention skirt to balloon outward and assume a mushroom shape, while in the optimum-sized group it still retained its plug-like shape. This typical shape of deformed occluder occurs whenever an optimum positioning is not obtained and the device is under tension, and the ballooning of the aortic side of the ADO should alert us of this effect and possibly indicate further scrutiny for long-term effects. The tendency to use larger than required devices stems from our deep inside fears of possible dislodgement and the misconception that by using bigger occluders, we will have less residual shunts. We should bear in mind however that even in the smallest sized PDA occluder device (4x5 mm), the retention skirt is 9mm while the largest diameters have retentions skirts of 18mm (10x12mm). Consequently, when we compare this to the mean size of our PDAs, which was 4.5 ± 1.5mm, it is very unlikely that it would be pulled out. On the contrary, the large-sized PDA occluder would not fit into the small canal and protrude into the aorta, potentially

leading to possible thromboembolic future events and in small sized infants, to potential obstruction.[10] Coil protrusions into the LPA have shown impaired pulmonary flows [4] and theoretically this could also apply for ADOs. More detailed studies in the future and follow-up of patients to evaluate whether this excess bulk will have late consequences seems necessary to clarify this issue. Also as our data showed, by using larger devices we did not necessarily achieve less residual shunts. On the other hand, the tendency to use large occluders resulted in a high percentage of patients deemed unsuitable for interventional duct closure and thus they were referred to surgeons for surgical closure.

Conclusion

A tendency to use rather large-sized ADO devices relative to PDA dimensions, although not increasing short-term complications, will result in a characteristic mushroom deformity of the Amplatzer device and lead to patients suitable for device closure being referred unnecessarily for surgery.

Conflict of Interest

No conflicts of interest have been claimed by the authors.

References

1. Masura J, Walsh KP, Thanapoulus B. Catheter closure of moderate to large size patent ductus arteriosus using the new Amplatzer duct occluder: immediate and short term results. J Am Coll Cardiol 1998; 31: 879-882.

2. Faella HJ, Hijazi ZM. Closure of the patent ductus arteriosus with the Amplatzer PDA device: immediate results of the international clinical trial. Cathet Cardiovasc Intervent 2000; 51: 50–4.

3. Bilkis AZ, Alwi M, Hasri S. The Amplatzer duct occluder: experience in 209 patients. J Am Coll Cardiol 2001; 37: 258–61.

4. Soaresa AM, Aiellob VD, Andradea JL Doppler flow evaluation can anticipate abnormal left lung perfusion after transcatheter closure of patent ductus arteriosus. European Heart Journal 2004; 25: 1927–1933.

5. Krichenko A, Benson LN, Burrows P, Moes CA, McLaughlin P, Freedon RM. Angiographic classification of the isolated, persistently patent ductus arteriosus and implications for percutaneous catheter occlusion. Am J Cardiol 1989; 63: 877– 879.

6. Masura J, Gavora P, Podnar T. Transcatheter occlusion of patent ductus arteriosus using a new angled Amplatzer duct occluder: Initial clinical experience. Cathet Cardiovasc Intervent 2003; 58: 261-267.

7. Simoes LC, Pedra CAC, Esteves CA, Camargo R, Braga SLN, Loureiro P, Santos MA, Fontes VF. Percutaneous closure of ductus arteriosus with the Amplatzer prosthesis: the Brazilian experience. Arq Bras Cardiol 2001; 77: 526-531.

8. Dessy H, Hermus JPS, Van den Heuvel F, Oei HY, Krenning EP, Hess J. Echocardiographic and radionuclide pulmonary blood flow patterns after transcatheter closure of patent ductus arteriosus. Circulation 1996; 94: 126-129.

9. Sreeram N, Tofeig M, Walsh KP, Hutter P. Lung perfusion studies after detachable coil occlusion of persistent arterial duct. Heart 1999; 81: 642-645.

10. Duke C, Chan KC. Aortic obstruction caused by device occlusion of patent arterial duct. Heart 1999; 82: 109-111.