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Original Article

Postoperative Outcome of the Transcatheter Closure of Atrial Septal Defects Using the AMPLATZER Septal Occluder

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ABSTRACT

Background: The AMPLATZER Septal Occluder (ASO) has successfully replaced surgery for the repair of atrial septal defects (ASDs) within the last decade. However, the outcome and clinical consequences of this procedure have not been fully assessed. Hence, the present study aimed to determine the results of the application of the ASO in the nonsurgical transcatheter closure of ASDs.

Methods: Forty-seven consecutive patients were assessed via transesophageal echocardiography to determine secundum ASDs. The study end points were the assessment of the echocardiographic consequences of ASD closure using the ASO and also the determination of the presence of postoperative complications. The patients were reassessed via transthoracic echocardiography 1 day, 1 month, and also 6 months after the intervention.

Results: An assessment of the trend of the changes in right ventricular dimension and functional status showed a significant decrease in right ventricular size as well as improvement in function within 6 months after ASD closure using the ASO. The mean pulmonary artery pressure was also significantly decreased. Unsuccessful ASD closure was detected in only 3 patients, with an overall failure rate of 6.4%. Regarding postoperative complications, device displacement was found in 2.1%, interatrial septum rupture in 12.8%, small pericardial effusion in 12.8%, tamponade in 2.1%, and small residual ASDs in 12.8%, all of which were resolved procedurally within the following month.

Conclusions: The clinical efficacy of the nonsurgical transcatheter closure of ASDs with the ASO was underlined in our experiment, indicating that it is a good and standard alternative to surgical repair. ***(Iranian Heart Journal 2017; 17(4): 30-35)***

Keywords: Atrial septal defect (ASD) ● ASD occluder ● RV enlargement

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Atrial septal defects (ASDs) account for about 10% of all congenital heart defects. Despite their benign nature, ASDs can lead to morbidity and even mortality if left untreated. [1,2] The closure of secundum ASDs with percutaneous devices was initially described by King et al in 1974. Later, the safety and efficacy of various devices were tested, which paved the way for the eventual introduction of these devices as proper alternatives to the surgical closure of secundum ASDs. [3-5] In most developed and even developing countries, the use of devices for ASD closure has become the preferred method. [6] Currently, the utilization of these devices confers variable degrees of success *vis-à-vis* ASD closure and minimization of residual shunts. [7]

In the past decade, the AMPLATZER Septal Occluder (ASO) has successfully replaced surgery for ASD closure, especially in adults, so much so that it is now deemed the standard method for the repair of secundum ASDs. [8,9] However, the outcome and clinical consequences of this procedure have yet to be fully elucidated. Hence, the present study aimed to determine the results of the application of the ASO in the nonsurgical transcatheter closure of ASDs.

METHODS

This prospective interventional case series was performed by the echocardiography and coronary angiography centers at Rajaie Cardiovascular, Medical, and Research Center, Tehran, Iran, in 2015. The study end points were the assessment of the echocardiographic consequences of ASD closure using the ASO and also the determination of the presence of postoperative complications with the size of the ASD, size of the ASD margins, size of the device, and also size of the balloon catheter. In total, 47 consecutive patients were assessed via transesophageal echocardiography to determine secundum ASDs, size of the ASD margins, dimensions and function of the right ventricle (RV), and also pulmonary artery pressure (PAP). Patients with the ASD size < 4 cm; anterior size of the rim < 2 mm; and the sizes of the anteroinferior rims, inferior vena cava (IVC) rims, superior vena cava (SVC) rims, and posterosuperior rims < 7 mm underwent echocardiography-guided catheterization for ASD closure. The patients were reassessed via transthoracic echocardiography 1 day, 1 month, and also 6 months after the intervention to assess postoperative complications, including pericardial effusion, tamponade, device displacement, clot formation on device, atrial tissue erosions, postoperative RV size and function, and also PAP.

The results are reported as medians (1st and 3rd quartiles) for the quantitative variables and percentages for the categorical variables. The groups were compared using the Student *t*-test for the continuous variables and the χ^2 test (or the Fisher exact test, if required) for the categorical variables. Changes in the postoperative parameters were determined by dividing the change between the baseline and the final measurements by the duration of the follow-up. A P value ≤ 0.05 was considered statistically significant. All the statistical analyses were performed using SPSS, version 16.0 (SPSS Inc., Chicago, IL, USA), and SAS, version 9.1 for Windows (SAS Institute Inc., Cary, NC, USA).

RESULTS

In total, 47 patients, candidated for ASD closure with the ASO, were assessed. The median age of the subjects was 32 (29, 43) years, and 72.3% were female. The mean ASD size was 17.4 mm, mean anteroinferior rim size was 10.3 mm, mean posterosuperior rim size was 10.2 mm, mean anterosuperior rim size was 3.36 mm, and the mean posteroinferior rim size was 11.2 mm. Also, the mean SVC and IVC rim sizes were 11.7 mm and 12.7 mm, respectively. Regarding RV size, none of the patients had a normal size, while dilatation was mild in 4.3%, mild

to moderate in 19.1%, moderate in 36.2%, moderate to severe in 12.7%, and severe in 27.7%. Moreover, 48.9% of the study population had a normal RV functional status, while RV dysfunction was mild in 38.3%, mild to moderate in 8.5%, and moderate in the remaining 4.3%. An assessment of the trend of the changes in RV dimension (Table 1) showed a significant decrease in RV size within 6 months after ASD closure with the ASO ($P < 0.001$). A normal RV size was revealed in 44.7% of the patients 6 months after the procedure. Similarly, RV function was gradually improved within 6 months after the procedure ($P < 0.001$) (Table 1). The mean PAP at baseline was 28.98 ± 6.46 mm Hg, which decreased to 27.57 ± 6.23 mm Hg at 1 day and 25.79 ± 5.90 mm Hg at 6 months after the procedure ($P < 0.001$). Apropos the postoperative complications, 1 day after the procedure, device displacement was detected in 2.1% of the patients, interatrial septum rupture in 12.8%, small pericardial effusion in 12.8%, tamponade in 2.1%, erosion on atrial tissue in 0%, and small residual ASDs in 12.8%, all of which were resolved procedurally within the following month. In addition, unsuccessful ASD closure was recorded in only 3 patients, with an overall failure rate of 6.4%. Table 2 summarizes the study indices between the groups with and without pericardial effusion event, indicating no difference between the 2 groups in terms of the sizes of the ASDs, posterosuperior rims, anterosuperior rims, anteroinferior rims, posteroinferior rims, SVC and IVC rims, balloons, and also the devices. Further, a comparison of the aforementioned parameters between the groups with and without residual ASDs showed no difference in all the parameters between the 2 groups (Table 3). The present study could not find any relationship between the presence of pericardial effusion and the study parameters.

Table 1. Trend of the change in RV size and function after the procedure

Parameters	Baseline	1 Day Later	1 Month Later	6 Months Later	*P*
PAP (mm Hg)	28	27	25	25	< 0.001
RV size					
Normal	0 (0%)	2 (4.3%)	10 (21.3%)	21 (44.7%)	< 0.001
Mild	2 (4.3%)	9 (19.1%)	20 (42.6%)	20 (42.6%)	
Mild to moderate	9 (19.1%)	11(23.4%)	12 (25.5%)	3 (6.4%)	
Moderate	17 (36.2%)	15 (31.9%)	2 (4.3%)	0 (0%)	
Moderate to severe	6 (12.7%)	4 (8.5%)	0 (0%)	0 (0%)	
Severe	13 (27.7%)	3 (6.4%)	0 (0%)	0 (0%)	
RV function					
Normal	23 (48.9%)	24 (51.1%)	36 (76.6%)	41(87.2%)	< 0.001
Mild	18 (38.3%)	15 (31.9%)	5 (10%)	1 (2.1%)	
Mild to moderate	4 (8.5%)	3 (6.4%)	3 (6.4%)	2 (4.3%)	
Moderate	2 (4.3%)	2 (4.3%)	0 (0%)	0 (0%)	
Moderate to severe	0 (0%)	0 (0%)	0 (0%)	0 (0%)	
Severe	0 (0%)	0 (0%)	0 (0%)	0 (0%)	

RV, Right ventricle; PAP, Pulmonary artery pressure

Table 2. Comparison of the study parameters between the groups with and without PE events

Parameters	Group With PE	Group Without PE	*P*
Size ASD mm	19 (13, 22)	15(13, 20)	0.493
Anteroinferior rim	10(5.75, 13.5)	10(8.7, 12.2)	0.828
Posterosuperior rim	9 (6.8, 16.2)	10(8, 12)	0.986
Anterosuperior rim	1 (0.5, 2)	2(0, 8)	0.472
Posteroinferior rim	16(10, 25)	10(6, 15)	0.84
SVC rim	11.5(6.5, 15)	11(10, 15)	0.677
IVC rim	14 (9.8, 21.2)	11(8, 16)	0.472
Sizing balloon	22(14, 24)	19(16, 22)	0.606
Device size	26(17, 26)	21(18, 25)	0.605

PE, Pericardial effusion; ASD, Atrial septal defect; SVC, Superior vena cava; IVC, Inferior vena cava

Table 3. Comparison of the study parameters between the groups with and without residual ASDs

Parameters	Group With Residual ASDs	Group Without Residual ASDs	*P*
Size ASD mm	15 (14, 24)	16 (13, 20)	0.514
Anterosuperior rim	12 (9.2, 13)	10(8, 12)	0.322
Posterosuperior rim	9.5 (7.5, 12)	10 (7.5, 12)	0.669
Anterosuperior rim	3.5 (0, 10)	2 (0, 5.2)	0.803
Posteroinferior rim	11.5 (5.2, 16.5)	10 (7, 15)	0.907
SVC rim	12.5 (9.5, 15)	10 (9, 14)	0.628
IVC rim	14.5 (8.7, 17)	11.7 (8, 16)	0.472
Sizing balloon	20 (17.1, 26)	19.5 (15.7, 22)	0.559
Device size	21 (18, 29)	21 (18, 26)	0.652

ASD, Atrial septal defect; SVC, Superior vena cava; IVC, Inferior vena cava

DISCUSSION

The clinical benefits of the catheter-based closure of ASDs using the ASO have been described in some recent studies. Almost all these studies have emphasized the superiority of this procedure for ASD closure in view of its favorable outcomes and minimal postoperative complications. In this regard, our results similarly demonstrated the high therapeutic effectiveness of the ASO procedure in terms of its favorable outcome and rare complications within a 6-month follow-up period. The overall success rate of the procedure in our experiment was 93.6%. In fact, it seems that employing the ASO technique can provide appropriate deployment in the closure of large secundum ASDs. In a study by Narin et al, [10] after adjusting for age and body weight, the conventional method was found 5.6 times more risky than the ASO technique in terms of process failure. Bartakian et al [11] showed that the procedural success rate of the ASO was 100% with no significant complication either during the procedure or at 1 year's follow-up, both in transthoracic and transesophageal echocardiographic assessments. In another study by Abid et al, [12] the final success rate of the procedure was 90.9% and 8.6% of the patients developed complications including 2 cases of prosthesis migration and 1 case of large residual shunting. The authors also reported that 11.7% of their study population needed to undergo surgery; however, no major complications such as thromboembolic events, obstruction of the intracardiac structures, cardiac perforation, device embolization, and endocarditis or death occurred during the follow-up—which is nearly similar to our observations. Behjati et al [13] also assessed the outcome of the ASO procedure in patients with ASDs and showed complete closure in 96.2% of their patients—with residual shunts in 3.8%, tamponade requiring drainage in 1.7%, device embolization to the left atrium and the RV outflow tract in 3.4%, and late wire fracture in 1.7%. Likewise, Knepp et al [14] reported a complete closure rate of 97% by using the ASO procedure for removing secundum ASD defects. The rare postoperative complications in their study were chest pain, supraventricular tachycardia, atrial fibrillation, premature ventricular beats, migraine, mild aortic insufficiency, and only 1 case of death. All the experiments underscored the clinical efficacy of the ASO procedure in closing secundum ASDs with a success rate ranging from 89% to 100% as well as with rare postoperative complications and very rare long-term postoperative mortality, emphasizing the high efficacy and safety of the procedure as an acceptable alternative to surgical approaches.

The ease of implantation and also the high success rate of ASD closure with the ASO have resulted in the widespread use of this transcatheter ASD occlusion device in lieu of routine surgical closure in several clinical settings. [15-20] The aforementioned success rate can be a result of the special design of the

ASO. Firstly, the device's waist between the left and right retention discs is a stent, which results in its self-centering within the defect: This requires only a small rim around the defect for firm cross-clamping with the retention discs. Secondly, because it does not require a large delivery system, the ASO can be retrieved without damaging the device. [21] Thus, the ASO can be indicated for almost all candidates.

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