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Original Studies

Device Therapy for Atrial Septal Defects in a Multicenter Cohort: Acute Outcomes and Adverse Events

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Background: Secundum atrial septal defect (ASD) closure devices were granted approval based on industry-sponsored, prospective, nonrandomized, single device studies, demonstrating acceptable efficacy and safety in selected patients. We sought to report community practice and outcomes. Methods and Results: Procedure specific data was collected on cases considered for ASD closure in the congenital cardiac catheterization project on outcomes (C3PO) between February 1, 2007 and June 31, 2010. Eight centers contributed data during this time period. All adverse events (AE) were independently reviewed and classified by a five level severity scale. In 40 months (2/07–6/10), 653 of 688 ASDs were occluded with a single device using an AMPLATZER® Septal Occluder (ASO) in 566 (87%), GORE® HELEX® Septal Occluder (HSO) in 33 (5%), and a CardioSEAL® or STARFlex™ device (CSD) in 54 (8%). Most patients had an isolated ASD (93%). 85% were >2 years of age. The ASD median diameter was 12 mm [8,16] for ASO, with smaller diameters in HSO 8 mm [7,10] and CSD 8 mm [5,10] ($P < 0.001$). AE ($n = 82$) were recorded in 76 cases, 11.5% (95% CI 9.2%, 14.1%) and classified as high severity in 4.7% (95% CI 3.2%, 6.5%), with no mortality. A new conduction abnormality was detected during 15 cases and did not resolve in one. Transcatheter device retrieval was possible in 7 of 10 device embolizations. Device erosion occurred in 3 of 566, 0.5% (95% CI 0.1%, 1.5%), ASO implants. Conclusion: Although device closure of ASDs is associated with low morbidity and rare mortality, ongoing assessment of device safety profiles are warranted, and registries offer opportunities to facilitate the required surveillance. © 2014 Wiley Periodicals, Inc.

Key words: pediatric intervention; closure; ASD/PDA/PFO; congenital heart disease; pediatrics; complications; pediatric catheterization/intervention

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INTRODUCTION

Atrial septal defects (ASD) have a reported prevalence of 10% among congenital heart defects and if left untreated, although recognized as a benign disease, can contribute to significant morbidity and mortality [1,2]. King and Mills, in 1974, originally described and subsequently demonstrated feasibility of closing a secundum ASD using a device. Pivotal device investigations have demonstrated that individual devices provide safe and efficacious alternatives to surgical closure of the secundum ASD [3–5]. Subsequently, in the United States, device closure has become an acceptable and often preferred method of closure for many secundum ASDs. However, limited reports exist on unselected practice and outcomes related to ASD device closure [6]. We sought to profile the procedural characteristics and safety of device closure of ASDs using a multi-institution collaborative registry, C3PO-The Congenital Cardiac Catheterization Project on Outcomes.

METHODS

Data Collection

Patient and procedural data was prospectively collected in the C3PO registry using a web based data entry tool at eight participating institutions between February 1, 2007 and June 21, 2010. Data collection, validation, and auditing methods have previously been reported [7]. IRB and/or equivalent institutional quality board approvals were maintained during data collection at each of the centers. In accordance with participant agreements, all interventional cardiologists who contributed to the data set reviewed and approved the manuscript prior to peer review submission.

Population and Characteristics

The study population included all patients that were considered and underwent transcatheter ASD closure at the participating institutions (appendix). Patients in which a device was considered but the procedure was aborted are reported separately. Patient characteristics reported include gender, age, weight, diagnosis, cardiac index, left ventricle end diastolic pressure, ratio of pulmonary to systemic flow (Q_p/Q_s), and number of ASDs. The following case data were recorded: admission source (elective or nonelective), airway management with mechanical ventilation, procedure time (from time of catheter insertion to removal), contrast dose, and type of device. The following devices were utilized at the participating institutions during the study period: AMPLATZER® Septal Occluder (ASO), GORE® HELEX® Septal Occluder (HSO), and a CardioSEAL® or STARFlex™ device (CSD). In cases in which the ASD was closed with a device the defect size was recorded with and without balloon sizing if performed. Further, confirmation of the lack of new valve insufficiency or pulmonary vein obstruction was recorded. Outcome reported till the time of discharge; however, all erosions were captured and reported even after discharge.

Adverse event (AE) for this registry have previously been defined as any event, for which avoidable injury

TABLE I. Patient and Procedure Characteristics of all Patients that Underwent ASD Device Closure

Patient characteristics	All patients ($N = 688$)
Gender female	450 (65%)
Age (years)	
<1	16 (2%)
1–2	88 (13%)
3–9	342 (50%)
10–17	122 (18%)
≥18 years	120 (17%)
Weight (kg)	
<15	164 (24%)
≥15	524 (76%)
Diagnosis	
Isolated ASD	638 (93%)
ASD and other CHD	47 (7%)
Pulmonary hypertension	3 (<1%)
Hemodynamic data	
Q_p/Q_s ($n = 567$)	1.6 [1.2,2.2]
Q_s ($n = 611$)	4.1 [3.2,5.0]
LV end diastolic pressure ($n = 379$)	10 [8,11]
Number of devices	
One	653 (95)
Two	35 (5)
Procedure characteristics	All Patients ($n = 688$)
Admission source	
Elective	680 (99%)
Mechanical ventilation	579 (84%)
Procedure time (minutes)	71 [54, 97]
<60	222 (33%)
60–119	385 (56%)
120–179	64 (9%)
≥180	17 (2%)
Inotropic support during the case	5 (1%)
Transfusion of PRBC	2 (<1%)
Contrast ($cm^3\ kg^{-1}$) ($n = 506$)	0.7 [1,1.3]
Type of device	
AMPLATZER® Septal Occluder (ASO)	594 (86%)
CardioSEAL® or STARFlex™ device (CSD)	59 (9%)
GORE® HELEX® Septal Occluder (HSO)	33 (5%)
Combination	2 (<1%)
Adverse event (AE)	
Any AE	76 (11%)
Any high severity AE	32(5%)

Values shown are number (percent) or median (interquartile range); ASD, atrial septal defect, CHD, congenital heart disease, LV, left ventricle.

*Combination: A CSD and ASO device were used to close defects in 2 of 35 cases with multiple ASDs.

TABLE II. ASD Characteristics by Device Type for Single Device Closures

	Type of device				
	Total ($N=653$)	ASO ($N=566$)	CSD ($N=54$)	HSO ($N=33$)	P value
Qp/Qs ($n=533$)	1.6 [1.2,2.2]	1.7 [1.2,2.3]	1.3 [1.1,1.8]	1.4 [1.1,1.8]	0.003
ASD size no balloon (mm) (n 5 3)	11 [8, 15]	12 [8, 16]	8 [5, 10]	8 [7, 10]	<0.001
ASD balloon size (mm) ($n=527$)	14 [11, 19]	15 [11, 19]	12 [8, 15]	10 [8, 12]	<0.001
ASD/balloon ratio ($n=488$)	1.2 [1.1, 1.4]	1.2 [1.1, 1.4]	1.4 [1.2, 1.8]	1.3 [1.2, 1.5]	<0.001

Median [interquartile range].

could have occurred, or did occur, as a potential or definite consequence of performing the catheterization [7,8]. AEs were recorded at the time of identification either during the procedure or following the procedure if potentially related to the catheterization. Participants recorded the name of the event and description. All events underwent independent review by two interventional cardiologists for consistent severity classification using established standardized nomenclature on a five level severity scale, based on clinical impact (1-none, 2-minor, 3-moderate, 4-major, 5-death) [7,9]. In cases of suspected erosion echocardiograms were requested and reviewed by the primary and senior author.

Statistical Analysis

Categorical variables are summarized by frequency and percentage. All continuous variables are summarized using median and interquartile range (25th, 75 percentile) expressed as [X,Y]. The cohort was stratified based on the first device chosen and delivered for ASD closure. The incidence of AE and 95% confidence intervals were calculated for any AE and for any high severity level 3, 4, or 5 events related to the procedure. Patient and procedural characteristics were compared for patients experiencing a higher severity AE versus those not experiencing such an event using Fisher's exact test or the Wilcoxon rank sum test. Case mix, device used for implant, and AE rates were explored by institution and comparisons assessed with Fisher's exact test.

RESULTS

Between February 1, 2007 and June 31, 2010, 688 ASD closures were recorded with 35 requiring greater than one device for multiple defects. The 653 isolated defects were closed using an AMPLATZER® Septal Occluder (ASO) in 566 (87%), GORE® HSO in 33 (5%), and a CSD in 54 (8%). In 33 of the 35 ASDs closed with two devices, ASO devices were used. In the remaining two, a combination of ASO and CSD was used. The patient and procedural characteristics for the cohort are summarized in Table I. Eighty five percent of the patients were older than 2 years of age, with a weight of greater than or equal to 15 kg in 76%. There were only 16 patients (2%) <1 year of age; all underwent closure with ASO. Most patients (93%) had an isolated ASD without any other congenital defects or pulmonary hypertension. Almost all cases were performed electively and general anesthesia was utilized in 84% of cases. Inotropic support and administration of blood transfusion were rare (<1%). Ninety percent of procedures were performed in <2 hr. Contrast was used in 506 cases (74%), and when used the median load of contrast given was 1.1 cm^3 kg^{-1} [0.6,1.6].

Table II summarizes the ASD characteristics for the 653 cases with a single treated defect. For the cases in which ASD size was recorded, the ASD median diameter was 11 mm (ranging from 2 to 32 mm), with the median defect size being larger for defects closed with an ASO device (12 mm [8,16] for ASO, vs. 8 mm [7,10] for HSO and 8 mm [5,10] for CSD ($P<0.001$). Accordingly, the left to right shunt was higher in the ASO population, (median 1.7, as compared to HSO 1.3 and CSD 1.4, $P=0.003$). Successful closure was achieved with the first device chosen in 659 of 688 (95%) cases. The same device either the same size ($n=1$) or larger ($n=10$) was chosen in seven ASO and four CSD cases. A different device was chosen in 13 cases, three CSD and 10 HSO converted to an ASO. Of the 10 HSO, 5 had technical issues where there was premature locking of the loop or fracture of the chord.

In 54 cases captured in the C3PO population, but not included in the device placement study cohort, ASD device closure was aborted. Among these no attempt was made in 41 of the 54 cases due to size, location, or hemodynamic factors. In the remaining 13 cases the device was never released from the delivery system and removed from the body due to unfavorable appearance according to the operator's judgment.

Eighty two AE were recorded in 76 of 688 cases (11.5%, 95% CI 9.2%, 14.1%) and classified as high severity in 4.7% (95% CI 3.2%, 6.5%), with no

TABLE III. Relationship and Severity Classification for all Adverse Events

	Adverse event severity classification ($n=82$)			
Relationship and event name	1	2	3	4
Sedation airway related				
Bleeding from ETT	1			
Other sedated			2[a]	
Unplanned extubation		1		
Catheterization related				
Air embolus systemic		1		
Atrial arrhythmia		6	4	
Heart block (resolved)		4	1	
Heart block (not resolved)				
None specific ST segment change		1		
Other trauma	1[b]			
Vessel trauma	1			
Access related				
Hematoma		1		
Rebleed	2	6		
Other access		2[c]	1[d]	
Device related				
Atrial arrhythmia	1	3	2	
Heart block resolved	4	2	3	
Heart block not resolved			1	
Device embolization			7	3
Device erosion				3
Device malposition		7	8	
Nonspecific ST change		1		
Other device problem	1[e]	1[f]		

[a]One had mucosal esophageal tear causing throat pain treated conservatively with NPO for a few days and the second had pharyngeal bleed from trauma induced by trans-esophageal probe that resolved spontaneously.
[b]Staining of the RUPV, no pulmonary vein obstruction on follow up.
[c]One had injury of the right iliac vein by 11F sheath used for ICE (intracardiac echo), treated conservatively and the second had drop in Hematocrit post hepatic access that had been closed with vascular plugs, no intervention needed.
[d]Bladder entered with a needle during venous access, lead to hematuria, treated conservatively and resolved.
[e]Cobra deformation of the device.
[f]Linear thrombus in the left atrium detected during device placement, resolved with no neurologic events.

TABLE IV. Patient and Procedural Characteristics by Occurrence of Level 3/4/5 Adverse Event (Univariate analysis)

Patient characteristics	At least one level 3/4/5 AE ($n=32$)	No level 3/4/5 AE ($n=656$)	P value
Age (years)			0.34
<1	0 (0%)	16 (2%)	
1–2	2 (6%)	86 (13%)	
3–9	14 (44%)	328 (50%)	
≥10	16 (50%)	226 (34%)	
Weight (kg)			0.14
<15 ($n=164$)	4 (2%)	160 (98%)	
≥15 ($n=524$)	28 (5%)	496 (95%)	
Hemodynamic data			
Cardiac index L/min/M2 ($n=582$)	3.7 [3.2,4.8]	4.1 [3.2,5.0]	0.23
LV end diastolic pressure ($n=359$)	9 [6,12]	10 [8,11]	0.14
Number of atrial septal defects			1.0
One	31 (97%)	631 (96%)	
Multiple	1 (3%)	25 (4%)	
Procedure time (minutes)	86 [65, 98]	71 [54, 97]	0.02
<60	4 (13%)	218 (33%)	0.007
60–119	23 (72%)	362 (55%)	
120–179	2 (6%)	62 (9%)	
≥180	3 (9%)	14 (2%)	
Type of device			0.40
AGA medical	27 (84%)	567 (86%)	
NMT	3 (9%)	56 (9%)	
HSO	1 (3%)	32 (5%)	
Combination	0 (0%)	2 (<1%)	

Values shown are number (percent) or median (interquartile range).

mortality. All AE with corresponding relationship and severity classification are listed in Table III. Ten device embolizations occurred in the cohort; eight at the time of the procedure, with the remaining identified 2 and 24 hr following the procedure, of those nine had an ASO and one had a HSO. Of those, balloon sizing was used in nine and the ratio of ASD size to balloon size was a mean of 0.84:1. Retrieval was possible in seven of 10 cases of device embolization and required surgical removal and ASD closure in the remaining. No significant mitral valve regurgitation or pulmonary venous obstruction was reported. There was no difference in AE in cases <15 kg, age <3 years, or in cases in which there were multiple ASDs. As would be expected the procedure was longer for those with higher severity AEs, but there was no difference in hemodynamic parameters, Table IV.

A new conduction abnormality was detected during 15 cases (9 CHB, 4 second degree and 2 first degree heart block) and did not resolve in one that required device removal in the cath lab the following day (patient's conduction recovered within a few days and went on to have surgical closure of the ASD). Among the remaining 14 cases that resolved, four patients were treated with steroids, one with glycopyrollate, and one device removed and repositioned. The rhythm returned to normal sinus in 7/14 in the catheterization laboratory and within 24 hr in 5/14. Two patients where discharged home with 1st degree AVB. Atrial tachy-arrhythmias were recorded in 16 cases, 7 of which required medical or electrical conversion at the time of the procedure. Other minor events included access related trauma, hematoma, and rebleeding. In univariate analysis there were no significant differences in AE rates among the patient and procedural characteristics reported or type of device used for closure.

TABLE V. ASO cases consistent with device erosion

Age (years)	ASD size (mm)	Balloon size (mm)	Device size (mm)	Time from implant (hours)	Presentation	Outcome
14	21	22	24	32	Chest pain and dizziness; diagnosed with pericardial effusion	Surgical removal Survival to discharge
6	16	NP	18	3	Collapse CPR; diagnosed with pericardial effusion	Surgical removal Survival to discharge
2	12	12	12	18	Effusion on screening echo	Surgical removal Survival to discharge

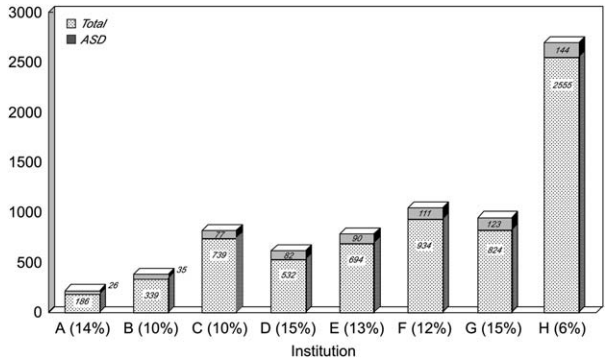

Fig. 1. Bar graph demonstrating the percent of ASD cases to total number of intervention cases in each institution.

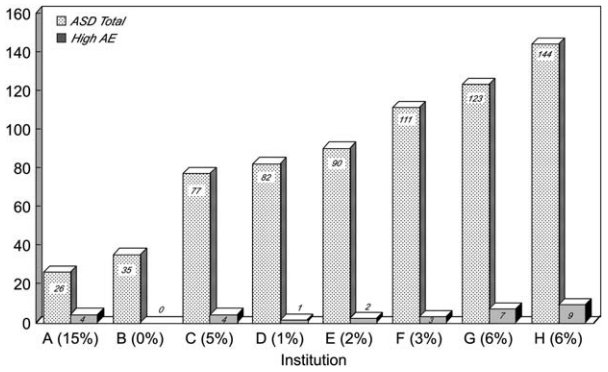

Fig. 2. Bar graph demonstrating number of high severity adverse events to total ASD cases for each institution. *Rates and 95% confidence intervals.

Three cases of suspected device erosion occurred in the cohort, Table V. Each case occurred at a different institution. All three cases were confirmed as erosions at surgery and all had received an ASO device. Therefore, the incidence of erosion after ASO implant in this series was 0.5% [95% CI (0.1%, 1.5%). Patients were 2, 6, and 14 years of age with corresponding defect sizes of 12, 16, and 21 mm. In two cases the erosion site was anterior superior (atrial wall-aorta) and in one it was posterior-superior. The common characteristics were a partially deficient retroaortic rim (with thin rims in two), a device that was not over-sized (possibly undersized as there was no aortic splaying) and movement of the device relative to movement of the heart. All three patients presented within 32 hr of device placement, were successfully resuscitated, and the ASD was repaired surgically after device removal.

In the group with multiple ASDs the total AE rate was 4/26 (15%), with only one high severity event (4%) with no reported embolization or erosion. One had 3rd degree heart block and was treated with steroids with conversion to 1st degree block.

The eight participating institutions contributed between 25 and 150 cases to the dataset, median 78, Fig. 1; two sites joined 14 and 26 months following the initiation of the registry (Site A and B). ASD device placement by site ranged between 5 and 15% of the average annual interventional case volume, Fig. 1. ASD closure comprised the smallest percentage of interventional volume in the center with the highest case volume. Six centers utilized a combination of ASO and HSO, one ASO and CSD, and the remaining exclusively ASO. When excluding the two sites that joined late with the lowest number of ASD cases, the high severity AE rates ranged from 1.2 to 6.9% without statistically significant differences among sites ($P = 0.21$), Fig. 2.

DISCUSSION

In this report, we describe procedural characteristics and AEs encountered during the common practice of ASD device closure at eight congenital heart centers participating in the C3PO registry over a period of 40 months. During the episodes of care reported by registry centers, patients undergoing attempted ASD device implant experienced an 11% rate of any AE and a 4.7% rate of a higher severity AE (level 3, or 4). Accounting for differences in definitions, the high severity rates are similar to the major AE rates reported in the original IDE trials and in the MAGIC cohort

[3,5,6]. As in the pivotal studies, there were no mortalities (level 5) in registry patients undergoing attempted ASD device implantation.

Although the pivotal studies reported no cases of erosion or cardiac perforation after ASD device implant, this rare but potentially fatal complication subsequently came to light as a consequence of cases reported to the FDA Manufacturer and User Facility Device Experience (MAUDE) database [10,11]. In our series, all devices resulting in erosion were ASOs (0.5% rate of erosion among patients having ASO implants). Although similar incidence rates have been estimated from MAUDE data, our data set is neither adequately powered nor longitudinal, and therefore, cannot be considered confirmatory. Likewise, specific parameters noted among registry patients having erosion, such as rim deficiencies, device sizing, or device motion relative to heart motion, must be considered anecdotal.

Other notable AEs reported in registry data include device embolization and heart block. The rate of ASO device embolization has previously been estimated to be 0.5–0.6% from MAUDE and survey data [11]. C3PO registry patients experienced a higher rate of 1.5%. Heart block was noted in 2.1% of cases in the registry patients. Thirteen patients reverted to normal conduction with observation or medical treatment. In our view, C3PO registry data tends to confirm other evidence that clinically important heart block is rare and usually not consequential in ASD device closure [12]. Our AE rate for multiple ASDs closure was similar to previously reported, however, there were no erosions or embolizations in this group [13].

This report of C3PO registry data provides the first profile of community practice with respect to ASD device closure in an environment of available alternative devices. A large study in Europe reported a large cohort of ASD device closure, in which a lower success rate was reported in the pediatric population [14]. An important aspect of the profile is the observation that many patients had diagnostic catheterizations as part of their final selection for device or surgical ASD closure. Although this phenomenon likely also occurred in the pivotal studies, the extent of "pre-catheterization" was neither defined nor emphasized in study reports. This observation is important because the patients "turned down" for device closure at catheterization have not been considered technical failures in medical reports and perhaps also have not been fully elucidated in the context of patient/family counseling. This study also reflects the more common use of the ASO device over the HSO device with almost a third of those attempted closures with an HSO eventually being converted to an ASO device. This may be due to the ease of use of the ASO device with less of a learning curve and technical issues and it being better suited for closure of larger defects.

The limitation of this study is that data was collected from a registry so some of the details that may help with analysis were not captured. In cases with important complications such as erosion, embolization and heart block more details were requested. Some complications namely vessel trauma or injury were reported based on clinical observation and may have been under-detected and thus under-reported.

In conclusion, this report confirms prior evidence and common notions that a high percentage of defects are currently closed with the ASO, that the procedure when attempted has a high degree of success, and that the procedure is generally safe. Finally, although device erosions were encountered among registry patients that underwent ASO implantation, this data is insufficient to further define incidence or primary causative factors of this troublesome complication.

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APPENDIX

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