JACC: CARDIOVASCULAR INTERVENTIONS VOL. 11, NO. 8, 2018

PUBLISHED BY ELSEVIER

Long-Term Outcomes After Percutaneous Closure of Ostium Secundum Atrial Septal Defect in the Young

A Nationwide Cohort Study

Zakaria Jalal, MD,[a,b,c] Sébastien Hascoët, MD,[d,e] Céline Gronier, MD,[f] François Godart, MD, PhD,[g] Lucia Mauri, MD,[d] Claire Dauphin, MD,[h] Bruno Lefort, MD,[i] Matthias Lachaud, MD,[j] Dominique Piot, MD,[d] Marie-Lou Dinet, MD,[a] Yael Levy, MD,[a] Alain Fraisse, MD, PhD,[k] Caroline Ovaert, MD, PhD,[k] Xavier Pillois, PhD,[b] Jean-René Lusson, MD, PhD,[h] Jérôme Petit, MD,[d] Alban-Elouen Baruteau, MD, PhD,[l] Jean-Benoit Thambo, MD, PhD[a,b,c]

ABSTRACT

OBJECTIVES This study sought to assess procedural characteristics, early clinical outcome, and long-term complications after transcatheter closure of atrial septal defect (ASD) in children.

BACKGROUND Transcatheter closure has become the preferred strategy in most cases of isolated secundum ASD. However, reported experience in the pediatric population is limited.

METHODS A 1998 to 2016 retrospective multicenter study was performed in 9 French tertiary institutions. All children who had an attempt of percutaneous ASD closure with an Amplatzer Septal Occluder were included.

RESULTS In 1,326 children (39% males; median age, 9 years [0.7 to 18]; weight, 29 kg [3.6 to 92]), transcatheter ASD closure was performed. Median ASD size was 15 mm (3 to 41); 254 (19.1%) patients had a large ASD (≥20 mm/m^2). Procedural success rate was 95.3% (95% confidence interval: 93.9% to 96.3%). No death was observed but periprocedural complications occurred in 24 patients (1.8%). After a median follow-up of 3.5 years (range 6 months to 18 years; 173 patients [13%] followed >10 years), delayed major complications were minimal (n = 12; 1.04%) including no death and/or cardiac erosion. Periprocedural and delayed complications rates were significantly higher in children ≤15 kg (5.2% vs. 1.5%; p = 0.007 and 3.1% vs. 0.7%; p < 0.007, respectively) and those with large ASD (3.5% vs. 1.4%; p = 0.008 and 1.7% vs. 0.7%; p = 0.052, respectively).

CONCLUSIONS Transcatheter ASD closure using Amplatzer Septal Occluder is safe in children with a minimal rate of periprocedural complications and a favorable long-term outcome, especially with no death or cardiac erosion despite a substantial proportion of large defects. Children ≤15 kg and those with large ASDs had a greater risk of complications. (J Am Coll Cardiol Intv 2018;11:795–804) © 2018 by the American College of Cardiology Foundation.

From the [a]Bordeaux University Hospital (CHU), Department of Paediatric and Adult Congenital Cardiology, Pessac, France; [b]IHU Liryc, Electrophysiology and Heart Modeling Institute, Fondation Bordeaux Université, Pessac-Bordeaux, France; [c]INSERM, Centre de Recherche Cardio-Thoracique de Bordeaux, U1045, Bordeaux, France; [d]M3C Marie-Lannelongue Hospital, Paediatric and Congenital Cardiac Surgery Department, Paris Sud University, Plessis-Robinson, France; [e]Department of Paediatric Cardiology, Hopital des Enfants, Paul-Sabatier University, CHU de Toulouse, Toulouse, France; [f]Cabinet de Cardiologie Foetale Pediatrique et Congenitale Adulte, Strasbourg, France; [g]CHRU de Lille, University Lille Nord-de-France, Faculté de Médecine, Hôpital Cardiologique, Service des Maladies Cardiovasculaires Infantiles et Congénitales, Lille, France; [h]Service de Cardiologie et Maladies Cardiovasculaires, Hôpital Gabriel-Montpied, CHU de Clermont-Ferrand, Clermont-Ferrand, France; [i]Unité de Cardiologie Pédiatrique, Hôpital des Enfants Gatien de Clocheville, INSERM UMR 1069 et Université François Rabelais, Tours, France; [j]Inserm UMR 1087—CNRS UMR6291, Institut du Thorax, Nantes University, Nantes, France; [k]Paediatric and Congenital Cardiology, La Timone Hospital, M3C CHU de Marseille, Marseille, France; and the [l]Department of Congenital Cardiology, Evelina London Children's Hospital, Guy's and St Thomas' NHS Foundation Trust, London, United Kingdom. This study was supported by the French Government as part of the Investments of the Future program managed by the National Research Agency (ANR-10-IAHU-04).

ISSN 1936-8798/$36.00 https://doi.org/10.1016/j.jcin.2018.01.262

ABBREVIATIONS AND ACRONYMS

ASD = atrial septal defects

ASO = Amplatzer Septal Occluder

AVB = atrioventricular block

CI = confidence interval

LA = left atrium

TEE = transesophageal echocardiography

TTE = transthoracic echocardiography

Atrial septal defect (ASD) is a common congenital heart defect with a reported incidence of 1.0/1,000 live births (1). Untreated ASD can cause right ventricular overload with right heart failure, atrial arrhythmias, pulmonary hypertension, or systemic embolism and premature death (2,3). Over the last 15 years, transcatheter closure has become the gold standard treatment strategy for isolated, secundum ASD with suitable anatomy (4,5). A recent study comparing 4,606 percutaneous procedures and 3,159 surgical ASD closures at 35 children's hospitals showed that transcatheter closure was as safe as surgery and provided better short-term value when compared with surgical closure (6).

SEE PAGE 805

The Amplatzer Septal Occluder (ASO, St. Jude Medical, Inc., St. Paul, Minnesota), a self-expandable double-disc consisting of a nitinol wire mesh, is the most widely used device for percutaneous ASD closure worldwide with more than 230,000 implantations reported so far (7). Feasibility and safety of ASO implantation has been demonstrated in adult and pediatric patients with a procedural success rate close to 95% (8,9). However, despite excellent early results, the expanding use of these devices brought to light some delayed but potentially lethal complications, such as aortic erosion, cardiac perforation, atrioventricular block (AVB), infective endocarditis, or cardiac arrhythmias (5,10–14). In the meantime, the growing experience with percutaneous ASD closure led to considering the treatment of younger and smaller patients (15–19). However, success and complication rates of transcatheter ASD closure in very small children are still poorly documented, mostly consisting in small series with a limited follow-up (20,21). Thus, in this specific pediatric population, there is a need to better assess early and long-term clinical outcomes, to provide an acute counseling to patients and comprehensive awareness of potential delayed complications to physicians (22–25).

We hypothesized that percutaneous closure of ASDs in children was feasible and safe. Here, we tested our hypothesis by evaluating early and long-term outcomes of children with ASD managed using the ASO in a large multicenter cohort.

METHODS

DATA COLLECTION. A retrospective multicenter study was conducted in 9 French tertiary institutions. All children who had an attempt of transcatheter closure of isolated ostium secundum ASD using the ASO between 1998 and 2016 were included in the database. Children were defined as patients <18 years. All patients had either a left-to-right shunt with evidence of right heart dilatation and/or paradoxical diastolic interventricular septal motion regardless of the presence of symptoms or a small ASD but a paradoxical embolism (2). Data were collected anonymously and retrospectively from medical records focusing on demographic characteristics, echocardiographic and procedural data, and both early and long-term follow-up data. All participating centers had exhaustive computerized databases for data collection of consecutive patients. The study was approved by the institutional review board of each participating center. Informed consent was obtained from each study participant's parents or legal guardian.

PRE-PROCEDURAL ASD ASSESSMENT. According to centers, transthoracic echocardiography (TTE) or transesophageal echocardiography (TEE) were performed routinely before ASD closure for each patient. Anatomic ASD features were recorded including ASD size (in mm, largest ASD diameter on any view), presence and location of deficient rims defined as <5 mm in length (20) (i.e., anteroinferior, posterosuperior, aortic, posterior, inferior, and superior rims), and left atrial (LA) maximal length (distance from the anterior mitral valve leaflet to the posterior LA wall). Anteroinferior and posterosuperior rims were analyzed on the 4-chambers view, aortic and posterior rims on the short-axis parasternal view, and inferior and superior rims on the subcostal view.

When not measured, LA length was calculated by the following formula: $0.597 + 0.404 \cdot \log$ body surface area (26). Special attention was given to pulmonary and systemic venous returns and pulmonary arterial pressure. Any potential associated cardiac

Dr. Baruteau was supported by a research grant from the French Federation of Cardiology. Drs. Jalal and Baruteau have received a research grant from St. Jude Medical. Dr. Hascoët has received consulting fees from Abbott. Dr. Fraisse is a proctor for Abbott. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose. Drs. Baruteau and Thambo contributed equally to this work.

Manuscript received December 18, 2017; revised manuscript received January 16, 2018, accepted January 23, 2018.