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REVIEW PAPER

Amplatzer occluders – a breakthrough in the interventional treatment of congenital heart defects. 27 years of experience

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ABSTRACT

This review synthesizes the experience of a single institution in the percutaneous closure of the most common congenital heart defects – atrial septal defect (ASD), ventricular septal defect (VSD), and patent ductus arteriosus (PDA) – using Amplatzer devices. For ASD, more than 2,000 procedures have been performed. Special attention is given to the age limits for this procedure. In the case of small PDAs, a documented shift in strategy from coils to the new Amplatzer Duct Occluder II Additional Sizes has occurred. The Amplatzer Duct Occluder type I remains the best device for closing larger PDAs (diameter > 2.5 mm). The most challenging percutaneous procedures remain VSD closures. Muscular VSDs (though less frequent) are likely the preferred candidates for this method, whereas perimembranous VSD closures remain a controversial issue. The article also describes an educational program for training foreign interventional cardiologists. In conclusion, the introduction of Amplatzer occluders into clinical practice represents a true breakthrough in the treatment of selected congenital heart defects.

KEY WORDS:

Amplatzer occluders, review, congenital heart defect, interventional cardiology.

INTRODUCTION

The most common congenital heart defects (CHD) are ventricular septal defects (VSD), atrial septal defects (ASD), and patent ductus arteriosus (PDA). In May 1997, during the World Congress of Pediatric Cardiology in Honolulu, USA, Professor Josef Masura from Slovakia presented, for the first time, human results of Amplatzer occluders for ASD and PDA closure. The Amplatzer Atrial Septal Occluder (ASO) and Amplatzer Duct Occluder type I (ADO I) (Figure 1 A, B), along with all Amplatzer devices, were invented by Dr. Kurt Amplatz (our mentor and friend) from the USA. These devices are constructed from a nitinol wire mesh with memory shape characteristics. At the end of 1997, we introduced these techniques (ASD and PDA closure) in our center with the assistance of Professor Masura, becoming the first to do so in our country and among the pioneers in Europe. The results were excellent: to date, we have closed more than 2,000 ASDs and over 1,000 PDAs [1].

ATRIAL SEPTAL DEFECTS

We recognize three types of ASD: the most common is ASD type II; less common are sinus venosus defects (SVD) and ASD type I, which require surgical closure. We published our preliminary experience with ASD II closure using ASO in the renowned journal *Revista Espa-*

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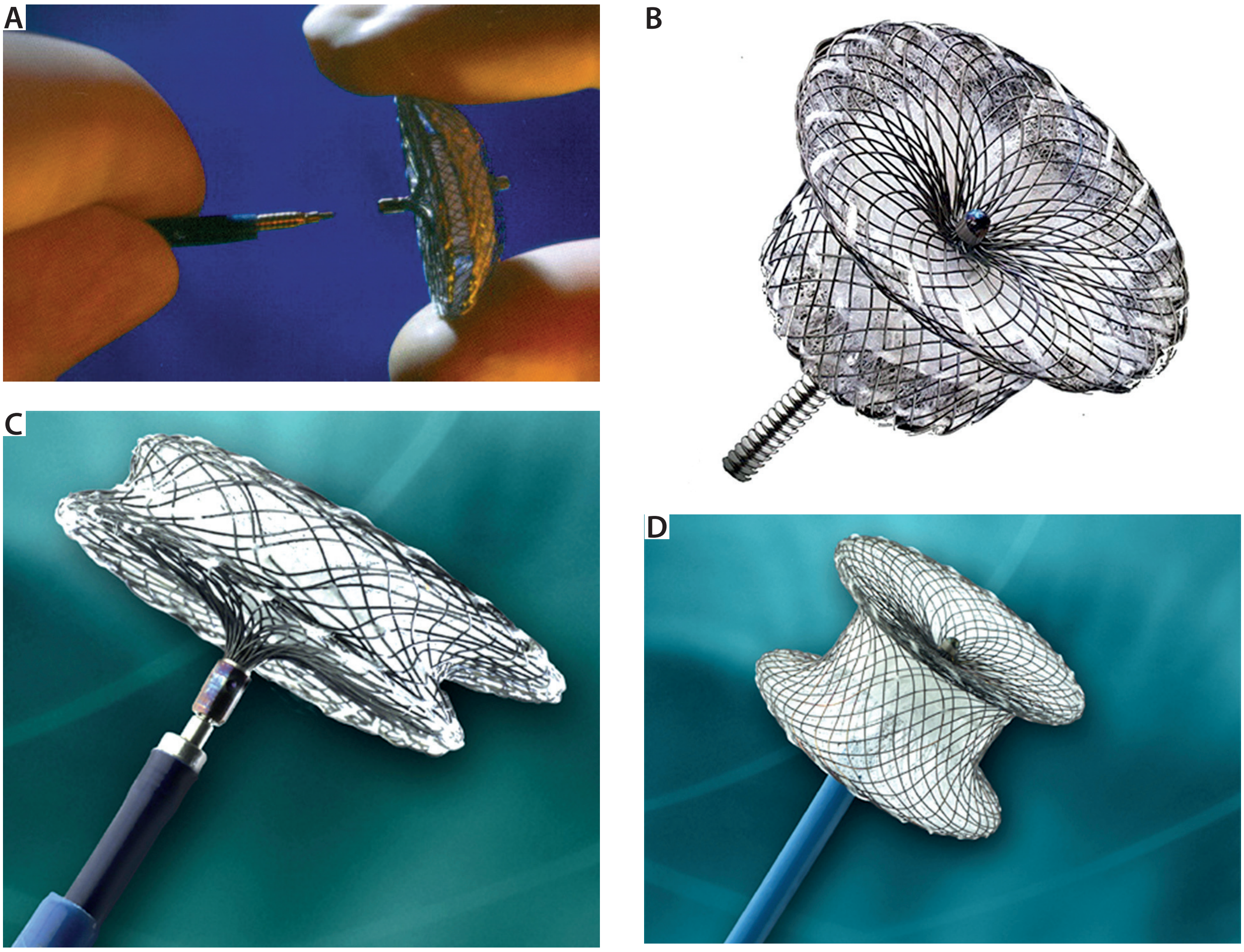

FIGURE 1. Different Amplatzer occluders. **A**) Atrial septal. **B**) Duct occluder type I. **C**) Perimembranous ventricular. D) Ventricular muscular

ñola de Cardiología in 2003 [2]. This paper was recognized and awarded by the Spanish Society of Cardiology in 2004 as the best article related to pediatric cardiology in the journal. Numerous devices other than ASO can be used for ASD closure (the majority very similar to ASO), e.g. Figulla, HeartR, and Cocoon, each one having similar efficacy as ASO [3]. Recently, transcatheter closure has become a possible option for SVD. The procedure consists of placing a long, covered stent to close the defect, diverting the superior vena cava flow to the right atrium, and redirecting the right upper pulmonary vein flow around the stent into the left atrium [4, 5].

In 2011, we were awarded by the Polish Society of Cardiology at their Congress in Wroclaw for our clinical presentation, which highlighted changes in the guidelines and eligibility criteria for ASD II closure using ASO in children under 3 years of age. Previously, many textbooks recommended ASD surgical closure at ages 5–6. This change helped prevent complications from this defect at an earlier age [6]. Another area of our research was establishing the limits of ASD closure in adults. Together with our German colleagues (Professor Sievert's team), we presented a group of 650 patients, including 153 patients over 60 years old, with excellent outcomes. We concluded that ASO is beneficial for all adult patients [7]. This paper has been cited 187 times to date.

PATENT DUCTUS ARTERIOSUS

According to Kirchenko *et al.*'s classification [8], PDAs are classified into various anatomical types (A, B, C, D, E). Recently, another type of PDA (F) was described in children born prematurely [9]. All types of PDAs are suitable for percutaneous closure. Initially, we used ADO I for larger PDAs and coils for smaller, more common PDAs. However, the latter were associated with residual shunts. Dr. Amplatz invented a special type of ADO for small children, known as Amplatzer Duct Occluder II Additional Sizes (ADO II AS). One of the authors (MSz) adapted this technique for older patients, with excellent results [10]. Currently, ADO I and ADO II AS are our primary devices for PDA closure. It should be mentioned that occluders other than Amplatzer PDA exist on the market (the majority very similar to them).

VENTRICULAR SEPTAL DEFECTS

Percutaneous VSD closure is perhaps the most challenging of all percutaneous procedures. Ventricular septal defects are typically classified as perimembranous (pmVSD), located near the tricuspid or aortic valve and conduction tissue, and muscular (MVSD), which may be located in the inlet (posterior) or outlet (anterior) of the interventricular septum. We recently published our experience with percutaneous VSD closure, including short- and long-term outcomes [11, 12]. We began closing MVSDs and pmVSDs in 2002 with the Amplatzer Muscular Septal Occluder (AMO), which at that time was the only device available. The AMO is designed in a tubular shape with symmetrical retention discs and a wide connecting waist (Figure 1 C).

Before starting pmVSD closures, we consulted Dr. Kurt Amplatz, who advised against using the AMO for pmVSDs, as it was designed for muscular defects only. In 2002, he developed an asymmetrical VSD occluder (asymVSO) specifically for pmVSDs (Figure 1 D) with a short connecting waist. We began using it in 2003. However, we soon realized that this procedure possessed a risk of late complete atrioventricular block (CAVB), likely due to mechanical trauma or compression of the conduction system. We published a case series with colleagues from Dublin and Poznań (2006), detailing the need for pacemaker implantation in patients who developed late CAVB after asymVSO use [13]. This paper has been cited 152 times to date. This may have contributed to the withdrawal of the device from the market.

In the same year (2006), we published our experience using the AMO for pmVSD closure (where the aortic rim was > 4 mm) [14]. In these cases, there were no rhythm disturbances or aortic regurgitation, although mild tricuspid insufficiency occurred in about 30% of cases. Graham [15] cited this work in 2007 as one of the most significant related to interventional cardiology in CHD. In 2009, we received a message from Professor Amplatz requesting long-term follow-up data for these patients, which confirmed favorable outcomes. This led him to develop a new type of pmVSD occluder, although it was not widely adopted [16].

We also described a case of tricuspid valve damage during inlet MVSD closure with the AMO [17], consulting Dr. Amplatz for advice on avoiding such complications. He responded that such occurrences were exceedingly rare and anatomically dependent, making them unavoidable in some cases. This comment was included in our published article [17], where we concluded that inlet MVSDs are contraindicated for percutaneous closure. Recently, new promising VSD devices were introduced into clinical practice, namely LifeTech Konar-MF VSD Occluder [18], and Nit-Occlud Le VSD coil [19], but we have had no experience with these devices.

Finally, percutaneous closure of post-infarction VSDs – a life-threatening complication – remains a significant challenge. We recently published our experience with 28 cases [20], highlighting that pediatric interventional cardiologists can play a valuable role in treating these difficult patients.

CONCLUSIONS

Our achievements in interventional CHD treatment were made possible through the guidance of many mentors. We organized numerous workshops at the Silesian Center for Heart Diseases in Zabrze, Medical University of Silesia, Poland (our *alma mater*), featuring esteemed experts such as Professor Chuck Mullins from Houston Children's Hospital (USA), Dr. Ramon Bermudez Canete from Ramon y Cajal Hospital in Madrid, Dr. Luigi Ballerini from Bambino Gesù Hospital in Rome, Dr. Alejandro Juarez from the National Institute of Cardiology in Mexico City, Professor Josef Masura from the Children's Hospital in Bratislava, Dr. Shak Quereshi from Evelina London Children Hospital, and many others.

From 2008 to 2012, one of the authors (JB) served as Chairman of the Interventional Cardiology Working Group of the Latin Pediatric Cardiology Society. Through the support of the Friends of Children with Heart Diseases Foundation in Zabrze (founded by us), we established a scholarship program for interventional cardiology from 2007 to 2019, training 21 cardiologists from 14 countries, including Bolivia, Colombia, Mexico, Argentina, Guatemala, China, Uzbekistan, Belarus, Russia, Georgia, Bulgaria, Italy, Ruanda and Ukraine [21]. We had the honor of hosting four doctors from Ukraine – two from the Amosov Institute in Kiev, and one each from Kharkiv and Lviv [22].

From 2015 to 2020, I (JB) had the honor of serving as the National Consultant for Pediatric Cardiology. During this time, we observed nearly a twofold increase in the number of annually performed transcatheter interventions (1221 in 2009 vs. 2271 in 2018). In 2018, the number of cardiac operations nearly equaled the number of interventional procedures performed in children with CHD (2294 vs. 2271) (Figure 2) [23].

Since 2022, both authors have retired and now serve as consultants. Dr. R. Fiszer continues the interventional CHD treatment strategy in our department.

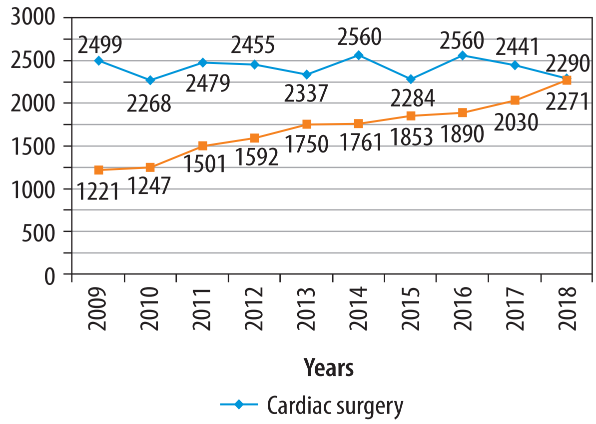

FIGURE 2. Interventional catheterizations (yellow) vs. cardiac surgery (blue curve) procedures in congenital heart diseases in the years 2009–2018 in Poland

DISCLOSURES

1. Institutional review board statement: Not applicable.
2. Assistance with the article: None.

3. Financial support and sponsorship: None.
4. Conflicts of interest: None.

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