

Atrial septal defect and ASO device: an unusual story



Pierre Aubry, MD; Jean Michel Juliard, MD; Eric Brochet*, MD

Cardiology Department, Hôpital Bichat, Paris, France

Usually, the commercial life of an implantable medical device is limited, rarely exceeding ten years in the absence of technological upgrading. The AMPLATZER™ Septal Occluder (ASO; Abbott/St. Jude, St. Paul, MN, USA) is an exception to the rule. The ASO is a transcatheter closure device intended for the percutaneous occlusion of atrial septal defects (ASD) which has been available on the market since 1998¹. To our knowledge, there have been no relevant changes to the ASO device, a braided nitinol self-centring double disc device designed by Dr Kurt Amplatz more than 20 years ago. Was the ideal device created? Obviously, for almost a decade, other ASD occluders have been developed with a design quite similar to the ASO device, such as the Cera™ Septal Occluder (CSO; Lifetech Scientific [Shenzhen] Co., Ltd, Shenzhen, China) and the Figulla® Septal Occluder (FSO; Occlutech, Helsingborg, Sweden)^{2,3}. Several technical characteristics differentiate these occluders from the ASO in terms of device design, coating and disc size with theoretical advantages in terms of clot formation, nickel leaching, cobra deformation, atrial arrhythmias and cardiac erosion. However, and probably not surprisingly due to the rarity of complications, these three

devices offer similar efficacy, safety and outcomes in the hands of experienced operators, as demonstrated by Bhattacharjya et al in this edition of EuroIntervention⁴.

Article, see page 321

In this study, the three occluders were serially allocated in a cycle of three to 450 consecutive patients undergoing transcatheter ASD closure in a single institution. Patients were comparable at baseline in all parameters and follow-up duration was 12-47 months. Early results showed no major complications and procedural success was 99.6%. The defect and device sizes were similar in all groups. The delivery system was significantly smaller with the ASO. The FSO needed special deployment techniques less often and formed a cobra deformity more often, though this was not statistically significant. Patient outcome was similar among the three groups. None of the patients presented with new significant pericardial effusion, new-onset arrhythmia, stroke, cardiac perforation, device erosion, or embolisation during the one-to four-year follow-up. The authors should be congratulated for having successfully performed this important study confirming the very high success rate of transcatheter ASD closure in experienced

*Corresponding author: Cardiology Department, Hôpital Bichat-Claude Bernard, 46 Rue Henri Huchard, 75877 Paris, France.
E-mail: eric.brochet@aphp.fr

hands with a very low rate of complications. However, despite the inclusion of 450 consecutive patients, this study was not powered to evaluate the rare (0.1-0.3%) but dramatic risk of erosion and tamponade⁵.

In fact, the currently available occluders are probably close to the ideal device (Table 1). After a learning curve using the same device, a fairly experienced operator could use the other devices. However, in some countries, the volume of percutaneous ASD closures by operator is relatively low and this does not make it easy to use different occluders.

Table 1. Comparison of ASO (AMPLATZER Septal Occluder), CSO (Cera Septal Occluder) and FSO (Figulla Septal Occluder) devices with an ideal atrial septal defect closure device.

	ASO device	CSO device	FSO device	Ideal device
Nitinol coated	No	Yes	Yes	No metallic component
Nickel leaching	++	+	+	0
Largest size	40 mm	42 mm	40 mm	>42 mm
Repositionable device	Yes	Yes	Yes	Yes
Cobra deformation	Possible	Possible	Possible	Impossible
Arrhythmias	Low risk	Low risk	Low risk	Lowest risk
Thrombus formation	Very rare	Very rare	Very rare	Lowest risk
Device embolisation	Possible	Possible	Possible	Possible
Retrievable device	Possible	Possible	Possible	Possible
Erosion with tamponade	0.1-0.3%	Unknown	Unknown	Lowest risk

Cardiology has a culture of randomised clinical trials and evidence-based medicine. Another characteristic of the transcatheter ASD closure story is the total absence of randomised controlled data. Naturally, percutaneous treatment has been adopted as it offers an excellent alternative to surgery for ASD with a favourable anatomy. All implantable medical devices must be evaluated continuously, even the oldest, and obviously also the most recent. Efforts to increase the evidence should continue by establishing large well-designed multicentre registries. Potential device-based

differences could then be shown in the future regarding the risk of tamponade⁶.

Conflict of interest statement

P. Aubry has received consultant fees/honoraria from Occlutech. E. Brochet has received proctor/consultant fees from Abbott Vascular. J. Juliard has no conflicts of interest to declare.

References

- Du ZD, Hijazi ZM, Kleinman CS, Silverman NH, Larntz K; Amplatzer Investigators. Comparison between transcatheter and surgical closure of secundum atrial septal defect in children and adults: results of a multicenter nonrandomized trial. *J Am Coll Cardiol.* 2002;39:1836-44.
- Kaya MG, Akpek M, Celebi A, Saritas T, Meric M, Soylu K, Karapinar H, Lam YY. A multicentre, comparative study of Cera septal occluder versus AMPLATZER Septal Occluder in transcatheter closure of secundum atrial septal defects. *EuroIntervention.* 2014;10:626-31.
- Godart F, Houeijeh A, Recher M, Francart C, Polge AS, Richardson M, Cajot MA, Duhamel A. Transcatheter closure of atrial septal defect with the Figulla(®) ASD Occluder: a comparative study with the Amplatzer(®) Septal Occluder. *Arch Cardiovasc Dis.* 2015;108:57-63.
- Bhattacharjya S, Pillai LS, Doraiswamy V, Satyanarayana RM, Chandrasekaran R, Pavithran S, Sivakumar K. Prospective concurrent head-to-head comparison of three different types of nitinol occluder device for transcatheter closure of secundum atrial septal defects. *EuroIntervention.* 2019;15:e321-8.
- DiBardino DJ, McElhinney DB, Kaza AK, Mayer JE Jr. Analysis of the US Food and Drug Administration Manufacturer and User Facility Device Experience database for adverse events involving Amplatzer septal occluder devices and comparison with the Society of Thoracic Surgery congenital cardiac surgery database. *J Thorac Cardiovasc Surg.* 2009;137:1334-41.
- Jalal Z, Hascoet S, Baruteau AE, Iriart X, Kreitmann B, Boudjemline Y, Thambo JB. Long-term Complications After Transcatheter Atrial Septal Defect Closure: A Review of the Medical Literature. *Can J Cardiol.* 2016;32:1315.e11-8.