

Editorial



Closure of Atrial Septal Defects with the Recent Generation Devices

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Conflict of Interest

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The Amplatzer® septal occluder (ASO; St. Jude Medical Inc., Plymouth, MN, USA) is a self-expanding, double-disk device with a self-centering mechanism, which is evolved into the dominant closure device of secundum atrial septal defect (ASD) following the initial clinical report in 1997.¹⁾ Further generations including Occlutech Figulla® Flex II device (FSO; Occlutech GmbH, Jena, Germany) and Gore® Cardioform Septal Occluder (GSO; W.L.Gore & Associates, Flagstaff, AZ, USA) have followed with design modifications leading to lack of a left sided-hub leading to a softer left-sided disc, less frictional forces against erosion and greater flexibility of the device following deployment.²⁾ Despite of the FSO and GSO are widely accepted as the suitable treatment for ASDs, little is known about the feasibility and safety of these recent generation devices compare to those of predominantly used ASO devices. Hence, this comprehensive comparison study of the 3 devices by Kim et al.³⁾ is both informative and timely.

They compared the clinical outcomes and complications of transcatheter ASD closure using the FSO, GSO, and the established ASO device, in 267 patients divided into 3 groups according to the respective devices implanted in a retrospective, single center setting. The follow-up period ranged from 23 to 29 months in the 3 groups. Of the 3 devices, the FSO was the most commonly implanted device (n=152, 56.9%), then followed by the ASO (n=98, 36.7%) and the GSO (n=17, 6.4%). The patients in the GSO group were significantly younger, had smaller mean defect size, and no pre-procedural tricuspid regurgitation compared to the other groups. The major complication rates (%) in the ASO, FSO, and GSO groups were less than 1%, respectively and the authors report no mid-term complications occurring during the follow-up period. Based on their results, the authors conclude that the FSO and GSO are feasible options for transcatheter ASD closure, and comparable to the ASO.

This study deserves attention in that it provides the similar clinical outcomes of transcatheter ASD closure in Korean patients using new devices such as the FSO and GSO in comparison to that of the established ASO device because of the scarce data regarding the reports on the use of the FSO and GSO in Korean patients. Also noteworthy is the first to report the early to mid-term outcomes of using the FSO to close secundum ASDs (n=152) in Korean patients, even including small children. These results suggest that recent generation ASO devices offer great practical

clinical value, and they could use them to be therapeutic alternatives by verifying their efficacy and safety with various morphologies in selected patients with feasible anatomy.³⁾

Some limitations of this study should be considered. First, the study was restricted to a single center experience. These findings may not be generalizable to other centers, particularly to those with relative small volume centers, or without an experienced interventionist. Second, this study is subject to selection bias with retrospective observations. As the authors mentioned, the selection of the device was based on the standard treatment guideline, rather than on randomization. Therefore, it needs a large randomized controlled trial stratifying the defect size, the number of defect and the presence of retro-aortic rim deficiency. Finally, the follow-up of this cohort was about 2 years, and the authors could not evaluate longer follow-up data. It also needs the long-term outcomes of recent general ASD devices or subsequent postmarketing studies of the devices.

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