ASD comparative study: Occlutech outperforms Amplatzer and Gore

Early to Mid-Term Follow-Up Outcomes of Percutaneous Closure of ASDs Using Recent Generation Devices: a Single-Center Experience by Kim proves safety and comparability between all three devices in a highly skilled Korean interventional center with a procedural success of 100%.

- **267 patients**: 152 FSO / 98 ASO / 17 GSO including very small children (39 children <15 kg) with a mean FU of 2 years
- **FSO performs excellently** while its group consisted of significantly more challenging anatomies and sicker patients:
  - **28 small children (<15 kg)**
  - Biggest mean defect size vs. GSO and ASO (21,2 mm)
  - 92% NYHA-Class I-III
  - 29 multiple ASDs
  - **127 deficient retro-aoritic rims (<5mm)**
  - Procedural success: 100%
- **Sizing of the GSO is not standardized**. Due to the missing selfcentering waist, it is **not feasible for big anatomies** (>15mm)
- **ASO-complications: One embolization** has been observed for ASO (1%), **Cardiac erosion** is discussed broadly as a serious complication **in up to 0.3% of the ASO-treated patients**

- **Low profile** of LA disc is "indispensable" in small children
- **Recapturablity** and **ballconnector** helps procedural success
- **unparalleled adaptability** and **minimization of implant material quantity**, greater **flexibility** reduces trauma risk
- usage of FSO is the **hospital standard for ASDs in small children**
- **The FSO is safe, effective and reliable with great practical value.**

Occlutech

Early to Mid-Term Follow-Up Outcomes of Percutaneous Closure of Atrial Septal Defects Using Recent Generation Devices: a Single-Center Experience

Ah Young Kim, MD1, Se Yong Jung, MD1, Jenny Yeonsoo Chang2, Jo Won Jung, MD, PhD1, and Jae Young Choi, MD, PhD, SCAI1

Abstract

Background and Objectives:

This study aimed to describe our early to mid-term experience with transcatheter atrial septal defect (ASD) closure using the Occlutech Figulla® Flex II device (FSO), Gore® Cardioform septal occluder (GSO), and Amplatzer® septal occluder (ASO) after they were first approved in Korea in 2014, and to compare the three aforementioned kinds of ASD closure devices.

Methods:

Between September 2014 and August 2016, 267 patients underwent transcatheter ASD closure in our institution. Baseline characteristics, hemodynamic features, comorbidities, and procedural success and complication rates were analyzed retrospectively. The unpaired Student t-test or variance analysis was used in the statistical analysis.

Results:

The FSO was most commonly used (n=152, 56.9%), followed by the ASO (n=98, 36.7%) and GSO (n=17, 6.4%). Baseline characteristics and hemodynamic features were similar between the devices, except that the defect size and pulmonary flow-to-systemic flow ratio were lower in the GSO group than in the other groups. Overall, the procedural success rate remained at 100%, and major complication rate was <1%. No late complication occurred during the follow-up.

Conclusions:

The FSO and GSO are feasible, safe options for use in transcatheter ASD closure, and they are comparable to the ASO.

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