Safety and Efficacy of the Occlutech® ASD Occluder Compared to the Amplatzer™ Septal Occluder

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Study Design and Endpoints

Meta-analysis including 11 studies on patients undergoing ASD closure with the Occlutech ASD Occluder (Figulla Flex, FSO) and Amplatzer Septal Occluder (ASO) devices.

Primary outcomes were procedural success, peri-procedural and long-term (at least 6 months of follow-up) complications.

Patient Population

1,827 patients were included:

- 873 implanted with Occlutech ASD Occluder
- 897 implanted with Amplatzer Septal Occluder
- 157 patients excluded because a different device was used
- Age and gender were similar between the two included groups

There were no statistically significant differences regarding cardiovascular risk factors, except for a higher incidence of hypertension and smoking in patients treated with the Amplatzer Septal Occluder. The rate of neurovascular events was very similar across both groups.

Aparisi A et al. Comparison of Figulla Flex® and Amplatzer devices for atrial septal defect closure: A meta-analysis. Cardiol J. 2020;27(5):524-532.

For more information or to place an order, please contact your local B. Braun Interventional Systems Inc. representative or call 1-877-836-2228.

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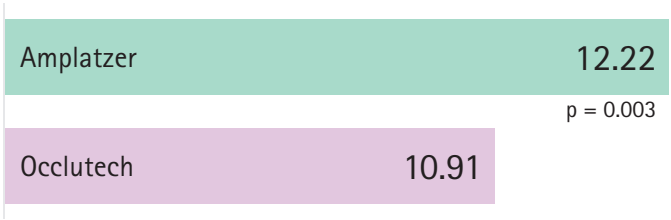
SHARING EXPERTISE

Occlutech

Procedural Data and Results

Procedural Success

Fluoroscopic Time (minutes)

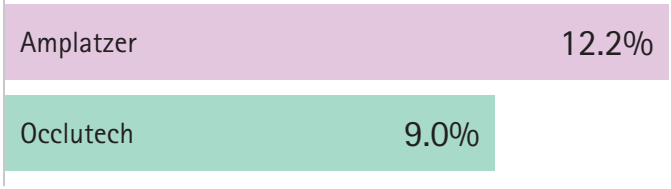


Despite similar device size, procedures were shorter requiring statistically significant less fluoroscopy time with an Occlutech device (p = 0.003).

Efficacy

"[..] the absolute rate of residual shunt after the procedure was higher in patients treated with the Amplatzer Septal Occluder than with the Occlutech ASD Occluder (12.2% vs. 9%; p = 0.075)."

Residual Shunt



Follow Up Outcomes

"The rate of supraventricular arrhythmia + atrial fibrillation was significantly higher after the Amplatzer Septal Occluder (14.7%) than after the Occlutech ASD Occluder (7.8%, p = 0.009)."

Device Fracture	Erosion
0%	0%

Conclusion

"[..] safety and effectiveness were similar (for Occlutech ASD Occluder and Amplatzer Septal Occluder) as well as global success rate. However, procedures were shorter with the Occlutech ASD Occluder device and the rate of supraventricular arrhythmias in follow-up was lower. Importantly, no cases of late cardiac erosion were detected."

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