First long-term Follow up of Occlutech PFO data published

A new publication analyses the Occlutech PFO Occluder in long-term follow-up like it has never been published before. Snijder et. al. show excellent results with **almost 6 years of follow up** and 7 years of recruitment in this “Dutch long term study” from Niewegein, the Netherlands. Great highlights – better than in most of known studies.

- 250 investigated patients with 5.9 years (≈1.300 patient years) of follow up
- Proves safety and efficacy of the Occlutech PFO Occluder family
- Very low annual cerebrovascular event rate of 0.01% per patient year
- High effective closure rate of 94.1% at 1 year FU

**Comparison of effective closure rates at first FU**

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<th>90,6%</th>
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Since a next generation product has been launched an improvement effect of the Occlutech patented ball connector and the reduction of the number of LA struts can be assumed.

Percutaneous patent foramen ovale closure using the Occlutech Figulla device: More than 1,300 patient-years of follow up

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Objective

To evaluate the safety and efficacy of the Occlutech patent foramen ovale (PFO) device at long-term follow-up (FU).

Background

The Occlutech device has been proven safe and effective six-months after percutaneous PFO closure. We describe the safety and efficacy after more than 1,300 patient-years of FU.

Methods

All consecutive patients who underwent PFO closure between October 2008 and December 2015 were included. All complications were registered. Residual right-to-left shunt (RLS) was diagnosed using contrast transthoracic echocardiography and graded as minimal, moderate, or severe.

Results

In total, 250 patients (mean age 53.5 ± 10.7 years, 46.8% female) underwent percutaneous PFO closure using the Occlutech device. Mean FU was 5.9 ± 1.8 years, a total of 1,345 patient-years. Transient ischemic attack (TIA) or stroke was the main indication for closure (89.6%). Implantation was successful in 100%, no major complications occurred. Minor complications were inguinal hematoma in 16 patients (6.4%), pericardial effusion without the need for intervention in one patient (0.4%) and a supraventricular tachycardia in one patient (0.4%). A moderate or large shunt at one-year follow up was present in 5.9%. A cerebrovascular vascular event occurred in 2.0% at 1-year FU (four TIA, one stroke) and in 7.4% at long-term FU (nine TIA, eight stroke). The total cerebrovascular event rate (TIA and CVA) was 0.02% per patient-year of FU, with a stroke rate of 0.01%.

Conclusion

The Occlutech device appears to be safe at long-term FU with a very low annual cerebrovascular event rate and a low moderate to large shunt rate at 1-year FU.

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