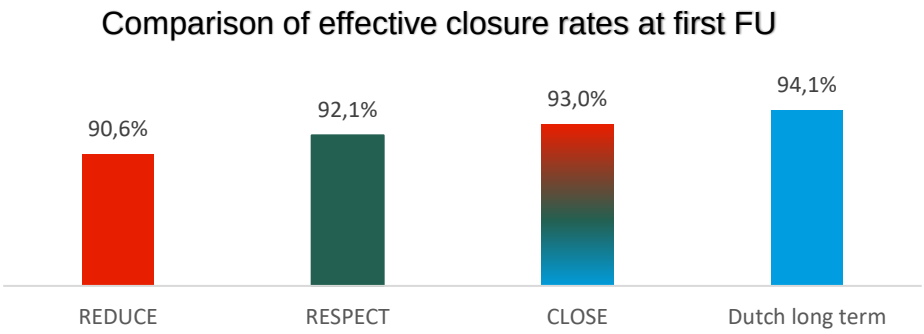
First long-term Follow up of Occlutech PFO data published

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



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.

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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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