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## Long term follow-up in a real-world study cohort after patent foramen ovale closure

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**Background:** Patent foramen ovale (PFO) closure is the treatment of choice after cryptogenic stroke according recent evidence. The indication is based on results of several randomized controlled trials; however, the results of these trials may not be extrapolated to a real-world clinical setting. Therefore, the aim of the present study was to evaluate long-term outcome regarding recurrent stroke, migraine, and/or peripheral embolism in patients after PFO closure.

**Methods:** We retrospectively analyzed outcomes of consecutive patients undergoing PFO closure from 2011 to 2018 at two interventional sites with respect to periprocedural events occurring during hospitalization and long-term follow-up. Follow-up data were collected from outpatient visits or telephone interviews.

**Results:** The analysis included 214 consecutive patients (mean age 52 years; 58% male). The follow-up rate was 96% and the mean follow-up time was 38 (SD 22) months. The index vascular event leading to PFO closure was stroke (n=190; 89%), including patients with repetitive stroke (n=36), embolic myocardial infarction (n=21), and migraine (n=3). One quarter (24.6%) of the population studied had an atrial septal aneurysm ($>$15 mm). Procedural success was achieved in 98%. There were no procedure-related strokes or deaths. Periprocedural complications occurred in 16 patients (7%): two cases of pericardial tamponade, seven complications at the access site mainly caused by bleeding, two cases of transient atrial fibrillation, and five other complications. The Amplatz Septal Occluder™ was used in two thirds (64.5%) of the cases and the Gore Cardioform™ device in one third (28.6%). Four (2%) patients died during follow-up. None of these patients experienced a recurrent stroke. Ten (5%) other patients experienced a recurrent stroke. Patients with recurrent stroke events were older than patients without recurrent stroke (mean 62.6 [SD 8.8] years vs. mean 52.2 [SD 13.8] years; p=0.015) and had a higher rate of preexisting cerebrovascular occlusive disease (5 [50%] vs. 10 [6%]; p$<$0.0001). There was no difference in risk for recurrent stroke between patients with one prior stroke and more than one stroke before PFO closure (p=0.71). Atrial fibrillation occurred in 6.6% of the patients during follow-up, but only one of these patients had recurrent stroke. No other anatomic and vascular risk factors or antithrombotic treatments were identified as being predictive of embolic events after closure.

**Conclusion:** In this real-world PFO closure cohort the recurrent stroke rate is low, although it is higher than reported in the recent randomized controlled trials. Recurrent strokes after PFO closure may reflect additional comorbid risk factors such as age or cerebrovascular occlusive disease that are unrelated to the potential for paradoxical embolism.