

# Prognosis and clinical outcomes in stroke patients with transcatheter closure of an atrial shunt

Akademisk avhandling

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av Alexia Karagianni

Fakultetsopponent:

Professor Sir Shakeel A Qureshi

Evelina London Children's Hospital, London Storbritannien

## Avhandlingen baseras på följande delarbeten

- I Alexia Karagianni, Putte Abrahamsson, Eva Furenäs, Peter Eriksson & Mikael Dellborg. Closure of persistent foramen ovale with the BioSTAR biodegradable PFO closure device: Feasibility and long-term outcome  
*Scandinavian Cardiovascular Journal, 2011; 45:267-272*
- II Alexia Karagianni, Zacharias Mandalenakis, Mikael Dellborg, Naqibullah Mirzada, Magnus Carl Johansson and Peter Eriksson. Recurrent cerebrovascular events in patients after percutaneous closure of patent foramen ovale  
*Journal of Stroke and Cerebrovascular Diseases, Vol. 29, No.8 (August), 2020: 104860*
- III Alexia Karagianni, Zacharias Mandalenakis, Savvas Papadopoulos, Mikael Dellborg, Peter Eriksson. Percutaneous atrial shunt closure and the risk of recurrent ischemic stroke: a register-based, nationwide cohort study  
*Submitted*
- IV Alexia Karagianni, Zacharias Mandalenakis, Savvas Papadopoulos, Mikael Dellborg, Peter Eriksson. Long-term outcome after closure of an atrial shunt in patients aged 60 years or older with ischemic stroke: A nationwide, registry-based, case-control study  
*Manuscript*

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# Prognosis and clinical outcomes in stroke patients with transcatheter closure of an atrial shunt

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## Abstract

**Background:** The percutaneous transcatheter closure of a patent foramen ovale (PFO) after a cryptogenic cerebrovascular event (CVE) has been performed for more than two decades. In contrast with previous randomized studies, recent randomized studies support the closure of the PFO after a cryptogenic CVE in preference to medical treatment alone. Although the absolute number of recurrent CVEs is low after closure of a PFO, they can still occur, and the reason remains unknown.

**Methods:** Papers I and II are single-center studies using the medical records of patients who, after a cryptogenic CVE, underwent transcatheter closure of a PFO at the Center for Adults with Congenital Heart Disease at Sahlgrenska University Hospital in Gothenburg, Sweden. In Paper I, patients who received a biodegradable device, BioSTAR, were compared with patients who received another widely used device. In Paper II, all the patients who underwent PFO closure because of a CVE were included and followed up with a telephone interview. Patients with a recurrent CVE were identified and matched with patients who did not have a recurrent CVE, as a comparison group. The patients in the matched groups were also invited for a clinic visit. In Papers III and IV, the Swedish National Patient Register, the Cause of Death Register and the Swedish Prescribed Drug Register were used. Patients with an ischemic CVE and a diagnosis of atrial shunt were identified and categorized into patients who received the intervention treatment of closure of the atrial shunt and patients who received medical treatment alone. From the Total Population Register, we identified matched controls without a diagnosis of ischemic CVE or atrial shunt. In Paper IV, we used the same groups of patients and controls but restricted to age 60 years and above. In Paper III and IV, the patients in the two treatment groups were matched using propensity score matching. The cumulative incidence of recurrent stroke and the hazard ratios among the groups were calculated with Cox regression analyses.

**Results:** Although the BioSTAR device was feasible and appropriate for small shunts, the risk of a recurrent CVE was twice as high in patients who received the BioSTAR device compared to patients with other devices. This was confirmed in Paper II, where the main reason for a recurrent CVE was residual shunting and having a BioSTAR device at a mean follow-up of 8.4±2 years. Moreover, through the national registries we found that although the absolute risk of recurrent stroke after transcatheter closure of an atrial shunt is low, it is 10 times as high compared to controls. Patients aged 60 years or older can undergo transcatheter closure of an atrial shunt because of an ischemic CVE after thorough assessment and they develop less vascular disease (Paper IV).

**Conclusion:** The risk of recurrent stroke after transcatheter closure of an atrial shunt because of a cryptogenic CVE remains, and it depends mostly on the device used and the residual shunting rather than the selection of the patients who undergo closure of the atrial shunt. However, the selection of the patients who undergo intervention is crucial, and further investigations need to exclude occult atrial fibrillation, especially in older patients.

**Keywords:** Atrial shunt, patent foramen ovale, cryptogenic stroke, transcatheter intervention, cerebrovascular event, residual shunting

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