

# **Patent Foramen Ovale – To close or not to close? An Audit on PFO Closure Outcome**

Authors: Norma Pavia, Jeremy Fleri-Soler, Maria Mallia, Andrew Cassar

## **Abstract**

**Introduction** Patent foramen ovale (PFO) is present in up to 26% of the general population and up to 56% of patients with cryptogenic stroke, the finding of which during work up of such patients may often be circumstantial. PFO closure is an invasive procedure with its own morbidity and mortality, large international trials (CLOSURE I, PC and RESPECT) have not identified a role for PFO closure in preventing recurrent stroke.

## **Aim**

To investigate the outcome, including morbidity and mortality of PFO closures undertaken at Mater Dei Hospital, over a 5-year period, as well as the impact of such a closure on recurrent or other future symptoms.

## **Methodology**

A retrospective study was performed; data from PFO closures taking place at Mater Dei Hospital between 2010 and 2015 was collected. Indication for closure, including diagnosis, and work up for a cryptogenic stroke were analyzed. Perioperative complications and any future recurring symptoms, despite closure of PFO were noted. The size of PFO was determined based on the device used during the closure.

## **Results**

57 closures were performed between 2010 and 2015, 28 (49.1%) were male. The average age at closure was 40.5 years. 5 (8.8%) patients operated were previously known to suffer from cardiovascular disease. 9 (15.8%) patients had high cholesterol levels at the time of stroke and 3 (5.3%) and 2 (3.5%) suffered from diabetes and hypertension, respectively. 17 (29.8%) patients had suffered a stroke whereas 21 (36.8%) had suffered a transient ischemic attack (TIA). Of these, 4 (10.5%) had recurrent episodes prior to closure. The average age at stroke or TIA was 39.7 years. Other indications included decompression illness in 4 (7.0%) patients, migraine in 4 (7.0%) patients, retinal ischemia in 3 (5.3%) patients and 8 (14.0%) were unspecified. Only 15 (26.3%) patients had objective evidence of stroke on imaging. 26 (45.6%) patients underwent Carotid Doppler investigation and in 12 (21.1%) patients a thrombophilic screen was taken with 10 (83.3%) of these being positive. Size of device

was used as an indication for size of PFO. 3 (5.3%) were less than 5mm in size, the majority, 26 (45.6%), were between 5 and 9mm, whereas 15 (26.3%) and 13 (22.8%) were between 10 and 14mm and more than 15mm in size, respectively. Procedural complications occurred in 5 (10.5%) patients. 2 (3.5%) patients suffered a TIA within an hour of surgery. Access site complications occurred in 2 (3.5%) patients and in another 2 (3.5%) patients there was failure of closure. No excessive bleeding was reported. 1 (1.8%) procedure resulted in dislodgement of device and required open surgical retrieval of device. At follow up, there was only 1 case of mortality (1.8%) – secondary to ovarian carcinoma. 8 (14.0%) patients were reported to have suffered another stroke after closure while a further 11 (19.3%) had suffered from other episodes of neurological phenomena – not necessarily ischaemic. 6 out of 19 patients (31.6%) who suffered neurological problems after closure reported symptoms similar to those prior to procedure. 2 (3.5%) patients required cardiology admission in view of palpitations, both within one month of closure and both were found to have frequent supraventricular ectopics, however no intervention was necessary.

## Conclusion

This audit raises questions with regards to the diagnosis and full work-up of cryptogenic strokes as well as the benefit of PFO closure in the long term. It is hoped that it will form the basis of a study which will ultimately affect the management of these patients in the future.