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ORIGINAL ARTICLE

Multidisciplinary Assessment in Optimising Results of Percutaneous Patent Foramen Ovale Closure

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Background Percutaneous patent foramen ovale (PFO) closure is a therapeutic option to prevent recurrent cerebral ischaemia in patients with cryptogenic stroke and transient cerebral ischaemia (TIA). The apparent lack of benefit seen in previous randomised trials has, in part, reflected inclusion of patients with alternate mechanisms of stroke. The role of formal neurology involvement in accurately delineating the likely aetiology of stroke or TIA is crucial in appropriate identification of patients for device closure. Furthermore, as the benefits of device closure may accrue over time, long-term follow-up is essential to define the role of device closure in management of presumed cryptogenic stroke.

Methods We retrospectively reviewed our experience with percutaneous PFO device closure since 2005. All subjects who underwent PFO closure at John Hunter and Lake Macquarie Private Hospitals were included in the study. All patients referred for device closure following cryptogenic stroke or TIA had first undergone formal neurology review with appropriate imaging and exclusion of paroxysmal atrial arrhythmia. Patients with a history of transient ischaemic attack (TIA) are frequently referred to a specialised clinic, aimed to identify patients with conditions not referable to cerebral ischaemia, with investigations initiated by the specialist clinic to elucidate an underlying aetiology. Outcome data was derived from the Hunter New England Area Local Health District Cardiac and Stroke Outcomes Unit, in addition to review of the medical record. The Cardiac and Stroke Outcomes Unit prospectively identified all patients presenting with stroke, TIA and atrial fibrillation.

Results One hundred and twelve consecutive patients undergoing percutaneous patent foramen ovale closure between 2005 and 2015 were identified. The average age was 42.7 years and 57 (50.9%) patients were male. Cryptogenic stroke (68.8%) and transient cerebral ischaemia (23.2%) were the most common indications for PFO closure, with the Amplatzer device used in 83 cases (74.1%).
Early residual shunting was visible in seven patients (6.3%), however on follow-up agitated saline study only two patients had residual shunt (1.8%). The annual risk of recurrent stroke or TIA was 0.21%.

Conclusions Percutaneous patent foramen ovale closure can be performed safely and effectively in patients with paradoxical embolism. In selected patients, following appropriate multidisciplinary specialist pre-procedural assessment, excellent long-term results with low incidence of recurrent events may be achieved.

Keywords Patent foramen ovale closure • Amplatzer • Premere • Occlutech • Long-term outcomes

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Introduction

While patent foramen ovale (PFO) is noted in up to 25% of individuals, there is an increased prevalence of PFO in patients who have suffered from cryptogenic stroke or transient cerebral ischaemia (TIA) [1]. Furthermore, patients with presumed paradoxical embolism in the presence of PFO have an increased risk of recurrent stroke [2]; case reports have demonstrated migrating thrombus across a PFO [3] supporting paradoxical embolism across PFO as a mechanism for stroke or TIA. On this basis, percutaneous PFO closure has emerged as a therapeutic option to prevent recurrent cerebral ischaemia in patients with cryptogenic stroke or TIA, with mounting evidence in support of its efficacy and safety [4]. Other novel indications for PFO closure have included refractory migraines [5–8], decompression illness and platypnoea/orthodeoxia syndrome [9–11], although the literature in support of closure in these settings is limited.

The Amplatzer PFO Occluder (AGA Medical, USA) device has been frequently used with a large body of procedural experience accumulated. Alternate devices such as the Premere (St Jude Medical, USA), Figulla Flex (Occlutech International) and Starflex (NMT Medical) have also been used for PFO closure. While generally considered a safe procedure, a number of potential complications have been reported, including thrombosis, erosion, device embolisation and arrhythmia [12].

This study aims to examine the procedural success and long-term outcomes of PFO closure within the Hunter New England Area Local Health District from 2005 to 2015, with an emphasis on the role for formal neurology involvement in terms of optimising procedural outcome.

Material and Methods

Patient Selection

All subjects who underwent PFO closure between 2005 and 2015 were included in the study. Preliminary diagnosis of PFO was made using transthoracic echocardiography with agitated saline contrast examination. All patients underwent transoesophageal echocardiography for confirmation of the diagnosis and to exclude atrial septal defect; when unclear, transcranial Doppler ultrasonography was utilised. There was no age criteria placed upon the diagnosis of cryptogenic stroke or TIA, noting all patients would undergo assessment to exclude alternate aetiology of cerebral ischaemia.

Patients with a presumptive diagnosis of paradoxical cerebral emboli underwent formal neurology review. Adjunctive investigations typically included magnetic resonance imaging (MRI) and angiography (MRA), Holter monitoring, transcranial Doppler assessment and thrombophilia screening at the discretion of the treating team. The diagnosis of stroke was based upon clinical review and abnormal MR imaging consistent with infarction; patients with typical symptoms in the absence of MR imaging changes were considered to have had a TIA by the stroke neurologist. The presence of intracranial and carotid artery disease, when considered to represent the aetiology of cerebral ischaemia, tended to obviate the need for device closure. Patients undergoing device closure for migraine had similarly undergone formal neurology review and were referred for treatment of refractory symptoms. Patients with a history of non-cerebral embolic events did not routinely undergo neurology review prior to device closure.

PFO Closure

The device used for each procedure was chosen according to physician preference. Three devices were available during the study period: The Amplatzer PFO Occluder, the Occlutech Figulla Flex and the St Jude Premere device. Local or general anaesthesia was administered according to physician preference. Heparin was administered according to the patient's body weight with all patients receiving antibiotic prophylaxis. Device deployment was performed using fluoroscopy with or without transoesophageal echocardiography at the operators' discretion. All patients were investigated for early residual shunting and presence of pericardial effusion using Doppler transthoracic echocardiography performed within 24 hours following the procedure. Patients were typically treated with aspirin and clopidogrel for six months post procedure and then maintained on aspirin long term; patients with an indication for anticoagulation were maintained on warfarin or an alternate oral anticoagulant.

Follow-up

Patients attended for clinical review during the first three to six months and were typically referred for agitated saline contrast study at six months. Data was collected on patient baseline characteristics, indications, PFO characteristics (presence of aneurysmal inter-atrial septum), and procedural characteristics (device used, device size, sheath size, total procedural and fluoroscopy time, procedural success, and complications). Cases of recurrent stroke or TIA and admissions for atrial fibrillation were identified using the Hunter Cardiac and Stroke Outcomes Unit database, which prospectively records all strokes within the district. Cases were cross-checked with the electronic medical record. Follow-up was complete up to 31 December 2015.

Statistical Analysis

Data analysis was performed using SPSS version 23 (IBM). Normally distributed data is displayed as mean (standard deviation) and non-normally distributed data is displayed as median (interquartile range). Student t-tests were used to compare normally distributed continuous data. Categorical data was analysed using Pearson chi squared test or Yates continuity corrected chi-square test. The study was approved by the Hunter New England Health Local Health District Ethics Committee.

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