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ORIGINAL ARTICLE

Percutaneous patent foramen ovale closure: The Paradoxical Cerebral Embolism Prevention Registry☆

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KEYWORDS
Stroke;
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Abstract
Introduction: The natural history and therapeutic interventions for secondary prevention after a cerebrovascular event in patients with patent foramen ovale (PFO) are not yet established. This study aims to assess the safety and efficacy of percutaneous PFO closure in a population of patients with ischemic cerebrovascular disease of unknown etiology.
Methods: This prospective observational study included patients with a history of cryptogenic transient ischemic attack (TIA) or stroke who underwent percutaneous PFO closure. The effectiveness of the device for the secondary prevention of TIA or stroke was assessed by comparing observed events in the sample with expected events for this clinical setting.
Results: The sample included 193 cases of percutaneous PFO closure (age 46.4±13.1 years, 62.2% female) with a mean follow-up of 4.3±2.2 years, corresponding to a total exposure to ischemic events of 542 patient-years. The high-risk characteristics of the PFO were assessed prior to device implantation. There were seven primary endpoint events during follow-up (1.3 per 100 patient-years), corresponding to a relative risk reduction of 68.2% in recurrent TIA or stroke compared to medical therapy alone. The procedure was associated with a low rate of device- or intervention-related complications (1.5%).
Conclusions: In this long-term registry, percutaneous PFO closure was shown to be a safe and effective therapy for the secondary prevention of cryptogenic stroke or TIA.

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PALAVRAS-CHAVE
Acidente vascular cerebral;
Foramen ovale patente;
Encerramento

Encerramento percutâneo de *foramen ovale* patente – registo da prevenção da embolia cerebral paradoxal

Resumo
Introdução e objetivos: A história natural e as intervenções terapêuticas para prevenção secundária, após um evento cerebrovascular em indivíduos com *foramen ovale* patente (FOP), não estão ainda estabelecidas. Esta investigação visa avaliar a eficácia e a segurança do encerramento de FOP numa população de doentes com doença cerebral isquémica de causa indeterminada.
Métodos: Estudo observacional e prospetivo, representativo da região centro de Portugal, que incluiu doentes com antecedentes de acidente isquémico transitório (AIT) ou acidente vascular cerebral (AVC) criptogénico que encerraram FOP por via percutânea. A eficácia do dispositivo na prevenção secundária de AIT/AVC (evento primário) foi avaliada comparando os eventos observados na amostra com os eventos estimados para este contexto clínico.
Resultados: A amostra incluiu 193 casos de encerramento percutâneo de FOP (46,4±13,1 anos, 62,2% do sexo feminino) com um seguimento médio de 4,3±2,2 anos, correspondendo a uma exposição total a eventos isquémicos de 542 doentes/ano. Foram registadas as características anatómicas de risco embólico do FOP previamente à implantação do dispositivo. Observaram-se sete eventos primários (1,3 por 100 doentes/ano), traduzindo uma redução de 68,2% no risco relativo de recorrência de AIT/AVC, em comparação com a terapêutica médica. O procedimento associou-se a uma baixa taxa de complicações relacionadas com a intervenção ou dispositivo (1,5% dos casos).
Conclusões: Neste registo de longa duração o encerramento percutâneo de FOP mostrou-se um procedimento seguro e eficaz na prevenção secundária do AIT/AVC criptogénico.

Introduction

Despite considerable investment in prevention, stroke remains one of the leading causes of death in Portugal and a major cause of long-term disability.[1]

Cerebral atherosclerosis is the cause of most ischemic cerebrovascular events, followed by cardioembolism (19% of cases) and carotid artery disease (15%).[2] The prevalence of patent foramen ovale (PFO) is around 25% in the general population, and PFO accounts for around 95% of right-to-left shunts. Although PFO is not considered a primary cause of stroke, paradoxical embolism can occur when right atrial pressure exceeds left atrial pressure; this is likely to be the cause of around 40% of cryptogenic strokes.[4]

In observational studies of patients undergoing antithrombotic therapy, the risk of recurrent stroke or transient ischemic attack (TIA) ranges between 3% and 12% in the first year, with a higher risk in cases with atrial septal aneurysm or large right-to-left shunt. A meta-analysis of 15 major clinical studies of medically treated patients with ischemic cerebrovascular disease of unknown etiology and PFO estimated the rate of recurrent ischemic stroke or TIA at 4.0 events per 100 patient-years and the rate of recurrent ischemic stroke at 1.6 events per 100 patient-years.[5]

The natural history and therapeutic interventions for secondary prevention after a cerebrovascular event in patients with PFO are not yet established. Percutaneous PFO closure is a therapeutic option for the secondary prevention of cryptogenic stroke, especially in cases of higher risk of paradoxical embolism, when PFO is associated with atrial septal aneurysm or a large shunt.

Methods

Study design and population

This prospective observational study was carried out in a university hospital. Informed consent was obtained from all patients prior to enrollment in the study. Inclusion criteria were age over 18 years, history of cryptogenic stroke or TIA, and PFO documented by transesophageal echocardiography. Patients were referred from various hospitals in the Central region of Portugal (Hospitais da Universidade de Coimbra and Hospital Geral do Centro Hospitalar e Universitário in Coimbra, Centro Hospitalar do Baixo Vouga in Aveiro, Hospital Distrital da Figueira da Foz, Centro Hospitalar de Leiria/Pombal, Hospital de São Teotónio in Viseu, Centro Hospitalar da Cova da Beira in Covilhã, and Hospital Amato Lusitano in Castelo Branco).

Ischemic cerebrovascular events were defined as an acute neurological deficit persisting for over 24 hours, or less than 24 hours but associated with evidence of cerebral infarction on magnetic resonance imaging or computed tomography. Known causes of stroke including cardioembolism, carotid artery disease, lacunar cerebral infarction due to small vessel disease, and documented hypercoagulable states, such as the presence of anticardiolipin