



ORIGINAL ARTICLE

## Registry of left atrial appendage closure and initial experience with intracardiac echocardiography<sup>☆</sup>



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### KEYWORDS

Atrial fibrillation;  
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appendage;  
Intracardiac  
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Stroke;  
Bleeding

### Abstract

**Introduction:** Percutaneous closure of the left atrial appendage (LAA) is a promising therapy in patients with atrial fibrillation with high risk for stroke and contraindication for oral anticoagulation (OAC). Intracardiac echocardiography (ICE) may make this percutaneous procedure feasible in patients in whom transesophageal echocardiography (TEE) is inadvisable. Our aim was to assess the efficacy and safety of LAA closure and the feasibility of ICE compared to TEE to guide the procedure.

**Methods:** In this cohort study of patients who underwent LAA closure between May 2010 and January 2017, clinical and imaging assessment was performed before and after the procedure. **Results:** In 82 patients (mean age  $74 \pm 8$  years, 64.4% male) the contraindications for OAC were severe bleeding or anemia (65%), high bleeding risk (14%), labile INR (16%), or recurrent embolic events (5%). The procedural success rate was 96.3%. The procedure was guided by TEE or ICE, and no statistically significant differences were observed between the two techniques. During follow-up, one patient had an ischemic stroke at 12 months, two had bleeding complications at six months, and there were four non-cardiovascular deaths. Embolic and bleeding events were less frequent than expected from the observed CHA<sub>2</sub>DS<sub>2</sub>VASc (0.6% vs. 6.3%;  $p < 0.001$ ) and HAS-BLED (1.2% vs. 4.1%;  $p < 0.001$ ) risk scores.

**Conclusions:** In this population percutaneous LAA closure was shown to be safe and effective given the lower frequency of events than estimated by the CHA<sub>2</sub>DS<sub>2</sub>VASc and HAS-BLED scores. The clinical and imaging results of procedures guided by ICE in the left atrium were not inferior to those guided by TEE.

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**PALAVRAS-CHAVE**

Fibrilhação auricular;  
Apêndice auricular  
esquerdo;  
Ecografia  
intracardíaca;  
Acidente vascular  
cerebral;  
Hemorragia

**Registo de encerramento percutâneo do apêndice auricular esquerdo e experiência inicial com ecografia intracardíaca****Resumo**

**Introdução:** O encerramento percutâneo do apêndice auricular esquerdo (AAE) constitui uma terapêutica de interesse clínico nos doentes de alto risco de acidente vascular cerebral (AVC) e contra-indicação para anticoagulação oral (ACO). A ecografia intracardíaca (ICE) pode tornar este procedimento exequível em doentes em que o ecocardiograma transesofágico (ETE) está desaconselhado. Os objetivos consistiram na avaliação da eficácia e segurança da técnica de encerramento do AAE e na avaliação da exequibilidade do ICE em comparação com o ETE para guiar o procedimento.

**Métodos:** Estudo de coorte em doentes submetidos a encerramento do AAE entre maio 2010 e janeiro 2017. Realizada uma avaliação clínica e imagiológica antes e após o procedimento.

**Resultados:** 82 doentes (idade  $74 \pm 8$  anos, 63% homens) em que a razão para não realizar ACO foi: hemorragia grave/anemia não controladas (65%), risco hemorrágico elevado (14%), INR lábil (16%) e eventos embólicos de repetição apesar de ACO terapêutica (5%). O procedimento foi guiado por ETE ou ICE. A taxa de sucesso de implantação de dispositivo foi de 96,3%. Foram comparadas as duas técnicas de imagem não se tendo verificado diferenças estatisticamente significativas. No seguimento houve um AVC isquémico, duas complicações hemorrágicas, quatro mortes de causa não cardiovascular. Os eventos embólicos e hemorrágicos foram menos frequentes do que o esperado de acordo com os scores  $CHA_2DS_2VASC$  (0,6% versus 6,3%,  $p < 0,001$ ) e HASBLED (1,2% versus 4,1%,  $p < 0,001$ ).

**Conclusões:** Nesta amostra, o encerramento percutâneo do AAE foi considerado seguro e eficaz comparativamente aos eventos estimados pelo  $CHA_2DS_2VASC$  e HASBLED. Os procedimentos guiados por ICE na aurícula esquerda não tiveram resultados clínicos ou imagiológicos inferiores aos procedimentos conduzidos por ETE.

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**Introduction**

According to the FAMA study,<sup>1</sup> the prevalence of atrial fibrillation (AF) in Portugal is 2.5% in individuals aged  $\geq 40$  years. It is more prevalent in the elderly and in those with hypertension, cardiac valve disease, obesity, diabetes and chronic kidney disease.<sup>2</sup>

Morbidity and mortality resulting from AF are high: it is independently associated with a two-fold increased risk of all-cause mortality and a five-fold increase in risk of stroke.<sup>2,3</sup> Embolic stroke is more clinically severe than other causes of brain damage; it is often fatal, and is associated with greater incapacity and recurrence rates.<sup>2-8</sup>

Although oral anticoagulation (OAC) is effective in preventing stroke, warfarin is contraindicated in 14-44% of patients at risk for cardioembolic stroke,<sup>12</sup> while even in eligible patients, only 54% are anticoagulated.<sup>9-12</sup> Various factors are responsible for these low figures, the most important of which is bleeding risk, but the need for frequent laboratory monitoring, problems with patient compliance, and concerns among physicians also contribute to the poor performance of this treatment.<sup>4</sup>

Novel oral anticoagulants (NOACs) have recently been developed: dabigatran, a direct thrombin inhibitor, and the factor Xa inhibitors rivaroxaban, apixaban and edoxaban. Clinical trials (RE-LY for dabigatran,<sup>12</sup> ROCKET-AF<sup>13</sup> for rivaroxaban, ARISTOTLE<sup>14</sup> for apixaban and ENGAGE<sup>15</sup> for

edoxaban) demonstrated their non-inferiority to warfarin for prevention of thromboembolic events in AF, and the European Society of Cardiology guidelines on the management of AF consider the NOACs to be preferable to warfarin.<sup>2</sup> However, these drugs carry significant bleeding risk, which is an obstacle to their use in some patients with more morbidity. Discontinuation rates in the clinical trials (mainly due to intolerance or side effects) were 25.3% for apixaban vs. 27.5% for warfarin in ARISTOTLE,<sup>14</sup> 34.4% for edoxaban vs. 34.5% for warfarin in ENGAGE,<sup>15</sup> 21% for dabigatran vs. 17% for warfarin in RE-LY,<sup>12</sup> and 23.7% for rivaroxaban vs. 22.2% for warfarin in ROCKET-AF<sup>13</sup> (in the latter two trials the discontinuation rate was actually higher for the NOAC than for warfarin). In addition, all these drugs are contraindicated in cases of a history of hemorrhagic stroke, uncontrolled non-intracranial bleeding, and end-stage chronic renal disease or dialysis.

In non-valvular AF most thrombi originate in the left atrial appendage (LAA).<sup>2</sup> Percutaneous LAA closure is recommended for patients with non-valvular AF, high stroke risk<sup>2</sup> and contraindication for OAC. The feasibility of this procedure has been demonstrated in multiple clinical trials using a variety of closure devices.<sup>4,8,9,16-22</sup> Bearing in mind the invasive nature of percutaneous LAA closure, patients for whom it presents a good risk/benefit ratio are those with high thromboembolic risk and contraindication for or failure of anticoagulant therapy.<sup>16-22</sup> In previous

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