Hipertens Riesgo Vasc. 2017;xxx(xx):xxx–xxx

Hipertensión y riesgo vascular

www.elsevier.es/hipertension

LETTER TO THE EDITOR

Atrial fibrillation recurrence after pulmonary vein isolation in patients with paroxysmal atrial fibrillation and the use of a pacemaker by single catheter *vs.* multiple catheter approach – Clinical and economic evaluation

Recidiva de la fibrilación auricular después del aislamiento de la vena pulmonar en pacientes con fibrilación auricular paroxística y un marcapasos por catéter único frente al método de múltiples catéteres: evaluación clínica y económica

Introduction

Sinus node dysfunction is branded by one or more of the following electrocardiographic signs: sinus bradycardia, sinus arrest, sino-atrial block, and supraventricular tachycardia interchanging with sinus bradycardia and asystole (Brady-tachycardia syndrome).[1] The existence of palpitations, dizziness, pre-syncope, or syncope related to these electrocardiographic modifications defines sinus node disease (SND). SND happens more frequently in women than in men, resulting in a high morbidity between 60 and 69 years.[2,3] The most common form of SND has no clear etiology and is considered idiopathic or primary.[4,5] Paroxysmal atrial fibrillation (AF) is common in subjects with sick sinus syndrome (SSS) and pacemakers and leads to morbidity and an increased risk of stroke or death.[6] The standard treatment to SND is the pacemaker implantation,[7] and the perfect line of attack for the management of AF is rhythm control, but this is sometimes very hard to accomplish.[8] For such actions, complete isolation of all pulmonary veins (PVI) is currently widely accepted as the best endpoint. The recommendations of the European Society of Cardiology (ESC) (Guidelines for the management of atrial fibrillation: the Task Force for the Management of Atrial Fibrillation of the European Society of Cardiology (ESC)).[8] For the individual patient with symptomatic AF, there must be sufficient potential benefit to justify a complex ablation procedure associated with possibly severe complications. Operator experience is an important consideration when considering ablation as a treatment option. The studies cited in support of the recommendations have been almost exclusively performed by highly experienced operators and expert staff working in specialized institutions, but in clinical practice, more junior and less experienced operators may be involved in many institutions. Catheter ablation is usually undertaken in patients with symptomatic paroxysmal AF that is resistant to at least one antiarrhythmic drug. Catheter ablation for paroxysmal AF should be considered in symptomatic patients who have previously failed a trial of antiarrhythmic medication (Class IIa, Level A). Ablation of persistent symptomatic AF that is refractory to antiarrhythmic therapy should be considered a treatment option (Class IIa, Level B). The goal of this prospective, randomized study was therefore to evaluate the impact of two different PVI approach regarding AF recurrence and AF burden in patients with a history of paroxysmal AF.

Methods

This prospective, longitudinal study involved 100 patients with a history of symptomatic paroxysmal AF and a dual-chamber pacemaker. The study was piloted in agreement with the Helsinki declaration and approved by the ethics committee of our institution. All patients signed the informed consent term before inclusion.

Study subjects

This study was conducted at the Hospital e Clínica São Gonçalo, Rio de Janeiro, Brazil. Patients were recruited from January 2014 until January 2016 from the Arrhythmias and Artificial Cardiac Pacing Service of the same hospital. Patients with the combination of the following criteria were consecutively enrolled: (i) a physically normal heart with an ejection fraction of >50% as measured by echocardiography (Simpson's method), (ii) a dual-chamber pacemaker implanted due to sinus node disease, (iii) symptomatic drug-refractory AF (with a history of failure of two classes of antiarrhythmic drugs) in patients referred for catheter ablation of AF, (iv) paroxysmal AF with one monthly episode registered by the pacemaker (paroxysmal AF was defined

http://dx.doi.org/10.1016/j.hipert.2017.05.003

Please cite this article in press as: Kiuchi MG, Chen S. Atrial fibrillation recurrence after pulmonary vein isolation in patients with paroxysmal atrial fibrillation and the use of a pacemaker by single catheter *vs.* multiple catheter approach – Clinical and economic evaluation. Hipertens Riesgo Vasc. 2017. http://dx.doi.org/10.1016/j.hipert.2017.05.003

as AF episodes lasting <7 days with spontaneous termination), (v) age of 18–80 years, (vi) estimated glomerular filtration rate (eGFR) $\geq$60 mL/min/1.73 m^2 estimated by the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation[9] without microalbuminuria, and (vii) the capacity to read, comprehend, and sign the informed consent form and attend the clinical tests.

The patients that presented any of the subsequent criteria were excluded: (i) pregnancy; (ii) valvular disease with significant adverse sequelae; (iii) unstable angina, myocardial infarction, transient ischemic attack or stroke within the 6 months before the procedure; (iv) allergy to ionic contrast; (v) the inability to be monitored clinically after the procedure; (vi) a known addiction to drugs or alcohol that affects the intellect; (vii) a serious health condition that, in the investigator opinion's, may adversely affect the safety and/or efficacy of the participant or the study; (viii) congestive heart failure presenting functional class II–IV symptoms according to New York Heart Association; (ix) a previous AF ablation procedure; or (x) treatment with amiodarone.

The individuals were randomly divided into two groups (single catheter PVI, $n = 60$, and multiple catheters PVI, $n = 50$). All of them were followed for exactly 1 year to assess maintenance of sinus rhythm and the AF burden.

The goal of this study was a 30-s recurrence of the arrhythmia and the AF burden recorded by the pacemaker. The blanking period (the first 3 months after ablation) was excluded from the analysis,[10] and the pacemaker was evaluated at baseline and 3, 6, 9, and 12 months after PVI.

Before the AF ablation procedure, the pacemaker generator, the atrial and ventricular leads were presenting normal functioning. The patient was submitted to general anesthesia by an anesthesiologist, and 1 g of vancomycin was administered intravenously. They presented bicameral programmed artificial pacing rhythm.

PVI – single catheter approach

Under fluoroscopic vision, two right femoral vein punctures were performed, with one 12F sheath. Through the sheath 12F, the Agilis™ NxT Steerable Introducer (St. Jude Medical, USA) was inserted. We performed a single transeptal puncture using a 98 cm BRK™ Transseptal Needle (St. Jude Medical, USA). Electro-surgical plate and EnSite™ Velocity™ Cardiac Mapping System (St. Jude Medical, USA) electrode for electro-anatomical mapping were positioned on the patient. Right heart chambers catheterization were performed, and left chambers catheterization were also performed after a single transseptal puncture, with the following catheter position:

- One Flexability™ ablation catheter (St. Jude Medical, USA), in the left atrium and pulmonary veins, alternately.

The esophagus was marked by a radiopaque silicone probe with contrast inside. The electro-anatomical map reconstruction of the left atrium and pulmonary veins by the EnSite™ Velocity™ Cardiac Mapping System (St. Jude Medical, USA) was performed, with subsequently electrical isolation of the pulmonary veins by Flexability™ ablation catheter (St. Jude Medical, USA). Radiofrequency applications were made in the antrum of the pulmonary veins of the left atrium, using the power of 35 W and maximum temperature of 42 °C. Atrial and pulmonary intra-vein stimulation to check pulmonary vein inlet and outlet blockade confirmed the isolation of pulmonary veins. New decrement atrial electrical stimulation at continuous cycles of 350–200 ppm did not induce sustained new arrhythmias, maintaining sinus rhythm. The mean total procedure time was approximately 1.1 h.

PVI – multiple catheters approach

Under fluoroscopic vision, two right femoral vein punctures were performed, with one 7F and another 12F sheath, more two left femoral vein punctures were performed, with the insertion of two 6F sheaths. Through the sheath 12F, the Agilis™ NxT Steerable Introducer (St. Jude Medical, USA) was inserted, and the sheath 8F was replaced by the long sheath Fast-Cath™ Transseptal Guiding Introducers SL-0 (St. Jude Medical, USA). A left femoral vein puncture was performed with the introduction of a 10F sheath, through which the intra-cardiac echocardiography probe (ViewFlex™ Xtra Intracardiac Echocardiography – St. Jude Medical, USA) was inserted, positioned in the lower right atrium. We performed two transeptal punctures using a 71 and 98 cm BRK™ Transseptal Needles (St. Jude Medical, USA), respectively, and the right femoral artery was punctured, being inserted an 8F sheath to monitor invasive blood pressure. Electro-surgical plate and EnSite™ Velocity™ Cardiac Mapping System (St. Jude Medical, USA) electrode for electro-anatomical mapping were positioned on the patient. Right heart chambers catheterization were performed, and left chambers catheterization were also performed after double transeptal punctures, with the following catheter positions:

- A quadripolar fixed curve catheter was positioned at the tip of the right ventricle;
- A decapolar dirigible catheter was positioned within the coronary sinus;
- A decapolar dirigible circular catheter, in pulmonary veins and left atrium, alternately;
- One TactiCath™ Quartz Contact Force Ablation Catheter (St. Jude Medical, USA), in the left atrium and pulmonary veins, alternately.

The long sheaths in the left atrium were maintained continuously irrigated with heparinized saline. Infusion of heparin was performed by an infusion pump, keeping the coagulation activated time >300 s. The esophagus was marked by a radiopaque silicone probe with contrast inside. The electro-anatomical map reconstruction of the left atrium and pulmonary veins by the EnSite™ Velocity™ Cardiac Mapping System (St. Jude Medical, USA) was performed, with subsequently electrical isolation of the pulmonary veins by TactiCath™ Quartz Contact Force Ablation Catheter (St. Jude Medical, USA). Radiofrequency applications were made in the antrum of the pulmonary veins of the left atrium, using the power of 35 W and maximum temperature of 42 °C. Atrial and pulmonary intra-vein stimulation to check pulmonary vein inlet and outlet blockade confirmed

Please cite this article in press as: Kiuchi MG, Chen S. Atrial fibrillation recurrence after pulmonary vein isolation in patients with paroxysmal atrial fibrillation and the use of a pacemaker by single catheter *vs.* multiple catheter approach – Clinical and economic evaluation. Hipertens Riesgo Vasc. 2017. http://dx.doi.org/10.1016/j.hipert.2017.05.003