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Substantial superiority of Niobe ES over Niobe II system in remote-controlled magnetic pulmonary vein isolation

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ABSTRACT

Background: Catheter ablation of atrial fibrillation (AFib) primarily relies upon pulmonary vein isolation (PVI), but such procedures are associated with significant X-ray exposure. The newer Epoch system has been developed so as to enable more precise magnetic navigation whilst limiting X-ray exposure.
Objectives: This study was aimed at quantifying both exposure time and X-ray reduction with the newer Epoch system compared to Niobe II during AFib ablation procedures.
Methods: From November 2011 to November 2013, our last 92 consecutive patients treated with the Niobe ES (Epoch Solution; 4th generation magnetic navigation technology) system were compared with the first 92 consecutive patients treated using the Niobe II system (3rd generation magnetic navigation technology) for symptomatic drug-refractory AFib.
Results: Mean patient age was 59 ± 11 years (20% female), and the study population was affected by either symptomatic paroxysmal (65.2%) or persistent (34.8%) AFib. Median procedure time was 2 ± 0.5 h and median total X-ray exposure 12.3 ± 6.4 min. Procedure time (1.9 ± 0.4 vs. 2.7 ± 1 h, $p < 0.0001$) and X-ray duration (12 ± 4 vs. 15 ± 7 min, $p = 0.001$) were significantly lower with Niobe ES than with the Niobe II system. X-ray ablation exposure time was also significantly lower with the Niobe ES system than with the Niobe II system (2.9 ± 2 vs. 4 ± 3.5 min; $p = 0.01$). Through multivariate analysis, the only predictive factors influencing both procedure duration and X-ray exposure were found to be the Niobe ES system use and LA size.
Conclusions: Our study was the first to demonstrate that the new Niobe ES magnetic robotic system substantially reduced overall operating, fluoroscopy, and ablation times during AFib ablation procedure.

1. Introduction

Over the past few years, radiofrequency (RF) therapy has played a decisive role in the treatment of complex arrhythmias and, in particular, atrial fibrillation (AFib) [1,2]. However, this technology requires experienced operators with special skills in handling catheters in difficult clinical situations, as said intervention may involve long, tedious, and potentially risky procedures [2]. The catheter technology presents a major limitation when used in the manual method, since catheter mobility is limited by the transmission of torque, which depends upon vessel tortuosity, catheter orientation within the heart, as well as catheter rigidity or instability. During these procedures, the operator is subjected not only to X-ray exposure but also to an unusually high degree of fatigue that may have a detrimental effect upon concentration. Such diminished concentration may result in delayed analysis, prolonged procedure time, and increased risk of complications. AFib treatment is increasingly being used in electrophysiological laboratories due to the prevalence of AFib (2%–3% of the population over 60 years of age) and the unfavorable benefit/risk ratio of antiarrhythmic drugs compared to RF techniques [3]. Current trends favor technology that is similar to or more effective than manual RF techniques, but safer in terms of potential complications and other parameters such as X-ray exposure to patients and operators. Such technology may allow more patients to be treated without adverse effects upon operators' health. The remote magnetic navigation system (RMNS) appears to be a technology of the future, demonstrating a very favorable benefit/risk ratio for both patients and operators [4–10]. A new Niobe ES (Epoch Solution; 4th generation magnetic navigation technology) system has been developed so as to facilitate robotic navigation with faster computing hardware and new motion controllers, but its superiority has not yet been proved in this clinical setting. In addition, predictive factors impacting magnetic robotic navigation in patients being treated for AFib have yet to be assessed.

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We therefore sought to evaluate: (1) the efficacy and extent of fluoroscopic exposure as well as procedure duration associated with the new Niobe ES system compared to Niobe II (3rd generation magnetic navigation technology) in patients requiring AFib ablation, and (2) the predictive factors affecting RMNS in this clinical setting.

1.1. Methods

Our last 92 consecutive patients to undergo pulmonary vein (PV) disconnection for symptomatic drug-refractory AFib catheter ablation and treated remotely using the Niobe ES RMNS (Stereotaxis, St. Louis, MO, USA) combined with a 3D non-fluoroscopic navigation system (Carto® 3 system, Biosense Webster, CA, USA) were compared with our first 92 consecutive patients treated with the Niobe II system in order to evaluate the impact upon procedure parameters.

1.2. Electrophysiological procedures

All patients received anticoagulation therapy with vitamin K antagonists (VKAs) for at least 2 months prior to the procedure (target international normalized ratio [INR] 2:3) and did not discontinue VKA treatment. Transesophageal echocardiography was performed within 48 h prior to the procedure in order to exclude left atrial (LA) thrombus. VKA administration was resumed on the day of the procedure. Surface ECG and bipolar endocardial electrogram (filtered from 30 to 500 Hz) parameters were continuously monitored and stored in a computer-based digital amplifier/recorder system. A deflectable quadripolar catheter (5 mm interelectrode spacing, Xtrem, ELA Medical, Montrouge, France) was positioned in the coronary sinus for pacing and recording purposes. The LA was accessed via a patent foramen ovale, if present, or via transseptal puncture, and a guidewire was inserted into the LA using an 8F-long sheath. During the procedure, the sheath was perfused with a heparinized solution (3000 U of heparin in 500 mL of sodium chloride 0.9% at a rate of 150 mL/h). A multipolar deflectable catheter (Lasso, Biosense Webster, Diamond Bar, CA, USA) was inserted via the long sheath so as to map the PV ostia for all ablation procedures. RF ablation was carried out using a 3.5 mm open irrigated-tip magnetic ablation catheter (NaviStar® RMT ThermoCool®, Biosense Webster, Diamond Bar, CA, USA). The catheter was pushed forward into the LA by means of a second transseptal puncture. Anticoagulation was managed as usual for this kind of procedure.

1.3. Radiofrequency catheter ablation procedures

Irrespective of the study group, ablation endpoints consisted of the isolation of PVs, defined by complete elimination or dissociation of pulmonary potentials and validated by means of a circumferential mapping catheter in all cases (paroxysmal and persistent AFib), thereby including additional lesion lines (LA roof and coronary sinus defragmentation) for persistent AFib. RF was applied using an open irrigated-tip catheter whose power output did not exceed 35 W near the PV ostia and 25 W near the posterior ostia wall or whilst performing coronary sinus defragmentation. Irrigation with sodium chloride 0.9% at a rate of 20–35 mL/min was used in order to maintain a tip temperature of <43 °C.

1.4. Carto 3 system features

The Carto 3 System used enables real-time Advanced Catheter Location™ and visualization of both ablation and circular mapping catheters (NaviStar and Lasso catheters). Catheter location is displayed in the same manner as with a fluoroscopic view. The Carto 3 System combines electromagnetic technology (similarly to the Carto XP System) with new Advanced Catheter Location technology that enables visualization of multiple catheters without fluoroscopy. The technology was described elsewhere [9].

1.5. Remote magnetic navigation system

The RMNS (Niobe II, Stereotaxis Inc., St Louis, MO, USA) is a technology employing a steerable magnetic field to remotely guide a flexible catheter inside the heart [4–10]. The steerable magnetic field contains two giant computer-controlled 1.8-ton magnets positioned at opposite sides of the fluoroscopy table. A magnetic field of 0.08 to 0.1 Tesla is generated (according to the initial settings) such that the three small magnets incorporated in parallel in the tip of the RF catheter allow for 3D (three-dimensional) navigation. The magnetic field is applied to a theoretical cardiac volume of 20 cm × 20 cm. The catheter tip can be steered with high precision using a vector-based computer system (Navigant system), which aligns the catheter relative to the generated magnetic field so that the catheter's movements depend upon direction changes of the two magnets in relation to each other. A computerized motor drive system (Cardiodrive, Stereotaxis Inc., St. Louis, MO, USA) advances or retracts the catheters, whilst its spatial orientation requires a computerized work station (Navigant 2.1, Stereotaxis Inc., St. Louis, MO, USA). By means of a keypad (arrow keys) or joystick, the catheter can be continuously advanced or retracted, or even adjusted (from 1 mm to 9 mm). Niobe II is a magnetic navigation system (MNS) featuring robotic catheter guidance capability. The catheter's direction is controlled by altering the direction of a magnetic field within the patient's heart. This is achieved by moving large, fixed magnets located on either side of the patient during a cardiac procedure. Constant application of the magnetic field during the procedure maintains contact between the catheter tip and endocardial tissue throughout the cardiac cycle. The Niobe II system provides discrete control whereby the operator sets a desired direction for the catheter and the system responds by computing the motions required and subsequently executing the request. With this older generation of magnetic system, the time between transmission of the direction command and completion of the motion by the system may take up to several seconds. The newer Niobe Epoch System (ES) constitutes the 4th generation of magnetic navigation technology, improving upon functionality with faster computing hardware and new motion controllers. The ensuing result is continuous solution calculation for motion control, allowing response to user input within <250 ms. The speed at which the external magnets are moved has also been increased so that the operator experiences a near-real-time response to catheter movement commands. New features in the navigation software have taken advantage of this improved responsiveness in order to provide the user with new ways to move the catheter and significantly improved automated targeting features. This new generation of magnetic navigation has resulted in faster control of the catheter, which has the potential of reducing the time necessary to navigate the catheter to the desired position.

1.6. Measurements: procedural and fluoroscopy parameters

The following parameters were recorded for all patients and compared within study groups: total duration (skin to skin); total X-ray and gray × cm^2 procedure time, from needle insertion to final catheter removal; skin to catheter positioning X-ray time and gray × cm^2 from femoral access to the final positioning of the catheter in the LA, including transseptal access; LA electroanatomical mapping X-ray time and gray × cm^2 from catheter positioning in the LA to the achievement of a satisfactory electroanatomical reconstruction as compared to an LA CT scan; ablation X-ray time and gray × cm^2 from the first up to the last RF delivery.

1.7. Endpoints

The primary endpoint for AFib ablation was wide area circumferential pulmonary vein isolation (PVI), as confirmed via spiral catheter recording during ablation in all patients. PVI was defined as the abolition or dissociation of activities in all PVs. The distinction was made between PV

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