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Original article

Nonfluoroscopic Catheter Ablation. Results From a Prospective Multicenter Registry

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ABSTRACT

Introduction and objectives: Nonfluoroscopic catheter ablation is feasible in most procedures. The aim of our registry was to evaluate the safety and feasibility of a zero-fluoroscopic approach to catheter ablation in several Spanish centers.

Methods: Eleven centers prospectively included a minimum of 20 patients. Patients with an arrhythmic substrate deemed suitable by the operator for a zero-fluoroscopic approach throughout the procedure were recruited. Patients with intracardiac devices were not included. Attending electrophysiologists, fellows, and resident physicians participated in each procedure, as in usual care.

Results: The study included 247 seven patients. Ablation was performed in 235 patients (95.2%). In 2 patients, who were not included in the analysis, fluoroscopy was performed as the first-line treatment. The arrhythmic substrate was located in the right chambers in most of the procedures (231 of 233 [99.15%]). Fluoroscopy was used in 24 procedures (10.3%). Catheter ablation was successful in 96.4% of the procedures and severe complications occurred in 2 patients (0.85%). Two variables were related to the need for fluoroscopy: the performing center (minimum 0% vs maximum 30.3%; $P = .001$) and procedural failure (13% vs 2.4%; $P < .05$).

Conclusions: The Spanish multicenter registry reveals that a zero-fluoroscopic approach is feasible in most right-sided catheter ablation procedures. Randomized trials are necessary to confirm the safety of this approach. The need for fluoroscopy was related to procedural failure, with significant differences among performing centers.

Ablación con catéter no guiada por fluoroscopia. Resultados de un registro prospectivo multicéntrico

Palabras clave:
Registro
Ablación con catéter
Fluoroscopia

RESUMEN

Introducción y objetivos: La ablación con catéter sin guía fluoroscópica es factible en la mayoría de los casos. El objetivo de nuestro registro es evaluar la factibilidad y la seguridad de la ablación no guiada por fluoroscopia en varios centros españoles.

Métodos: Once hospitales incluyeron prospectivamente a, al menos, 20 pacientes afectados de un sustrato arrítmico cuyo procedimiento de ablación, a juicio de cada operador, se podía abordar sin fluoroscopia durante todo el procedimiento. No se incluyó a pacientes portadores de dispositivos intracardiacos. Electrofisiólogos de plantilla, becarios y residentes participaron en cada procedimiento de forma habitual.

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◇ The list of participants can be found in the Appendix.

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Resultados: Se incluyó a un total de 247 pacientes (n = 247). Se realizó ablación en 235 casos (95,2%), y en 2 casos que no se incluyeron en el análisis la fluoroscopia se utilizó como primera intención. En el 99,15% (231/233) de los procedimientos analizados el sustrato arrítmico abordado se localizaba en cavidades derechas. Se requirió fluoroscopia en 24 (10,3%), se obtuvo éxito en el 96,4% de los procedimientos y hubo complicaciones graves en 2 pacientes (0,85%). Las variables relacionadas con la necesidad de fluoroscopia fueron el centro realizador (máximo, 33,3%; mínimo, 0; p = 0,001) y el fracaso del procedimiento (el 13 frente al 2,4%; p < 0,05).
Conclusiones: El registro multicéntrico muestra que la ablación sin escopia de sustratos localizados en cavidades derechas es factible en la mayoría de los procedimientos. Se necesitan estudios aleatorizados para confirmar su seguridad. La necesidad de fluoroscopia es mayor en los procedimientos sin éxito y es variable en los centros realizadores.

Abbreviations

AVNRT: atrioventricular nodal reentrant tachycardia
NFINS: nonfluoroscopic intracardiac navigation system

INTRODUCTION

The treatment of choice for most cardiac tachyarrhythmias is catheter ablation. Catheter movement within a patient's cardiovascular system is typically visualized using fluoroscopy. Unfortunately, ionizing radiation has adverse effects on both patients and staff. Some of these effects are serious, such as cancer and genetic mutation induction (stochastic effects),[1] and can develop despite the judicious use of fluoroscopy and radiation protection clothing.[1] Additionally, these garments can cause vertebral injuries that lead to invasive treatments and/or sick leave.[2]

Nonfluoroscopic intracardiac navigation systems (NFINSs) reduce the amount of fluoroscopy required for safe and successful ablation.[3] However, there are differences between the methodology of an ablation procedure aiming to avoid fluoroscopy use (zero-fluoroscopy approach) and that of a procedure using a NFINS to merely reduce fluoroscopy use (minimal fluoroscopy approach). Data on zero-fluoroscopy ablation have been published by centers with extensive experience.[4–14] However, there is little information on the results of centers with very different experience levels. The aim of this multicenter registry was to evaluate the results of zero-fluoroscopy ablation procedures in various Spanish centers with distinct experience levels.

METHODS

The 11 participating centers had variable experience with the use of mapping systems in zero-fluoroscopy procedures. Two centers had performed fewer than 10 such procedures before the registry started, whereas the other 9 had performed more than 10, although not all operators had conducted this type of procedure. Each center had to enroll a minimum of 20 patients but was free to enroll more until all the centers had enrolled the minimum number. Patients were prospectively enrolled. All staff members who typically took part in ablation procedures in each center could participate in the registry. Approval of the registry was first granted by the Ethics Committee of the *Complejo Hospitalario Universitario* of Granada (coordinating center) and then ratified by the other relevant committees. All patients provided written informed consent.

Inclusion Criteria

The registry included patients with arrhythmic substrates who, according to the treating physician, could be managed with a completely nonfluoroscopic procedure from the beginning (zero-fluoroscopy approach). All substrates localized to the right heart (atrioventricular nodal reentrant tachycardia, accessory pathways, atrial tachycardia, and right ventricular outflow tract tachycardia) were considered, although other substrates could be included as long as they met the study criteria.

Exclusion Criteria

Patients without electrocardiographic evidence of clinical tachyarrhythmia were excluded, as well as those with intracardiac leads or an arrhythmic substrate requiring a transseptal or epicardial approach. If the presumptive diagnosis was not confirmed and the arrhythmic substrate to be addressed could not be treated without first-line fluoroscopy, the procedure was considered a protocol deviation and was omitted from the final analysis.

Ablation Procedure

The entire procedure, from first puncture to catheter removal, had to have been performed without the support of first-line fluoroscopy. The Ensite-NavX™ system (St. Jude Medical; St. Paul, Minnesota, United States) was used in all procedures. Fluoroscopy use was at the discretionof the attending electrophysiologist; no patient's safety was jeopardized in an attempt to avoid its use. The reasons for fluoroscopy use were analyzed.

All centers performed the ablation according to their standard practice in terms of personnel training, number, access, and position of diagnostic catheters, and type and access of ablation catheters. The analysis included the identity of the operators of the electroanatomy system (technician, nurse, resident, electrophysiologist fellow, attending electrophysiologist), the diagnostic catheters, and the ablation catheter in each procedure.

The total procedure time was defined as the interval between the first puncture and catheter removal. Waiting time was not predefined. The recorded complications corresponded to those appearing during the hospitalization period; also analyzed were the rate of repeat ablations of a previously treated substrate. Recurrence was not considered to have occurred if there was no evidence of specific recurrence in the previously ablated substrate. The follow-up time was not predefined and was the standard duration for each center.

Statistical Analysis

Categorical variables are expressed as frequencies and percentages. The normality assumption of continuous variables was assessed with the Kolmogorov-Smirnov test. Variables following a

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