

Original article

Clinical Profile and Incidence of Ventricular Arrhythmia in Patients Undergoing Defibrillator Generator Replacement in Spain



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Article history:

Received 17 December 2013

Accepted 17 January 2014

Available online 2 June 2014

Keywords:

Implantable cardioverter-defibrillator
Generator replacement
Ventricular arrhythmias
Appropriate therapies

ABSTRACT

Introduction and objectives: Implantable cardioverter-defibrillators reduce mortality in some patients with heart disease. Battery replacement is a frequent occurrence in clinical practice and is required in up to 30% of implants. The benefit/risk ratio of defibrillators varies over time and should be reevaluated at the time of replacement. The aim of this study was to determine the clinical characteristics and incidence of defibrillator therapies in patients who underwent generator replacement.

Methods: This multicenter retrospective study involved patients from the UMBRELLA national registry who underwent replacement due to defibrillator battery depletion. The incidence of ventricular arrhythmias was determined via remote monitoring. Risk factors for sustained ventricular arrhythmia after replacement were analyzed.

Results: A total of 354 patients were included (mean age [standard deviation], 61.8 [14.5] years; men, 80%; secondary prevention, 42%; ventricular arrhythmias in the explanted generator, 62%). After a 25-month follow-up, 70 patients (20%) received appropriate therapies and 8 (2.3%) received inappropriate discharges. Male sex, structural heart disease, heart failure, and the absence of resynchronization were independent predictors of ventricular arrhythmia occurrence.

Conclusions: One-fifth of patients had appropriate defibrillator therapies in the first 2 years after generator replacement. Determination of the factors associated with arrhythmia occurrence after replacement may be useful to optimize implantable cardioverter-defibrillator treatment.

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Perfil clínico e incidencia de arritmias ventriculares de los pacientes sometidos a recambio de generador de desfibrilador en España

RESUMEN

Introducción y objetivos: Se ha demostrado que los desfibriladores automáticos implantables reducen la mortalidad de ciertos pacientes con cardiopatía. El recambio de su batería es una situación frecuente en la práctica clínica, hasta un 30% de los implantes. El beneficio/riesgo del desfibrilador no es constante en el tiempo, y debe reevaluarse en el momento del recambio. El objetivo del estudio es conocer las características clínicas y la incidencia de terapias del desfibrilador en los pacientes sometidos a un recambio de generador.

Métodos: Se realizó un estudio retrospectivo multicéntrico basado en los pacientes del registro nacional UMBRELLA, sometidos a recambio por agotamiento de la batería del desfibrilador. Se analizó la incidencia de arritmias ventriculares mediante monitorización a distancia. Se analizaron los factores de riesgo de arritmia ventricular sostenida tras el recambio.

Resultados: Se incluyó a 354 pacientes (media de edad, 61,8 ± 14,5 años; varones, 80%; prevención secundaria, 42%; arritmias ventriculares en el generador explantado, 62%). Tras un seguimiento de 25 meses, 70 pacientes (20%) presentaron terapias apropiadas y 8 (2,3%) tuvieron descargas inapropiadas. El sexo masculino, la presencia de cardiopatía estructural, la insuficiencia cardiaca y la ausencia de resincronización fueron predictores independientes de la aparición de arritmias ventriculares.

Palabras clave:

Desfibrilador automático implantable
Recambio de generador
Arritmias ventriculares
Terapias apropiadas

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<http://dx.doi.org/10.1016/j.rec.2014.07.010>, Rev Esp Cardiol. 2014;67:971–3.

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Conclusiones: Una quinta parte de los pacientes tiene terapias apropiadas de desfibrilador en los primeros 2 años desde el recambio de generador. El conocimiento de los factores asociados a la aparición de arritmias tras el recambio puede ser útil para optimizar el rendimiento de la terapia.

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Abbreviations

CRT: cardiac resynchronization therapy
ICD: implantable cardioverter-defibrillator

INTRODUCTION

Implantable cardioverter-defibrillator (ICD) therapy has reduced overall mortality in numerous clinical trials of heart disease patients at risk of sudden cardiac arrest in both secondary^{1–3} and primary^{4–8} prevention. Consequently, ICD use is indicated in clinical practice guidelines,⁹ and the number of implantations has grown annually in both Europe and the United States.¹⁰ However, ICDs are associated with a number of disadvantages, such as inappropriate shocks,^{11,12} deterioration in the quality of life related to device discharge,¹³ and a high economic cost.¹⁴

Implantable cardioverter-defibrillator replacement is the perfect time to reevaluate the indication of a treatment whose risk/benefit ratio may no longer be favorable.¹⁵ Replacement, moreover, carries some risks,^{16,17} and the complications rate at the surgical wound is double that of the first implantation.¹⁸

The number of ICD replacements performed in Spain is growing annually, both in absolute numbers and in proportion to the number of first implants. According to data published in the latest national ICD registries, 950 generator replacements were performed in 2009 (24.4% of all ICD implants),¹⁹ which increased to 1135 (26.12%) in 2010²⁰ and 1253 (29.8%) in 2011.²¹

Although generator replacement increases health care activity and costs, few data have been published on the performance of ICD therapy in this population. The present study aimed to determine the clinical profile of patients undergoing ICD generator replacement in Spain, the incidence of this treatment in this population, and the factors associated with the occurrence of sustained ventricular arrhythmias after replacement.

METHODS

This study was conducted within the framework for observational research provided by the Scientific Cooperation Platform (SCOOP). This platform is based on the UMBRELLA national registry (incidence of arrhythmias in the Spanish population with a Medtronic ICD), registered at ClinicalTrials.gov as NCT01561144. This voluntary registry, promoted by Medtronic, includes patients in both primary and secondary prevention implanted with a Medtronic ICD with remote monitoring (CareLink). Of the 72 Spanish centers CareLink systems have been implanted, 44 voluntarily participated. At the time of writing, 1661 patients had been enrolled in the study. Patient participation was approved by the ethics committees of the participating centers and all patients provided informed consent.

The study population consisted of all patients included in the UMBRELLA registry upon undergoing ICD generator replacement due to battery depletion. We excluded replacements made for other reasons, such as infection or system updating.

The prevalence of sustained ventricular arrhythmias at the time of replacement was obtained via a questionnaire completed by the treating physician. Patient follow-up was systematically performed using remote monitoring. Sustained ventricular arrhythmias were considered to be those that provoked an appropriate ICD therapy. Patients with Brugada syndrome, long QT syndrome, or idiopathic ventricular fibrillation were considered to be “without structural heart disease”.

A committee consisting of 6 experts studied the incidence of ventricular arrhythmia following replacement by analyzing the electrograms of the events stored in the CareLink network. Each event was reviewed in a double-blind manner by 2 committee members, who classified the type of arrhythmia and the effectiveness of the therapy. If there was disagreement, the event was referred to a third reviewer. If no agreement was reached

Table 1
Clinical Characteristics of Patients Undergoing Generator Replacement

Patients, no.	354
Age, mean (SD), y	61.8 (14.5)
Men	285 (80.5)
Indication (secondary prevention)	153 (42.2)
History of AF	109 (30.7)
Renal failure	40 (11.2)
Structural heart disease	316 (89.3)
LVEF %	
> 50	80 (22.7)
41–50	30 (8.5)
36–40	25 (7)
31–35	61 (17.2)
< 30	158 (44.6)
Heart failure	237
NYHA functional class	
I	37 (15.6)
II	124 (52.3)
III	75 (31.6)
IV	1 (0.4)
Left bundle branch block	87 (24.6)
QRS, mean (SD), ms	127 (37)
Baseline rhythm	
Sinus	252 (71.3)
AF	62 (17.5)
Stimulated	40 (11.2)
ICD model	
Single-chamber	150 (42.4)
Dual-chamber	70 (19.8)
Triple-chamber	134 (37.9)
Previous ATP	156 (55.4)
Previous discharge	169 (47.7)
Previous sustained VT/VF episode	220 (62.1)

AF, atrial fibrillation; ATP, antitachycardia pacing; ICD, implantable cardioverter-defibrillator; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; SD, standard deviation; VF, ventricular fibrillation; VT, ventricular tachycardia.

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