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Implant rates of cardiac implantable electrical devices in Europe: A systematic literature review☆,☆☆

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ABSTRACT

Background: In recent years, indications for cardiac implantable electrical devices (CIEDs) have broadened; however, budget constraints can significantly impact patient access to these life-saving health technologies.
Objective: To perform a systematic literature review on the implant rates of pacemakers, cardioverter-defibrillators, and cardiac resynchronization therapy devices in Europe over the last decade to provide insight into the possible reasons for differences across regions or countries.
Methods: Four electronic databases were searched to find studies describing CIED implant rates in Europe. Fifty-eight studies were included.
Results: An overview showed a recent rise in CIED implants, with large geographic differences. The ratio between the regions with the highest and lowest implant rates within the same country ranged between 1.3 and 3.4 for pacemakers and between 1.7 and 44.0 for defibrillators. The ratio between the countries with the highest and lowest implant rates ranged between 2.3 and 87.5 for pacemakers, between 3.1 and 1548.0 for defibrillators, and between 4.1 and 221.0 for resynchronization therapy devices. Implant rate variability appears to be influenced by health care, economic, demographic, and cultural factors.
Conclusion: Publications on CIED implant rates in Europe show a wide variability within and across countries, the determinants of which are only partially investigated. Policy making should improve regarding equity of access to better care.

1. Introduction

In recent years, European health care systems have faced several administrative, organizational, and financial issues related to the implementation in clinical practice of cardiac implantable electrical devices (CIEDs) for brady- and tachyarrhythmia treatment, sudden cardiac death prevention, and cardiac resynchronization therapy (CRT) [1]. CIEDs include the following: pacemakers, which are able to deliver electrical impulses via intracardiac electrodes to avoid bradyarrhythmias; implantable cardioverter-defibrillators (ICDs), which can interrupt life-threatening ventricular tachyarrhythmias through programmable anti-tachycardia pacing and/or DC shocks; and CRT devices, which are able to perform right and left ventricular pacing, usually in synchrony, to resynchronize ventricular

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contraction in patients with heart failure and conduction disturbances [2,3].

A steady increase in pacemaker and ICD implantations has occurred in Europe over the last decades as a consequence of the results of large clinical trials, the development of scientific guidelines, and the implementation of knowledge in clinical practice [2,3]. Based on the growing evidence on primary prophylactic ICD therapy in patients with severe left ventricular dysfunction, the spectrum of candidates for ICD implantation has significantly broadened [3]. Furthermore, the use of CRT, either delivered by a pacemaker (CRT-P) or a cardioverter-defibrillator (CRT-D), has become an established additive treatment for heart failure patients with left ventricular systolic dysfunction and conduction delay [4,5].

With the increase in clinical indications and cardiac pacing practice, survey- and registry-based data on pacemaker and ICD implantations in different geographic and socio-economic realities are now being published [6]. In addition to within-country analyses, comprehensive surveys of pacing and ICD practices across European countries [7,8] and worldwide [9–11] have been developed to assess the status quo of implanting activity under a global perspective. Within-country and across-country analyses of pacemaker and ICD practices have therefore become a useful tool for assessing the implementation of guidelines in the 'real-world' clinical practice.

However, evidence suggests that clinical guidelines are not always fully adopted due to the presence of barriers to the widespread use of CIEDs. Indeed, their high upfront cost has been discussed as one of the major limiting factors; other factors that have been mentioned include organizational, administrative and cultural issues [12].

Available studies have shown a wide heterogeneity in pacemaker, ICD, and CRT implant rates across countries [8,13], with substantial geographic variations within a country [14–16] and even within a region [17]. The observed discrepancies appear to be largely related to epidemiological, cultural, and socio-economic reasons; nonetheless, very few studies have empirically investigated the influence of these factors on pacemaker and ICD implant rates in Europe [12,18–22]. Moreover, the studies that are available present some important methodological limitations.

Although studies to date provide valuable insight into the major differences in implant rates across countries and the potential drivers of those differences, the results show a wide temporal and geographic heterogeneity and do not provide conclusive evidence that could be of value to researchers and policy makers. Our paper aims to fill in this gap by providing a comprehensive, systematic overview of the literature on the implant rates of pacemakers, ICDs, and CRT devices in Europe over the last 10 years. Furthermore, we sought to report available data on the possible reasons for differences in implant rates over time and across countries. We believe that this review contributes to the literature in two ways. From a research point of view, it sheds light onto the methodological strengths and weakness of the available studies and identifies the gaps to be addressed by further investigations. From a policy point of view, it comprehensively analyzes all available evidence on the utilization rates in Europe to provide insight into the main determinants of differences in implant rates over time and across countries in Europe [12,18–22]. Accordingly, this study reveals the existence of policy-driven factors that could be governed to influence CIED utilization rates in Europe.

The utilization rates of CIEDs is a very relevant policy topic for investigation because these devices represent the most challenging examples of health technologies that have proven to remarkably improve health outcomes of populations with, at the same time, increasing barriers that prevent their full diffusion into clinical practice. Given the epidemiological trend in cardiovascular diseases on the one hand and the rapid pace of health technology innovation on the other, the demand for these devices is expected to increase in the future. This is occurring amidst EU trends aimed at (i) increasing the quantity and quality of clinical evidence of medical devices for regulatory purposes [23], (ii) harmonizing the methods and processes for assessing medical devices, as fostered by the European Commission through several initiatives such as EUnetHTA, and (iii) enhancing EU patients' freedom to receive health services in any member state of the EU. These trends aim at collecting robust clinical evidence around medical technologies in an effort to prioritize those that would be worth including into clinical practice by assessing them through harmonized tools and methods that can guarantee similar evaluation processes by EU governments. Within this context, it therefore becomes highly relevant to analyze why this does not occur and what are the key issues related to different practices and policies leading to such wide variations in EU patients' access to technological innovation.

2. Methods

2.1. Study subjects

The review protocol was conducted in accordance with published guidelines [24]. The review question was defined using the following PICOS [24]:

- Population (i.e. characteristics of study participants): patients with rhythm disturbances and/or heart failure
- Intervention (i.e. treatment received by participants): first implant or replacement of a CIED in an EU country or region in the past 10 years
- Comparators (i.e. treatment against which the index intervention is compared): not assessed
- Outcome (i.e. surrogate for intervention impact): within-country and across-country implant rates
- Study design (i.e. methodological characteristics of included studies): survey- and registry-based studies and observational reports.

The research question examined was:

What is the incidence of CIED implants within and between countries in Europe, and what are the possible reasons for temporal and geographical implant rate discrepancies?