REVIEW OF LITERATURE ON IMPLANT RATES FOR THE SELECTED MEDICAL DEVICES

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About MedtecHTA

The MedtecHTA project (Methods for Health Technology Assessment of Medical Devices: a European Perspective) aims at improving the existing methodological framework within the paradigm of Health Technology Assessment (HTA) for the assessment of medical devices, and to develop this framework into a tool that provides structured, evidence-based input into health policies. The research activities are conducted by a consortium of six European Universities and one Scientific Association. The project is funded under the European Union's 7th Framework Programme as Small or Medium-Scale Focused Research Project (2013-2015).

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1. Introduction

In the last years pacemakers and implantable cardioverter-defibrillators (ICD) implant rates (IR) have steadily increased due to large clinical trial results and implementation of current guidelines.[1-5] In particular, in the last decade the evidence on primary prophylactic ICD therapy has widened the spectrum of patients eligible for ICD implantation.[2-5] Moreover, the use of cardiac resynchronization therapy (CRT), delivered by a pacemaker (CRT-P) or a cardioverter-defibrillator (CRT-D), spread rapidly, and it is currently established firmly as a valuable additive treatment for heart failure patients.[1,6,7]

Following the broadening in indications and the increase in device implantations, survey- and registry-based data regarding local pacing and electrophysiological practice from several European countries have been published. Health registries became a valuable source of information to assess the 'real -world' clinical practice and the actual outcomes of applying clinical guidelines.[8] At the same time, it was deemed more than necessary to assess the status quo for the whole European countries.[9] This guided the development of comprehensive surveys of pacing and ICD practices in the European[9] and world-wide[10] context. However, concerns have risen as regards to the relatively limited information obtained.[11] Clinical data were initially lacking in a number of implanting centres, where the surveys were conducted with the assistance of pacemaker companies.[11]

Available studies have shown substantial geographic variations in the annual rate of first-time pacemaker and ICD implantations,[9-12] reflecting a large gap in education and guideline implementation between countries.[9] Large variations in IR were observed not only across European countries but also within each country. Still little is known on the causes of these discrepancies, which seem to be related to epidemiological, medical, and socio-economical issues.

Since heterogeneous data are available on pacing and ICD practices across Europe, a comprehensive view of published studies on this topic would help to identify existing gaps and future directions for research and action. Our aim was therefore to perform a systematic review of the literature concerning IR of medical devices in Europe.

2. Methods

2.1. Data Sources and Search Strategies

We performed electronic literature searches supplemented by hand–searching bibliographies of included studies and review articles. Four databases were consulted: Medline, Embase, Cochrane Library, and Web Of Science. We limited our search to studies published in the last ten years, written in the English language, and concerning humans. The search was last updated on 20 June 2013. Table 1 shows the keywords selected for the search strategy.

Table 1. Keywords included in the search strategy.

- Pacemaker, Artificial/utilization*
- Pacemaker, Artificial/uptake*
- Pacemaker, Artificial/registry*
- Pacemaker, Artificial/diffusion*
- Defibrillators, Implantable/utilization*
- Defibrillators, Implantable/uptake*
- Defibrillators, Implantable/registry*
- Defibrillators, Implantable/diffusion*
- Cardiac Pacing, Artificial/utilization*
- Cardiac Pacing, Artificial/uptake*
- Cardiac Pacing, Artificial/registry*
- Cardiac Pacing, Artificial/diffusion*
- Electric Countershock/utilization*
- Electric Countershock/uptake*
- Electric Countershock/registry*
- Electric Countershock/diffusion*
- Pacemaker, Artificial
- Cardiac Pacing
- Cardiac Resynchronization Therapy Devices/utilization*
- Cardiac Resynchronization Therapy Devices/uptake*
- Cardiac Resynchronization Therapy Devices/registry*
- Cardiac Resynchronization Therapy Devices/diffusion*
- Europe
- Europe/epidemiology
- Geography
- Humans
- Socioeconomic Factors
- Pacemaker, Artificial/economics*
- Defibrillators, Implantable/economics*
- Electric Countershock/economics*
- Cardiac Resynchronization Therapy Devices/economics*
- Delivery of Health Care/economics
- Health Care Costs/statistics & numerical data*
- Cardiac Electrophysiology
- Defibrillators, Implantable
- Cardiac Resycnhronization Therapy Device

2.2. Study Selection and Data Extraction

We included studies that analyzed IR of pacemakers, ICDs, and CRT devices (CRT–P and CRT–D), across European countries or within a single European country. Both retrospective studies/reports and reviews were included. In

studies analyzing the world distribution of medical devices, the subset of data concerning European countries was selected.

The primary literature search was performed by one of the authors, who screened each citation for inclusion. After removing irrelevant articles by title search and duplicates, abstracts of potentially relevant articles were reviewed. The full–text version of selected relevant articles was retrieved to extract the following data: geographical context, analyzed years, data source, type of device, yearly IR, IR variability between years, variables considered in the analysis of IR variability.

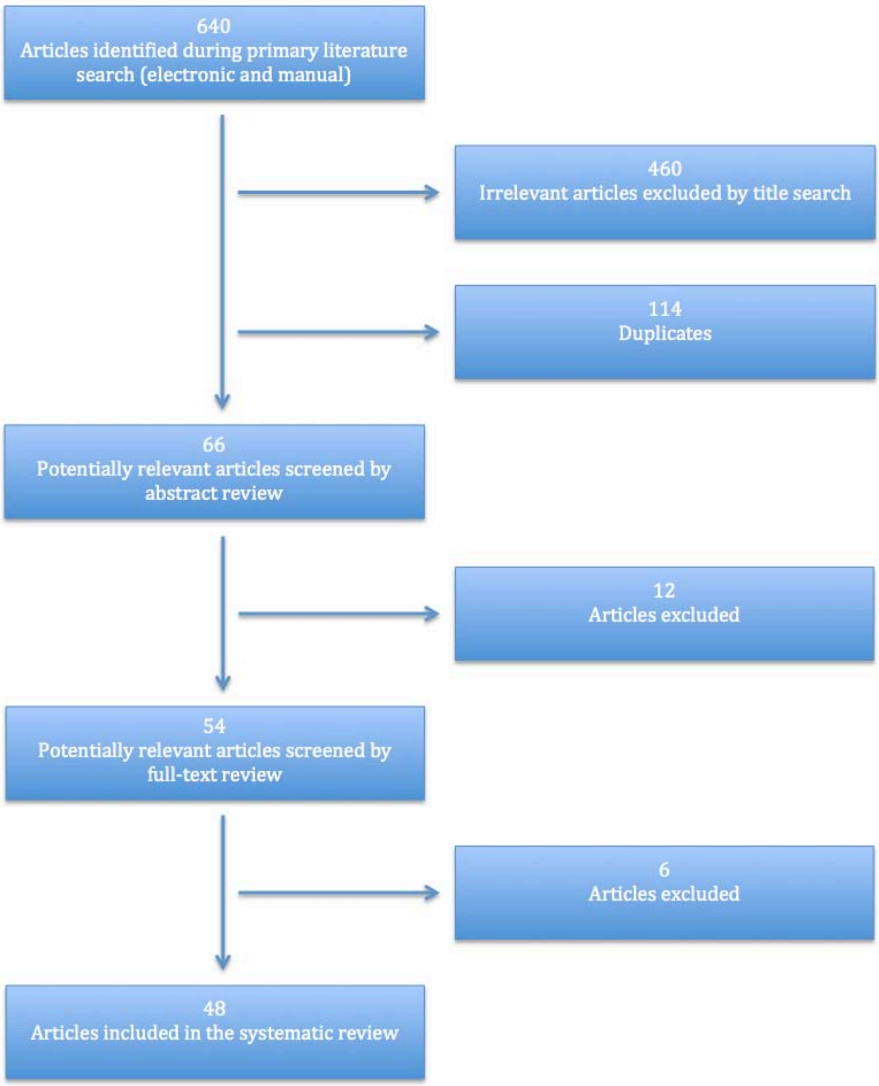
Issues concerning study selection and data extraction were discussed with a second independent reviewer to achieve consensus.

3. Results

3.1. Literature search results

The initial literature search yielded 640 citations (Figure 1). Of these, 460 were excluded by title search because of irrelevant content, and 114 were removed as duplicates. The abstracts of the remaining 66 articles were reviewed. Of these, 12 were excluded because referred to editorials (n=3), unrepresentative multicenter studies (n=1), economic evaluations (n=1), non-European studies (n=5), or conference abstracts (n=2). The remaining 54 articles were retrieved for full-text review. Of these, 6 were excluded because unrepresentative (n=1), data lacking (n=2), or economic/cost-effectiveness evaluations (n=3). The remaining 48 studies were included in the systematic review.

Figure 1: Flow diagram of selection of clinical studies included in the systematic review.

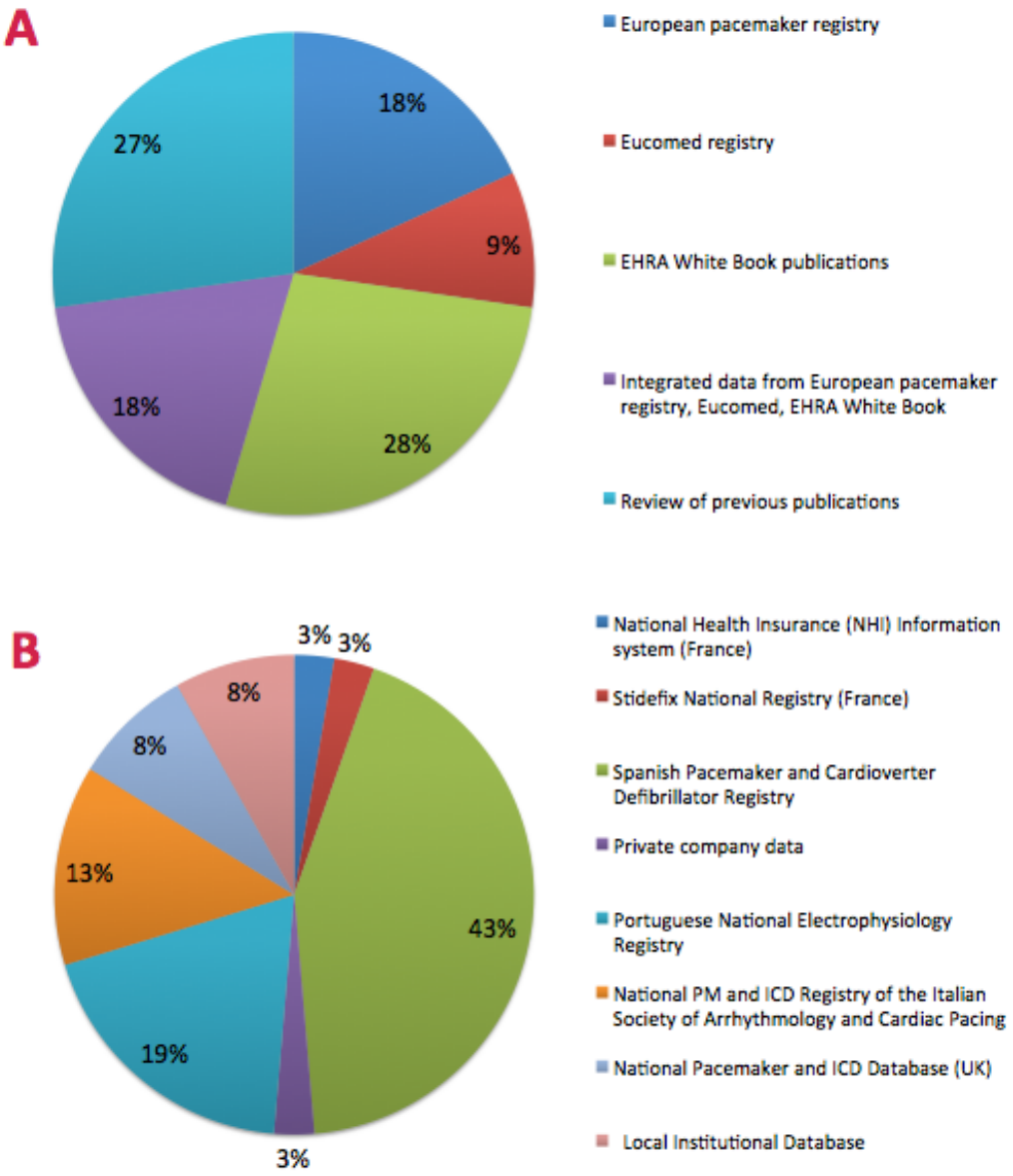


3.2. Across countries and within country analyses

Among the 48 retrieved articles, 11 (23 %) were related to across countries IR analyses. The remaining 37 (77%) articles reported IR data within distinguished European countries: Spain (n=17), Portugal (n=7), Italy (n=5), United Kingdom (n=4), France (n=2), Hungary (n=1), and Poland (n=1).

Data sources of across countries and within country analyses are presented in Figure 2. Data for across countries analyses were mainly derived from the European pacemaker registry, EHRA White Book publications, or Eucomed (European Confederation of Medical Devices Association) registry. Within country analyses were mostly based on National pacemaker and ICD registries. In detail, data from the Spanish, Portuguese, Italian, French, and UK Pacemaker and ICD registries were available.

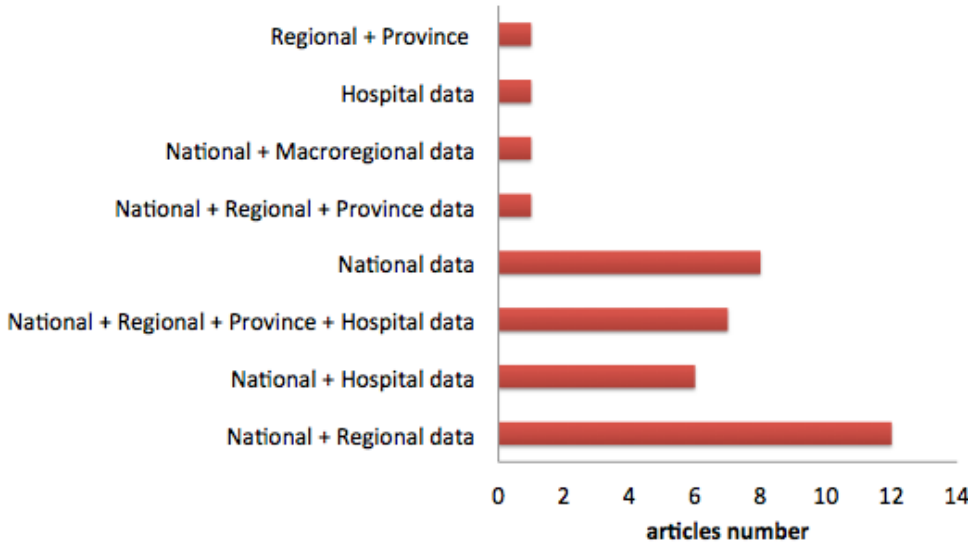
Figure 2: Data sources of across countries and within country analyses (A: across countries; B: within country).



As regards the object of across countries and within country analyses, most studies were related to ICDs and CRT-D devices (n=26). A minor number of studies (n=11) dealt with pacemakers and CRT-P implantations. The remaining studies analyzed pacemaker and ICD implantations (n=4), or pacemaker, ICD and CRT implantations (n=7) in different temporal and geographic contexts.

The level of detail of within country analyses (n=37) differed between the studies. As shown in Figure 3, only 7 (19%) studies reported a comprehensive analysis of national, regional, province, and hospital data. The remaining 30 (81%) within-country studies presented national (n=8), regional/macroregional (n=13), province (n=2), or hospital (n=7) data, respectively.

Figure 3: Level of detail of data provided by within-country analysis (n = 37)



3.3. Device implant rates

An overview of studies on pacemaker and ICD IR is presented in the following tables. There is a broad heterogeneity among the studies as regards to data presentation (first implants/replacements versus first implants only; IR versus absolute implant number; CRT-P/CRT-D included or not). Published data on within country and across countries IR refer to different time intervals and show wide time dispersion.

Table 2 presents within country and across countries studies on pacemaker (± CRT-P) IR. Over the time period from 2003 to 2010 there was a trend towards increasing pacemaker and CRT-P use in Spain.[13-19] In 2011 the use of conventional pacemakers remained stable with respect to previous years.[20] In Italy, over the quinquennium 2003-2007 the absolute number of conventional pacemaker implantations was substantially stable (30820 in 2003, 32047 in 2004, 31870 in 2005, 31813 in 2006, and 31146 in 2007).[22] An increase in pacemaker and CRT-P

implantations was observed in France between 2008 and 2009.[23] In the world surveys of cardiac pacing,[10,24,25] most European countries showed an increase in new pacemaker implants per million population compared with previous years. However, data from the EHRA registry showed wide variations in pacemaker implant rates from country to country.[26] Among the countries participating to the EHRA White Book,[9] the mean pacemaker IR in 2011 was 604 units per million inhabitants, with the highest IR in Germany (1313) and the lowest in Azerbaijan (15).

Table 2: Studies on pacemaker IR (per million inhabitants). *: CRT-P included. ^: first implants. □: data reported as absolute implant number.

Study	Country	PM implantations per million inhabitants								
		2003	2004	2005	2006	2007	2008	2009	2010	2011
Coma Samartin.[13]	Spain	521.9								
Coma Samartin et al.[14]	Spain			638.7						
Coma Samartin et al.[15]	Spain				668.6*					
Coma Samartin et al.[16]	Spain					680.4*				
Coma Samartin et al.[17]	Spain						708.3*			
Coma Samartin et al.[18]	Spain							729.2*		
Coma Samartin et al.[19]	Spain								738.0*	
Coma Samartin et al.[20]	Spain									738.2*
Morais et al.[21]	Portugal	497.0^								
Proclemer et al.[22]	Italy	□	□	□	□	□				
Tuppin et al.[23]	France						955.7*	1003.7*		
Mond et al.[10]	22 EU countries									
Mond et al.[24]	16 EU countries			(Ref.13)						
Mond et al.[25]	25 EU countries							(Ref.14)		
Ector et al.[26]	20 EU countries	(Ref.15)	(Ref.15)	(Ref.15)						

Arribas et al.[9]	46 EU countries									(Ref.16)
Ovsyshcher et al.[12]	EU countries	(Ref.17)								
Merkely et al.[27]	Hungary				561.0					
Short R.[28]	Poland				548.0					

Table 3 presents within country and across countries studies on ICD (± CRT-D) IR. In the last decade there has been a progressive increase in the number of ICD implantations in Europe. Detailed data from the Spanish[8,29-35], Portuguese[37-42], Italian,[43-46] and French ICD registries have been published. A marked heterogeneity in the geographic distribution of ICD IR has been observed across countries.[9,26,53] Among the countries participating to the EHRA White Book, over the years 2006 to 2008 the median ICD implantations was constantly increasing from 39 to 75 per million inhabitants.[55] In 2008 highest ICD IR were observed in Italy, Germany, and Denmark.[55] In 2011 the mean ICD IR was 103 units per million inhabitants;[9] after excluding San Marino, the countries with the highest ICD IR were Germany (326) and Czech Republic (270), and those with the lowest IR were Ukraine and Morocco (1).[9] Also the number of CRT implantations (CRT-P and CRT-D) showed great geographic variability, from as low as 1/million inhabitants (Morocco) to as high as 203/million inhabitants (Italy) in 2011.[9]

Table 3: Studies on ICD IR (per million inhabitants). *: CRT-D included. ^: first implants. ✓: implant rates per 100000 inhabitants. □□ : data reported as absolute implant number.

Study	Country	ICD implantations per million inhabitants									
		2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
Peinado et al.[8]	Spain		24.0*	33.0*							
Peinado et al.[29]	Spain				46.5*						
Peinado et al.[30]	Spain					60.0*					
Peinado et al.[31]	Spain						72.8*				
Peinado et al.[32]	Spain							76.0*			

Alzueta et al.[33]	Spain								89.0*		
Alzueta et al.[34]	Spain									100.6*	
Alzueta et al.[35]	Spain										97.0*
Fitch-Warner et al.[36]	Spain		46.0								
De Sousa et al.[37]	Portugal		21.6^*								
Bonhorst et al.[38]	Portugal			34.4^*							
Bonhorst et al.[39]	Portugal				54.0^*						
Da Silva et al.[40]	Portugal					67.4^*					
Da Silva et al.[41]	Portugal						82.7^*	96.5^*			
Ventura et al.[42]	Portugal								98.1^*		
Proclemer et al.[43]	Italy	70.0*	98.3*	125.0*							
Proclemer et al.[44]	Italy	69.0*	93.3*								
Proclemer et al.[45]	Italy				180.6*	192.5*	220.6*				
Boriani et al.[46]	Emilia Romagna (Italy)					11.0✓	12.6✓	16.2✓			
Tuppin et al.[23]	France							116.9*	140.8*		
Lazarus et al.[47]	France							126.0*	147.0*		
McComb et al.[48]	England	☐									
Scott et al.[49]	Wessex Cardiothoracic Unit (UK)						☐				
Cunningham et al.[50]	UK	31.5									
Parkes et al.[51]	UK	30.0									
Mond et al.[10]	22 EU countries										
Mond et al.[24]	16 EU countries				(Ref.13)						
Mond et al.[25]	25 EU countries								(Ref.14)		
Seidl et al.[52]	Western Europe	(Ref.44)									

Ector et al.[26]	20 EU countries		(Ref.15)	(Ref.15)	(Ref.15)						
Arribas et al.[9]	46 EU countries										(Ref.16)
Ovsyshcher et al.[12]	EU countries		(Ref.17)								
van Veldhuisen et al.[53]	15 EU countries			(Ref.45)	(Ref.45)	(Ref.45)	(Ref.45)	(Ref.45)			
Merkely et al.[54]	41 EU countries					(Ref.46)	(Ref.46)	(Ref.46)			
Lubinski et al.[55]	41 EU countries							(Ref.47)	(Ref.47)		
Camm et al.[56]	16 EU countries				(Ref.48)	(Ref.48)	(Ref.48)				
Merkely et al.[27]	Hungary					561.0					
Short R.[28]	Poland					548.0					

3.4. Variables influencing implant rate variability

Among the variables taken into consideration to explain across countries and within country IR variability, the following seem to play an important role: demographic structure of the population; epidemiology of heart disease; associated risk factors; practices and recommendations; health system and social security system; clinical implementation of scientific evidence. However, few studies[36,48,54] have reported a systematic analysis of the relationship between IR and factors that might influence access to device therapy.

ICD IR was found to correlate with financial indicators like gross domestic product or healthcare spending.[36] Beyond reimbursement, the number of CRT implantations correlated with the number of ICD, suggesting that the limitations for widespread utilization of CRT may also be technical. However, discrepancies were observed between different analyses, and in the study by McComb et al.[40] none of the factors examined was found to correlate with regional ICD implantations per million in England.

4. Discussion

In this systematic review of 48 studies on pacemaker and ICD implantations in Europe, a marked heterogeneity in data sources, time intervals, considered devices, and detail of the analysis was observed. An increase in pacemaker and ICD IR was observed in European countries over the last decade, with substantial geographic variations across countries and within country. IR variability seems to be affected by several epidemiological, medical, and socio-economical factors, but few systematic analyses have been performed on the relationship between IR and variables that might influence access to device therapy.

Within country and across countries analyses were based on heterogeneous data sources. National registries for pacemaker and ICD implantations exist only in selected European countries, where they have represented the source of yearly-published reports. Of note, national registry data which were available online but not published were not included in this review. The EHRA White Book publications gathered data from several European countries[9,54,55] providing comprehensive information from specific questionnaires: in many countries, national registry data were used as data source; in other countries, a national survey was conducted, or reasonable estimates were used if no exact data were available.[54,55] Alternatively, data on ICD and pacemaker implantations were provided by the Eucomed registry, based on raw data from device sales provided by manufacturers on a voluntary basis.[53] Owing to the nature of the Eucomed registry, many clinical data were not available.[53] Therefore, concerns on the survey formats have arisen as regards to heterogeneous data sources and limited clinical information. It should be noted that published data represent a reasonable estimate but not the absolute reality of device IR, since even the best national or international registry does not cover 100% of the implants.[54]

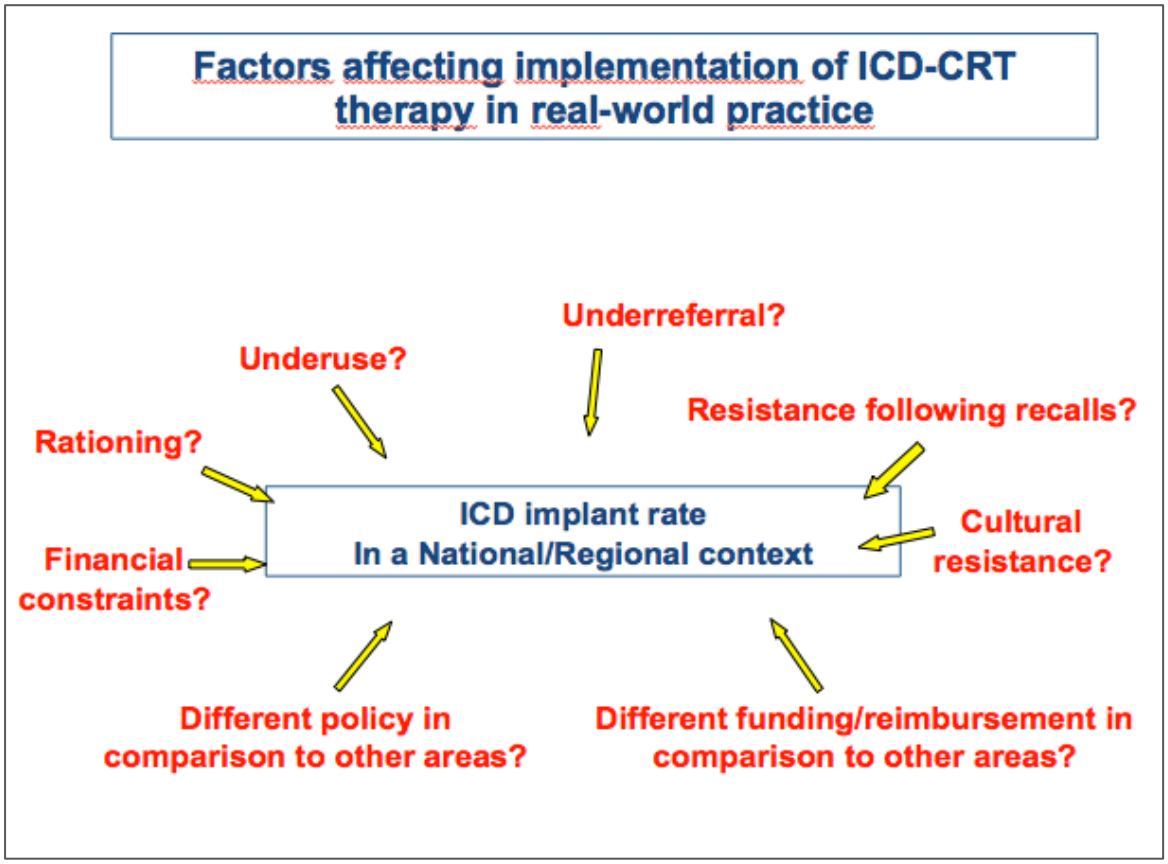
Yearly reports on ICD implantations have been published only from the Spanish and Portuguese registries. Studies on pacing and ICD implantations in the other European countries show a broad temporal dispersion. Moreover, available literature is heterogeneous as regards to the object of the analysis (pacemakers, ICDs, CRT devices), and the level of provided details. National, regional, province, and hospital data are variously reported by the available studies. These data give a multiform picture of pacemaker and ICD IR across European countries.

In the last decade pacemaker and ICD (with or without CRT) IR have increased in all the Western European countries.[56] More specifically, IR of ICD and CRT-D have increased enormously,[53] based on large clinical trial results and implementation of current guidelines.[1-5] However, despite continuing annual growth in the rate of device implantations, still in many countries these devices are underused by comparison with the European average.[9,56]

Large differences in IR have been documented across European countries.[9,12,52-56] Despite the established efficacy of pacemakers and ICDs in clinical practice and the broadening indications for heart failure devices, pacemaker and ICD IR seem to depend heavily on national economic status.[12] The cost of implantable devices and the overall cost of medical care are primary determinants of across countries IR variations.[12] The total Gross Domestic Product (GDP) and GDP per capita were shown to directly correlate with ICD implants.[55] Moreover, a higher expenditure on health positively correlated with implantation rates.[55] Beside economic factor, demographic variables seem to influence IR variability. Population distributions vary among countries, resulting in different proportions of candidates for device therapy.[12] Another important reason for geographic differences in ICD utilization seems to be the number of implanting centres and electrophysiologists.[56] Indeed, some correlation was found between the rate of ICD implantations and the number of implanting centres.[56] As regards CRT devices, the recent growth in IR was found to be higher in countries with better adherence to clinical guidelines and reimbursement practices.[54] Since the number of CRT implantations was found to have a better correlation with ICD implantations than with financial indicators, limitations for widespread utilization of CRT may also be technical.[54]

In a general view, many factors should be taken into account to explain IR variability in a national and even in a regional context (Figure 4). Among these, cultural resistance, under referral, different policies or funding/reimbursement practices seem to play an important role. Potential barriers to device therapy are more complex than those existing for pharmacological therapy, and a systematic approach at the level of patients, providers, hospitals, and health care organization systems is required.[46]

Figure 4



Geographic variations in the rate of pacemaker and ICD implantations were found not only across countries but also within each country. In Spain significant variations in the number of ICD implants were observed between the autonomous communities.[8,29-35] The same was described in Portugal.[37-42] In the study by Lazarus et al,[47] the Ile de France region showed the highest crude number of ICD implantations in France and a number of centres per million inhabitants identical to the national average. Use of ICDs was also found to vary between English health regions.[50] In Italy the rate of ICD implantations differed markedly in the three different macro regions, with the highest IR in North Italy.[43-44] Moreover, differences in device IR were observed even between provinces within the same Italian region (i.e. Emilia Romagna).[46]

These wide differences in IR within country may be attributed to economic factors, aspects of health care organization, number and level of development of electrophysiology centres.[35] In a study on the variations in the utilization of cardiovascular technologies between Spanish autonomous communities, Fitch-Warner et al[36] drew

attention to the influence of the offer of health care linked to regional resources. In the same study, the regional variation in the use of medical technologies was mainly explained by differences in regional wealth and not in disease burden.[36] Other possible reasons of within country IR variability might be demographic (incidence of sudden death and ischemic heart disease in the general population), and cultural (degree of acceptance of the results of clinical trials and practice guidelines, level of education of the population).[35] However, in the study by McComb et al,[40] no factor was found to correlate with regional ICD implantations per million in England.

Further systematic analyses are therefore warranted on the relationship between device IR variability and socio-economical and clinical factors. This would help clarify geographic discrepancies in device IR across and within European countries, in the attempt of ensuring a more homogeneous access to this technology.

5. Conclusions

Pacemaker, ICD, and CRT devices IR have been the objects of several across countries and within country analyses. The available published data differ for heterogeneous data sources, time intervals, level of detail of the analysis, and considered devices. Differences in IR can be observed between countries, between regions in the same country, and even between provinces in the same region. Several factors may affect IR variability, and further research is required to clarify the reasons for the observed differences in device therapy implementation.

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