European Journal of Internal Medicine xxx (xxxx) xxx–xxx

Contents lists available at ScienceDirect

European Journal of Internal Medicine

journal homepage: www.elsevier.com/locate/ejim

Original article

Seventeen-year trend (2001–2017) in pacemaker and implantable cardioverter-defibrillator utilization based on hospital discharge database data: An analysis by age groups

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ARTICLE INFO

Keywords:
Health administrative data, Registry, Pacemaker
Implantable cardioverter-defibrillator
Cardiac Resynchronization Therapy

ABSTRACT

Aims: To analyze temporal trends (2001 -2017) of Pacemakers (PM) and Implantable Cardioverter-Defibrillators (ICD) procedures in Italy, according to the national Hospital Discharge Database (HDD).
Methods: Frequency and implant rate (IR) in the Italian population were analyzed by age groups (<50, 50–79, ≥80 years).
Results: From 2001 (2009 for Cardiac Resynchronization Therapy-Defibrillator – CRT-D) to 2017, first PM implants (1stPM) increased from 36,823 (637/million inhabitants) to 49,716 (820/million), ICD implants from 3,141 (54/million) to 24,255 (400/million) and CRT-D from 2,915 (49/million, 16.5% of ICD) to 8,595 (142/million, 35.4% of ICD).

ICD implants due to ventricular tachycardia or ventricular fibrillation decreased from 55.6% to 13.5% and from 15.9% to 4.5% respectively, while the proportion increased among patients with heart failure (from 22.9% to 46.8%), hypertension (from 11.1% to 15.0%), diabetes (from 6.5% to 10.9%), and renal insufficiency (from 4.4% to 7.6%). Both PM and ICD procedures markedly increased in patients ≥80 years old. However, while IR for ICDs increased from 82/million to 1,038/million inhabitants, IR of 1stPM only changed from 6,111/million to 6,212/million as the population in this age group nearly doubled in Italy.
Conclusion: Since 2001, the increase of 1stPM in Italy was mainly due to the ultra-octogenarian population growth. No differences were observed for IR in each PM age group, while the absolute number and IR increased in all groups (especially ≥80 years old) for ICDs and CRT-Ds. An increase in comorbidities and a reduction in implants for secondary prevention were observed in the ICD population.

1. Introduction

National Registries are needed to monitor health care interventions, optimize the resources and utilize them appropriately [1], but are challenging to implement and manage due to the possible lack and/or inadequacy of data. Moreover, considerable human commitment and substantial economic resources are required to ensure high-quality data collection [2]. Currently, participation in Registries is still mainly voluntary, while to achieve comprehensive data, it should be mandatory and ruled at a national level [3]. Also, thorough databases can be widely variable within and across countries [4]. In Italy, the Registry of Pacemakers (PM) and Implantable Cardioverter-Defibrillators (ICD) is provided by the National Society of Arrhythmology (Associazione Italiana di Aritmologia e Cardiostimolazione-AIAC). Data are collected voluntarily by implanting physicians, according to the European PM card and European Patient-Implantable Cardioverter/Defibrillator Identification Card (EURID/Eucomed) [5].

Cardiovascular Implantable Electronic Devices (CIED) are almost

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https://doi.org/10.1016/j.ejim.2020.09.003
Received 5 January 2020; Received in revised form 31 August 2020; Accepted 2 September 2020

totally provided by the national health system, and implant procedures are routinely recorded in the national Hospital Discharge Database (HDD) of the Hospital Discharge Records (HDR). Every year the Italian National Institute of Health (NIH, Istituto Superiore di Sanità-ISS) receives the HDD from the Ministry of Health (MoH) to run epidemiological studies in the public health domain. In particular, the Italian National Registry of the implantable prostheses, established at NIH (Italia. Decreto del Presidente del Consiglio dei Ministri 3 Marzo 2017. Gazzetta Ufficiale – Serie Generale n. 109, 12 Maggio 2017), analyses HDRs to map and monitor the national implant activity of selected prostheses. Analysing HDRs grants several advantages. Firstly, it allows accurate quantification of all implanted devices; as a matter of fact, both private and public clinics receive reimbursement only if the HDR related to the procedure is correctly submitted to the regional health authority. Secondly, all the procedures and diagnoses are coded by following the international standards ("International Classification of Diseases, 9th Revision, Clinical Modification" ICD9-CM).

On the other hand, HDRs present some limitations as they are mainly considered as administrative and not as scientific tools. Consequently, in some cases, the coding might be inaccurate or biased mainly by under-coding comorbidities and risk factors [6]. Finally, HDRs do not provide any association between patients and device information, hampering any investigation on device duration.

Our study aimed to review HDD, in order to quantify the PM and ICD procedures that were performed throughout 17 years (2001–2017) in Italy and the related diagnoses and to analyze their temporal trends by age groups of patients.

2. Methods

2.1. The national health system and the hospital discharge data collection

In Italy, the National Health System (NHS) is public. It was set up in 1978 (Law 23, December 1978, n. 833) and founded on the three fundamental principles of universality of assistance, equality of access, and solidarity. Although each Region is autonomously responsible for its health service, both public and private hospitalizations are routinely recorded in the HDD. This one is a standardized data collection at a national level, based on the ICD-9-CM, that includes demographic and clinical information, such as diagnoses (principal and up to five secondary diagnoses, or comorbidities) and performed procedures (principal and up to five secondary procedures). Hospitals send data to the Regional Health Authority, which on its side, is responsible for the quality check before transmitting data to the MoH. Hospital admissions are reimbursed by the Regional Health Authority, according to the Diagnosis Related Groups of the reported principal diagnosis [3].

2.2. National population data

The Italian National Institute of Statistics (ISTAT, www.istat.it/en/ISTAT) is the main producer of official statistics for citizens and policymakers. It operates independently in agreement with the academic and scientific community; since 2001, it publishes yearly the resident population data, distinguished by age and gender.

2.3. Analysis of procedures

Two cardiologists (MZ, GB) selected the ICD9-CM codes, single and combined, relating to PM and ICD procedures and, in cooperation with an Information Technology expert (ECa) and a mechanical engineer (MT), defined a taxonomy arranged into 16 groups of procedures to be further analyzed (**online Table 1**). All HDRs between 2001 and 2017 (the latest year available on April 2020) were reviewed; among these, only the records including ICD or PM procedures correctly reporting patient's age and gender, were selected. Duplicated procedures in the same record were counted once. The frequency and implant rate (IR) of PMs, ICDs, and CRT-Ds for all the patients were computed based on the national population data. Also, data were analyzed by pre-determined age groups (<50; 50–79; ≥ 80 years).

The statistical analysis concerned counts and the computation of descriptive statistics, without inferential approaches, and was performed by using the software R, version 3.6.3 (2020–02–29) "Holding the Windsock".

2.4. Analysis of diagnoses

In the subset of the selected procedures, all the different diagnoses were identified and sorted by frequency. Among these, only diagnoses associated with PM and ICD implants and most significant comorbidities were selected by a cardiologist (MZ), to capture $>98\%$ of the subset. Then, these diagnoses were classified and sorted by indication, etiology, cardiac diagnosis, and non-cardiac diagnosis. The frequency of each diagnosis associated with 1stPM and ICD implants was calculated for each age group (<50; 50–79; ≥ 80 years). Only the most frequent or clinically relevant diagnoses were displayed. For ICD implants, patients with a diagnosis of Ventricular Tachycardia (VT) or Ventricular Fibrillation (VF) were considered treated for secondary prevention of sudden death.

3. Results

Between 2001 and 2017, 1202,975 procedures were performed (**online Table 2**). Among the 5672 different diagnoses associated to the selected procedures, 418 single ICD9-CM codes were identified to capture $>98\%$ of the procedures. These diagnoses were classified in 42 classes, grouped by indication, etiology, cardiac diagnosis, and non-cardiac diagnosis) (**online Table 3**).

3.1. Pacemakers

In the time-lapse from 2001 to 2017 (Table 1) the Italian population increased from 57,844,017 to 60,589,445 (http://demo.istat.it/). According to the HDRs analysis, during the same period, 1stPMs increased from 36,823 (637/million inhabitants) in 2001 to 49,716 (821/million inhabitants) in 2017 (**Fig. 1a, 1c**). Regarding PM replacements, there was an increase in both the number and proportion out of the total PMs implanted from 2001 (respectively 11,205 and 23%) to 2010 (18,402 and 29%), while a reduction was observed from 2010 to 2017 (16,207 PM replacements and 25%) (**online Table 2, Fig. 1a**). As a consequence, the total number of implanted PMs was stable and even decreased during the last year under analysis (**Fig. 1a**).

Table 1 reports demographic data, principal diagnosis, and comorbidities among patients receiving a 1stPM in years 2001, 2009 and 2017. More detailed data are available online (**online Table 4**)

The most frequent diagnosis for 1stPMs was atrioventricular (AV) block (51.5% in 2001, 51.2% in 2017); atrial fibrillation (AF) was diagnosed in 21.0% (2001) and 23.2% (2017) of patients. The proportion of patients affected by sick sinus syndrome (SSS) increased (20.3% to 27.2%) while those with syncope (14.9% to 17.3%) were quite unchanged. Ischemic heart disease decreased from 17.5% to 14.2% of cases. The most frequent non-cardiac diagnosis was hypertension (31.9% in 2001 and 28.8% in 2017).

3.1.1. Patients younger than 50 years

Throughout the period under observation, people younger than 50 years represented the highest portion of the Italian population (Table 1), but 1stPMs in this age group accounted for only about 2% of all performed procedures (**Fig. 1b**), with an IR varying from 18 to 23/million inhabitants (**Fig. 1c**).

Even in this group, AV block was the most frequent indication (52.5% in 2001, 49.9% in 2017); and the increase in SSS (from 11.4% to 19.3%) was evident. Syncope was present in 18.1% to 18.4% while

Table 1
1st PM implant procedures. Demographic data of patients and distribution of diagnoses per age group and per year (Source Italian Hospital Discharge Database and ISTAT population database for years 2001, 2009 and 2017).

Diagnosis group	Age group / Diagnosis class	All ages 2001	All ages 2009	All ages 2017	< 50 years 2001	< 50 years 2009	< 50 years 2017	50 - 79 years 2001	50 - 79 years 2009	50 - 79 years 2017	≥ 80 years 2001	≥ 80 years 2009	≥ 80 years 2017
	Italian population	57,844,017	60,045,068	60,589,445	36,555,227	36,724,895	34,30,099	18,899,836	19,947,458	22,149,692	2388,954	3372,715	4132,654
	N. of procedures	36,823	44,067	49,716	648	746	794	21,575	23,107	23,249	14,600	20,214	25,673
	Mean age (years)	76	77	78	35	35	33	71	72	72	85	85	85
	SD (±)	11	10	10	14	14	16	6	6	6	4	4	4
	% Males	*56.7%*	*56.6%*	*58.0%*	*61.3%*	*61.8%*	*60.2%*	*61.4%*	*61.8%*	*63.5%*	*49.7%*	*50.5%*	*53.0%*
Indication	Atrio-Ventricular block	.51.5%	50.3%	51.2%	52.5%	53.8%	49.9%	48.9%	48.3%	50.1%	55.2%	52.4%	52.3%
	Sick sinus syndrome	20.3%	25.1%	27.2%	11.4%	17.4%	19.3%	21.8%	26.9%	29.3%	18.4%	23.2%	25.6%
	Syncope	14.9%	17.5%	17.3%	18.1%	20.5%	18.4%	14.0%	17.4%	17.5%	15.9%	17.5%	17.1%
	Bifascicular block*	3.5%	3.2%	3.1%	1.9%	1.6%	1.4%	3.8%	3.1%	3.1%	3.2%	3.3%	3.5%
Etiology	Ischemic heart disease	17.5%	15.7%	14.2%	5.4%	4.2%	4.4%	18.5%	16.7%	15.3%	16.4%	15.0%	13.5%
	Valvular heart disease	8.4%	9.3%	10.3%	12.3%	9.0%	10.2%	9.1%	9.3%	9.5%	7.2%	9.3%	11.1%
	Hypertensive heart disease	2.2%	2.8%	2.7%	0.2%	0.4%	0.4%	2.0%	2.3%	2.1%	2.5%	3.5%	3.3%
	Idiopathic cardiomyopathy	3.2%	1.6%	1.0%	5.4%	3.8%	2.8%	4.3%	1.8%	1.2%	1.7%	1.3%	0.8%
	Congenital heart disease	0.3%	0.3%	0.2%	7.6%	8.2%	6.7%	0.2%	0.2%	0.2%	0.0%	0.0%	0.1%
	Hypertrophic cardiomyopathy	0.3%	0.1%	0.2%	0.8%	0.3%	0.8%	0.4%	0.2%	0.2%	0.2%	0.1%	0.1%
Cardiac diagnosis	Atrial Fibrillation	21.0%	21.4%	23.2%	8.0%	5.2%	5.2%	20.8%	20.3%	20.9%	21.9%	23.3%	25.8%
	Heart failure	13.0%	10.0%	10.3%	9.1%	5.8%	4.4%	12.5%	8.3%	8.3%	13.8%	12.1%	12.3%
Non Cardiac diagnosis	Hypertension	31.9%	33.6%	28.8%	5.7%	8.4%	6.0%	32.6%	34.6%	29.1%	32.2%	33.4%	29.2%
	Diabetes	11.6%	12.6%	11.6%	3.1%	2.9%	2.6%	12.7%	14.1%	12.7%	10.4%	11.3%	10.9%
	Vascular disease	7.7%	7.2%	5.8%	2.8%	3.1%	3.5%	6.9%	6.4%	5.2%	9.2%	8.3%	6.3%
	Renal insufficiency	4.90%	7.0%	8.4%	2.0%	1.3%	2.0%	3.9%	5.1%	5.7%	6.5%	9.3%	11.0%
	Obstructive pulmonary disease	6.6%	5.7%	4.3%	1.4%	1.6%	0.8%	5.9%	4.8%	3.5%	7.7%	6.9%	5.1%

* Bifascicular block: Right Bundle Branch Block and Left Posterior Fascicular Block (RBBB + LPFB); Right Bundle Branch Block and Left Anterior Fascicular Block (RBBB + LAFB); Left Bundle Branch Block (LBBB).

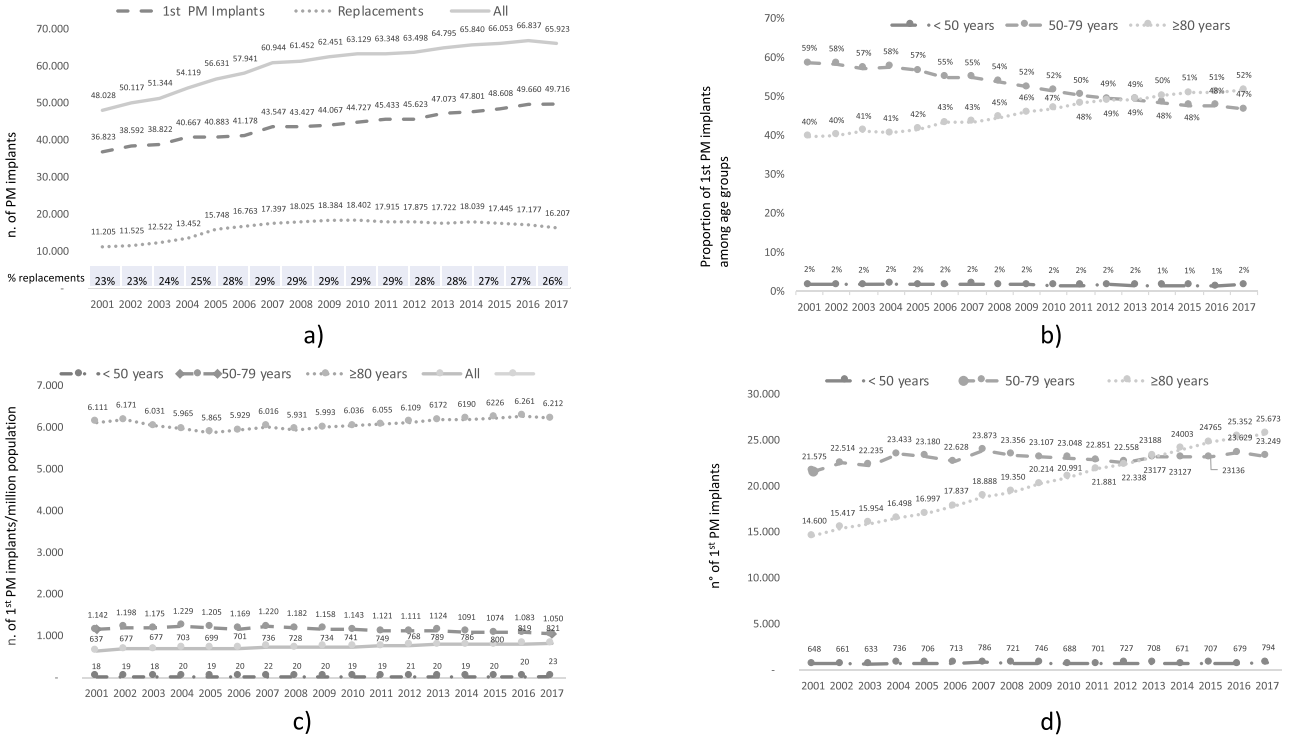

Fig. 1. PM implant procedures. a) N. of 1st implants, replacement and all PM implant procedures and percentage of replacements per year; b) Distribution of 1stPM implant procedures by age class per year; c) Implant rate (IR) per million inhabitants by age group per year; d) N. of 1stPM implants by age group per year.

AF percentage was lower (8.0% in 2001, 5.2% in 2017); the most recurrent aetiologies were valvular (12.3% in 2001, 10.2% in 2017), congenital (7.6% in 2001, 6.7% in 2017) and ischemic heart disease (5.4% in 2001, 4.4% in 2017).

As for comorbidities, a reduction in the diagnosis of heart failure (9.1% in 2001, 4.4% in 2017) and minor variations of the proportion of patients affected by diabetes (3.1% to 2.6%), hypertension (5.7% to 6.0%), obstructive pulmonary disease (1.4% to 0.8%) and renal insufficiency (2.0%) were observed.

3.1.2. *Patients older than 80 years*

During the period under analysis there was an increase in the number of 1stPMs among patients >80 years old, from 14,600 (representing 40% of total 1stPMs) to 25,673 (52% of 1stPMs) (Table 1, Fig. 1**b**, 1**d**). However, the IR only changed slightly, from 6111 to 6212/million (Fig. 1**c**), as the number of ultra-octogenarians living in Italy nearly doubled, from 2388,954 in 2001 to 4132,654 in 2017.

The proportion of patients affected by AV block and SSS, the distribution of heart diseases, the frequency of syncope and AF as well as non-cardiac diagnoses kept similar to those of general population who underwent 1stPM implantation.

3.2. *Implantable Cardioverter-Defibrillators*

During the period under study, the total number of implanted ICDs (either 1st implant or replacement) and IR increased from 3141 to 24,255 and from 54 to 400/million inhabitants, respectively (Fig. 2**a,** 2**c**).

The number of implanted CRT-Ds increased from 2915 in 2009 (the first year with a specific code for these devices) to 8595 in 2017 (Fig. 2**b**) with an IR increase from 49 to 142/million inhabitants (Fig. 2**d**) and a rise in the CRT/total ICD proportion from 16.5% to 35.4% (Table 2).

Cardiac diagnosis and comorbidities among patients treated with ICD in the years 2001, 2009, and 2017 are shown in Table 2. More detailed data are available online (**online Table 5**).

The mean age increased from 65 ± 13 to 68 ± 13 years, while the proportion of males reduced from 81% to 78.6%.

The ischemic heart disease was the most frequent diagnosis throughout the period, although its proportion decreased through the years (41.8% in 2001, 32.6% in 2017).

From 2001 to 2017, patients with VT dropped from 55.6% to 13.5% and patients with VF from 15.9% to 4.5%.

An increase in the proportion of heart failure (from 22.9% to 46.8%), hypertension (from 11.1% to 15.0%), diabetes mellitus (6.5% to 10.9%) and renal insufficiency (from 4.4% to 7.6%) was observed.

3.2.1. *Patient younger than 50 years*

In this group, the number of implanted ICDs increased from 367 (10/million inhabitants) to 1987 (58/million) (Fig. 2**c**); however, the weight of this group on the total number of ICDs decreased from 11.7% to 8.2% (Table 2).

The most frequent diagnosis was idiopathic cardiomyopathy (30.2% in 2001, 26.1% in 2017); ischemic heart disease was present in 13.6% of patients in 2001, and 10.9% in 2017.

From 2001 to 2017, patients with VT dropped from 49% to 14.7% and patients with VF from 22.3% to 10.1%.

Finally, the proportion of patients with a diagnosis of heart failure (from 12.0% to 30.9%), hypertension (from 3.8% to 7.2%), diabetes mellitus (1.4% to 3.8%) and renal insufficiency (from 1.1% to 1.6%) increased during the period under analysis.

3.2.2. *Patient older than 80 years*

Among patients aged more than 80, the number of ICDs increased from 195 (82/million inhabitants) to 4290 (1038/million inhabitants) (Fig. 2**a,** 2**c**); the highest IR value was registered in 2016 with a slight reduction in 2017 (Fig. 2**c,** 2**d**). The weight of this group on the total number of ICDs increased from 6.2% in 2001 to 17.7% in 2017

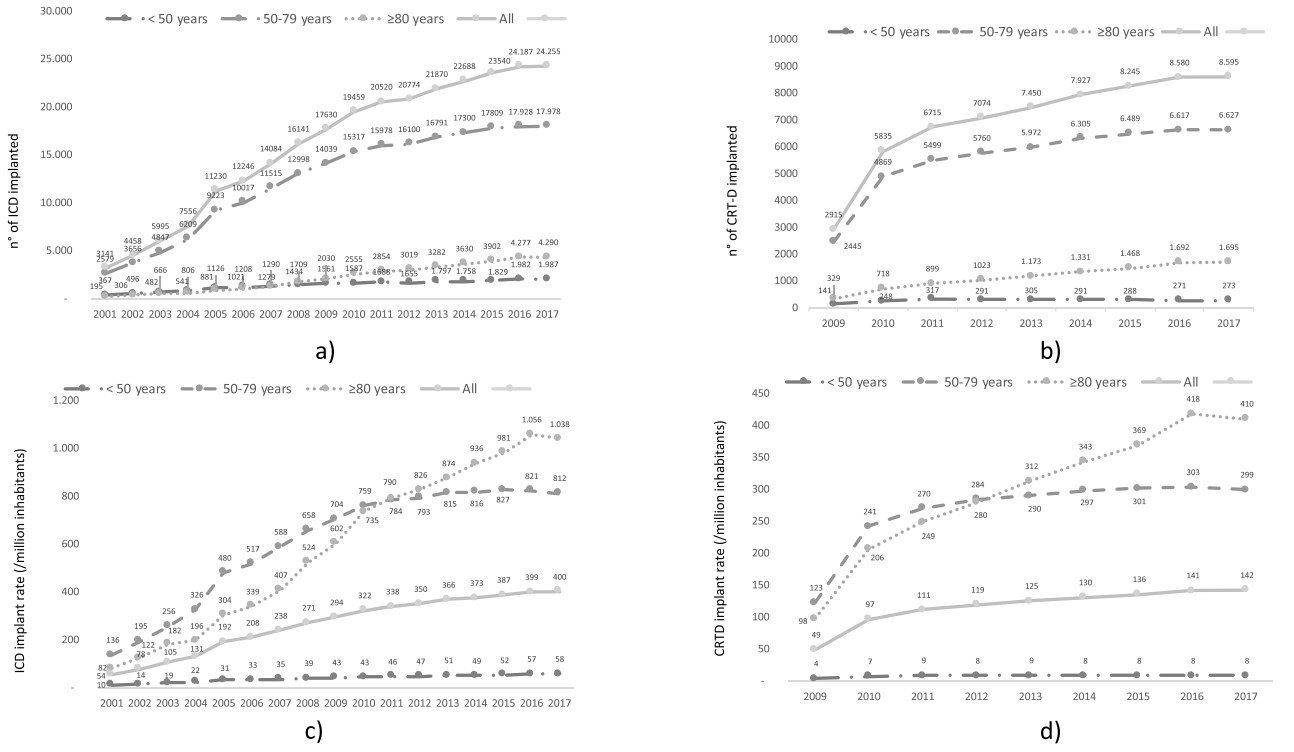

Fig. 2. All ICD implant procedures. a) N. of ICD implants by age group per year; b) N. of CRT-D implants by age group per year; c) ICD Implant rate (IR) per million inhabitants by age group per year; d) CRT-D IR per million inhabitants by age group per year.

(Table 2).

Ischemic heart disease was the most frequent diagnosis like it appears to be for the general population undergoing ICD procedures, even though a decrease was observed in the last years (43.6% in 2001, 31.9% in 2017).

As observed in the other two age groups, patients with VT decreased from 50.3% to 13.9% and with VF from 15.4% to 2.9%.

Instead, there was an increase in the proportion of diagnoses of heart failure (from 22.1% to 44.4), hypertension (from 11.8% to 15.9%), diabetes mellitus (5.6% to 10.2%), and renal insufficiency (from 7.2% to 11.9%).

4. Discussion

The analysis of PM and ICD procedures performed in Italy from 2001 to 2017 resulted in seven key findings:

1) There was a steady rise in ICDs, CRT-Ds, and 1stPMs;
2) The increase in the 1stPMs was only due to the augmentation of the ultra-octogenarian population, but IR remained unmodified in each group;
3) There was a reduction in PM replacements since 2010;
4) The increase in IR for ICDs and CRT-Ds was evident in all age groups, but particularly among ultra-octogenarians;
5) CRT-Ds represented only 1/7 of all ICDs implanted among patients <50 years old, while it was about 1/3 in the other age groups;
6) The proportion (but not the absolute number) of patients treated for secondary prevention (VT or VF) dramatically decreased since early 2000;
7) An increase in comorbidities was observed among ICD patients, but not among those treated with 1stPM.

A review of data collected from 2006 to 2016 by the existing cardiac implant registries was recently published [7]. Completeness is the "ratio between the number of procedures submitted to the Registry and the number of procedures performed in a specific geographical area" [8]. It is a widely used indicator to assess data collection quality. However, even if mandatory, data collection can be incomplete [9]: an analysis performed by the French Society of Cardiology (comparing data from manufacturer's database) revealed that only 57% of all ICDs implanted in 2009 were reported, with marked regional differences.

European data about the PM and ICD implants are provided by the EHRA White Book (https://www.escardio.org/Sub-specialty-communities/European-Heart-Rhythm-Association-(EHRA)/Research-and-Publications/The-EHRA-White-Books). However, even these data are incomplete, as not collected in a reliable Registry in all European countries. In Italy, the National PM and ICD Registry of the Italian Society of Arrhythmology and Cardiac Pacing (AIAC) collects data about implants, based on the European PM card and the European Patient-Implantable Cardioverter/Defibrillator Identification Card (EURID/Eucomed) [5,9-12]. The Registry provides a full overview of the recorded implantable devices, their attributes, and some information relating to patients' personal and clinical data. It also collects specific information to identify and monitor devices over time, providing data about their lifespan. Currently, data are only collected on a voluntary basis; therefore, the Registry cannot ensure high completeness. Also, data about comorbidities are not available, and only limited information about diagnosis/etiology is provided.

In our study all procedures (if provided by the Nation Health System) performed were included, together with major cardiac and non-cardiac diagnosis resulting al Hospital discharge.

4.1. Pacemaker

According to our data, the increase in 1stPMs observed in Italy during the period under analysis was mostly due to the rise in the number of implants performed in ultra-octogenarians, even if the IR did not change in any group. The increased need of devices was explained

Table 2
ICD implant procedures. Demographic data of patients and distribution of diagnoses per age group and per year (sources: Italian Hospital Discharge Database and ISTAT population database for years 2001, 2009 and 2017).

	Age group	All ages			< 50 years			50–79 years			≥ 80 years		
Diagnosis group	Diagnosis class	2001	2009	2017	2001	2009	2017	2001	2009	2017	2001	2009	2017
	Italian population	57,844,017	60,045,068	60,589,445	36,555,227	36,724,895	34,307,099	18,899,836	19,947,458	22,149,692	2,388,954	3,372,715	4,132,654
	Number of procedures	3,141	17,630	24,255	367	1,561	1,987	2,579	14,039	17,978	195	2,030	4,290
	% of CRT-D among all ICD	*n.a.*	*16.5%*	*35.4%*	*n.a.*	*9.0%*	*13.7%*	*n.a.*	*17.4%*	*36.9%*	*n.a.*	*16.2%*	*39.5%*
	% of CRT-D among all CRT-D	*n.a.*	*100.0%*	*100.0%*	*n.a.*	*4.8%*	*3.2%*	*n.a.*	*83.9%*	*77.1%*	*n.a.*	*11.3%*	*19.7%*
	% of ICD among all ICD	*100.0%*	*100.0%*	*100.0%*	*11.7%*	*8.9%*	*8.2%*	*82.1%*	*79.6%*	*74.1%*	*6.2%*	*11.5%*	*17.7%*
	Mean age (years)	65	67	68	38	40	40	67	68	68	83	83	83
	SD (±)	13	12	13	10	9	9	7	8	8	3	3	3
	% Males	*81.0%*	*79.8%*	*78.6%*	*69.8%*	*76.0%*	*75.7%*	*83.4%*	*80.7%*	*79.9%*	*70.3%*	*75.9%*	*74.7%*
Indication	Ventricular Tachycardia	55.6%	19.6%	13.5%	49.0%	21.0%	14.7%	56.9%	19.2%	13.3%	50.3%	21.6%	13.9%
	Ventricular Fibrillation	15.9%	4.8%	4.5%	22.3%	10.1%	10.1%	15.0%	4.3%	4.3%	15.4%	3.8%	2.9%
	Left bundle branch block (LBBB)	1.6%	3.9%	4.1%	1.9%	2.0%	2.1%	1.5%	4.1%	4.4%	1.5%	3.6%	3.6%
	Syncope	8.0%	3.9%	2.7%	10.9%	4.7%	3.9%	7.4%	3.6%	2.5%	10.8%	5.5%	3.1%
	Other Intraventricular blocks*	0.8%	0.6%	0.5%	0.3%	0.5%	0.4%	0.7%	0.6%	0.6%	2.1%	0.6%	0.5%
Aetiology	Ischemic heart disease	41.8%	35.8%	32.6%	13.6%	13.7%	10.9%	45.7%	38.1%	35.1%	43.6%	36.7%	31.9%
	Idiopathic cardiomyopathy	20.5%	26.3%	18.6%	30.2%	34.1%	26.1%	19.9%	26.3%	18.8%	9.2%	20.5%	14.2%
	Valvular heart disease	5.3%	7.2%	7.7%	3.8%	6.0%	4.9%	5.5%	7.5%	7.7%	4.6%	6.7%	8.7%
	Hypertensive heart disease	1.1%	1.7%	2.3%	0.0%	0.4%	0.8%	1.1%	1.8%	2.3%	2.6%	1.5%	2.9%
	Hypertrophic cardiomyopathy	1.2%	0.7%	0.9%	5.4%	2.3%	2.6%	0.7%	0.6%	0.8%	0.5%	0.3%	0.3%
Cardiac diagnosis	Heart failure	22.9%	40.4%	46.8%	12.0%	27.7%	30.9%	24.5%	42.3%	49.2%	22.1%	37.4%	44.4%
	Atrial Fibrillation	9.2%	12.3%	14.4%	4.1%	5.7%	4.7%	9.8%	12.6%	14.4%	9.7%	15.5%	19.2%
Non-Cardiac diagnosis	Hypertension	11.1%	15.2%	15.0%	3.8%	6.6%	7.2%	12.1%	15.6%	15.6%	11.8%	18.7%	15.9%
	Diabetes	6.5%	12.4%	10.9%	1.4%	3.8%	3.8%	7.3%	13.7%	11.8%	5.6%	10.0%	10.2%
	Renal insufficiency	4.4%	7.2%	7.6%	1.1%	1.6%	1.6%	4.6%	7.1%	7.2%	7.2%	11.7%	11.9%
	Obstructive pulmonary disease	4.6%	5.2%	3.7%	1.9%	1.7%	1.2%	4.4%	5.4%	3.8%	11.3%	6.7%	4.5%
	Vascular disease	4.8%	4.3%	3.2%	1.9%	1.6%	1.1%	5.2%	4.5%	3.3%	4.6%	5.2%	4.0%

* Other intraventricular blocks: Left Anterior Fascicular Block; Right Bundle Branch Block (RBBB); Right Bundle Branch Block and Left Posterior Fascicular Block (RBBB + LPFB); Right Bundle Branch Block and Left Anterior Fascicular Block (RBBB + LAFB); Bundle branch block, unspecified.

by significant rise of ultra-octogenarian population (2388,954 in 2001, 4132,654 in 2017), the group with the highest IR (6111 in the 2001, 6212 in 2017). Our results confirm data observed in the AIAC Registry, where a gradual and significant increase of first implants in the ninth decade was evident [13]

Despite the constant increase in 1stPMs, replacements steadily increased until 2010 and then gradually decreased. The most likely explanation is the longer duration of batteries, confirming data observed in the AIAC Registry [5,12].

For 1stPMs, relevant cardiac diagnoses and comorbidities were constant, as already reported [5,12,13]. When comparing our results from the HDR analysis with the AIAC Registry data for 2017, similar proportions of patients with AV block (HDR: 51.2%, AIAC Registry: 50.3%) and SSS (HDR: 27.2%, AIAC Registry: 19.5%) were observed. The increase in the diagnosis of SSS, more evident in younger patients, is difficult to explain. Possible reasons could be a more favorable adherence to the European and US published guidelines, and/or a greater awareness of the topic, possibly for legal reasons (for example need of driving license permission). However, other explanations could be the chance (as a statistical analysis was not performed and the number of procedures limited in this group) or an under-reporting of the diagnosis in the past; in fact, data from the AIAC registry are different, as indication associated to Sick Sinus Syndrome did not change or actually reduced from 2001 to 2017 [5,12,13]. The diagnosis of ischemic heart disease among 1stPMs was 14.2% in our study, much more frequent than observed in the AIAC Registry (3.6%). This is probably due to an underestimation in the AIAC Registry, as the European PM card allows the collection of only one possible diagnosis/etiology while in the HDR are admitted up to five different cardiac and non-cardiac diagnoses, not necessarily associated with the procedure.

4.2. Implantable Cardioverter-Defibrillators

During the period under study, an increase of both ICD implants and IR were observed. This trend can be explained as the effect of the publication of some trials proving the beneficial effects of ICD for primary prevention of sudden death and CRT for the treatment of heart failure [14-17]. As a consequence, less selected patients (older and with more co-morbilities, as hypertension, diabetes and renal insufficiency) have been treated. In addition, an increase of the proportion of patients with hypertension and diabetes was observed also in the overall population in Italy **(Annuario Statistico Italiano 2001** http://www.quadernidellasalute.it/portale/documentazione/p6_2_2_1.jsp?lingua=italiano&id=1912 **e 2017** http://www.salute.gov.it/portale/documentazione/p6_2_2_1.jsp?lingua=italiano&id=2879)

An increase in the mean age among ICD patients, with a more considerable rise in devices utilization in ultra-octogenarians, was observed. In this group, there was a very high rate of ICDs and CRT-Ds (1038/1000,000 and 410/1000,000 respectively in 2017), with an increasing proportion of CRT-D/ICD rate (35.4% in 2017, **Table 2** and **online Table 5**). ICD and CRT-D implants and IR increased in this age group more than in the others (**Fig. 2**). This situation might be explained both by the growing number of ultra-octogenarians in Italy and the increased adherence to international guidelines, not considering the patient's age a limitation to implant if life expectancy is > 1 year. In addition, the rise in the CRT utilization can explain the increased proportion of patients with heart failure (22.9% in 2001, 46.8% in 2017).

As confirmed by data derived from AIAC Registry [5-12], the rise in ICD utilization was mostly due to the increased number of patients treated for primary prevention. Despite the absolute number of patients with diagnosis of VT/VF (extrapolated by Table 2), increased, the proportion of patients treated for secondary prevention dramatically dropped from 2001 to 2017.

Finally, the increased number of ICD might also be the result of the increase in the number and proportion of replacements. However, data from AIAC Registry [18], showed that ICD service life, independently from ICD type, indication, and settings, significantly improved over a 10-year period, resulting in a relative reduction of replacements.

In the last observed years, such increase of ICD implants was less evident, possibly as a consequence of the Danish study [19] suggesting a limited effect of ICDs on patients' survival; this trend should be confirmed in the future. In the AIAC Registry, a reduction of ICD implants in the last years, partially explained by lower completeness in reporting ICD implants than previously, was also recorded [5,12].

5. Limitations of the study

Given the administrative nature of the data source, many limitations should be considered. Specifically, the association between codes and procedures might be critical because the same code can be used for different procedures, and different codes can be used for the same procedure. In particular, the code "implant or replacement" for both ICDs and CRT-Ds can be interchangeable; therefore, a distinction between first implant and replacement is impossible for these devices. For this reason, data should be interpreted with caution, as our results could be due to an increase in first-time implants, or in replacements, or both; however, given the extended duration of current devices [18] and according to AIAC Registry data (**online Table 6 and 7**), the first explanation seems more plausible. Despite such distinction was not possible, we believe that our results regarding ICD and CRTDs were so definite that most considerations would not have significantly changed even after distinguishing between first ICD implants and replacements.

Our classification of some codes can be questionable (for example, for PMs code 0053, identifying first CRT implant or replacement, was considered as a replacement if no leads were added). However, the distinction between first PM implant and PM replacements could be considered very reliable.

Another significant limitation was the small number of diagnoses reported in the HDR (five at most). Since diagnosis and combination of diagnoses can lead to different DRGs that have distinct reimbursements, a selection bias could occur when multiple diagnoses are present.

Finally, data about patients and devices outcome were not provided. At the moment, HDD cannot replace the function of a clinical Registry, which allows the complete follow-up of both patients and devices after implant. Present HDD does not include either information about device characteristics or their serial number. Therefore, it is not possible to identify potentially defective devices or perform any clinical follow-up. Hypothetically, raw data about a patient intervention outcome could be obtained by combining the HDRs analysis with the mortality data provided by ISTAT, but this was not the aim of our study.

Last but not least, considering the nature and the time-related structure of data, statistical analysis was limited to counts and computation of descriptive statistics, as the application of usual statistical techniques was not suitable in this setting.

6. Conclusions

The study of the administrative healthcare data provided by the National Hospital Discharge Database showed an increase of both PM and ICD implants in Italy during the last two decades.

The increase of the 1stPMs was mainly due to the rise of population aged >80, but no changes were observed in IR in each age group (< 50, 50–79, ≥ 80 years old). Both the total number and IR increased in all groups (especially ≥80) for ICDs and CRT-Ds. An increase in comorbidities and a reduction in implants for secondary prevention was observed in ICDs.

Funding

The study was funded by the Directorate General of Medical Devices and Pharmaceutical Services of Ministry of Health (public funds from the Italian goverment). No funders were involved in the study design, in

the collection, analysis, and interpretation of data, in the writing of the manuscript, and in the decision to submit the manuscript for publication.

Declaration of Competing Interest

G.B. reported speaker's fees of small amount from Biotronik, Boehringer Ingelheim, Boston and Medtronic.

The authors have no other conflicts of interest to disclose

Acknowledgments

This study was performed within the framework of the national project to set up the Italian National Registry of Defibrillators and Pacemakers (Registro Italiano Defibrillatori e Pacemaker, RIDEP) coordinated by the Italian National Institute of Health (ISS), with the collaboration of the National Society of Arrhythmology (AIAC).

The authors wish to thank Prof. Christine Maria Salvatore (Weill Cornell Medicine – New York), and Laura Borghino MLang for their revision of the language in this manuscript, and Alessia Biondi, Stefania Ceccarelli and Mascia Masciocchi of the scientific and technical secretary of the Italian National Implantable Prostheses Registry for their secretary work.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.ejim.2020.09.003.

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