Implantable cardioverter–defibrillators in France: practices and regional variability

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Aims The rates of cardiac defibrillator implantation (ICD) in Europe and within countries are heterogeneous. We examined the characteristics of ICD recipients and device implantation rates in France, with the goal of identifying patterns and regional differences in medical practices.

Methods and results We compiled the information available on devices and patients from a manufacturer’s database for the years 2008 and 2009 and the Stidefix national registry from January 2008 to April 2010 and reported the descriptive statistics and comparisons of implantation practices among regions. We analysed data from 10 766 patients enrolled in Stidefix (mean age = 63 ± 13 years; 83% men) after implantation of single-chamber (24%), dual-chamber (33%), or triple-chamber (43%) ICD. Implantation was for primary prevention in 63% of patients. Between 2008 and 2009, the national implant rate increased from 126 to 147 per million inhabitants, with regional variations related to the number of cardiologists and of implant centres. Patients were significantly older and more likely to undergo implantation for primary prevention or for cardiac resynchronization therapy (CRT) in higher-volume regions. In Île de France (Paris and its suburbs), patients tended to be younger, as in low-implantation regions, but with a high rate of CRT implants, as in high-implantation regions. A comparison of the Stidefix data with the manufacturer’s database revealed that only 57% of all ICD implanted in 2009 were reported to Stidefix.

Conclusion Despite an increasing rate of ICD implantation in France, important regional disparities persist, with a median position occupied by Île de France.

Keywords Implantable cardioverter–defibrillator • Medical device registry • Ventricular tachyarrhythmia • Sudden cardiac death • Public health

Introduction

In clinical use for over 30 years, the implantable cardioverter–defibrillator (ICD) is a validated therapy for major ventricular tachyarrhythmias, as well as for prevention in patients at high risk of sudden cardiac death. Several randomized clinical trials1–4 have shown that the ICD lowers the mortality of patients with a history of sustained ventricular arrhythmias compared with antiarrhythmic drug therapy. Subsequent trials have shown a survival benefit conferred by ICDs preventively implanted in subgroups of patients at risk of sudden cardiac death.1,5–10

In France, ICDs have been reimbursed since 2005 in a limited number of centres accredited on the basis of an activity target of >50 implants per year. The French health authorities have mandated the organization of a national registry recording all implantation procedures. Although it is mandatory, compliance with this registry is not enforced. The present report presents the French ICD activity, patient characteristics, practices, and factors that might be responsible for regional differences in implantation rates.
Methods

The ICD activity in France can be obtained from two sources. Active since March 2007, Stidefix is a national prospective multicentre registry hosted by the French Society of Cardiology, which has three main objectives: (i) to respond to the legal mandate of the French health authorities requiring the enrolment of all new ICD implants in a national registry by the medical centres; (ii) to create a database enabling analysis of the French practices in the area of cardiac pacing and defibrillation; and (iii) to provide a computer-based tool to the implanting centres for managing implantations. A second source of data is the database maintained by the manufacturers, which includes all ICDs implanted from each manufacturer but does not include clinical information.

The Stidefix registry

The clinical data of the enrolled patients and the technical characteristics of the implanted ICDs are registered online in Stidefix by each centre. All ICD recipients should be prospectively enrolled in Stidefix after having obtained their informed consent, without exclusion criterion. The data are validated only by the implanting centre. Our study population exported from the Stidefix database includes all patients who received ICDs between 1 January 2008 and 13 April 2010. We excluded patients who underwent implants outside of mainland France, whose implantation date was uncertain, and/or whose records were not validated by the implanting centre. In case of multiple records, we retained the most recent ones for this analysis. The Stidefix registry includes medical information, indications for ICD implantation, and type of device implanted—single chamber (VR-D), dual chamber (DR-D), or resynchronization therapy (CRT-D, cardiac resynchronization therapy-D)—and distinguishes first implants from device replacements. Stidefix does not systematically collect data regarding survival, clinical outcomes, or complications.

Manufacturer’s database

This database lists by centre the type of device implanted and the year of implantation but does not include medical data. The data on defibrillators implanted in years 2008 and 2009 were used as the reference for ICD implant activity in our analysis. A comparison between Stidefix and the total ICD activity supplied by the manufacturer’s trade organization was used to assess the completeness of Stidefix for the study period.

Statistical analysis

Analyses of patient and device data were based on the Stidefix registry. Analyses of implantation activity were based on the manufacturer’s database. The data were analysed at the national and regional levels. We compared regions with high- and low-implantation rates, as well as two groups of regions with the Île de France region (Paris and its suburbs). Regions with implantation rates corresponding to the national average minus ≥ 35 implants or plus ≥ 35 implants per million inhabitants were defined as implanting, respectively, below or above the national average. The population-based data used to calculate these rates at the national and regional levels were obtained from estimates reported up to 1 January 2007 by the French National Institute for Statistics (INSEE).

Continuous variables are expressed as means ± standard deviation (SD), and categorical variables as counts and percentages. Percentages were based on the known total number of implants pertaining to the variable analysed. Student’s t-test and analysis of variance were used to compare continuous variables, after verification of their normal distribution with the Kolmogorov–Smirnov test. Categorical variables were compared using the χ² test. Potential correlations between continuous variables were tested using Pearson’s correlation coefficient. A P value <0.05 was considered significant. The data were analysed using the SAS® version 9.1 for Windows statistical software (SAS Institute, Cary, NC, USA).

Results

Out of 13 531 patients who underwent first ICD implants or replacements, as reported in the Stidefix registry since its creation in 2007, 10 766 from 66 medical centres were retained for analysis (Figure 1).

National perspective

The baseline characteristics of the patients are summarized in Table 1. The mean age of the men was 64 ± 13 years and that of women was 61 ± 15 years; 34% of the sample was >70 years of age. The left ventricular ejection fraction (LVEF) ranged from 10 to 80%. The devices implanted were divided by type with 43% CRT-D, 33% DR-D, and 24% VR-D. The implant rate increased from 126 per million inhabitants in
2008 to 147 per million in 2009, with an increase in the percentage of primary prevention ICD indications from 61.8% in 2008 to 63.6% in 2009.

**Effects of underlying heart disease**

Patients who presented with underlying heart disease were older (64 ± 12 years) than patients with isolated electrical abnormalities (55 ± 17 years; P < 0.001), were more likely to have undergone ICD implant for prophylactic indications (65 vs. 45%, P < 0.001), and had a lower mean LVEF (30 ± 10 vs. 54 ± 15%; P < 0.001). Patients with isolated electrical abnormalities were more likely to present with syncope (41 vs. 20%; P < 0.001) or cardiac arrest (36 vs. 8%; P < 0.001), and to be in New York Heart Association (NYHA) functional class I or II (93 vs. 53%; P < 0.001).

**Types of devices implanted**

The differences in patients receiving VR-D or DR-D, compared with CRT-D were as follows: recipients of VR-D or DR-D were younger (61 ± 14 years) than recipients of CRT-D (66 ± 11 years; P < 0.001), were more often asymptomatic (6 vs. 4%; P < 0.001), more often presented with syncope (28 vs. 13%; P < 0.001) or cardiac arrest (15 vs. 3%; P < 0.001), and were more likely to present in NYHA functional classes I or II (85 vs. 21%; P < 0.001). Their mean LVEF was higher (35 ± 14% vs. 26 ± 6%; P < 0.001) and were less likely to undergo ICD implant for prophylactic indications (52%) than recipients of CRT-D (79%; P < 0.001).

**Regional perspective**

Figure 2 shows the regional and national rates of implants per million inhabitants in 2009, based on the manufacturer’s data.
Pearson’s correlation showed a significant relationship between the number of ICDs implanted in 2009 and the number of cardiologists (63%; \(P = 0.002\)) and number of implanting centres per million inhabitants (51%; \(P = 0.022\)). Regions with implantation rates >112 per million inhabitants included Alsace, Basse-Normandie, Bourgogne, Bretagne, Champagne-Ardenne, Franche-Comté, and Picardie, while regions at or above this threshold included Aquitaine, Languedoc-Roussillon, Provence-Alpes-Côte-d’Azur, Corse, and Rhône-Alpes. The baseline characteristics of patients from the Ile de France region are compared with those of patients from regions with low and high implantation rates in Table 1.

**Number of implants and completeness of the Stidefix registry**

Table 2 shows the numbers of implanting centres and numbers of ICDs implanted per million inhabitants in years 2008 and 2009 in France and in Ile de France, according to the manufacturer’s database and the percentages of implants entered in the Stidefix registry. In 2009, 32% of the 96 French accredited medical centres implanted <50 ICDs per year (low-volume centres), and 40% of centres implanted >100 ICDs per year (high-volume centres). In the Ile de France region, 39% of the 18 accredited centres remained below the 50 ICD implants per year threshold, while 39% were high-volume implanting centres. Between 2008 and 2009, the percentage of ICD implants recorded in Stidefix increased from 51 to 57%, and ICD data were entered in the registry by 61 of 88 centres (69%) in 2008 and 65 of 96 centres (68%) in 2009. Compared with the manufacturer’s database, only 25% of all ICD implants from Ile de France were entered in the Stidefix registry in 2008 and 2009. This was not related to difficulties in obtaining the patient consent for the data to be entered but mainly due to the lack of participation by some teams or centres, despite the legal requirement to participate in the Stidefix registry.

**Discussion**

This survey, based on a national registry and on the manufacturer’s sales database, provides a global overview of the consumption of ICDs and implantation activities in France and its various regions. The median age of French ICD recipients was 63 years, the majority were men, and one-third of patients were ≥70 years of age. LVEF was <35% (due to ischemic or dilated cardiomyopathy) in 80% of ICD recipients, and 44% were in NYHA functional classes III or IV. The main indication was primary prevention, which accounted for most of the growth in implant rates between 2008 and 2009. The patients who presented with underlying heart disease were more likely to undergo CRT-D and prophylactic ICD implantations. VR-Ds and DR-Ds tended to be implanted in younger patients in lower NYHA functional classes.
and with higher LVEFs, and these implantations were more often for purposes of secondary prevention.

Based on the manufacturer’s data, major regional disparities were observed in ICD implantation rates in 2009, ranging from 72 to 211 per million inhabitants. The patients were significantly older in higher-rate regions and were significantly more likely to undergo CRT-D implants for primary prevention indications. Our analysis suggests that the higher ICD implant rate observed in some regions may be attributable to a more active management of elderly patients, as well as to a wider acceptance or better understanding of the role of ICDs in primary prevention and CRT.

The Ile de France region had the highest crude number of device implantations in France and a number of centres per million inhabitants identical to the national average. While the population of Ile de France is generally a high consumer of health care, the implant rate was uncharacteristically lower than the national average. The patterns of ICD implantation in Ile de France are paradoxical: patients are younger than the national average, as in other regions with low implantation rates, but CRT-D devices were implanted more frequently, as in high-implantation regions. These two findings may explain the median regional position of Ile de France, reflecting a reluctance to refer or implant elderly patients, especially in primary prevention where no immediate clinical benefit is usually obtained from VR-D/DR-D ICD therapy, and a possible preference for CRT-P (resynchronization pacemaker) instead of CRT-D in older patients. Resynchronization therapy is well accepted in Ile de France, given that patients can perceive a clinical improvement soon after implantation of a CRT-D, and that some Ile de France centres were among the pioneers of this therapy.

Regional differences have also been observed in other European and non-European countries. The reasons behind variable clinical practices are widely debated and are not all well understood. A common explanation is a higher number of implanting centres found in regions with higher ICD implantation rates. We also found significant relationships between the numbers per million inhabitants of ICDs implanted, implanting centres, and cardiologists, highlighting the influence of the health care supply on the implantation of ICDs.

Other explanations for the variability in ICD implantation rates include variable awareness or adherence to practice guidelines, under-utilization of ICDs in primary prevention due to insufficient proactive screening, competition for the time of electrophysiologists with complex ablation procedures reducing the time available for ICD implantation, and uncertainty regarding which patients are the best candidates for implantation of an ICD. These reasons are among the factors identified by the Heart Rhythm Association Group of the European Society of Cardiology to explain national variations. Differences in patient, physician and hospital characteristics, distribution of the cardiovascular diseases, or economic limitations placed on ICD implants may also account for these regional or national disparities.

Based on the manufacturer’s database, the number of ICD implants in France increased from 126 to 147 per million inhabitants, consistent with the increase observed in recent years in other European and non-European countries. Technological progress, broadening of the indications for ICD implantation to primary prevention, and a wider communication of these indications seem to be the main explanations for this trend. However, despite the increasing rate of ICD implants in France, it remains far below the European average of 234 per million inhabitants in 2009.

Finally, the French ICD implantation practice did not fulfill the ministerial mandates on two grounds: one-third of centres had implantation rates below the lower legal limit for accreditation of 50 ICD implants per year; and just over half of all ICDs implanted in France were included in the national Stidefix registry in 2008–10. As a result, this national registry is not fully representative of the nationwide ICD population, a significant loss for the French medical community, since registries provide important, comparative, independent information on the consumption of devices, their indications, and the appropriateness of their implantation.

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Appendix

Medical centres implanting ICD in Ile de France, participants in the Stidefix registry (by decreasing number of records included in Stidefix): Clinique Bizet, Paris; Hôpital Pitié-Salpêtrière, Paris; Hôpital Européen G. Pompidou, Paris; Hôpital Le Raincy-Montfermeil, Montfermeil; Hôpital Antoine Béclère, Clamart; Centre Cardiologique du Nord, Saint Denis; Hôpital Lariboisière, Paris; Hôpital Percy, Clamart; Clinique Ambroise Paré, Neuilly-sur-Seine.

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