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Current use of implantable electrical devices in Sweden: data from the Swedish pacemaker and implantable cardioverter-defibrillator registry

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Aims The National Swedish Pacemaker and Implantable Cardioverter-Defibrillator (ICD) Registry collects prospective data on all pacemaker and ICD implants in Sweden. We aimed to report the 2012 findings of the Registry concerning electrical devices implantation rates and changes over time, 1 year complications, long-term device longevity and patient survival.

Methods and results Forty-four Swedish implanting centres continuously contribute implantation of pacemakers and ICDs to the Registry by direct data entry on a specific website. Clinical and technical information on 2012 first implants and postoperative complications were analysed and compared with previous years. Patient survival data were obtained from the Swedish population register database. In 2012, the mean pacemaker and ICD first implantation rates were 697 and 136 per million inhabitants, respectively. The number of cardiac resynchronization therapy (CRT) first implantations/million capita was 41 (CRT pacemakers) and 55 (CRT defibrillators), with only a slight increase in CRT-ICD rate compared with 2011. Most device implantations were performed in men. Complication rates for pacemaker and ICD procedures were 5.3 and 10.1% at 1 year, respectively. Device and lead longevity differed among manufacturers. Pacemaker patients were older at the time of first implant and had generally worse survival rate than ICD patients (63 vs. 82% after 5 years).

Conclusion Pacemaker and ICD implantation rates seem to have reached a level phase in Sweden. Implantable cardioverter-defibrillator and CRT implantation rates are very low and do not reflect guideline indications. Gender differences in CRT and ICD implantations are pronounced. Device and patient survival rates are variable, and should be considered when deciding device type.

Keywords Pacemaker • Implantable cardioverter defibrillator • Cardiac resynchronization therapy • Registry • Implant rates

Introduction

Over the last decades, clinical indications for pacemakers and implantable cardioverter-defibrillator (ICD) implantation have widened based on the results of large randomized clinical trials and implementation of European guidelines.[1] Moreover, the indications for cardiac resynchronization therapy (CRT), delivered by a pacemaker (CRT-P) or a cardioverter-defibrillator (CRT-D), have rapidly expanded, and CRT is currently established as a valuable additive treatment for symptomatic heart failure patients with wide QRS.[1–4] With the broadening of clinical indications, electrical device implantations have increased in several countries, although the implementation of ICD and in particular CRT therapy in clinical practice is still suboptimal,[5] and marked differences can be observed between European countries.[6]

This raised the need for monitoring the 'real-world' pacing and electrophysiology practice within and across European countries. Local survey- and registry-based studies[7–12] and comprehensive European surveys[6,13–19] have started to be published in this field. The European CRT Survey indicated that the prescription of CRT in Europe varied between countries, and was often outside guidelines.[16]

The Swedish Pacemaker and ICD registry (http://www.pacemakerregistret.se) provides a real-time picture of the use of pacemakers, ICDs and CRT devices in clinical practice across Sweden. Of note, data are provided by all implanting centres, making the Registry highly representative of all implanting activity in Sweden. The very long time course of the Registry allows interpreting the current results in a temporal perspective, with pacemakers being entered since 1989 and ICDs since 2004. A comprehensive analysis of clinical

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What's new?

- This is the first article presenting data collected by the Swedish Pacemaker and Implantable Cardioverter-Defibrillator (ICD) registry on device implant rates, longevity, and complications.
- Device implant rates are presented for the entire Swedish country as well as for its regions.
- Pacemaker and ICD longevity data are presented together with patient survival data, obtained from the Swedish population register database. This approach should be considered when deciding device type, in the attempt to improve cost-effectiveness of pacing and ICD therapy.

and technical data from the Swedish Pacemaker and ICD Registry may therefore expand the knowledge of implantation patterns reflecting practice in Europe.

Our aim was to report the 2012 findings of the Swedish Pacemaker and ICD Registry on pacemaker, ICD, and CRT implantation rates, with expanded data concerning patient and device characteristics, complication rates, device longevity, and patient survival.

Methods

The Swedish Pacemaker Registry was developed in 1989. Clinical and technical information were first reported in the Registry using EURID implant forms. Since 2002 the Swedish Pacemaker Registry has become accessible online, (http://www.pacemakerregistret.se) and pacemaker data have been reported by the participating centres using direct data entry on the website. Data on ICD implants have been entered online since 2004. Collected data are regularly checked for internal consistency by the Registry administrator, and online statistics are updated on a daily basis (http://www.pacemakerregistret.se). So far, 121 744 pacemaker implants and 10 503 ICD implants have been included in the Registry since 1989 and 2004, respectively.

Forty-four centres have contributed to the Registry, covering almost 100% of the total pacemaker and ICD implanting activity in Sweden. Informed consent for data entry is required by the ethics committee of each participating hospital. Individual patient data are collected and the following variables are monitored in the Registry: number of pacemaker and ICD implants or replacements per centre, patient demographics (i.e. age and gender), clinical indication, aetiology, perioperative and post-operative complications (occurring within 1 year from implantation), fluoroscopy time, surgical time, and technical information on generators and leads (serial number, manufacturer, model, side and position). Complications may refer to first implants and replacements (discontinued surgery due to haemodynamic reasons, perioperative arrhythmias requiring acute medication, infection/perforation, local bleeding, and death), or to first implants only (lead electrical dysfunction, perforation/tamponade, pneumothorax, electrode displacement, subclavian or other related thrombosis). Patient survival data were obtained by matching the Pacemaker and ICD Registry with the Swedish population register database (SPAR database).

Statistical analysis was performed by using a Java platform supported by a private consultant company (Omegapoint AB, Sweden). Categorical variables are reported as percentages, and continuous variables as mean values and standard deviations. Implantation rates are standardized by sex and age for regional comparisons, based on the census estimate provided by the National Board of Welfare. Regional data referred to the area where the patients lived at the time of intervention, and not to the area where they were treated. This was to eliminate any bias related to patient referral (for example to centres performing CRT). Patient survival and device longevity statistics was performed according to the Kaplan–Meier estimate.

Results

Pacemakers

Pacemaker implantation rate

In 2012, a total of 6657 conventional pacemakers (DDD, VVI, AAI) were implanted in Sweden as first implants. Given a population census of 9.555.893 inhabitants in 2012, the mean implantation rate was 697 per million inhabitants. Of a total of 44 pacemaker implanting centres, there were 8 centres in northern Sweden, 5 in southern Sweden, 6 in southeast Sweden, 5 in Stockholm/Gotland, 11 in Uppsala/Örebro, and 9 in western Sweden. Regional differences in pacemaker implantation rates were observed, with the highest implantation rates in northern Sweden (*Figure 1*). Temporal information available over the last decades on pacemakers show a progressive increase in implantation rates since 1970, reaching a level phase since 2009 (*Figure 2*).

Patient characteristics

As presented in *Table 1*, the mean age of patients requiring a first pacemaker implant in 2012 was 76 ± 16 years (75 and 77 years in men and women, respectively). Most implants were performed in males (58%). The most common aetiology for pacemaker treatment was conduction system fibrosis (76%), followed by ischaemic heart disease (11%). Clinical indications were mainly syncope (41%), dizziness (25%), and breathlessness/tiredness (20%). Electrocardiographic indications were mostly related to atrioventricular (AV) conduction disorders (38%), followed by sick sinus syndrome (34%), and chronic atrial fibrillation (15%).

Types of pacemakers and leads

Pacemaker lead access was cephalic in 53.8% of patients, subclavian in 42.5% of patients, other in 3.7% of patients. Atrial and ventricular leads were predominantly bipolar (99.7 and 99.5%, respectively). The dominance of bipolar leads has been unchanged over the last 10 years. An active fixation system was used in 98% of the cases in the atrial position, and in 70% of the cases in the ventricular position. Dual-chamber pacing (DDD/DDDR) was the most used pacing modality in high-degree AV block (94%) and sinus node dysfunction (91%). The use of DDDR generators in sick sinus syndrome has increased over the last 5 years (from 82.1% in 2008 to 91% in 2012).

Mean fluoroscopy and surgical times for a first pacemaker implant were, respectively, 4.0 ± 5.3 min and 47.0 ± 28.4 min for AAI/AAIR pacemakers, 3.0 ± 5.4 min and 38.0 ± 24.0 for VVI/VVIR pacemakers, 4.0 ± 4.8 min and 48.0 ± 26.3 min for DDD/DDDR pacemakers.

One-year complication rate associated with pacemaker implant and long-term survival of patients and pacemakers

In 2012, the total 1-year complication rate for new pacemaker implants and replacements was 5.3%: electrode displacement was the most common event (2.2%), followed by lead electrical dysfunction (0.7%), infection (0.6%), pneumothorax (0.5%), local bleeding

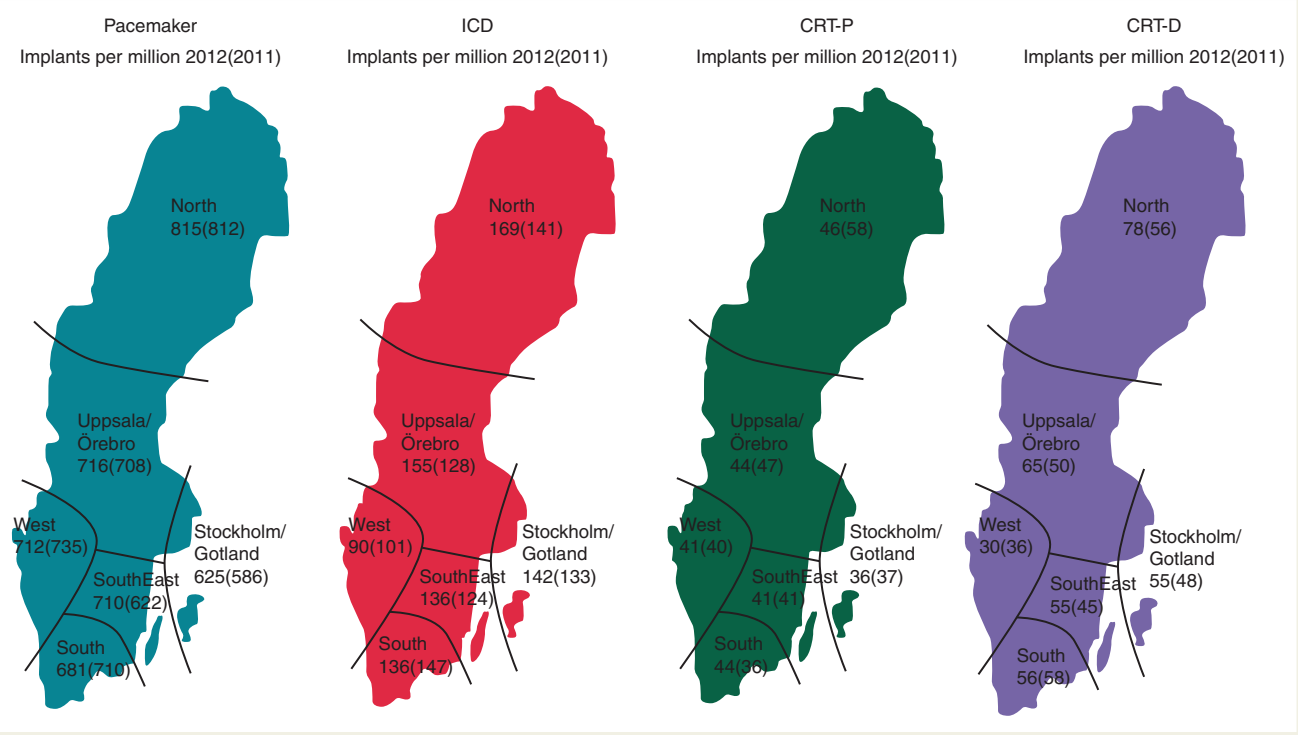

Figure 1 Device implant rates per million inhabitants in 2012 in different Swedish regions. Values in brackets refer to 2011.

(0.3%), perforation/tamponade (0.3%), subclavian or other related thrombosis (0.2%), other (0.5%). None of the patients died. Complication rates were 3.6% for new pacemaker implants and 1.7% for replacements. Rates of pneumothorax were 0.37% with the subclavian vein access, 0.09% with the cephalic vein access, 0.03% with the axillary vein access, and 0.01% with the jugular vein access. Based on data of all pacemaker implants and lead replacements since 2004, the rate of lead dislocations was 1.6% in the right atrium and 1.5% in the right ventricle, with fixed screw leads displaying the lowest displacement frequency.

Overall, generator survival rate was 98% after 5 years and 33% after 10 years. Pacemaker lead survival rate was 98% after 10 years. Pronounced differences in generator longevity were observed between manufacturers (*Figure 3*). Based on all implant data since 1990, the average pacemaker patient survival rate was slightly shorter than that in the whole population (63 vs. 71% after 5 years, with an average age at implant of 75 years).

Implantable cardioverter-defibrillators

Implantable cardioverter-defibrillator implantation rate

In 2012, the total number of ICD first implants in Sweden was 1298. Overall, the mean ICD implantation rate has increased in particular since 2009 and was 136 per million inhabitants in 2012. Thirty-two ICD implanting centres were identified (six in northern Sweden, three in southern Sweden, three in southeast Sweden, five in Stockholm/Gotland, eight in Uppsala/Örebro, and seven in western Sweden). Similar regional differences in implantation rates were observed for pacemakers and ICDs, with the highest values in the northern region and the lowest in the western region. A marked heterogeneity in the geographical distribution of ICD implantation rates was observed mainly in primary prevention (104 vs. 53 implants per million in the northern and western regions, respectively). Changes in ICD implantations rates over time are displayed in *Figure 2*. The number of ICD implants showed only a slight increase in 2012 compared with 2011 (136 vs. 128 implants per million). In 2012, ICD implantations for primary and secondary prevention were 59 and 41%, respectively. Noteworthy, since 2008 there has been a steady increase in primary preventive ICD implantation rate (*Figure 4*).

Patient characteristics

As reported in *Table 1*, the mean age of patients treated with new ICD implantation in 2012 was 63 $\pm$ 13 years (63 and 61 years in men and women, respectively). Most patients were males (80%).The underlying heart disease most commonly was coronary artery disease (57% in men, 39% in women) and non-ischaemic dilated cardiomyopathy (25% in men, 28% in women). Other aetiologies are presented in *Table 2*. Among the patients receiving ICD therapy for secondary prevention (41%), sustained ventricular tachycardia was the most frequent arrhythmia (17%), followed by ventricular fibrillation (14%), ventricular tachycardia plus ventricular fibrillation (5.0%), and non-sustained ventricular tachycardia (5.0%). Aborted sudden cardiac arrest had been reported in 16% of patients undergoing ICD implant.

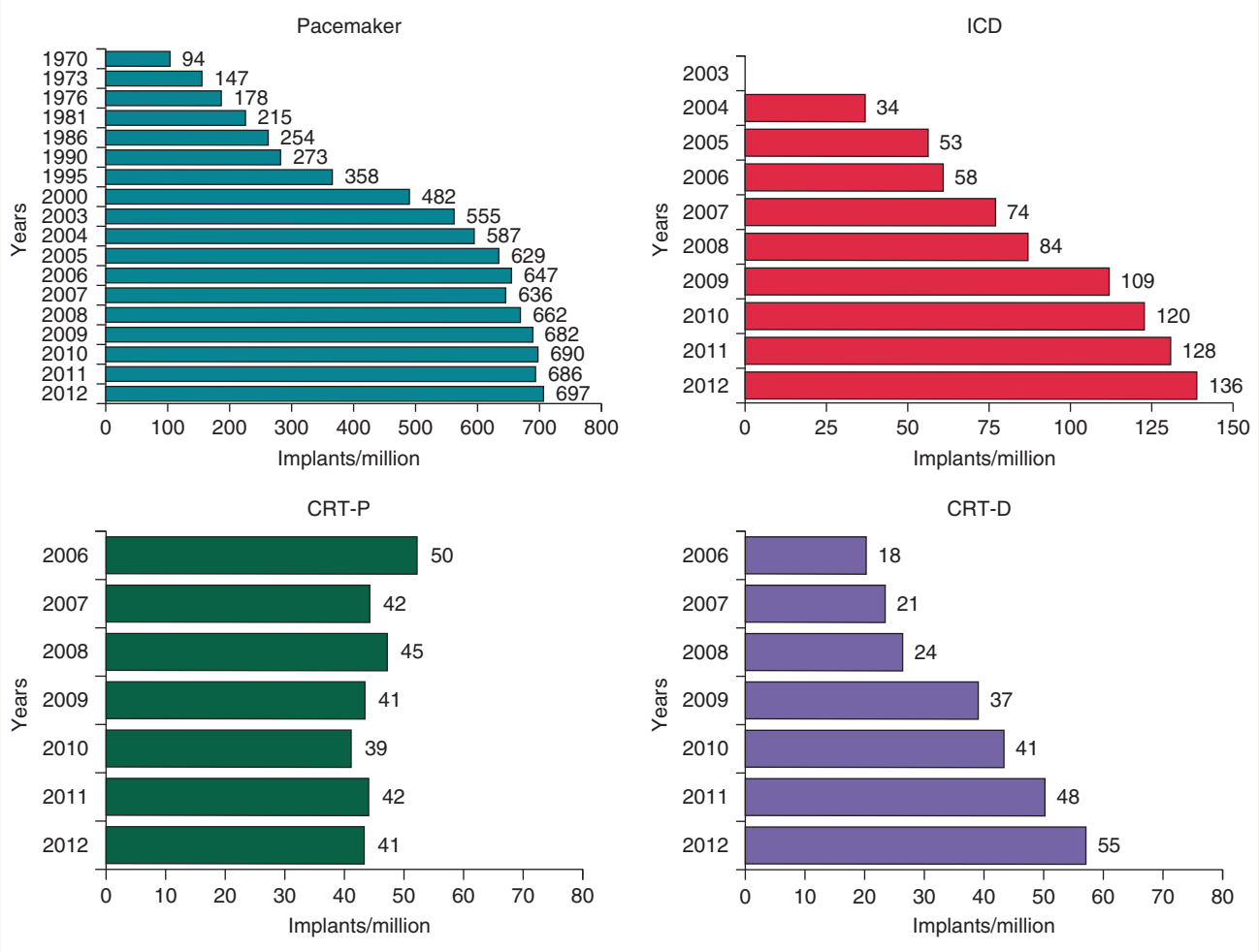

Figure 2 Historical implantation rates of pacemakers, ICDs, and CRT devices in Sweden over the past decades.

Table 1 Clinical characteristics of the patients included in the Swedish Pacemaker and ICD Registry undergoing a new pacemaker, ICD, CRT-P, or CRT-D implantation in 2012

	Pacemaker	ICD	CRT-P	CRT-D
Mean age (year)	76	63	74	65
Male sex (%)	58	80	74	81
Ischaemic heart disease (%)	11	54	39	46
Dilated cardiomyopathy (%)	1	25	32	43
Heart disease of other causes (%)	88	21	29	11
Paroxysmal/chronic AF (%)	19	11	25	14
Left bundle branch block (%)	3	20	40	45
Aborted sudden death (%)	0	16	0	8
Syncope (%)	41	14	7	6

Types of implantable cardioverter-defibrillators and leads

Dual-chamber ICDs with or without CRT properties were implanted in 39 and 41% of the recipients, respectively. Single-chamber ICDs accounted for 20% of implants. Single-coil right ventricular leads were implanted more frequently than dual-coil leads (59.4 vs. 40.4%, respectively). Implantation of a subcutaneous ICD was rare and performed in 0.2% of patients ($n = 3$). Active fixation leads were chosen in 94% of cases. Venous access was comparable with pacemaker implants, with an equal distribution between cephalic cutdown and direct subclavian puncture. Over the last 5 years, there has been a steady increase in the use of single-coil leads (from 26.4% in 2008 to 59.4% in 2012), with a decrease in dual-coil right ventricular leads.

Mean fluoroscopy and surgical times for a first ICD implant were respectively 6.0 ± 12.9 min and 50.0 ± 34.9 for single-chamber ICDs, and 5.0 ± 6.6 min and 55.0 ± 28.5 for dual-chamber ICDs.

One-year complication rate associated with implantable cardioverter-defibrillator implant and long-term survival of patients and systems

In 2012, the total complication rate for new ICD implants and replacements was 10.1%, slightly higher than in 2011 (8.4%): infection/perforation accounted for 3.0% of complications, followed by electrode displacement (2.1%), lead electrical dysfunction (1.5%), local

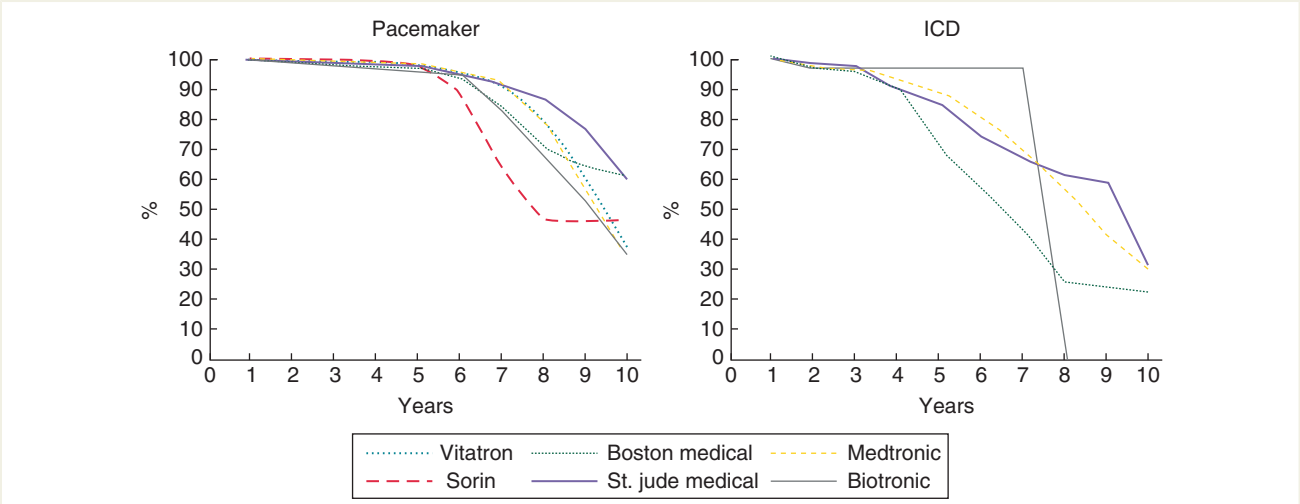

Figure 3 Mean survival probability for pacemaker and ICD generators by different manufacturers. Based on all implant data after 1990.

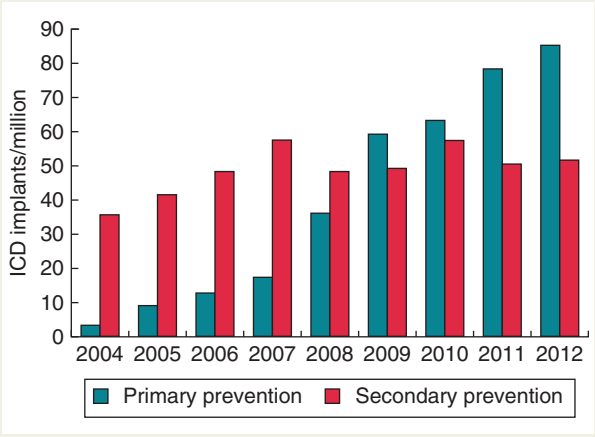

Figure 4 Implantable cardioverter-defibrillator implant rates for primary and secondary prevention in Sweden since 2004.

Table 2 Main aetiology of heart diseases leading to ICD first implants in male and female patients

	Male (%)	Female (%)
ARVC	1.0	1.6
Amyloidosis	0.2	0.0
Dilated cardiomyopathy	24.6	27.6
Hypertrophic cardiomyopathy	3.0	6.7
Ischaemic cardiomyopathy/post-infarction	57.0	39.0
Congenital	0.6	0.8
Idiopathic	9.2	12.2
Long QT syndrome	0.4	5.1
Myocarditis	0.6	0.8
Sarcoidosis	0.6	0.0
Other structural heart disease	2.8	6.2

ARVC, arrhythmogenic right ventricular cardiomyopathy.

bleeding (0.8%), pneumothorax (0.6%), discontinued surgery due to haemodynamic reasons (0.5%), tamponade (0.5%), subclavian or other related thrombosis (0.1%), death (0.1%), and other complications (0.9%). Complication rates were 6.4% for new ICD implants, and 3.7% for replacements. Probability of ICD complication free survival was 89% after 1 year, and 45% after 5 years. One-year complication rate was 6.2% for single-chamber ICD implants and replacements, and was 10.4% for dual-chamber ICD (including CRT-D) implants and replacements. Generator survivals were shorter for ICDs than for pacemakers, with great variations between different manufacturers (*Figure 3*) and models. Overall, ICD *generator* survival rate was 88% after 5 years and 13% after 10 years, while ICD right ventricular *lead* survival rate was higher, with a 92% survival rate after 10 years. Based on all implant data since 1990, the average ICD *patient* survival rate was 82% after 5 years, and not unexpectedly markedly longer than for pacemaker patients (63% after 5 years), reflecting the more than 10 year age difference between ICD and pacemaker recipients. The 5-year survival rate of octogenarian ICD recipients was 5%.

Cardiac resynchronization therapy devices

Cardiac resynchronization therapy implantation rate and patient characteristics

CRT-P and CRT-D implantation rates in 2012 were 41 and 55 per million capita, respectively. Despite widening indications, only a slight increase in CRT implantations was observed compared to 2011 (when CRT-P and CRT-D implantation rates were 42 and 48 per million, respectively) (*Figure 2*). Twenty-five Swedish centres performed CRT implantations. The distribution between CRT-P and CRT-D implantations was heterogeneous within the country, with southeast regions implanting more CRT-D than CRT-P systems (*Figure 1*).

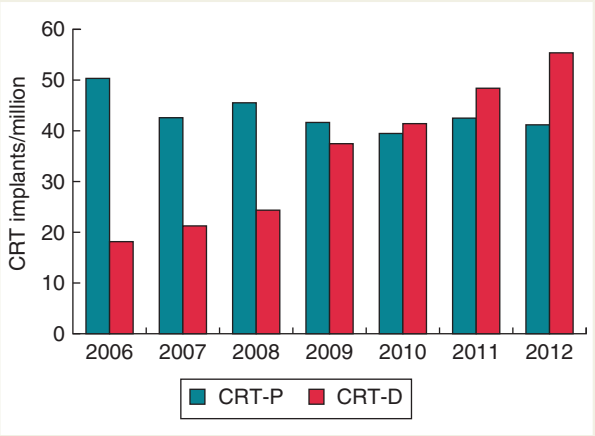

Figure 5 CRT-P and CRT-D implant rates in Sweden since 2006.

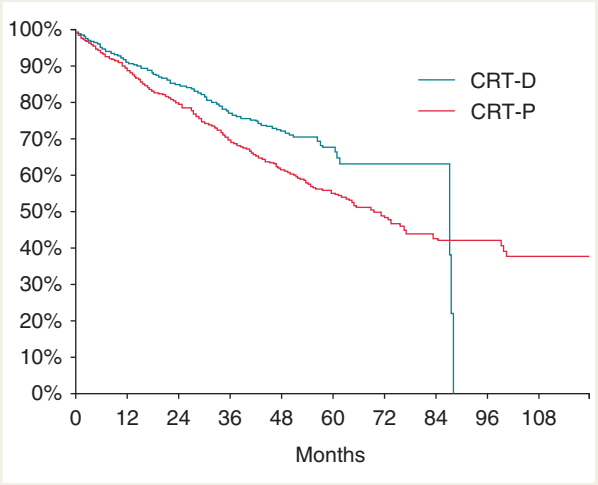

Figure 6 Survival rates of CRT-P and CRT-D patients from the Swedish Pacemaker and ICD registry.

As regards patient characteristics, the mean age of CRT-P patients was higher than CRT-D patients (74 ± 10 vs. 65 ± 10 years) (*Table 1*). The majority of CRT patients were male (74 and 81% of CRT-P and CRT-D recipients, respectively). Success rate of CRT-P and CRT-D implantations was 97 and 94%, respectively. Mean fluoroscopy and surgical times for a first CRT implant were, respectively, 35.0 ± 18.5 and 85.0 ± 33.1 min for CRT-P systems, 20.0 ± 16.5 and 126.0 ± 31. for CRT-D systems.

In 2012 only 17 CRT-P systems were upgraded to CRT-D systems. Since 2006 there has been a progressive increase in CRT-D implants, whereas CRT-P implant rate has remained stable over the past 4 years (*Figure 5*).

One-year complication rate associated with cardiac resynchronization therapy implant and long-term survival of patients and systems

The total complication rates for CRT-P and CRT-D new implants and replacements were 3.2 and 8.2%, respectively. Left ventricular lead displacement occurred in 1.8% of CRT-P first implants and in 0.7% of CRT-D first implants. No peri-implantation death occurred. Probability of CRT complication-free survival was 86% after 1 year, and 37% after 5 years. Complication rate of CRT-D first implants was slightly lower than ICD complication risk, probably reflecting skilled operator experience and no significant additional procedural risks. CRT-P generator survival was 96% after 5 years and 65% after 10 years. As regards CRT-D generators, survival rate was 86% after 5 years and 69% after 10 years. Average survival rate of CRT-D vs. CRT-P patients is shown in *Figure 6*. CRT-D patients showed a better survival rate than CRT-P patients, but the age difference between the two groups was almost 10 years.

Discussion

This report of the Swedish Pacemaker and ICD Registry provides a comprehensive overview of current pacing activity in Sweden and its regions. The Swedish Pacemaker and ICD Registry can be considered a reliable reference for 'real-world' clinical practice due to its high representativeness and continuous update. Registry data suggest that pacemaker and ICD implantation rates seem to have reached a level phase in Sweden, with a slow implementation of CRT-D therapy. Gender differences are pronounced especially in ICD and CRT-D first implantations. Marked differences in device longevity are present between manufacturers and should be considered when deciding device type. In our opinion, these data may expand the knowledge on pacemaker and ICD activity across European countries.

With the broadening of clinical indications and the widespread use of implantable electrical devices, registry-based studies from different European countries have started to be published.[7–12,20] The European CRT survey collected data on current CRT practice from 141 centres in 13 European countries.[5,16–19] The survey provided results consistent with previous clinical trials on CRT, and also extended observations to a wider range of patients that were older and with more comorbidities than in the landmark trials.[16–19] This highlights the relevance of surveys and registries to assess the implementation of randomized trials and guidelines in clinical practice.

Implantation rates: comparison with the European context

In Europe the mean pacemaker implantation rate in 2011 was 604 units per million inhabitants, with a marked heterogeneity between countries.[6] Data from the Swedish Pacemaker Registry are in line with the European average, showing a mean pacemaker implantation rate in Sweden of 697 units per million inhabitants in 2012. As regards ICDs, the mean implantation rate in Europe was 103 per million inhabitants in 2011,[6] in line with 2012 data from the Swedish ICD Registry (136 ICD implants per million inhabitants). Swedish CRT-P implantation rate seems to be higher than the mean European value[6] (41 CRT-P implants per million in Sweden in 2012, 19 CRT-P implants per million in Europe in 2011), with a lower ratio of CRT-D/CRT-P implants (on average 60% in Sweden vs. 80% in Europe). This high rate of CRT-P may reflect the opinion of the key opinion leaders that CRT-P is good enough or may reflect the somewhat lower costs and lower complication rate of CRT-P compared with CRT-D.

Substantial geographical variations in pacemaker, ICD, and CRT implantation rates have been observed across European countries and within each country.[5–15] As regards ICDs, the ESC countries with the highest implantation rates in 2011 were Germany, Czech Republic, and Austria.[6] Accordingly, the distribution of CRT implantation rates in 2011 across ESC countries was skewed, with the highest implantation rate in Italy.[6] Low implantation rates have been observed in countries with lack of infrastructures, limited training programmes for professionals, and low referral rates.[6,21,22] Local practices and recommendations, health system, and social security system characteristics may also play an important role.[6,21] This may be the case of Italy, where CRT-D implantation rates are among the highest in Europe probably due to raising awareness of the medical community, creation of dedicated referral pathways and training programmes, and high number of implanting centres.

Implantable cardioverter-defibrillator therapy has had a slower acceptance in Sweden than in other Nordic countries, i.e. Denmark, and implant rates are well below those reported by the Danish Registry (http://www.pacemaker.dk) (136 vs. 256 per million capita). There are no clear underlying explanations for this, as economical resources and access to hospital care are comparable between the countries. The influence of key opinion leaders, a well-organized cardiology community, and differences in economical reimbursement systems may be reasons for better compliance with guidelines. For example in Denmark, a tight cardiology community may partly explain a much higher implementation of guidelines than in Sweden. The influence of key opinion leaders may concern clinical judgement, creation of referral pathways, device type choice, and resource administration.

Changes in implantation rates over time and within country

Especially notable is the lack of significant increase in implant rates in Sweden between 2011 and 2012 (+1.6% for conventional pacemakers and +6.2% for ICDs). The use of CRT therapy follows the same pattern as ICD implant rates, showing slow changes (+14.6% vs. 2011 for CRT-D, −2.4% for CRT-P). Still the referral of patients from the general practitioner to heart failure centres seems to be low,[23] and in general a gap between guidelines and heart failure management in clinical practice persists not only in Europe but also in the USA.[24] In Sweden from 2007 to 2012, there has been a trend towards a wider use of ICD plus CRT (from 28 to 39% of total ICD implants) and a decrease in dual-chamber ICD without CRT (from 52 to 41%), while the percentage of single-chamber ICD implants appears to be stable (~20%). This has most probably reflected a wider diffusion of recent CRT trials[3,4] and application of clinical guidelines, with a true but modest increment in CRT therapy implementation.

Differences in pacemaker and ICD implant rates were observed between Swedish regions. The highest implant rates were noticed in the northern region, and the lowest in the western region. As regards CRT, southeast regions were found to implant more CRT-D than CRT-P systems. This heterogeneous geographical distribution of device implant rates is present throughout the years the Registry has been active. The access to hospital care, ongoing research in the field, proximity, and number of specialists have been shown to influence implant rates,[12,21] and these factors have shown small changes over years.

Gender differences

Data from the National Swedish Pacemaker and ICD Registry show that the majority of patients receiving an implantable electrical device are men. In particular, women represent only 20% of total ICD and CRT-D patients. Similar gender differences in the use of ICD therapy for primary or secondary prevention of sudden cardiac death have been shown by previous studies and registry-based reports,[16,25–27] and seem to be persistent across countries and over time.[25] However, available studies suggest that women implanted with an ICD have a similar risk of death compared with men,[28] and may even respond better than men to CRT therapy.[29,30] Several epidemiological and clinical factors have been taken into account in the attempt of explaining the observed gender differences.[25,28] Curtis *et al.*[25] found that after controlling for demographic variables and comorbid conditions, men were still more likely than women to receive ICD therapy. Accordingly, in our study gender differences in first implant rates could not be completely explained by age or disease prevalence. This highlights the need for further studies in this field.

Device and lead longevity

The Registry data show marked differences in device longevity between different manufacturers and models (http://www.pacemakerregistret.se). This clearly has an influence on therapy costs and should be taken into account when implanting devices. Device longevity is especially important when ICD or CRT-D therapy is started. Implantable cardioverter-defibrillator patients generally live longer than pacemaker patients, and this can be partially due to different ages at the time of the first implant. Since the average 10-year survival rate of an ICD patient has been shown to be over 60%, if a device survival is only 5 years, unnecessary generator replacements have to be performed, with a great increase in treatment cost per year and high risk of complications in the perspective of a lifelong therapy. Therefore, the cost-efficacy of ICD treatment may depend greatly on device longevity.[31] In a previous modelling study, with expected patient survival and complications cost undertaken from a hospital perspective, extending device longevity influenced significantly the long-term costs of ICD and CRT-D therapy.[31] In this perspective, device longevity and patient survival data from large patient registries could be valuable to guide clinical decision-making and to increase the cost-efficacy of ICD and CRT therapies.

Pacemaker lead longevity is generally very good, with a 10-year survival rate over 99%. Implantable cardioverter-defibrillator leads have also very good survival rates (on average 98% after 10 years). Only well-known specific models, as the Medtronic Sprint Fidelis leads, show lower survival. The SJM Riata leads have not yet shown significantly lower survival rates than the average.

Complications

Data from the Registry on pacemaker, ICD, and CRT complication rates were in line with previously reported data.[1,32,33] Complication rates were lower for pacemakers and CRT-P than for ICDs with or without CRT properties. Lead-related complications, in particular lead dislodgment, were the main reason for re-intervention. Notably, LV lead displacement rates were quite low compared with earlier findings. Also the incidence of lead infection was low,

probably reflecting better technique and leads. However, the result may be influenced by a relatively short duration of the follow-up (1 year). Probability of complication-free survival was almost similar for ICD and CRT patients.

Limitations

The study was conceived as a descriptive report of data collected by the National Swedish Pacemaker and ICD Registry. A systematic analysis of factors potentially influencing global and regional implantation rates was out of the aim of this report and needs to be investigated further. Information on NYHA class, left ventricular ejection fraction, and phrenic nerve stimulation are not available in the Registry. Clinical and echocardiographic response to CRT could therefore not be assessed.

Conclusion

This report of the National Swedish Pacemaker and ICD registry provides an overview of the current use of implantable electrical devices in clinical practice in Sweden. Pacemaker and ICD implantation rates have increased over the past years, and seem to have currently reached a level phase. The use of CRT-D therapy is increasing slowly. Implantable cardioverter-defibrillator therapy has had a slower implementation in Sweden than in other Nordic countries, i.e. Denmark, probably due to differences in medical community tightness and economical reimbursement systems. There is an heterogeneous distribution of implantation rates between the Swedish regions, most likely influenced by different access to hospital care and local practice. Gender differences in first implant rates are pronounced and not entirely justified by disease prevalence. Differences in device longevity can be observed between manufacturers. Expected device longevity and patient survival should be considered in clinical practice to reduce device therapy costs and improve the cost-efficacy of ICD and CRT therapies.

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A right-sided subcutaneous implantable cardioverter defibrillator in a patient with congenital heart disease

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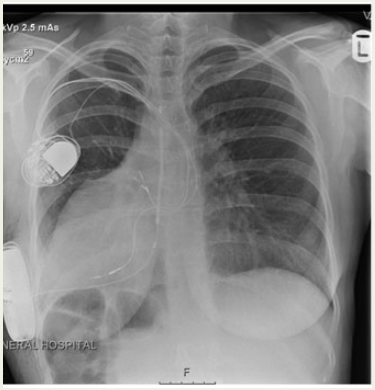
Sudden cardiac death is the leading cause of death in adults with complex congenital heart disease. Subcutaneous implantable cardioverter defibrillators (S-ICD) have been shown to be effective at treating ventricular arrhythmias. We are not aware of any other previously published cases where the device is implanted on the right side.

A 31 years old woman had transposition of the great arteries, situs inversus with dextrocardia and a Mustard procedure aged 18 months. She presented with an out-of-hospital ventricular fibrillation arrest. She had a transvenous dual chamber pacemaker *in situ* for bradycardia, and initially underwent an atrial lead revision due to failure to capture of the original lead.

A decision was made to implant an ICD but there were concerns over potential baffle stenosis and superior vena cava obstruction, both of which are well recognized complications of both the Mustard procedure and transvenous pacing. A S-ICD (Boston Scientific, Model SQRX) was implanted on the right side in the fifth to sixth intercostal space and a wire with two sensing electrodes separated by a defibrillation coil was tunnelled towards the xiphisternum and then cranially to the right of the sternum. Defibrillation checks were performed successfully.



The full-length version of this report can be viewed at: http://www.escardio.org/communities/EHRA/publications/ep-case-reports/Documents/A-right-sided-subcutaneous.pdf.