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Trends in Cardiovascular Implantable Electronic Device Implantation Between 1988–2018 in Olmsted County: Decrease in Defibrillator and Pacemaker Usage and Increased Use of Cardiac Resynchronization Therapy

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Abstract

Background: We sought to describe trends in cardiovascular implantable electronic device (CIED) implantation over the past three decades in Olmsted county.

Methods: The Rochester Epidemiology Project (REP) is a medical records linkage system comprising records of all residents of Olmsted County from 1966-current. CIED implantation between 1988–2018 was determined using ICD-9, ICD-10 and CPT codes. Age and gender-adjusted incidence rates, adjusted to the 2010 United States White population, were calculated. Trends in incidence over time, across age groups, and between genders are estimated using Poisson regression models.

Results: The age and sex-adjusted incidence of device implants for the study period were as follows: overall CIED: 82.4 per 100,000 per year (95% confidence interval [CI] 79.2–85.6), Pacemaker (PPM): 62.9 (95% CI 60.0–65.7), implantable cardioverter defibrillator (ICD): 14.0 (95% CI 12.6–15.3) and cardiac resynchronization therapy (CRT): 5.6 (95% CI 4.7–6.4) per 100,000 per year. The overall incidence of CIED implantation increased between 1988–93 and 2000–05, and then decreased between 2000–05 and 2012–18 (p<.0001). PPM and ICD implantation incidence followed these trends, while the incidence of CRT implantation increased between 2000–05 and 2012–18. CIED implantation incidence increased with age (p<0.0001). CIED implantation incidence was greater in men (116.3 vs. 57.3 per 100,000 per year in males vs. females, p<.0001). The overall survival of CRT recipients improved (p=0.0044).

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Conclusions: The incidence of PPM and ICD implants is decreasing, while incidence of CRT implants is increasing. CIEDs are increasingly implanted in the elderly, males, and patients with higher comorbidities.

Keywords

Cardiovascular implantable electronic devices; pacemaker; implantable cardioverter-defibrillator; cardiac resynchronization therapy; epidemiology

Introduction:

Cardiac implantable electronic devices (CIEDs) such as the implantable cardioverter-defibrillator (ICD), permanent pacemaker (PPM), and cardiac resynchronization therapy (CRT) systems are widely utilized for alleviating a variety of cardiac diseases. (1–4). Implantation of CIEDs has been associated with increased patient quality of life, reduced length of hospital stays, and prolonged survival (5–8). Description of the temporal trends in CIED utilization in a population-based manner can inform clinicians, researchers and policymakers of the relevant changes in device implantation trends; and could guide future research projects and healthcare policies. Description of the demographics and comorbidities of CIED recipients may highlight over-utilization or under-utilization of CIEDs in specific subgroups.

Prior studies describing device implantation trends in the United States have suggested a significant increase in the use of PPMs and ICDs as their clinical indications continued to expand (1, 7, 9–11). However, the incidence of CIED utilization in the United States utilization since the mid-2000s, including PPM, ICD and CRT implantation for all indications, has not been extensively studied (12, 13). Some existing epidemiological studies on CIED incidence have relied on data from individual institutions or surveys of physicians and device manufacturers, which may not provide as accurate an estimation as a population-based study that incorporates all implantations during a given period (14–16). Hence, we conducted a retrospective population-based study of CIED implantation between 1988 and 2018. We sought to describe novel findings, beyond currently published data, focusing on the incidence, temporal trends, age and sex distribution, comorbidities and survival of patients receiving CIED implantation.

Methods:

Data source

This study was approved by the Mayo Clinic Institutional Review Board (ID 17–000371) and received proper ethical oversight. The Rochester Epidemiology Project (REP) was the data source for this study. The REP is a medical records linkage system containing medical records of all residents of Olmsted County, MN, from January 1, 1966 to present, consisting of follow up data on more than 500,000 unique individuals (17). Patient demographics, diagnostic codes such as the international classification of diseases 9th revision (ICD-9-CM) codes, and surgical procedure codes are recorded for all individuals. Paper and electronic medical records of these individuals are available for the abstraction of additional data. The

REP permits collection of population-based data and has been used to define the incidence of various medical conditions. It is inclusive of two major hospital systems in Olmsted County (Mayo Clinic and Olmsted Medical Center), in addition to smaller practices.

Study population

The REP database was used to determine all patients receiving CIED implantation between 1988 and 2018. During the majority of the study period, Mayo Clinic was the only institution in Olmsted County performing CIED implantation and follow-up. Between 2015–2018, device implantation was additionally performed at Olmsted Medical Center in Rochester, MN. These patients were also included in the study. Between 1988–2015, patients receiving CIEDs were determined based on ICD-9-CM codes. Patients were classified as receiving a pacemaker (ICD-9-CM: 37.81, 37.82, 37.83), implantable cardioverter defibrillator (ICD-9-CM: 37.94) or cardiac resynchronization therapy device (ICD-9-CM: 0.50, 0.51). Data on subsequent device upgrades from PPM to ICD or CRT, or ICD to CRT were collected using ICD-9-CM codes and manually verified. Between 2015–2018, patients receiving CIEDs were based on the previously mentioned ICD-9-CM codes, ICD-10 codes and CPT codes, and then manually verified (supplementary table 1). Data regarding baseline demographics and comorbidities were obtained from the REP and abstracted from the medical records. Charlson comorbidity index was assessed as a combined index of comorbidities and was calculated according to Charlson et al (36). Individual weights assigned to comorbid conditions as part of this score are listed in supplementary table 2.

Statistical analysis

The overall incidence of CIED implantation was determined using the total number of cases divided by the population in Olmsted County in the same period. The population of Olmsted County was estimated using the census results as well as an interpolation of the populations in the years between the census years. Incidence rates were age and gender-adjusted to the 2010 United States White population. Trends in incidence over time, across age groups, and between genders are estimated using Poisson regression models. Comparisons between implant groups for categorical factors were completed using Chi-square tests. Continuous factors were compared between groups using the Analysis of Variance. Overall survival was estimated using the Kaplan-Meier method. These curves were compared between groups using log-rank tests. P-values less than 0.05 were considered significant. All analysis was completed using SAS version 9.4.

Results:

Between the years of 1988 and 2018, there were 2536 CIED initial implants in Olmsted County, including 1927 PPMs (single and dual-chamber), 440 ICDs, and 169 CRT (pacemaker N=52 and defibrillator N=117) devices (Central Illustration). The mean age at device implantation was higher for PPM recipients (76.7 years) compared to ICD (63.1 years) or CRT recipients (69.4 years). Women comprised 42.1% of all CIED recipients in the study. Baseline comorbidities of PPM, ICD and CRT patients are listed in table 1. The overall age and sex-adjusted incidence of CIED implants for the study period was 82.4 per

100,000 per year (95% CI 79.2–85.6). The age and sex-adjusted incidence of PPM, ICD, and CRT implantation were 62.9 (95% CI 60.0–65.7), 14.0 (95% CI 12.6–15.3), and 5.6 (95% CI 4.7–6.4) per 100,000 per year respectively. Among CRT recipients, the incidence of CRT-P implantation was 1.8 per 100,000 per year (95% CI 1.3–2.3), the incidence of CRT-D implantation was 3.8 per 100,000 per year (95% CI 3.1–4.5).

Temporal trends in CIED implantation

Temporal trends were compared between five intervals: 1988–93, 94–99, 2000–2005, 2006–11, and 2012–18. There was a significant change in the age and sex-adjusted incidence of any CIED implantation over time (Figure 1A). The age and sex-adjusted incidence increased between 1988–93 to 2000–05; from 56.7 (95% CI 49.2–64.1) to 102.7 (95% CI 94.4–111.0) per 100,000 per year; and subsequently decreased to 89.0 (95% CI 82.8–95.2) per 100,000 per year in 2012–2018, $p<0.001$. Similar trends were noted in the PPM and ICD groups. The age and sex-adjusted incidence of PPM implantation increased between 1988–93 and 2000–05, from 52.4 (95% CI 45.3–59.6) to 76.9 (95% CI 69.8–84.1) per 100,000 per year; then decreased to 61.1 (95% CI 56.0–66.3) per 100,000 per year in 2012–2018 ($p<0.001$). The age and sex-adjusted incidence of ICD implantation increased between 1988–93 and 2000–05, from 4.2 (95% CI 2.2–6.2) to 21.7 (95% CI 17.8–25.5) per 100,000 per year; then decreased to 16.2 (95% CI 13.6–18.9) per 100,000 per year in 2012–2018 ($p<0.001$). In contrast, the age and sex-adjusted incidence of CRT implantation continued to increase significantly from 2000–05 to 2012–18, from 4.1 (95% CI 2.5–5.8) to 11.6 (95% CI 9.4–13.8) per 100,000 per year ($p=0.009$). These increases in implantation incidence were noted in both CRT-P (2000–05: 0.4 [95% CI 0.0–0.9], 2012–18: 5.4 [95% CI 3.8–6.9] per 100,000 per year) and CRT-D (2000–05: 1.1 [95% CI 0.3–1.9], 2012–18: 10.8 [95% CI 8.6–12.9] per 100,000 per year) populations (Figure 1B).

CIED upgrades

Between 1988 and 2015, 88 patients underwent a device upgrade from PPM to ICD (N=24), PPM to CRT (N=39), and ICD to CRT (N=25). To examine the potential impact of device upgrades on ICD and CRT implant incidence, we included upgrades as new implants in a separate analysis. With this methodology, there was an increase in overall age and sex-adjusted ICD implantation rate to 14.5 per 100,000 per year (95% CI 13.1–15.9); and in CRT implantation rate to 6.5 per 100,000 per year (95% CI 5.6–7.5).

The inclusion of device upgrades did not change the observations of temporal trends in ICD or CRT implantation between 1988–2015 (Supplementary Figure 1).

Age and sex differences in CIED implantation

The incidence of CIED implantation increased significantly with age ($p<0.001$). The incidence of PPM implantation was highest in the 90–99 age group (incidence 762.5 per 100,000 per year. The incidence of ICD implantation was highest in the 70–79 age group (incidence 61.3 per 100,000 per year). The incidence of CRT implantation was highest in the 80–89 age group (incidence 34.5 per 100,000 per year). The incidence of CRT-D was highest in the 70–79 age group (20.1 per 100,000 per year), while the incidence of CRT-P was highest in the 80–89 age group (15.4 per 100,000 per year).

CIED implantation incidence was significantly greater in males compared to females (p<0.001) (Figure 2) The incidence for any CIED implant for the entire study period was 116.3 per 100,000 per year in males (95% CI 110.1–122.5) and 57.3 per 100,000 per year in females (95% CI 53.8–60.8). The incidence data for PPM, ICD, and CRT implant were consistent with these observations, with increased CIED utilization among males compared to females. The incidence of PPM implant was 82.7 per 100,000 per year in males (95% CI 77.4–88.1) and 49.2 per 100,000 per year in females (95% CI 46.0–52.4) (p<0.001). The incidence of ICD implant was 24.0 per 100,000 per year in males (95% CI 21.4–26.6) and 5.7 per 100,000 per year in females (95% CI 4.5–6.8) (p<0.001). The incidence of CRT implant was 9.5 per 100,000 per year in males (95% CI 7.8–11.2) and 2.5 per 100,000 per year in females (95% CI 1.8–3.3) (p<0.001).

Trends in comorbidities of patients receiving CIEDs

The comorbidities of patients receiving CIED as assessed by the Charlson comorbidity index have increased over time.The increase in overall comorbidity is noted in the PPM and ICD groups between 1988–1993 and 2012–2018, but not in the CRT group. There is a numerical decline in the Charlson comorbidity index for the CRT group, but this change was not statistically significant. Trends in patient demographics and comorbidities for the entire population and for the PPM, ICD and CRT groups are presented in tables 2, 3, 4 and 5. Frequency of several comorbidities including atrial fibrillation, chronic kidney disease, diabetes, hypertension and hyperlipidemia increased over time.

Overall survival after CIED implantation

The median follow-up period was 6.0 years (interquartile range 3.0–10.9 years). Survival after CIED implantation was 67.5% at 5 years (95% CI 65.7–69.4%). After PPM, ICD and CRT implantation the survival rate was 65.7% (95% CI 63.6–67.8%); 76.2% (95% CI 72.3–80.3%) and 66.7% (95% CI 60.5–73.6%) at 5 years.

Survival after PPM implantation changed significantly over time (figure 3B, p<0.0001), with most favorable survival among PPM recipients in 1988–93. Survival among patients with CRT improved over time (Figure 3A, p=0.0014). Survival among patients receiving ICD was unchanged over time, with a trend toward significance (p=0.066). Additionally, survival among those receiving initial ICD implant vs. upgrade to ICD was not different (p=0.94). Similarly, survival among those receiving initial CRT implant vs. upgrade to CRT was not different (p=0.10).

Gender differences in survival

Five-year survival among males receiving CIED was 68.7% (95% CI 66.3–71.0%), and among females was 66.0% (95% CI 63.2–68.9%), and there was no difference in survival after adjusting for age and Charlson comorbidity index (p=0.19, figure 4A). There were no differences in survival among males and females receiving PPM, ICD or CRT (figures 4B-D).

Discussion:

Using a large population-based records-linkage study, we describe trends in the epidemiology of CIED implantation. Our principal findings are (1) PPM remains the most commonly implanted device, comprising 76.0% of initial device implants, followed by ICD (17.4%) and CRT (6.7%). (2) After 2005, the incidence of overall CIED implantation is *decreasing*, driven by reduced incidence of PPM and ICD implantation. (3) However, the incidence of CRT implantation, both initial implantation, and upgrade of PPM or ICD to CRT is increasing. The incidence of CRT-P and CRT-D implantation are both increased. (4) The incidence of CIED implantation increases notably with increasing age. (5) Gender disparity in CIED implantation is marked and continues to be present, with the incidence of overall CIED implantation twice as high in men than in women. (6) Overall survival of CRT recipients has improved over time, while overall survival after PPM has worsened and remains unchanged for ICD recipients. (7) Finally, the overall comorbidities of patients receiving CIEDs have increased over time, especially among PPM and ICD recipients.

Trends in device implantation

The incidence of CIED implantations in Olmsted County increased significantly between 1988 and 2005. Following FDA approval of cardiac resynchronization therapy devices in 2001, an immediate increase in the incidence of CRT implantation was reported (7). Several previously conducted studies, which collected data from administrative sources, surveys, and national registries, observed a similar increase in CIED implant incidence during this time period (1, 7, 14).

Our data demonstrate that the substantial increase in CIED implantation until 2005 was, however, followed by an overall decline until 2015 by around 20%. The overall implantation rate in 2012–2015 was still 50% greater than 1988–1993. The decrease in CIED implant incidence was driven by a reduction in PPM and ICD implant rates between 2000–05 and 2012–15. The incidence of CRT implantation actually increased during the same period, but did not change the overall trend of reduction in CIED implantation rates.

These observations are consistent with multiple studies utilizing the nationwide inpatient sample datasets that have reported on CIED implantation rates since 2005 (9, 13, 18, 19). However, NIS methodology does not allow for estimation of device implantation in the outpatient setting or a direct population-based analysis of the incidence of device implantation. Our data from a population-based records-linkage study demonstrate that in the contemporary era, the incidence of CIED implantation, especially PPM and ICD implantation is decreasing.

The reasons for the decline in contemporary PPM/ICD implantation rates are not clear from our study. It is possible that because indications for PPM/ICD grew so rapidly in decades prior, a “saturation point” was eventually reached, such as ICD for primary prevention, where the number of patients newly eligible for these implants began to diminish. It is also possible that improvements in medical therapy of heart failure with reduced ejection fraction have decreased the requirement for ICD implantation. Finally, penalties imposed for inappropriate ICD usage could have contributed to the decline in

ICD implantation (20). Potential contributors to the increase in CRT de-novo implantation and upgrades over time could be expanded indications for CRT implantation in patients with right ventricular pacing-induced cardiomyopathy, high expected percentage of right ventricular pacing (Biventricular Versus Right Ventricular Pacing in Heart Failure Patients With Atrioventricular Block - BLOCK-HF study) and observational data supporting the safety and efficacy of CRT upgrade in patients with previous PPM or ICD implantation (21–25).

The clinical implications of a decline in CIED implantation incidence are multiple. These include estimation of the expected device volumes in the community, which can aid health care policy planning. These data also support that training of new electrophysiologists should focus on not only PPM and ICD de-novo implantation, but also on CRT implantation, including techniques for device upgrades. Electrophysiologists should also emphasize training on the follow-up of devices, including device troubleshooting and extraction.

Age at device implantation

The mean age at PPM implantation was consistent with previously reported real-world data; while the mean age at ICD and CRT implantation was only slightly older than patients enrolled in randomized clinical studies (mean age at ICD implantation: 63.1 vs. 60 years in SCD-HeFT; mean age at CRT implantation; 69.4 vs 65 years in MADIT-CRT) (9, 26, 27). CIED implantation incidence increased significantly with age, as well as the implantation incidence of any of the three device types individually, which has been shown previously (28, 29). However, the incidence of CIED implantation for the overall population was greatest in markedly older individuals (90–99 years for PPM, 70–79 years for ICD, and 80–89 years for CRT). Our data describe contemporary practice patterns of CIED implantation, where the incidence of device implantation is greatest among the elderly.

Gender disparity in device implantation

We observed a large gender disparity in the incidence of any CIED implants, with males twice as likely to receive a device than females. These findings are consistent with gender disparity in CIED clinical trial enrollment.(27, 30) The reasons behind the marked gender disparities in CIED implantation are unclear from our study. These findings could represent differences in the epidemiology of heart disease between men and women, physician referral bias, or patient preferences. Heart failure with reduced ejection fraction or with antecedent myocardial infarction, for which ICD and CRT implantation can be indicated, is more common in men compared to women (31–33). Another possibility is that criteria for ICD implantation may be more stringently followed in women compared with men, although this was not demonstrated in a previous National Cardiovascular Data Registry (NCDR) study (34). Under-referral for device implantation in women is another possible reason, with one study demonstrating that among hospitalized patients with heart failure, women were less likely than men to receive ICD implantation (35). Further studies are required to understand the reasons for the marked gender disparity in CIED implantation.

Comorbidities among patients with device implantation

The Charlson comorbidity index is derived from multiple risk factors that predict 1-year survival and can be used as a surrogate for comorbidity of a particular case mix (1, 36). Our data demonstrate that CIEDs continue to be implanted in patients with increasing comorbidities, consistent with previous data from the Rochester Epidemiology project as well as reports from other data sources (1, 9).

Survival after device implantation

Temporal changes in survival after CIED implantation have not been well elucidated before the current study. We report that the survival of ICD recipients has not changed significantly over the three decades, and that survival after PPM implantation has actually worsened after 1988–1993. The reasons for the lack of improvement are not clear from our study but may indicate a ceiling effect of the expected benefit from PPM and ICD implantation. Comorbidities of patients receiving PPM and ICD has increased over time, as evident from the increase in the Charlson Comorbidity index and may be contributing to the reduction of survival in PPM patients. However, the survival of CRT patients has improved, even after adjustment for comorbidities. This finding may reflect an improvement in the medical management of these patients including pharmacological advances in guideline-directed medical therapy and developments in mechanical circulatory support for heart failure including remote monitoring of fluid status via implanted devices.

Finally, despite adjustment for age and comorbidities, women have similar survival rates after CIED implantation, consistent with prior observational data (38). Our data suggest that women benefit equally from CIED implantation, despite being less likely to receive CIED implantation.

Limitations:

Demographic disparities in device implantation highlight a potential limitation of our patient population, which is relatively ethnically homogeneous, especially among the elderly. Prior studies have indicated that the REP data could be generalized to a large proportion of the United States population (39). However, our data may not be generalizable to populations with a higher proportion of ethnic minorities. We were also limited by the use of ICD codes for CIED implantation. However, the number of CIED implantations is consistent with previous REP studies with manual verification of all implantations, and all device upgrades were manually verified for the current study (40).

Although our data is population-based, all CIED related care during majority of the study period was provided by a single large tertiary care center, which may have different practice patterns compared to community-based practices. However, when comparing our findings to a large study from another data source, the incidence of PPM implantation was almost identical (62.8 per 100,000 in our study and 61.6 per 100,000 in the other) (9).

Initial indications for device implantation are not available, and we were unable to analyze any changes in implant indications over time. Data regarding primary vs. secondary prevention ICD implantation are currently unavailable.

Conclusions:

The incidence of pacemaker and defibrillator implants is decreasing, while the incidence of CRT implantation is increasing. Further study is necessary to understand the causes and implications of these trends. CIED implantation incidence is highest in the elderly, and these devices are implanted in increasingly comorbid patients. Women are far less likely than men to receive CIED implantation, despite similar rates of survival after device implantation. The overall mortality after device implantation remains high, although survival is improving among patients with CRT.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

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Abbreviations:

CIED	Cardiac Implantable Electronic Devices
ICD	Implantable Cardioverter-Defibrillator
PPM	Permanent Pacemaker
CRT	Cardiac Resynchronization Therapy
CRT-P	Cardiac Resynchronization Therapy – Pacemaker
CRT-D	Cardiac Resynchronization Therapy – Defibrillator
FDA	Food and Drug Administration
REP	Rochester Epidemiology Project
ICD-9/10	International Classification Of Diseases 9th /10th Revision
CPT	Current Procedural Terminology
NIS	National Inpatient Sample
NCDR	National Cardiovascular Data Registry

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Perspectives:

Clinical Competencies:

Medical Knowledge:

There exists a knowledge gap in the recent trends of CIED implants. The incidence of pacemaker and defibrillator implants is decreasing. The overall mortality after device implantation remains high, although survival is improving among patients with CRT.

Patient Care:

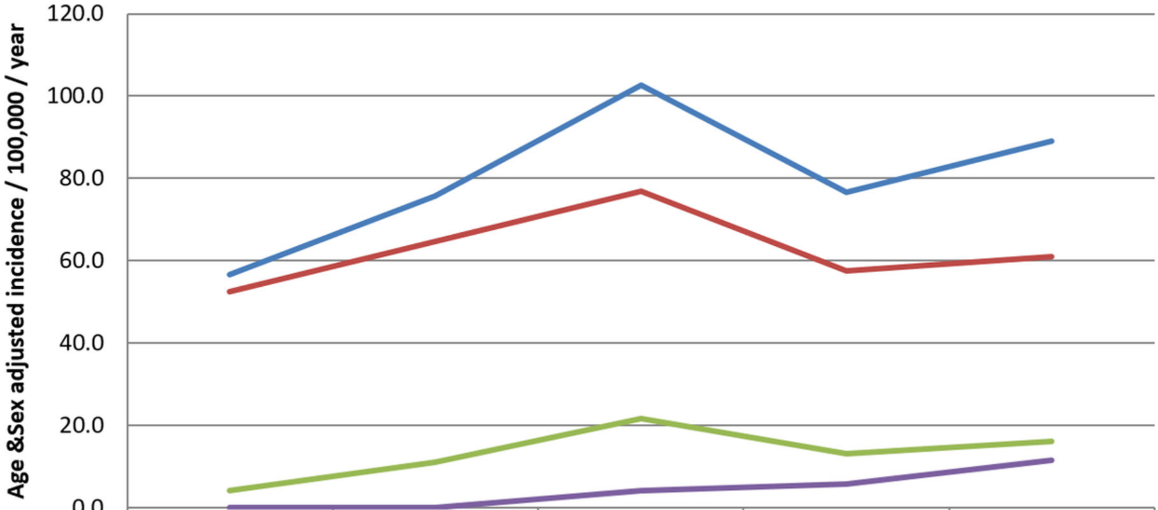
The clinical implications of a decline in CIED implantation incidence are multiple. These include estimation of the expected device volumes in the community, which can aid health care policy planning. These data also support that training of new electrophysiologists should focus on not only PPM and ICD de-novo implantation, but also CRT implantation, including techniques for device upgrades.

Translational Outlook 1:

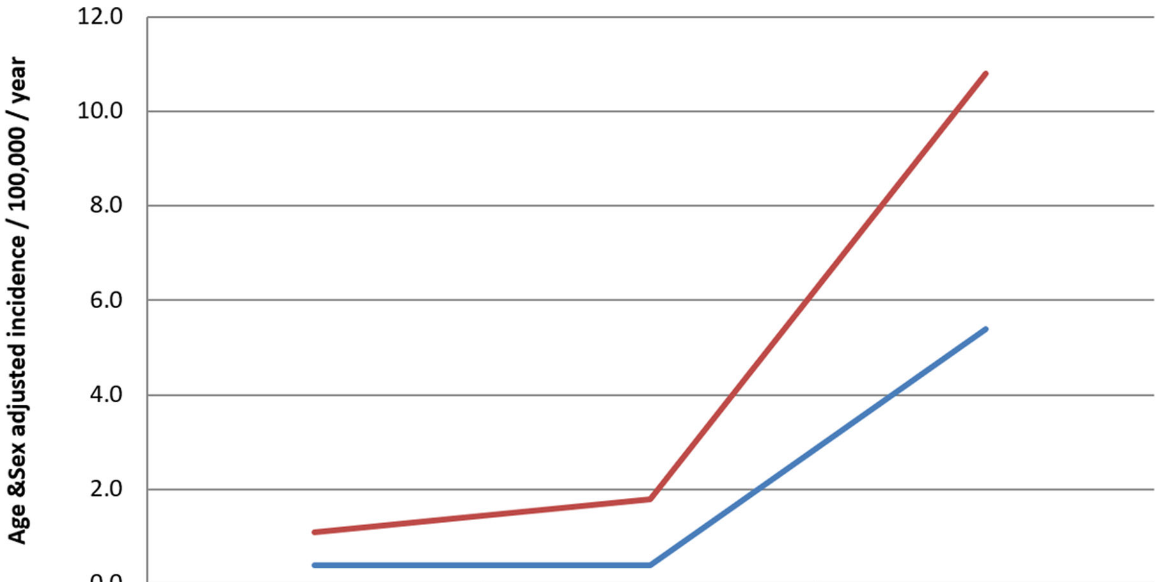
Further studies would be needed to understand the cause and implications of the trends in CIED implants.

Translational Outlook 2:

Techniques to help improve CRT implant success, and conduction system pacing will need to be continually investigated to improve clinical outcomes.



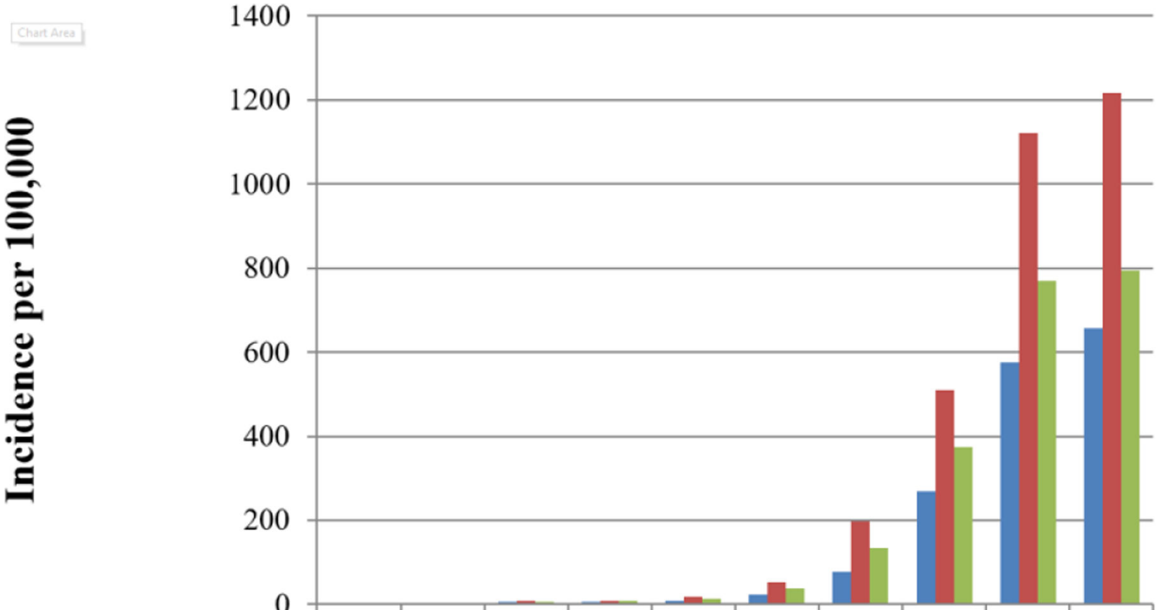
	1988-1993	1994-1999	2000-2005	2006-2011	2012-2018
CIED	56.7	75.8	102.7	76.6	89.0
PPM	52.4	64.8	76.9	57.6	61.1
ICD	4.2	11.0	21.7	13.1	16.2
CRT	0.0	0.0	4.1	5.9	11.6



	2000-2005	2006-2011	2012-2018
CRT-P	0.4	0.4	5.4
CRT-D	1.1	1.8	10.8

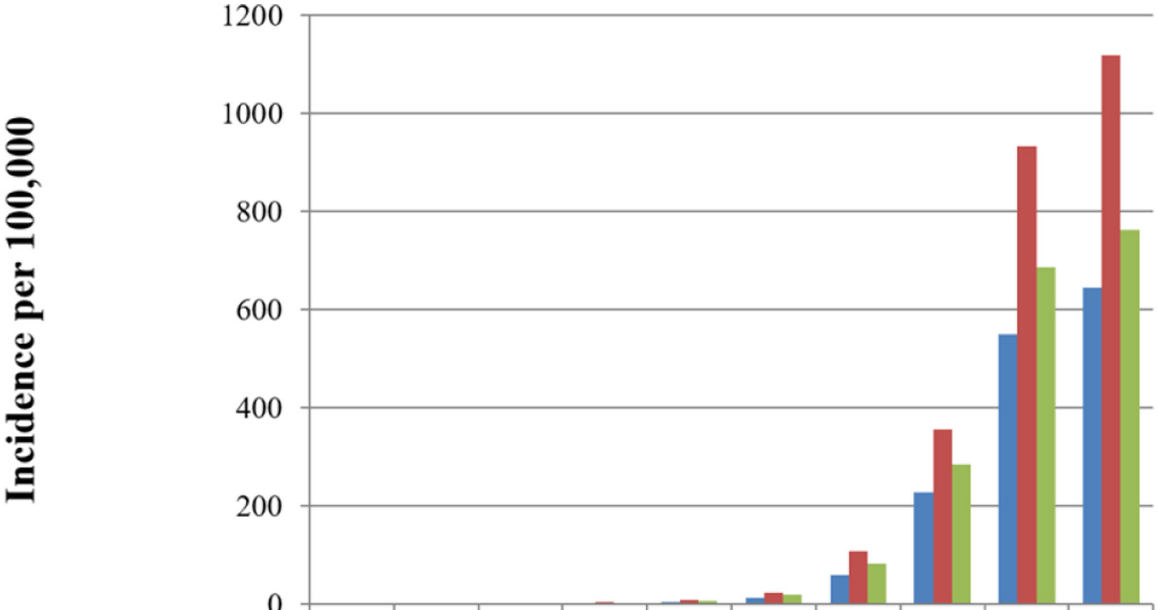
FIGURE 1.

Trends in CIED Insertion in Olmsted County



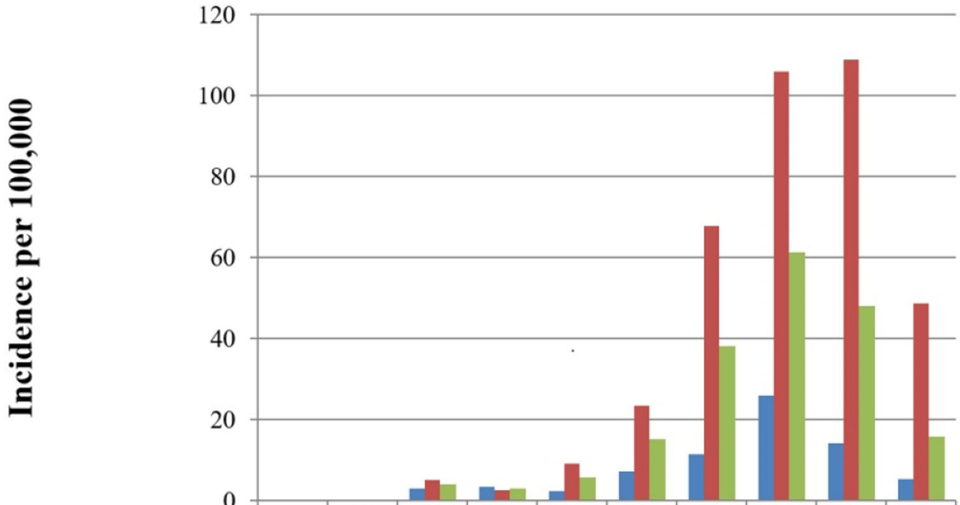
	0-9	10-19	20-29	30-39	40-49	50-59	60-69	70-79	80-89	90-99
Incidence (per 100,000) Female	0	0	5	7	10	24	77	268	575	657
Incidence (per 100,000) Male	0	1	8	8	20	53	196	509	1122	1216
Incidence (per 100,000) Overall	0	1	7	8	14	38	134	375	771	794

Age (in years)



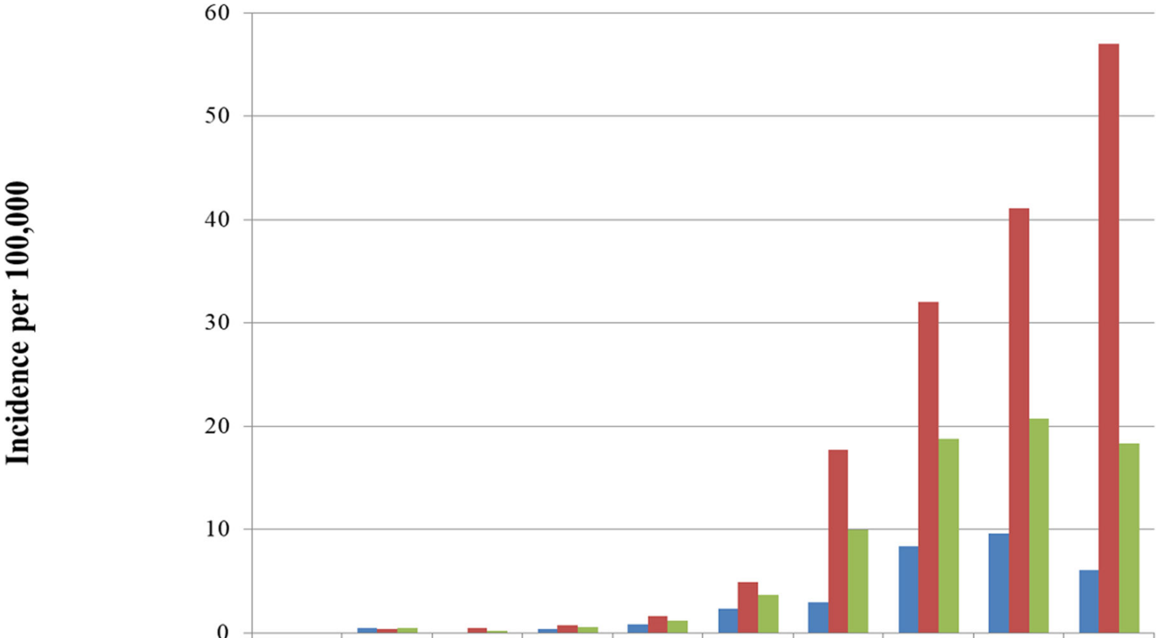
	0-9	10-19	20-29	30-39	40-49	50-59	60-69	70-79	80-89	90-99
Incidence Rate (per 100000) Female	0	0	2	3	6	14	61	227	551	646
Incidence Rate (per 100000) Male	0	0	3	5	9	24	108	357	934	1118
Incidence Rate (per 100000) Overall	0	0	2	4	8	19	83	285	688	763

Age (in years)



	0-9	10-19	20-29	30-39	40-49	50-59	60-69	70-79	80-89	90-99
Incidence Rate (per 100000) Female	0	0	3	4	2	7	11	26	14	5
Incidence Rate (per 100000) Male	0	0	5	3	9	23	68	106	109	49
Incidence Rate (per 100000) Total	0	0	4	3	6	15	38	61	48	16

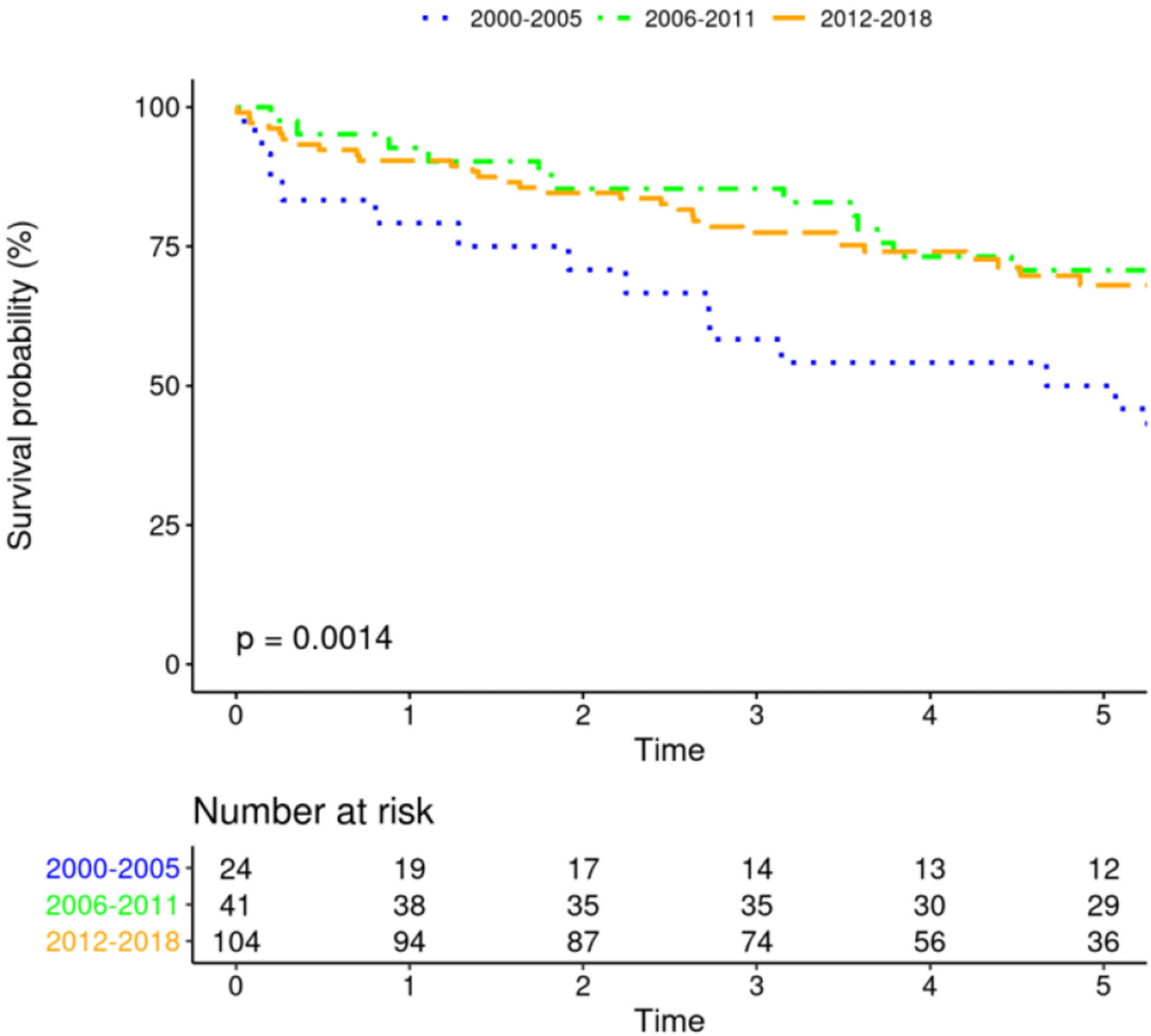
Age (in years)



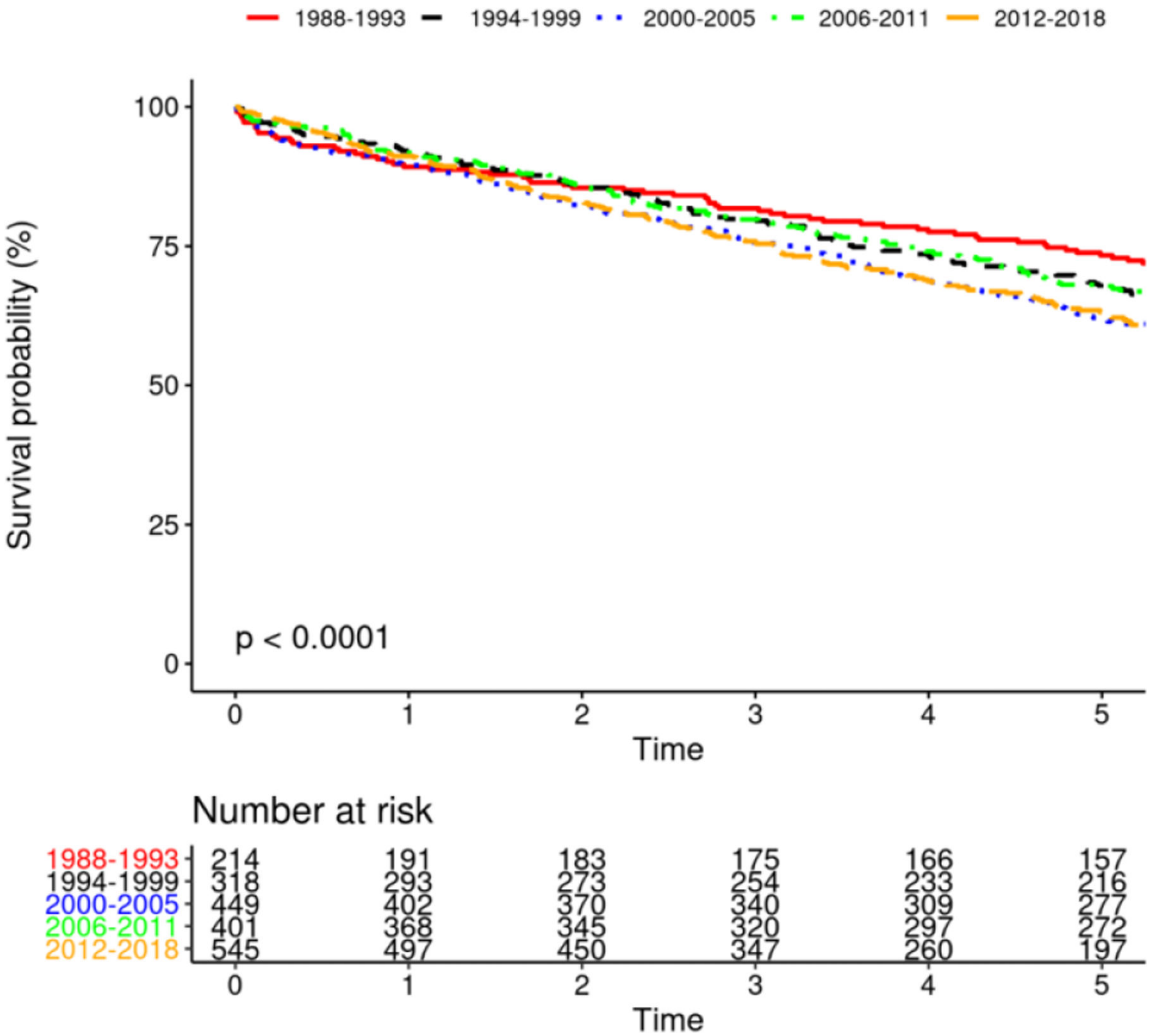
	0-9	10-19	20-29	30-39	40-49	50-59	60-69	70-79	80-89	90-99
Incidence Rate (per 100000) Female	0	0	0	0	1	2	3	8	10	6
Incidence Rate (per 100000) Male	0	0	0	1	2	5	18	32	41	57
Incidence Rate (per 100000) Total	0	0	0	1	1	4	10	19	21	18

Age (in years)

FIGURE 2.
Age- and Sex-Adjusted Incidence of CIED Insertion



2000-2005
2006-2011
2012-2018
Survival probability (%)
100
75
50
25
0
p = 0.0014
0 1 2 3 4 5
Time
Number at risk
2000-2005 24 19 17 14 13 12
2006-2011 41 38 35 35 30 29
2012-2018 104 94 87 74 56 36
0 1 2 3 4 5
Time


1988-1993
1994-1999
2000-2005
2006-2011
2012-2018
Survival probability (%)
100
75
50
25
0
p < 0.0001
0 1 2 3 4 5
Time
Number at risk
1988-1993 214 191 183 175 166 157
1994-1999 318 293 273 254 233 216
2000-2005 449 402 370 340 309 277
2006-2011 401 368 345 320 297 272
2012-2018 545 497 450 347 260 197
0 1 2 3 4 5
Time

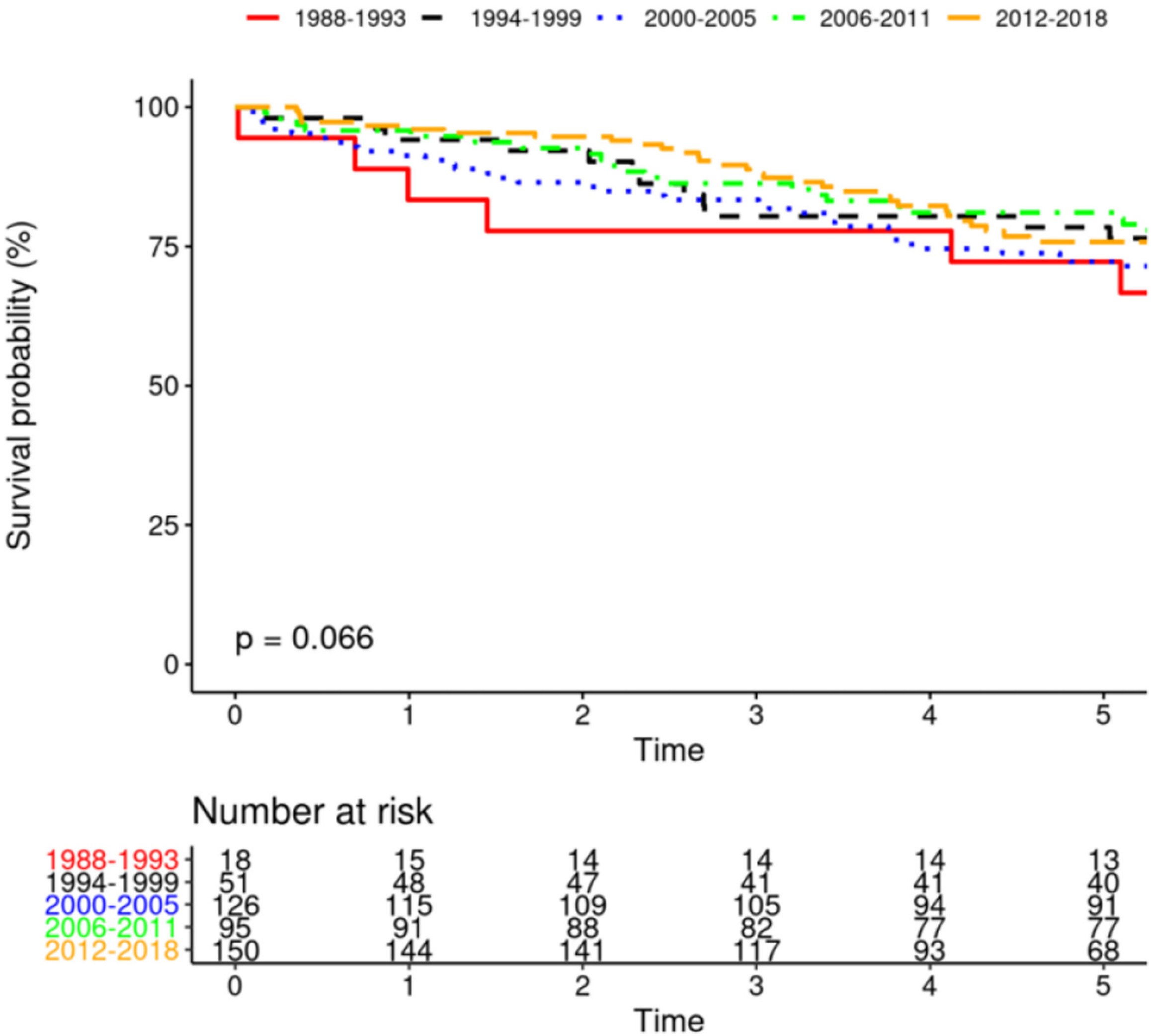
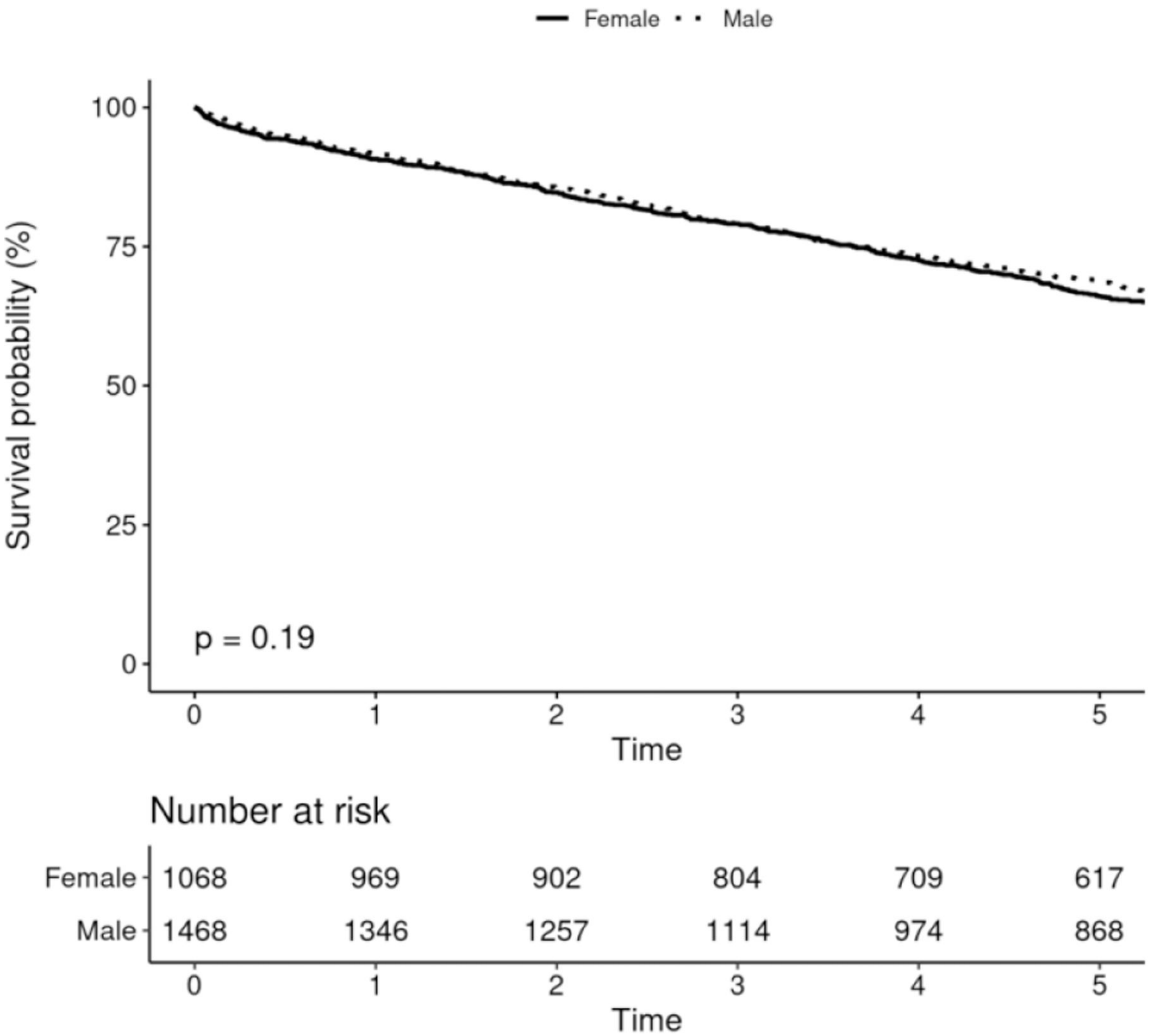
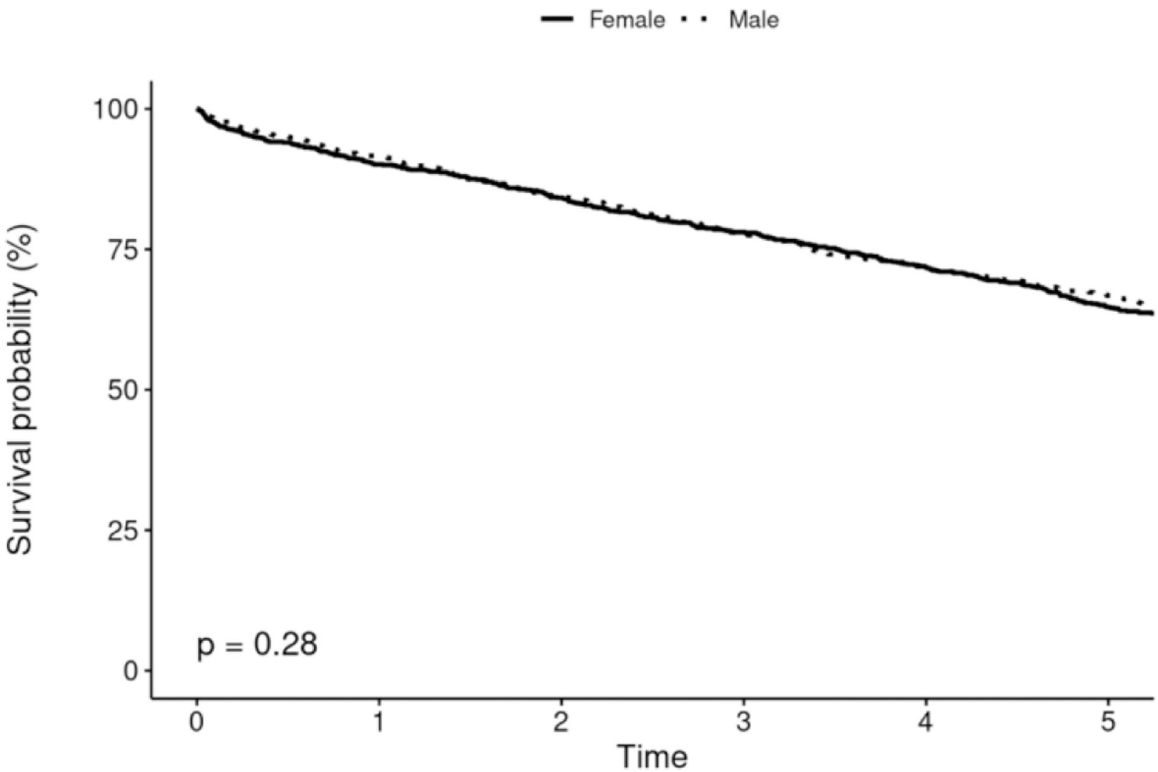


FIGURE 3.
Mortality After Device Insertion

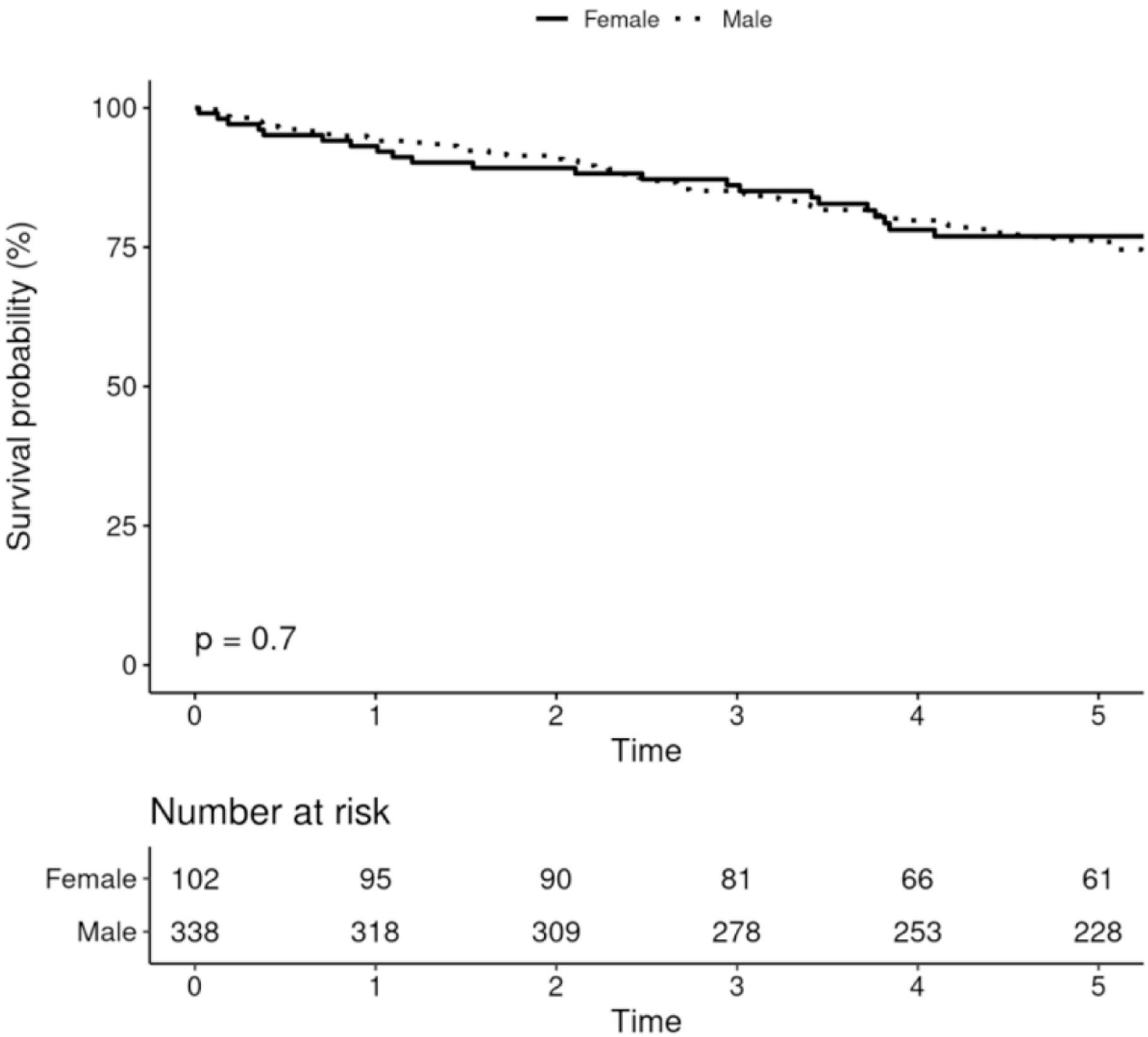

Female
Male
Survival probability (%)
100
75
50
25
0
p = 0.19
0
1
2
3
4
5
Time
Number at risk
Female 1068 969 902 804 709 617
Male 1468 1346 1257 1114 974 868
Time



Number at risk

	0	1	2	3	4	5
Female	922	831	774	688	614	535
Male	1005	920	847	748	651	584

Time


Female
Male
100
75
50
25
0
Survival probability (%)
p = 0.7
0
1
2
3
4
5
Time
Number at risk
Female 102 95 90 81 66 61
Male 338 318 309 278 253 228
Time

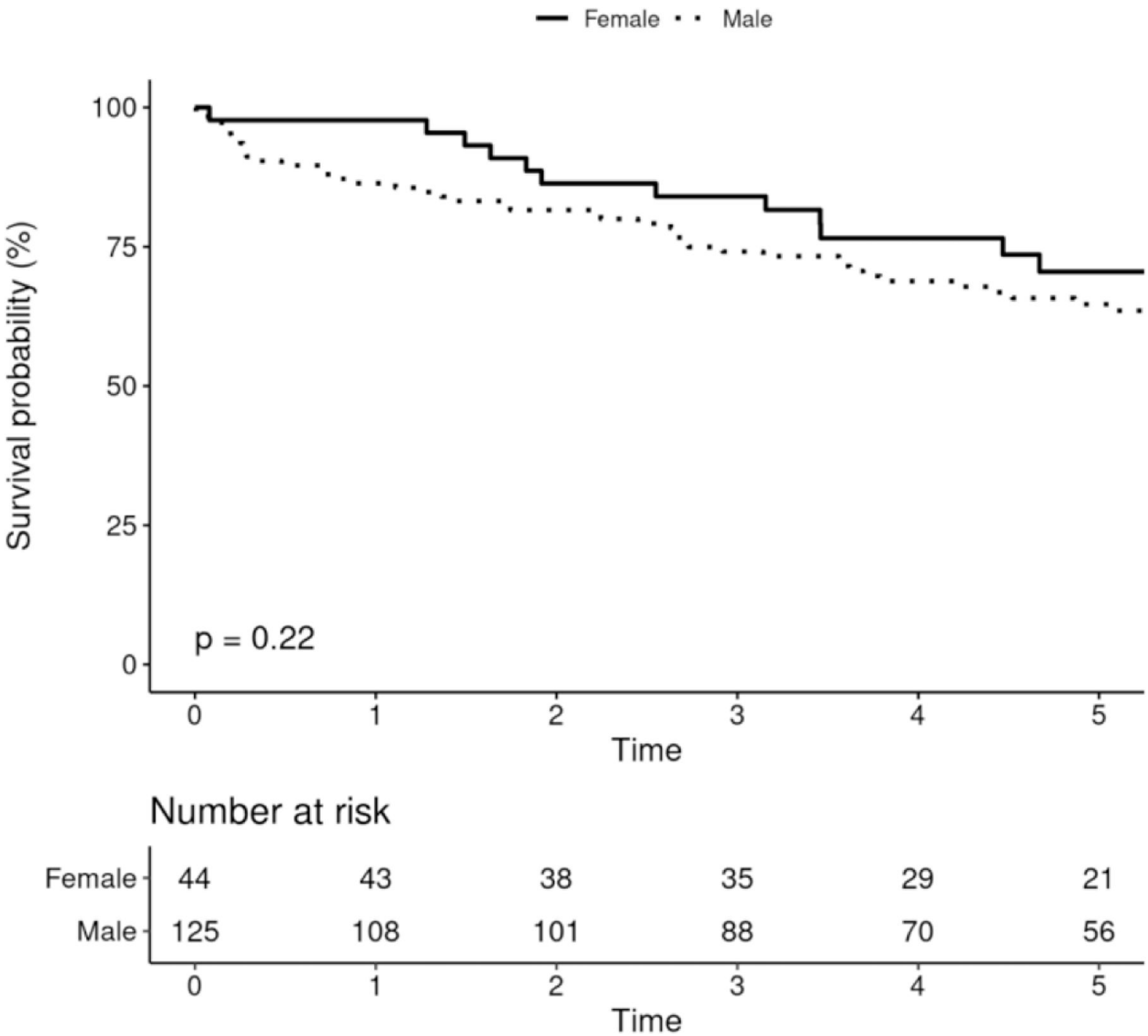


FIGURE 4.
Survival After Device Implantation by Sex

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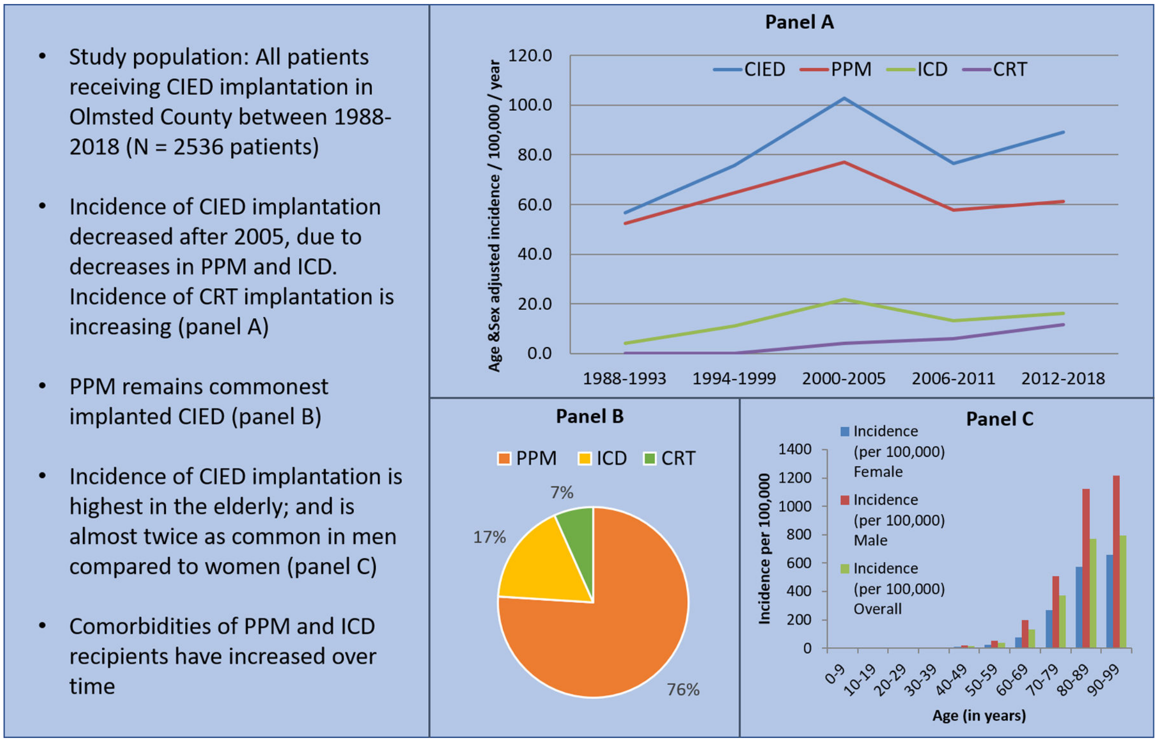

Central Illustration:

Trends in Cardiovascular Implantable Electronic Device Implantation in Olmsted County

Table 1:

Baseline demographics

	PPM (N=1927)	ICD (N=440)	CRT (N=169)	Total (N=2536)
Age				
Mean (SD)	76.7 (12.5)	63.1 (15.8)	69.4 (14.1)	73.9 (14.3)
Range	21.0 – 100.0	19.0 – 98.0	18.0 – 93.0	18.0 – 100.0
Sex				
Female	922 (47.8%)	102 (23.2%)	44 (26.0%)	1068 (42.1%)
Male	1005 (52.2%)	338 (76.8%)	125 (74.0%)	1468 (57.9%)
Atrial	1375 (71.4%)	291 (66.1%)	124 (73.4%)	1790 (70.6%)
Fibrillation				
Coronary artery disease	1435 (74.5%)	365 (83.0%)	147 (87.0%)	1947 (76.8%)
Congestive heart failure	1346 (69.8%)	357 (81.1%)	155 (91.7%)	1858 (73.3%)
Chronic kidney disease	956 (49.6%)	233 (53.0%)	98 (58.0%)	1287 (50.7%)
Chronic obstructive pulmonary disease	709 (36.8%)	165 (37.5%)	76 (45.0%)	950 (37.5%)
Diabetes	1170 (60.7%)	292 (66.4%)	118 (69.8%)	1580 (62.3%)
Hypertension	1698 (88.1%)	361 (82.0%)	147 (87.0%)	2206 (87.0%)
Obesity	1042 (54.1%)	249 (56.6%)	101 (59.8%)	1392 (54.9%)
Valvular heart disease	316 (18.3%)	87 (22.9%)	33 (28.0%)	436 (19.6%)
Hyperlipidemia	1216 (63.1%)	308 (70.0%)	91 (53.8%)	1615 (63.7%)
Charlson Score				
Mean (SD)	1.63 (1.73)	1.88 (2.17)	1.89 (2.08)	1.69 (1.84)
Range	0.0 – 9.0	0.0 – 18.0	0.0 – 8.0	0.0 – 18.0

Table 2:

Distribution of demographics and comorbidities over time for all patients

	1988–1993 N=232)	1994–1999 (N=369)	2000–2005 (N=599)	2006–2011 (N=537)	2012–2018 (N=799)	Total (N=2536)	p-value[**]
Age							0.95
Mean (SD)	73.9 (14.7)	74.1 (13.8)	74.0 (13.5)	73.4 (15.0)	74.0 (14.4)	73.9 (14.3)	
Range	19.0 – 97.0	26.0 – 100.0	23.0 – 99.0	21.0 – 100.0	18.0 – 99.0	18.0 – 100.0	
Sex							0.03
Female	109 (47.0%)	162 (43.9%)	274 (45.7%)	215 (40.0%)	308 (38.5%)	1068 (42.1%)	
Male	123 (53.0%)	207 (56.1%)	325 (54.3%)	322 (60.0%)	491 (61.5%)	1468 (57.9%)	
Atrial fibrillation	150 (64.7%)	242 (65.6%)	435 (72.6%)	374 (69.6%)	589 (73.7%)	1790 (70.6%)	0.009
Coronary artery disease	175 (75.4%)	300 (81.3%)	480 (80.1%)	413 (76.9%)	579 (72.5%)	1947 (76.8%)	0.002
Congestive heart failure	181 (78.0%)	276 (74.8%)	468 (78.1%)	371 (69.1%)	562 (70.3%)	1858 (73.3%)	< 0.001
Chronic kidney disease	85 (36.6%)	192 (52.0%)	348 (58.1%)	274 (51.0%)	388 (48.6%)	1287 (50.7%)	< 0.001
Chronic obstructive pulmonary disease	80 (34.5%)	157 (42.5%)	250 (41.7%)	187 (34.8%)	276 (34.5%)	950 (37.5%)	0.007
Diabetes	93 (40.1%)	188 (50.9%)	369 (61.6%)	370 (68.9%)	560 (70.1%)	1580 (62.3%)	< 0.001
Hypertension	170 (73.3%)	316 (85.6%)	538 (89.8%)	482 (89.8%)	700 (87.6%)	2206 (87.0%)	< 0.001
Obesity	111 (47.8%)	188 (50.9%)	298 (49.7%)	311 (57.9%)	484 (60.6%)	1392 (54.9%)	< 0.001
Valvular heart disease	46 (19.8%)	55 (14.9%)	108 (18.0%)	100 (18.6%)	127 (26.0%)	436 (19.6%)	< 0.001
Hyperlipidemia	88 (37.9%)	234 (63.4%)	474 (79.1%)	461 (85.8%)	358 (44.8%)	1615 (63.7%)	< 0.001
Any cancer[*]	16 (6.9%)	49 (13.3%)	120 (20.0%)	114 (21.2%)	171 (21.4%)	470 (18.5%)	<0.001
Charlson comorbidity index							< 0.001
Mean (SD)	1.1 (1.3)	1.5 (1.5)	2.0 (1.8)	2.1 (1.8)	2.3 (1.9)		

[*] including lymphoma, leukemia and metastatic solid organ tumors

[**] p-value compares demographics over time groups

Table 3.

Distribution of demographics and comorbidities over time for patients receiving PPM

Overall comparisons between groups	**1988 – 1993 (N=214)**	**1994 – 1999 (N=318)**	**2000 – 2005 (N=449)**	**2006 – 2011 (N=401)**	**2012 – 2018 (N=545)**	**Total (N=1927)**	**p value**[**]
Age							0.04
Mean (SD)	75.4 (13.5)	75.4 (13.7)	76.8 (11.8)	76.8 (12.7)	77.9 (11.7)	76.7 (12.5)	
Range	(23.0–97.0)	(26.0–100.0)	(25.0–99.0)	(21.0–100.0)	(23.0–99.0)	(21.0–100.0)	
Sex							0.005
Female	108 (50.5%)	150 (47.2%)	246 (54.8%)	182 (45.4%)	236 (43.3%)	922 (47.8%)	
Male	106 (49.5%)	168 (52.8%)	203 (45.2%)	219 (54.6%)	309 (56.7%)	1005 (52.2%)	
Atrial fibrillation	139 (65.0%)	208 (65.4%)	333 (74.2%)	288 (71.8%)	407 (74.7%)	1375 (71.4%)	0.005
Coronary artery disease	160 (74.8%)	255 (80.2%)	349 (77.7%)	305 (76.1%)	366 (67.2%)	1435 (74.5%)	0.0001
Congestive heart failure	166 (77.6%)	236 (74.2%)	341 (75.9%)	263 (65.6%)	340 (62.4%)	1346 (69.8%)	<0.0001
Chronic kidney disease	77 (36.0%)	160 (50.3%)	254 (56.6%)	202 (50.4%)	263 (48.3%)	956 (49.6%)	<0.0001
Chronic obstructive pulmonary disease	71 (33.2%)	136 (42.8%)	183 (40.8%)	139 (34.7%)	180 (33.0%)	709 (36.8%)	0.01
Diabetes	87 (40.7%)	158 (49.7%)	267 (59.5%)	277 (69.1%)	381 (69.9%)	1170 (60.7%)	<0.0001
Hypertension	161 (75.2%)	276 (86.8%)	409 (91.1%)	372 (92.8%)	480 (88.1%)	1698 (88.1%)	<0.0001
Obesity	106 (49.5%)	162 (50.9%)	224 (49.9%)	233 (58.1%)	317 (58.2%)	1042 (54.1%)	0.01
Valvular heart disease	39 (18.2%)	43 (13.5%)	76 (16.9%)	68 (17.0%)	90 (16.5%)	316 (16.4%)	0.62
Hyperlipidemia	79 (36.9%)	193 (60.7%)	346 (77.1%)	350 (87.3%)	471 (86.4%)	1439 (74.7%)	<0.0001
Any cancer [*]	14 (6.5%)	47 (14.8%)	96 (21.4%)	93 (23.2%)	135 (24.8%)	385 (20.0%)	<0.0001
Charlson comorbidity index							
Mean (SD)	1.1 (1.3)	1.6 (1.5)	1.9 (1.6)	2.0 (1.8)	2.3 (1.9)		<0.001

[*] including lymphoma, leukemia and metastatic solid organ tumors

[**] p-value compares demographics over time groups

Table 4.

Distribution of demographics and comorbidities over time for patients receiving ICD

Overall comparisons between groups	**1988 – 1993 (N=18)**	**1994 – 1999 (N=51)**	**2000 – 2005 (N=126)**	**2006 – 2011 (N=95)**	**2012 – 2018 (N=150)**	**Total (N=440)**	**p value**[**]
Age							0.27
Mean (SD)	57.1 (18.1)	66.2 (11.6)	65.0 (14.4)	61.6 (18.0)	62.1 (16.3)	63.1 (15.8)	
Range	(19.0–78.0)	(36.0–86.0)	(23.0–91.0)	(21.0–98.0)	(20.0–90.0)	(19.0–98.0)	
Sex							0.048
Female	1 (5.6%)	12 (23.5%)	21 (16.7%)	24 (25.3%)	44 (29.3%)	102 (23.2%)	
Male	17 (94.4%)	39 (76.5%)	105 (83.3%)	71 (74.7%)	106 (70.7%)	338 (76.8%)	
Atrial fibrillation	11 (61.1%)	34 (66.7%)	85 (67.5%)	58 (61.1%)	103 (68.7%)	291 (66.1%)	0.76
Coronary artery disease	15 (83.3%)	45 (88.2%)	109 (86.5%)	75 (78.9%)	121 (80.7%)	365 (83.0%)	0.43
Congestive heart failure	15 (83.3%)	40 (78.4%)	103 (81.7%)	75 (78.9%)	124 (82.7%)	357 (81.1%)	0.93
Chronic kidney disease	8 (44.4%)	32 (62.7%)	77 (61.1%)	48 (50.5%)	68 (45.3%)	233 (53.0%)	0.048
Chronic obstructive pulmonary disease	9 (50.0%)	21 (41.2%)	55 (43.7%)	33 (34.7%)	47 (31.3%)	165 (37.5%)	0.17
Diabetes	6 (33.3%)	30 (58.8%)	85 (67.5%)	68 (71.6%)	103 (68.7%)	292 (66.4%)	0.019
Hypertension	9 (50.0%)	40 (78.4%)	108 (85.7%)	78 (82.1%)	126 (84.0%)	361 (82.0%)	0.005
Obesity	5 (27.8%)	26 (51.0%)	64 (50.8%)	58 (61.1%)	96 (64.0%)	249 (56.6%)	0.014
Valvular heart disease	7 (38.9%)	12 (23.5%)	29 (23.0%)	22 (23.2%)	17 (11.3%)	87 (19.8%)	0.012
Hyperlipidemia	9 (50.0%)	41 (80.4%)	107 (84.9%)	79 (83.2%)	127 (84.7%)	363 (82.5%)	0.006
Any cancer[*]	2 (11.1%)	2 (3.9%)	15 (11.9%)	14 (14.7%)	15 (10.0%)	48 (10.9%)	0.37
Charlson comorbidity index							
Mean (SD)	1.4 (1.4)	1.4 (1.7)	2.3 (2.1)	2.3 (1.8)	2.0 (1.9)		0.018

[*] including lymphoma, leukemia and metastatic solid organ tumors

[**] p-value compares demographics over time groups

Table 5.

Distribution of demographics and comorbidities over time for patients receiving CRT

Overall comparisons between groups	2000 – 2005 (N=24)	2006 – 2011 (N=41)	2012 – 2018 (N=104)	Total (N=169)	p value[#]
Age					0.35
Mean (SD)	69.0 (16.4)	67.8 (12.8)	70.1 (14.2)	69.4 (14.1)	
Range	(26.0–91.0)	(37.0–90.0)	(18.0–93.0)	(18.0–93.0)	
Sex					0.77
Female	7 (29.2%)	9 (22.0%)	28 (26.9%)	44 (26.0%)	
Male	17 (70.8%)	32 (78.0%)	76 (73.1%)	125 (74.0%)	
Atrial fibrillation	17 (70.8%)	28 (68.3%)	79 (76.0%)	124 (73.4%)	0.61
Coronary artery disease	22 (91.7%)	33 (80.5%)	92 (88.5%)	147 (87.0%)	0.33
Congestive heart failure	24 (100.0%)	33 (80.5%)	98 (94.2%)	155 (91.7%)	0.007
Chronic kidney disease	17 (70.8%)	24 (58.5%)	57 (54.8%)	98 (58.0%)	0.36
Chronic obstructive pulmonary disease	12 (50.0%)	15 (36.6%)	49 (47.1%)	76 (45.0%)	0.45
Diabetes	17 (70.8%)	25 (61.0%)	76 (73.1%)	118 (69.8%)	0.36
Hypertension	21 (87.5%)	32 (78.0%)	94 (90.4%)	147 (87.0%)	0.14
Obesity	10 (41.7%)	20 (48.8%)	71 (68.3%)	101 (59.8%)	0.015
Valvular heart disease	3 (12.5%)	10 (24.4%)	20 (19.2%)	33 (19.5%)	0.50
Hyperlipidemia	21 (87.5%)	32 (78.0%)	97 (93.3%)	150 (88.8%)	0.03
Any_cancer[*]	9 (37.5%)	7 (17.1%)	21 (20.2%)	37 (21.9%)	0.13
Charlson comorbidity index					
Mean (SD)	3.3 (2.2)	3.0 (2.0)	2.7 (1.7)		0.31

[*] including lymphoma, leukemia and metastatic solid organ tumors

[#] p-value compares demographics over time groups