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ORIGINAL ARTICLE

Patient characteristics, predictors and outcome of pacemaker patients upgraded to an implantable cardioverter defibrillator

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Summary: This systematic characterization of a large PM population upgraded to ICD shows that five percent of ICD implantations are upgrades from PM. Predictors for subsequent ICD upgrade are male sex and lower LVEF. At least one in 30 PM patients will require an ICD in the following 10 years. Outcome of PM patients with ICD upgrade is worse compared to matched PM patients without ICD upgrade, and to patients with de novo ICD implantation.

Abstract

Aims: Pacemaker (PM) patients may require a subsequent upgrade to an implantable cardioverter defibrillator (ICD). Limited data exists on this patient population. We sought to characterize this population, to assess predictors for ICD upgrade, and to report the outcome.

Methods: From our prospective PM and ICD implantation registry, all patients who underwent PM and/or ICD implantations at our center were analyzed. Patient characteristics and outcomes of PM patients with subsequent ICD upgrade were compared to age- and sex-matched patients with de novo ICD implantation, and to PM patients without subsequent upgrade.

Results: Of 1′301 ICD implantations, 60 (5%) were upgraded from PMs. Median time from PM implantation to ICD upgrade was 2.6 years (IQR 1.3-5.4). Of 2′195 PM patients, 28 patients underwent subsequent ICD upgrades, corresponding to an estimated annual incidence of an ICD upgrade of at least 0.33%. Lower LVEF ($p = .05$) and male sex ($p = .038$) were independent predictors for ICD upgrade. Survival without death, transplant and LVAD implantation were worse both for upgraded ICD patients compared to matched patients with de novo ICD implantation ($p = .05$), as well as for PM patients with subsequent upgrade compared to matched PM patients not requiring an upgrade ($p = .036$).

Conclusions: One of 20 ICD implantations are upgrade of patients with a PM. At least one of 30 PM patients will require an ICD upgrade in the following 10 years. Predictors for ICD upgrade are male sex and lower LVEF at PM implantation. Upgraded patients have worse outcomes.

Abbreviations: LVAD, left ventricular assist device..

Andreas Haeberlin and Laurent Roten contributed equally to this manuscript and share last authorship.

KEYWORDS
implantable cardioverter defibrillator, mortality, pacemaker, risk factors, upgrade

1 | INTRODUCTION

Implantable Cardioverter Defibrillators (ICDs) are indicated in patients with sustained ventricular arrhythmias or patients at risk for malignant arrhythmias and sudden cardiac death. Among ICD recipients, some patients already have a pacemaker (PM) implanted due to earlier bradyarrhythmias or bundle branch block with heart failure. Reasons for an ICD upgrade in PM patients include the new occurrence of sustained ventricular arrhythmias, prompting secondary preventive ICD implantation. Another important reason for an ICD upgrade is a decrease of the left ventricular ejection fraction (LVEF) due to a progressive disease or a cardiac event such as a myocardial infarction (MI) with subsequent primary preventive ICD indication. However, conditions or events that lead to an upgrade from a PM to an ICD have not been systematically assessed, nor the prevalence of ICD recipients with previous PM implantation. Only a few publications include this particular patient population as a subgroup, but without specific characterization and without reporting outcomes.[1,2] The aim of this study was to characterize the patient population with PM and subsequent ICD upgrade in detail, including outcome.

2 | METHOD

At our tertiary care center, all ICD operations performed since January 2009, and all PM operations performed since January 2011 have been prospectively recorded in the Swiss national device implantation registry. This registry includes information on baseline patient characteristics, implanted hardware as well as previous and subsequent device-related procedures. From this source, and by reviewing all ICD implantation reports, we identified all ICD upgrades performed at our center in patients with a prior PM implantation. No exclusion criteria were applied. Patient characteristics at the time of PM implantation and at the time of ICD upgrade were completed from patient charts.

Patient characteristics at the time of ICD upgrade were compared to patients with de novo ICD implantation. Patient characteristics at the time of PM implantation of patients with subsequent ICD upgrades were compared to patients without subsequent upgrades. Outcome data was retrieved from our centralized institutional health records database and from the National Social Security Death Index. The primary outcome measure was survival without death, heart transplantation and left ventricular assist device (LVAD)-implantation. Secondary outcome in the ICD population was freedom from ICD re-intervention, excluding simple generator exchange for battery depletion but including both conventional or surgical ICD re-interventions.

This study was approved by the local ethics committee (approval number 2018-00048) and conducted according to the principles of the Declaration of Helsinki. All patients gave written informed consent to be included in the Swiss national device implantation registry. The authors designed the study, collected and analyzed the data, and vouch for data accuracy and analysis.

2.1 | Statistical analysis

Categorical variables are expressed as numbers and percentages. Continuous variables are shown as median and interquartile range (IQR). Comparisons between patient groups were performed using a Wilcoxon rank-sum test. Proportions were compared using Pearson's χ^2 test or Fisher's exact test as appropriate.

Transplant- and LVAD-free patient survival, and incidence of ICD re-interventions were analyzed using Kaplan-Meier estimates and compared with the log-rank test. ICD upgrade patients were compared to an age- and sex-matched cohort of ICD patients with de novo implantation. Similarly, patients that underwent an upgrade from PM to ICD were compared to an age- and sex-matched cohort of PM patients that did not undergo an upgrade. The patient cohorts were matched for age and sex using sequential 10:1 nearest neighbor propensity score matching.

To identify predictors for a subsequent upgrade to an ICD, uni- and multivariate Cox proportional hazard regression models were fitted. Data at the time of PM implantation was used to identify potential predictors. The multivariate model included all variables from the univariate models with a p-value $< .1$. A two-sided p-value $\leq .05$ was considered significant. R version 4.1.1 for Windows (R Foundation, Vienna, Austria) and SPSS version 25 (IBM, Armonk, NY) were used for statistical analysis. Propensity score matching was performed using the "MatchIt" package.

3 | RESULTS

3.1 | ICD patients with versus without prior PM implantation

Of 1'301 ICD patients recorded in our device implantation registry, 60 patients (5%) were upgrades from a PM (Figure 1). None of these patients had an ICD indication at the time of PM implantation. Median time from PM implantation to ICD upgrade was 2.6 years (IQR 1.3-5.4). Table 1 shows the baseline characteristics of ICD patients with de novo ICD implantation compared to ICD upgrade patients.

Compared to patients with de novo ICD implantation, ICD upgrade patients were older (median 66 years [IQR 58-7]) vs. 62 years [IQR 52-69], $p = .039$), more frequently had prior cardiac surgery (33% vs. 14%, $p < .001$), and had worse NYHA class (3 [IQR 2-3] vs. 2 [IQR 1-3], $p = .008$). Single-chamber devices (57%) were most fre-

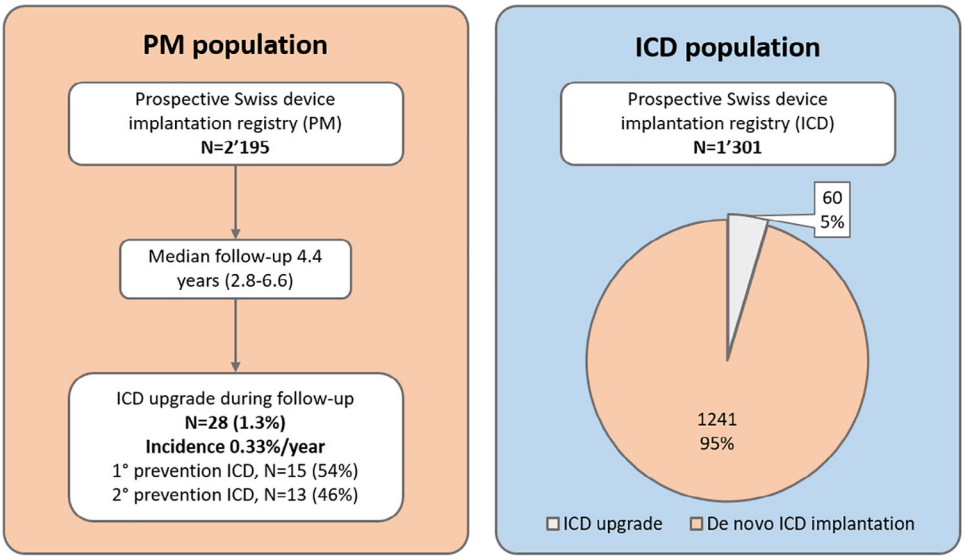

FIGURE 1 Overview of the pacemaker and ICD population of the present study, and respective findings. [Color figure can be viewed at wileyonlinelibrary.com]

quently implanted in de novo ICD implantations, whereas CRT-D (55%) devices were mainly implanted in patients with ICD upgrades ($p < .001$).

Of the 60 upgraded ICD patients, 26 patients (43%) had coronary artery disease (CAD) 25 (42%) had non-ischemic cardiomyopathy (NICM), and 9 (15%) had no structural heart disease at PM implant. Figure 2 summarizes patient characteristics and the clinical course of upgraded ICD patients, stratified by the initial cardiac disease. Overall, secondary prevention was the reason for an ICD upgrade in 27 patients (45%). Among patients with CAD, secondary prevention was the reason for the upgrade in 12 of the 26 patients (46%) and among patients with NICM in six of the 25 patients (24%; $p = .1$). All nine patients without structural heart disease at PM implantation received the ICD upgrade for secondary prevention after the occurrence of a malignant tachyarrhythmia. The arrhythmia and etiology in these patients were as follows:

Polymorphic ventricular tachycardia (VT)/ventricular fibrillation (VF) in Long-QT-Syndrome (LQTS) in two patients (22%); VT/VF in newly diagnosed NICM in four patients (44%); idiopathic VF in one patient (11%); VF in mitral valve prolapse syndrome in one patient (11%); and recurrent, therapy refractory, syncopal monomorphic VT without structural heart disease in one patient (11%). Figure 3 shows an example of a polymorphic VT recorded by the PM in a patient with LQTS that prompted ICD upgrade.

Median follow-up time after ICD upgrade was 5.8 years (IQR 3.5-7.3). Appropriate anti-tachycardia therapy (ATP or shock) was delivered in 14 of 27 patients (52%) with ICD upgrade for secondary prevention and in 13 of 33 patients (39%) with ICD upgrade for primary prevention ($p = .436$).

Survival without death, transplant, or LVAD implantation was lower in upgraded ICD patients compared to patients with de novo ICD implantation ($p = .05$; Figure 4A). Twelve of the 60 upgraded patients (20%) underwent a re-intervention on the ICD other than simple generator change including two subsequent CRT-D upgrades (7%) and one device explantation and lead extraction due to device-related endocarditis. However, there was no difference in the rate of ICD re-interventions other than simple generator change for battery depletion in patients with ICD upgrade compared to patients with de novo ICD implantation ($p = .65$; Figure 4B).

3.2 | PM patients with versus without subsequent ICD upgrade

Of 2'195 PM patients recorded in our device implantation registry, 28 patients (1.3%) had subsequent ICD upgrades (Figure 1). Of note, these 28 patients are also included in the population of 60 ICD patients with prior PM implantation described in the section above. CAD was present in 14 patients (50%) and NICM in 11 (39%). The remaining three patients (11%) had no overt structural heart disease. Median follow-up time of all PM patients was 4.4 years (IQR 2.8-6.6). The incidence of subsequent ICD upgrades in these PM patients was 0.33%/year. Table 2 shows the baseline characteristics of PM patients with and without subsequent ICD upgrade. At PM implantation, patients with subsequent upgrade were younger (65 years [IQR 62-70] vs. 78 years [IQR 70-83], $p < .001$), had lower LVEF (40% [IQR 35-60] vs. 60% [IQR 50-65], $p < .001$) and were more frequently men (96% vs. 61%; $p = .012$).

Table 3 shows uni- and multivariate predictors for subsequent ICD upgrades. In the multivariate Cox proportional hazard regression model, a lower LVEF ($p = .05$) and male sex ($p = .038$) remained the only independent predictors for subsequent ICD upgrades. Secondary prevention was the indication for ICD upgrade in 13 patients (46%). Six of these patients (21%) had documented VT, and seven (25%) had VF. The remaining patients had a decrease in LVEF over time, prompting ICD implantation for primary prevention. Survival without death,

TABLE 1 Baseline characteristics of patients undergoing ICD implantation as an upgrade from a previous PM system and with de novo ICD implantation.

	ICD upgrade from previous PM ($n = 60$)	De novo ICD implantation ($n = 1'241$)	p-value
Clinical patient characteristics			
Female [n]	12 (20%)	234 (19%)	0.958
Age at PM implant [years]	63 (52-67)	-	-
Age at ICD implant [years]	66 (58-71)	62 (52-69)	**0.039**
LVEF at PM implant [%]	45 (35-60)	-	-
LVEF at ICD implant [%]	30 (25-45)	30 (25-45)	0.930
NYHA class at PM implant	2 (2-3)	-	-
NYHA class at ICD implant	3 (2-3)	2 (1-3)	**0.008**
Prior MI	16 (27%)	575 (46%)	**0.004**
MI between PM and ICD	5 (8%)	-	-
Prior cardiac surgery	20 (33%)	172 (14%)	**<0.001**
Cardiac surgery between PM and ICD	16 (27%)	-	-
Initial PM indication			
SSS syndrome [n]	12 (20%)	-	-
AV conduction disease [n]	47 (78%)	-	-
Other	1 (2%)	-	-
Initial PM type			
Single-chamber PM [n]	22 (37%)	-	-
Dual-chamber PM [n]	37 (62%)	-	-
CRT-P [n]	1 (2%)	-	-
Cardiopathy at time of ICD implantation			
Coronary artery disease	28 (47%)	636 (51%)	0.575
Non-ischemic cardiomyopathy	28 (47%)	506 (41%)	0.440
No structural heart disease	4 (7%)	61 (5%)	0.724
ICD indication			
Primary prevention	33 (55%)	682 (55%)	
Secondary prevention	27 (45%)	559 (45%)	1
ICD type			
Single-chamber ICD [n]	7 (12%)	705 (57%)	**<0.001**
Dual-chamber ICD [n]	20 (33%)	234 (19%)	**0.009**
CRT-D [n]	33 (55%)	302 (24%)	**<0.001**

Note: Median values with interquartile ranges (IQR) in brackets and absolute numbers with percentages are shown. Abbreviations: CRT-D—cardiac resynchronization defibrillator; CRT-P—cardiac resynchronization pacemaker; ICD—implantable cardioverter defibrillator; MI—myocardial infarction, NYHA—New York Heart Association; PM—pacemaker; SSS—sick sinus syndrome.

transplant, or LVAD implantation of PM patients with subsequent ICD upgrade was worse compared to matched PM patients not requiring an ICD upgrade ($p = .036$; Figure 4C).

4 | DISCUSSION

This is a retrospective, single-center study of patients who underwent PM implantation and subsequently had an upgrade to an ICD at our high-volume tertiary care center. The analyses are based on a large PM- ($n = 2'195$) and ICD-cohort ($n = 1'301$) included in the prospective Swiss national device implantation registry.

The main findings of the present study are:

1. One out of 20 ICD implantations (5%) are upgrades in patients with a PM.
2. The incidence of ICD upgrades in PM patients is at least 0.33% per year.
3. Predictors at PM implantation for subsequent ICD upgrade are male sex and lower LVEF.

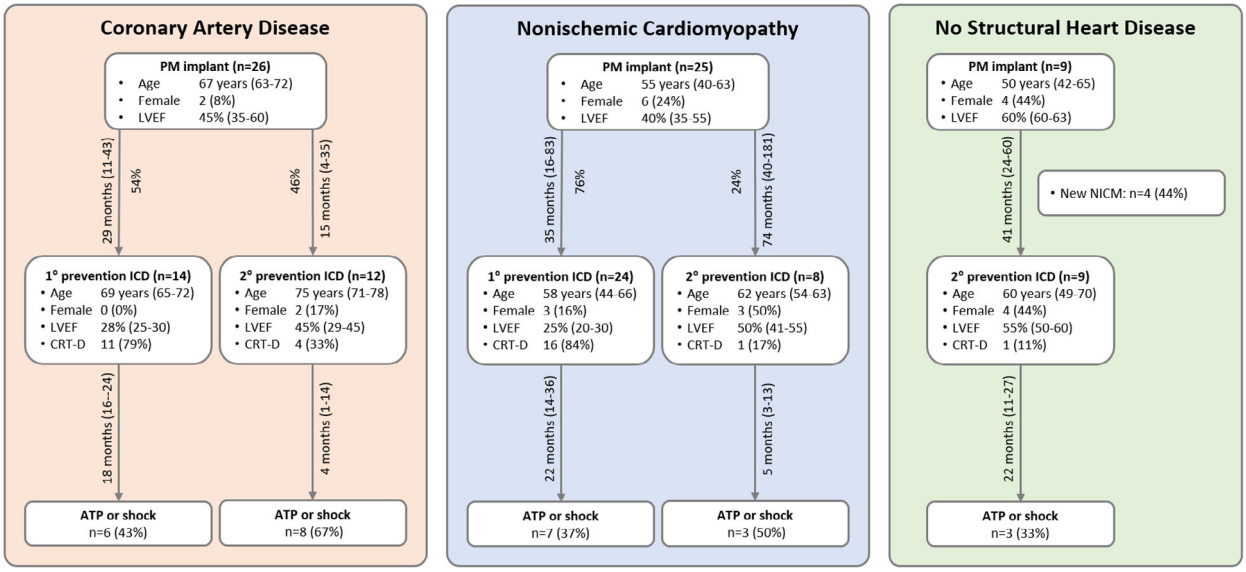

FIGURE 2 Patient characteristics and disease progression of all 60 patients with ICD upgrade from prior PM, stratified according to heart disease at PM implant. Median values with interquartile ranges (IQR) in brackets and absolute numbers with percentages are shown. ATP—anti-tachycardia pacing; CAD—coronary artery disease; CRT-D—cardiac resynchronization defibrillator; ICD—implantable cardioverter defibrillator; LVEF—left ventricular ejection fraction; NICM—non-ischemic cardiomyopathy; PM—pacemaker. [Color figure can be viewed at wileyonlinelibrary.com]

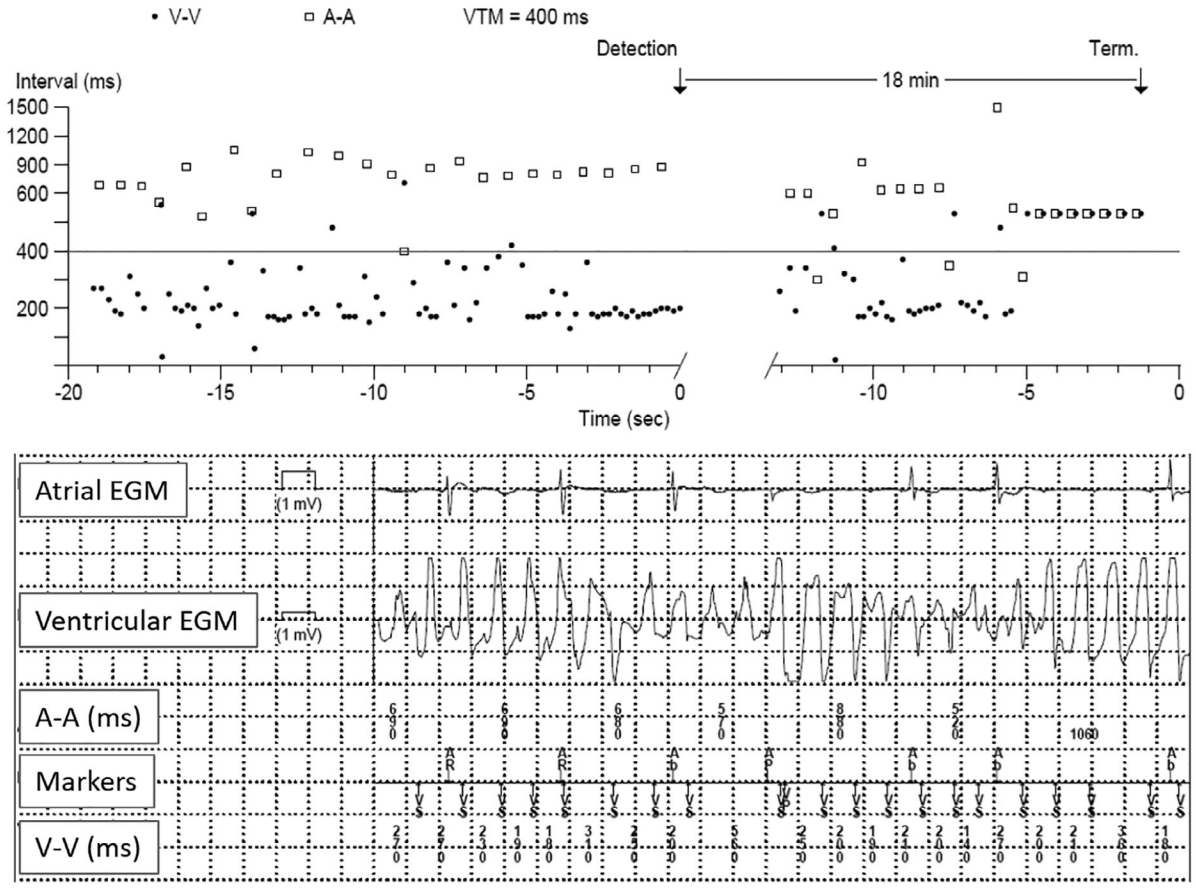

FIGURE 3 Example of a PM patient with Long-QT syndrome (LQT3) who was resuscitated for polymorphic ventricular fibrillation with successful external defibrillation. A PM was implanted 18 years earlier for symptomatic sinus bradycardia because of betablocker therapy. This was his first episode of ventricular fibrillation. The upper panel shows the tachogram and the lower panel the electrograms of the ventricular fibrillation episode recorded by the PM. EGM—electrogram; PM—pacemaker.

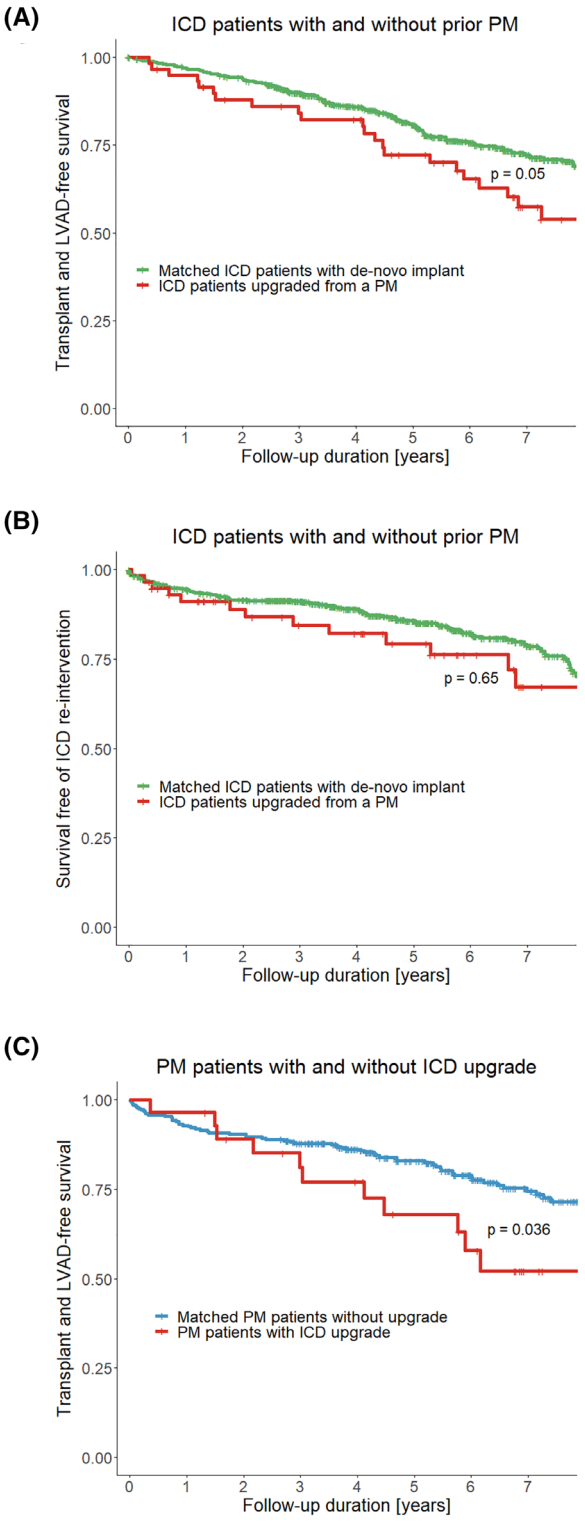

FIGURE 4 Shown are Kaplan-Meier estimates of (A) freedom from death, heart transplantation or implantation of a LVAD for upgraded ICD patients versus matched ICD patients with de novo ICD implantation; (B) freedom from ICD re-interventions other than simple generator exchange for battery depletion for upgraded ICD patients versus matched ICD patients with de novo implant; and (C) freedom from death, heart transplantation or implantation of a LVAD for upgraded PM patients versus matched PM patients without subsequent upgrade. [Color figure can be viewed at wileyonlinelibrary.com]

4. Outcome of PM patients upgraded to an ICD is worse compared to matched PM patients without upgrade, and outcome of upgraded ICD patients is worse compared to patients with de novo ICD implantation.

The specific population of patients that are upgraded from a PM to an ICD is barely described in the literature. To the best of our knowledge, this is the first systematic characterization of this population. Small and elderly studies—mainly from the era prior to the broad availability of ICDs and the establishment of current ICD indications—reported an incidence of malignant ventricular arrhythmias and sudden cardiac death in 12%–31% of PM patients, months or even years after PM implantation.[3–6] Faber and coworkers followed 231 patients with a PM for 15 months and found non-sustained VT in 31 patients. Only one patient had sustained VT and was upgraded to an ICD.[2] Sweeney and coworkers described upgrades of single-chamber PMs or ICDs to dual-chamber ICDs in 2002. Twenty-nine of 57 patients were upgraded from a PM to an ICD. The study, however, focused on the technical feasibility of ICD upgrade in this earlier area of ICD therapy and did not specifically characterize this population.[1] Two additional studies focused on the prognostic relevance of non-sustained VT in PM patients but likewise did not comment on characteristics of the PM population upgraded to an ICD.[7,8] Adelstein and coworkers studied patients with NICM, reduced LVEF and right ventricular pacing, that were upgraded to CRT-D and included 36 patients with prior PM. However, the study focused on LVEF improvement with biventricular stimulation.

With a yearly incidence of at least 0.33% only a minority of PM patients require a subsequent upgrade to an ICD. Nevertheless, 5% of first ICD implantations are upgrades from PMs. As compared to PM patients without upgrade, patients with subsequent upgrade were younger at initial implantation, had a lower LVEF, and were more likely to be men. The indication for PM implantation was AV conduction disease in the vast majority of cases (93%) with subsequent upgrade. Our data suggests that lower LVEF at PM implantation and male sex are independent predictors for a subsequent ICD upgrade. LVEF is an established predictor of mortality in patients with cardiovascular disease and plays a central role in risk stratification.[9] An already reduced LVEF at PM implantation may predict a further deterioration of cardiac function or the occurrence of malignant arrhythmias prompting subsequent ICD implantation. Of note, none of our PM patient with subsequent ICD upgrade fulfilled the criteria for ICD implantation at the time of PM implantation. The other independent predictor for subsequent upgrade was male sex. Male patients with a PM indication may have a less favorable disease progression, for example, due to a higher incidence of cardiovascular disease, particularly CAD. On the other hand, women may be less likely to receive an ICD than men despite an appropriate indication.[10] Since we only have data on actually performed procedures, our data does not allow to draw any conclusions on potential undertreatment of women.

Among the patients with structural heart disease at the time of PM implantation, but without indication for primary prevention ICD implantation, 46% of patients with CAD, and 24% with NICM received the ICD for secondary prevention after the occurrence of a malignant

TABLE 2 Baseline characteristics of PM patients with and without a subsequent upgrade to an ICD.

	PM patients with ICD upgrade ($n = 28$)	PM patients w/o ICD upgrade ($n = 2'167$)	*p*-value
Clinical patient characteristics			
Female sex [n]	4 (14%)	856 (40%)	**0.012**
Age at PM implant [years]	65 (62-70)	78 (70-83)	<**0.001**
Age at ICD upgrade [years]	67 (63-72)	-	-
LVEF at PM implant [%]	40 (35-60)	60 (50-65)	<**0.001**
LVEF at ICD upgrade [%]	30 (25-45)	-	-
NYHA class at PM implant	2 (2-3)	2 (1-2)	**0.121**
NYHA class at ICD upgrade	3 (2-3)	-	-
PM indication			
SSS syndrome [n]	2 (7%)	519 (24%)	0.064
AV conduction disease [n]	26 (93%)	1610 (74%)	**0.043**
PM type			
Single-chamber PM [n]	8 (29%)	1013 (47%)	0.085
Dual-chamber PM [n]	19 (68%)	1045 (48%)	0.061
CRT-P [n]	1 (4%)	107 (5%)	1.000
ICD indication			
Primary prevention [n]	15 (54%)	-	-
Secondary prevention [n]	13 (46%)	-	-
CPR prior to ICD implantation [n]	6 (21%)	-	-
ICD type			
Single-chamber ICD [n]	4 (14%)	-	-
Dual-chamber ICD [n]	8 (29%)	-	-
CRT-D [n]	16 (57%)	-	-

Note: Median values with interquartile ranges (IQR) in brackets or absolute numbers with percentages in brackets are shown. Abbreviations: CPR—cardiopulmonary resuscitation; CRT-D—cardiac resynchronization defibrillator; CRT-P—cardiac resynchronization pacemaker; ICD—implantable cardioverter defibrillator; NYHA—New York Heart Association; PM—pacemaker; SSS—sick sinus syndrome.

TABLE 3 Predictors of ICD upgrade (uni- and multivariate Cox proportional hazard regression models).

	Univariate analysis		Multivariate analysis	
Variables	HR (95%-CI)	*p*-value	HR (95%-CI)	*p*-value
Age	0.98 (0.97-1.00)	**.100**	0.99 (0.96-1.01)	.38
Female sex	0.25 (0.09-0.71)	**.009**	0.19 (0.04-0.91)	**.038**
LVEF	0.95 (0.93-0.97)	<**.001**	0.96 (0.92-1.00)	**.05**
NYHA class	2.34 (1.28-4.26)	**.006**	1.63 (0.68-3.67)	.26
PM indication AV conduction disease	1.82 (0.94-3.52)	**.074**	1.54 (0.70-3.81)	.34

Abbreviations: CI—confidence interval; CRT-P—cardiac resynchronization pacemaker; HR—hazard ratio; ICD—implantable cardioverter defibrillator; LVEDD—left ventricular end-diastolic diameter; LVEF—left ventricular ejection fraction; NYHA—New York Heart Association; PM—pacemaker.

ventricular arrhythmia. The remaining patients had a deterioration of LVEF with subsequent ICD implantation for primary prevention.

More patients with ICD upgrade received a dual-chamber ICD or CRT-D as compared to patients with de novo ICD implantation, which were more likely to have a single-chamber ICD implanted. This reflects the need for continuous ventricular stimulation in upgraded patients and the necessity of biventricular stimulation in those with impaired LVEF. However, there was no differ-

ence in the rate of ICD implantations for secondary prevention in patients with ICD upgrade compared to patients with de novo ICD implantation.

Prior cardiac surgery was frequent in upgraded patients (33%), and most of them (27%) had cardiac surgery between initial PM implantation and ICD upgrade.

The outcome of upgraded PM patients was worse compared to a matched PM population without subsequent upgrade. Similarly, upgraded ICD patients had a worse prognosis compared to patients with de novo ICD implantations. These findings probably reflect a longer disease course and patient history of arrhythmias in the upgraded population.

Upgraded patients have at least one device intervention in addition to generator exchange: they either underwent implantation of an additional ICD lead or extraction of the original ventricular PM lead with re-implantation of an ICD lead. It is well described that the risk for subsequent device infections or other device-related complications increases with the number of device interventions.[11–13] However, in this series we found no difference in the rate of re-interventions other than ordinary generator replacement in patients with ICD upgrade as compared to patients with de novo ICD implantation. This may be owed to the limited follow-up duration of 5.8 years.

4.1 | Limitations

This is a retrospective study of patients who underwent PM implantations and subsequently had an upgrade to an ICD at a single, high-volume tertiary care center. The population of cases with upgrades is small in our study and the results of our study need to be confirmed in a larger population. The Swiss National Device Implantation Registry served as the source of data. All available data were analyzed. Additional parameters of potential clinical interest like e.g. LVEF or adverse events of device implantations were not available. The fact, that only a small number of device patients need an upgrade, results in a limited effective population of interest. Even though patient charts have been screened carefully, some patients may have undergone device upgrade at other centers without our knowledge and may be missing in the analyses. Therefore, incidence of ICD upgrades in PM patients may be underestimated. We have no complete information on the percentage of ventricular pacing in the PM population available and can therefore not assess the potential influence of ventricular pacing on the evolution of left ventricular function. Likewise, we have no information on the incidence of ICD therapies for the entire ICD population. The number of ICD therapies delivered during follow-up depends on device programming. We did not use uniform programming in the entire ICD population, which may have introduced a bias. Over time, some patients with a PM may have become eligible for an upgrade to an ICD but either declined the procedure or were not offered the upgrade due to co-morbidities or physician decisions.

5 | CONCLUSIONS

One of 20 ICD implantations are upgrades in patients with a previous PM.

Conversely, at least one in 30 patients undergoing a first PM implantation will require an ICD upgrade in the following 10 years. Upgrade may relate to worsening cardiomyopathy qualifying for primary prevention ICD, or new need from secondary prevention. Predictors for subsequent ICD upgrade are male sex and lower LVEF at initial PM implantation. Outcome of PM patients upgraded to an ICD is worse when compared to PM patients without subsequent upgrade, and to ICD patients without previous PM.

AUTHOR CONTRIBUTION

Samuel H. Baldinger: concept/design, data collection, data analysis/interpretation, drafting of manuscript. Désirée Burren: data collection, drafting of manuscript. Fabian Noti, Helge Servatius, Jens Seiler, Antonio Madaffari, Hildegard Tanner, and Tobias Reichlin: data collection, critical revision. Babken Asatryan: critical revision. Andreas Haeberlin: data collection, data analysis/interpretation, drafting of manuscript. Laurent Roten: concept/design, data collection, drafting of manuscript, critical revision

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

DETAILED DISCLOSURES

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