CHAPTER XIV

Suitability for Subcutaneous Defibrillator Implantation: Results Based on Data From Routine Clinical Practice

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ABSTRACT

Objective: To assess the proportion of current implantable cardioverter defibrillator (ICD) recipients who would be suitable for a subcutaneous lead ICD (S-ICD).

Design: A retrospective cohort study.

Setting: Tertiary care facility in the Netherlands.

Patients: All patients who received a single- or dual-chamber ICD in the Leiden University Medical Center between 2002 and 2011. Patients with a pre-existent indication for cardiac pacing were excluded.
Main outcome measure Suitability for an S-ICD defined as not reaching one of the following endpoints during follow-up: (1) an atrial and/or right ventricular pacing indication, (2) successful antitachycardia pacing without a subsequent shock or (3) an upgrade to a CRT-D device.

Results: During a median follow-up of 3.4 years (IQR 1.7–5.7 years), 463 patients (34% of the total population of 1345 patients) reached an endpoint. The cumulative incidence of ICD recipients suitable for an initial S-ICD implantation was 55.5% (95% CI 52.0% to 59.0%) after 5 years. Significant predictors for the unsuitability of an S-ICD were: secondary prevention, severe heart failure and prolonged QRS duration.

Conclusions: After 5 years of follow-up, approximately 55% of the patients would have been suitable for an S-ICD implantation. Several baseline clinical characteristics were demonstrated to be useful in the selection of patients suitable for an S-ICD implantation.

INTRODUCTION

In the past decades implantable cardioverter defibrillators (ICDs) have become an established therapy for the prevention of sudden cardiac death.[1–4] Since the first implantation in 1980, ICDs have undergone many improvements and have evolved from large abdominally placed devices into substantially smaller devices placed pectorally.[5] Currently, ICDs rely on transvenously implanted leads for cardiac sensing, defibrillation and if necessary also for cardiac pacing. Recently, however, a new, entirely subcutaneous, ICD system avoiding the need for the placement of sensing and therapy electrodes within or on the heart has been developed. Initial results demonstrated that this device adequately detected and treated episodes of sustained ventricular tachyarrhythmia.[6] It is suggested that the subcutaneous ICD might be easier to implant and will result in a lower proportion of device related complications when compared with a transvenously implanted ICD.[6] However, despite the supposed advantages, an important drawback of the subcutaneous ICD is the incapability of cardiac pacing.[7] Therefore, patients who have a cardiac (atrial and or ventricular) pacing indication at implantation are unsuitable for such a device. Moreover, patients who develop such an indication during follow-up should preferably also not receive a subcutaneous ICD. Furthermore, the latter device is also not capable of antitachycardia pacing (ATP), resulting in a diminished suitability for the subcutaneous ICD in patients receiving successful ATP for ventricular arrhythmias. Finally, for patients requiring an upgrade to a cardiac resynchronisation therapy defibrillator (CRT-D) due to worsening heart failure, an initial transvenously implanted ICD is preferred over a subcutaneous implanted ICD.

The objective of this study was to establish in a large clinical cohort of ICD recipients the suitability for an entirely subcutaneous ICD system. Furthermore, among baseline clinical parameters, predictors of the unsuitability for a subcutaneously implanted ICD were established.

METHODS

Patients

This retrospective analysis comprised all consecutive patients who received an ICD system at Leiden University Medical Center. Implant procedures were registered in the departmental Cardiology Information System (EPD-Vision, Leiden University Medical Center). Characteristics at baseline, data of the implant procedure and all follow-up visits were recorded. The data for the current registry were collected between January 2002 and April 2011.

Eligibility for ICD implantation in this population was based on international guidelines for primary and secondary prevention. Due to evolving guidelines, indications will have changed over time.[8,9]

Device implantation and programming

All defibrillator system implantations were performed transvenously without thoracotomy. During the implant procedure, sensing and pacing thresholds were determined and a defibrillation test was performed. The systems used were manufactured by Biotronik (Berlin, Germany), Boston Scientific (Natick, Massachusetts, USA, formerly CPI, Guidant (St Paul, Minnesota, USA)), Medtronic (Minneapolis, Minnesota, USA) and St Jude Medical/Ventritex (St Paul, Minnesota, USA).

Devices were programmed according to a strict protocol to guarantee uniformity. In single-chamber ICD recipients, cardiac stimulation parameters were set to VVI 40. In dual-chamber ICDs, a non-tracking backup mode of DDI 40 was programmed with sufficiently long Atrioventricular (AV) delay to secure intrinsic conduction at the lower rate. If applicable, algorithms such as managed ventricular pacing or remote mode switching were also used to avoid unnecessary right ventricular pacing.[10]

The antitachycardia modes in all devices were programmed with three consecutive zones with limits slightly varying per manufacturer: a monitor zone (lower limit between 150 and 155 bpm; upper limit between 185 and 190 bpm), an ATP shock zone (lower limit between 185 and 190 bpm; upper limit between 205 and 210 bpm) and an initial shock zone (≥205–210 bpm). In the monitor zone, no therapy was programmed unless a ventricular arrhythmia was detected during follow-up. In the ATP shock zone, arrhythmias were initially attempted to be terminated by two bursts of ATP and, if the arrhythmia persisted, defibrillator shocks were used. In case of a ventricular arrhythmia faster than the ATP shock zone, device shocks were the initial therapy. Detection times or number of intervals for ATP treatment were programmed as follows: 26 intervals for Biotronik, 1.5 s for Boston Scientific/Guidant, 18 out of 24 intervals for Medtronic and 12 intervals for St Jude Medical/Ventritex devices. Furthermore, atrial arrhythmia detection was set to >170 bpm with supraventricular tachycardia discriminators enabled. Therapy settings were adapted only when clinically indicated.

Device interrogation was scheduled every 3–6 months after implantation. Delivered therapies were then adjudicated by a trained electrophysiologist. Data of these ICDs were included until the last date of ICD check-up.

Endpoints

Patients who received a CRT-D device were not included in the current analysis. Furthermore, all patients who were pacemaker-dependent or had another clear indication, for pacing directly following implantation (ie, settings other than VVI 40 or DDI 40) were excluded from the study population (figure 1).[8,9] For the remaining patients (ie, the study population), the combined primary endpoint of this analysis was the unsuitability for an subcutaneous lead ICD (S-ICD), which was defined as the occurrence of one of the following individual endpoints:

1. The development of an atrial and/or right ventricular pacing indication: In the event that patients during follow-up required atrial and/or right ventricular pacing, this was considered as the development of a pacing indication.[8,9] Also, if the pacing settings of the ICD required adaptation by the treating physician (eg, due to a reduced heart rate on heart rate histogram in combination with fatigue), this was considered as the development of a pacing indication. Furthermore, when the pace burden significantly increased between two routine follow-up visits (pace burden became >20%), it was also considered as an indication for pacing. The date at which the development of a pacing indication became apparent was considered the date of the endpoint.
2. ATP delivery: the first date of successful appropriate ATP (ie, without subsequent appropriate shock) was considered the endpoint.
3. Device upgrade: if a patient required upgrade to a CRT-D device (New York Heart Association (NYHA) III/IV despite optimal medical therapy, left ventricular ejection fraction (LVEF) ≤35% and QRS ≥120 ms or NYHA II despite optimal medical therapy, LVEF ≤35%, QRS ≥150 ms and sinusrhythm), the date of the upgrade was considered as the endpoint.[11,12]

For all patients, the first date at which a patient reached one of the above endpoints was considered the date for reaching the primary endpoint. If the patient did not develop one of the above mentioned endpoints, the patient was censored at the date of last ICD follow-up.
If a patient deceased during follow-up, censoring at the date of death occurred.

Statistical analysis

Continuous data are expressed as mean and SD or median with 25th and 75th percentiles where appropriate; dichotomous data are presented as numbers and percentages. Event-free rates from all three individual endpoints, indicating the suitability for an S-ICD (ie, patients without pacing dependence, ATP delivery or device upgrade during follow-up), were analysed separately using the method of Kaplan–Meier and the log-rank test. Consequently, the combined endpoint was also analysed using the same statistical tests. In patients with more than one endpoint, the date of the first endpoint was used for analysis with the method of Kaplan–Meier and the log-rank test. In order to correct for competing risk of the S-ICD unsuitability (ie, death), a competing-risk model was used.[13,14] Univariate and multivariate Fine-Gray regression models were constructed to identify independent determinants of the combined endpoint.[15] All variables with a $p<0.20$ in univariate analysis were retained in the multivariate model. A $p<0.05$ was considered statistically significant. Statistical analyses were performed with SPSS software (V.18.0, SPSS Inc., Chicago, Illinois, USA) and R software (V.2.15.1, R Foundation, Vienna, Austria).

RESULTS

Patients

During the study period, a total of 2712 patients received a ventricular antitachycardia device. Hereof, 1205 (44%) patients received a CRT-D and 162 (6%) patients were pacing-dependent directly following implantation. Consequently, these patients were excluded from the current analysis (figure 1). The remaining 1345 (50%) patients were considered the study population and had a median follow-up of 3.4 years (IQR 1.7–5.7 years). Of these patients (81% men, average age 60±14 years), 57% received an ICD for primary prevention (table 1).

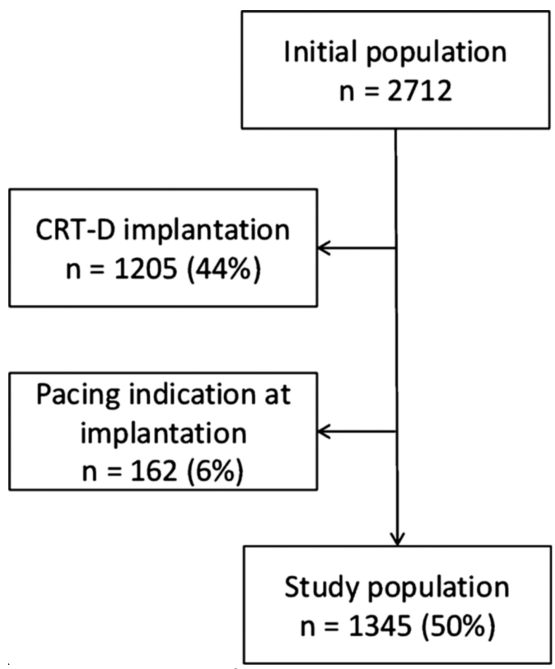


Figure 1. Flowchart describing the selection of the study population.

Follow-up

In primary prevention patients, the 5-year cumulative incidence for an appropriate shock was 14.2% (95% CI 11.1% to 17.3%) and the 5-year cumulative incidence for an inappropriate shock was 23.5% (95% CI 19.4% to 27.6%). At the end of follow-up, 84 (11%) patients were deceased, which resulted in a cumulative incidence for all-cause mortality of 14.2% (95% CI 11.1% to 17.3%) at 5 years following device implantation.

In secondary prevention patients, 5-year cumulative incidences for appropriate and inappropriate shock were 36.1% (95% CI 31.2% to 41.0%) and 26.0% (95% CI 21.5% to 30.5%), respectively. A total of 98 (17%) of these patients died, resulting in a 5-year

Table 1: *Baseline characteristics*

Clinical characteristics	Total (n = 1345)	Primary prevention (n = 772)	Secondary prevention (n = 573)
Age, mean (SD), years	60 ± 14	58 ± 13	61 ± 16
Male (%)	1086 (81)	617 (80)	469 (82)
Ischemic heart disease (%)	896 (67)	530 (69)	366 (64)
Monogenetic congenital heart disease (%)	113 (8)	77 (10)	36 (6)
Structural congenital heart disease (%)	18 (1)	12 (2)	6 (1)
LVEF (%)	39 ± 16	36 ± 15†	44 ± 15
QRS duration, mean (SD), ms	109 ± 25	107 ± 24	112 ± 27
NYHA functional class III/IV (%)	151 (11)	110 (14)	41 (7)
Renal clearance, mean (SD), mL/min	87 ± 39	89 ± 36	85 ± 42
History of atrial fibrillation (%)	251 (19)	131 (17)	120 (21)
Device type			
Single-chamber (%)	133 (10)	71 (9)	62 (11)
Dual-chamber (%)	1212 (90)	701 (91)	511 (89)
Medication			
Statins (%)	829 (62)	510 (66)	319 (56)
Diuretics (%)	663 (49)	418 (54)	245 (43)
ACE inhibitors/AT II antagonist (%)	960 (71)	594 (77)	366 (64)
Calcium antagonist (%)	129 (10)	85 (11)	44 (8)
Antiarrhythmic medication			
Beta-blockers* (%)	775 (58)	485 (63)	290 (51)
Sotalol* (%)	189 (14)	92 (12)	97 (17)
Amiodarone* (%)	196 (15)	63 (8)	133 (23)
Antiarrhythmic medication combined* (%)	1061 (79)	604 (78)	457 (80)

ACE = angiotensin-converting enzyme; AT = angiotensin; LVEF = left ventricular ejection fraction; NYHA = New York Heart Association; SD = standard deviation. * Patients could be taking >1 antiarrhythmic drug. † The mean is above 35% due to substantial proportion of patients with a congenital heart disease (e.g. hypertrophic cardiomyopathy).

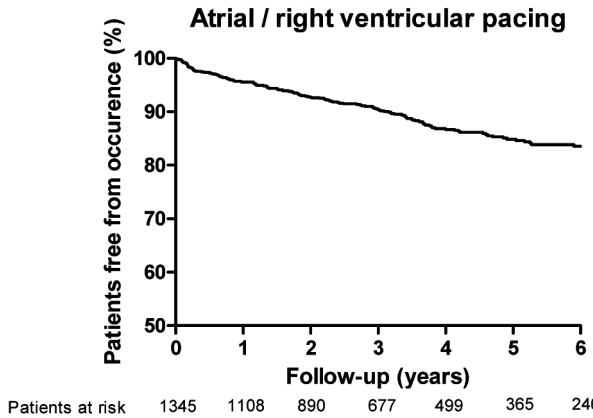
cumulative incidence for all-cause mortality of 17.4% (95% CI 13.7% to 21.1%) following ICD implantation.

Incidence of the individual endpoints

During follow-up, 151 (11%) patients developed an indication for atrial and/or ventricular pacing. The cumulative incidence for the necessity of cardiac pacing was 4.4% (95% CI 3.2% to 5.6%) at 1-year follow-up and increased to 15.1% (95% CI 12.6% to 17.6%) at 5-year follow-up (figure 2A).

With respect to ATP, a total of 365 patients (27%) experienced at least one successful appropriate ATP delivery during follow-up. Consequently, the cumulative event rate for a

A



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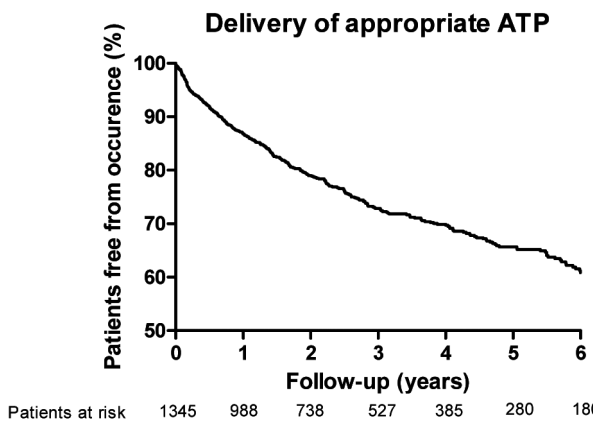

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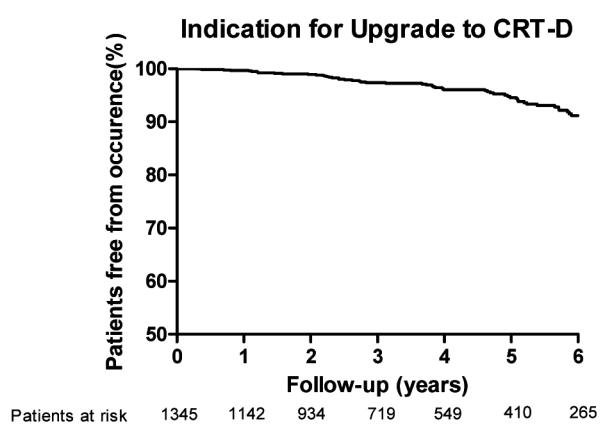

Figure 2. Kaplan-Meier curve showing the cumulative event-free survival of A) the occurrence of atrial and/or right ventricular pacing; B) delivery of ATP; C) indication for upgrade to CRT-D.

first successful appropriate ATP was 13.2% (95% CI 11.2% to 15.2%) at 1-year follow-up and increased to 34.3% (95% CI 31.0% to 37.6%) at 5-year follow-up (figure 2B).
CRT-D upgrades were performed, according to the then current guidelines, in 58 (4%) of the patients. Consequently, the cumulative incidence for the requirement of a CRT-D upgrade was 0.3 (95% CI 0.0% to 0.7%) at 1-year follow-up and increased to 5.4% (95% CI 3.6% to 7.2%) at 5-year follow-up (figure 2C).

Incidence of the combined endpoint

The combined endpoint (the necessity for cardiac pacing, appropriate ATP without subsequent shock or device upgrade) was reached in 463 patients (34%). At 1-year follow-up, the cumulative incidence of the combined endpoint was 16.8% (95% CI 14.6% to 19.0%) (ie, S-ICD suitability 83.2%), which increased to 44.5% (95% CI 41.0% to 48.0%) (S-ICD suitability 55.5%) at 5-year follow-up (figure 3). Appropriate ATP and the necessity of cardiac pacing resulted in the unsuitability for an S-ICD in approximately 94% of the cases, whereas device upgrade was responsible for the unsuitability in approximately 6% of the cases.

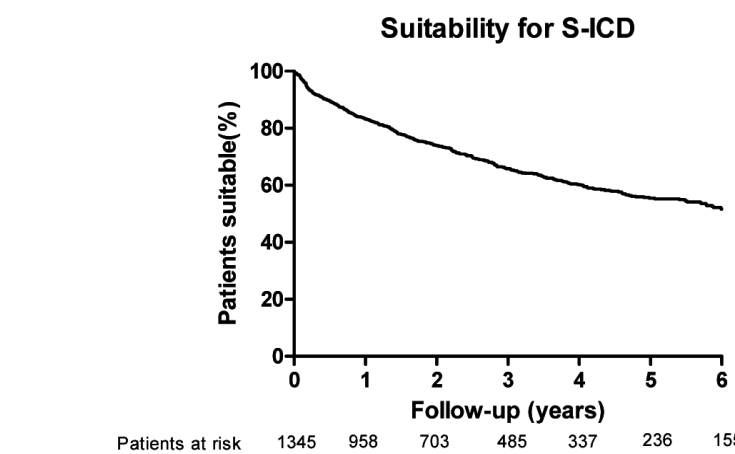

Figure 3. Kaplan-Meier curve showing the cumulative suitability for an S-ICD.

Monogenetic congenital heart disease

A monogenetic congenital heart disease (eg, Brugada syndrome, hypertrophic cardiomyopathy) was present in 113 (9%) of the patients included in the current study (table 1). In all, 77 patients had a primary prevention indication and, of these, 12 (16%) patients received appropriate ATP, 1 (1%) patient underwent a CRT-D upgrade and 5 (7%) patients developed the necessity for cardiac pacing. This resulted in a cumulative incidence for the combined endpoint of 9.5% (95% CI 2.8% to 16.2%) at 1-year follow-up and 26.6% (95% CI

15.4% to 37.8%) at 5-year follow-up. For secondary prevention patients with a monogenetic heart disease (n=36), ATP occurred in 10 (28%) patients, a CRT-D upgrade was performed in 0 (0%) patients and 7 (19%) patients required cardiac pacing. This resulted in a cumulative incidence for the combined endpoint of 21.5% (95% CI 7.4% to 35.6%) at 1-year follow-up and 56.4% (95% CI 37.4% to 73.4%) at 5-year follow-up for secondary prevention patients with a monogenetic congenital heart disease.

Predictors of the unsuitability for an S-ICD

A Fine-Gray regression analysis was performed in order to establish determinants of the unsuitability for an S-ICD. Multivariate analysis controlling for factors with a univariate p<0.2 indicated that secondary prevention (HR 2.15; 95% CI 1.74 to 2.67, p < 0.01), NYHA class III/IV (HR 1.66; 95% CI 1.25 to 2.20, p<0.01) and QRS duration (HR 1.30 per 30 ms increase; 95% CI 1.16 to 1.45, p<0.01) were independent determinants of the unsuitability for an S-ICD (table 2).

Table 2: *Predictors of the unsuitability for a S-ICD.*

Parameter	Univariate analysis	P	Multivariate analysis	P
Age (per 10 years)	1.22 (1.13 – 1.32)	<0.01	1.10 (0.99 – 1.24)	NS
Male gender	1.14 (0.90 – 1.45)	0.26		
Secondary vs. Primary prevention	1.94 (1.62 – 2.34)	<0.01	2.15 (1.74 – 2.67)	<0.01
Ischemic vs. non-ischemic CMP	1.07 (0.88 – 1.30)	0.49		
Congenital vs. acquired	0.80 (0.58 – 1.09)	0.15	1.17 (0.77 – 1.76)	NS
Renal Clearance (per 20 ml/m/m2)	0.91 (0.87 – 0.96)	<0.01	0.99 (0.91 – 1.08)	NS
LVEF (per 10%)	0.96 (0.90 – 1.01)	0.14	0.97 (0.89 – 1.05)	NS
NYHA class III/IV vs. I/II	1.57 (1.20 – 2.04)	<0.01	1.66 (1.25 – 2.20)	<0.01
History of Atrial fibrillation	1.58 (1.27 – 1.96)	<0.01	1.24 (0.95 – 1.61)	NS
QRS (per 30 ms)	1.36 (1.23 – 1.50)	<0.01	1.30 (1.16 – 1.45)	<0.01
Antiarrhythmic medication	1.20 (0.95 – 1.51)	0.13	0.95 (0.72 – 1.24)	NS

CMP = Cardiomyopathy

DISCUSSION

In the assessment of the suitability for an S-ICD, findings can be summarised as follows: (1) a considerable proportion (55.5%) of the patients currently having a transvenously implanted ICD without a pre-existent indication for pacing could have been considered suitable for an S-ICD implantation, retrospectively, after 5 years of follow-up; (2) a subanalysis in patients with a structural or monogenetic congenital heart disease

demonstrated that after 5 years of follow-up, approximately 75% of primary prevention ICD recipients with a monogenetic heart disease would have been suitable for an S-ICD implantation; and (3) important predictors for the unsuitability of an S-ICD are: secondary prevention, severe heart failure and prolonged QRS duration.

Unsuitability for the S-ICD

In the current analysis, three variables excluding the suitability for an S-ICD implantation were defined and merged as a combined endpoint. First, those who developed an indication for atrial and/or right ventricular pacing during follow-up were considered unsuitable for an S-ICD.[8,9] It is conceivable that these patients would be better off with a transvenously implanted device system, which would only require changes in device settings when the patient develops a pacing indication. Based on the results of the current study, atrial and/or right ventricular pacing during follow-up was indicated approximately in 15% of the patients. The significance of the proportion of patients who developed an indication for atrial and/or right ventricular pacing during follow-up thus underlines the importance of an adequate selection of patients suitable for an S-ICD implantation. Hence, implantation of an S-ICD in these patients would otherwise result in unnecessary additional procedures (ie, pacemaker implantation or conventional ICD implantation).

The second distinguishing difference between the subcutaneous and conventional ICD is the ability for the delivery of ATP. ATP has proven to effectively and safely terminate life threatening ventricular tachycardias thereby avoiding the consequences of painful shocks.[16,17] Therefore, ATP is currently programmed as the initial therapy for life threatening ventricular tachyarrhythmias in conventional devices followed by device shocks if conversion to a normal rhythm is unsuccessful. Although S-ICDs have the ability to successfully terminate life threatening ventricular arrhythmias (ie, ventricular tachyarrhythmias and ventricular fibrillation) with shocks, they are unable to deliver ATP. This might be considered an important drawback since it has been reported that ICD patients who receive shocks might exhibit a decline in the quality of life.[18] Therefore, for this study, the first date of successful appropriate ATP (ie, without subsequent appropriate shock) was registered as an endpoint. According to the results of the present study, 34% of the patients implanted with a conventional ICD would be considered unsuitable for an S-ICD implantation because of the delivery of successful appropriate ATP.

It is however important to realise that due to a short detection time or low number of intervals, a number of these appropriate ATPs are treating potentially self-limiting VTs and therewith underestimate the proportion of patients suitable for an S-ICD implantation.[19,20] On the other hand, a less aggressive shock zone (ie, higher cut-off values before the devices deliver a shock) will likely result in more successful treatment of fast monomorphic VTs with ATP, and therewith reduce the number of patients suitable for an S-ICD implantation.

The third and last variable included in the combined endpoint is the upgrade to a CRT-D

device. During follow-up, ICD patients may require an upgrade to a CRT-D system due to a deterioration of heart failure.[11,12] In these patients, conventional ICD upgrade would require pulse generator replacement and implantation of a left ventricular pacing lead. However, if those patients were implanted with an S-ICD, upgrading to a CRT-D device would often require total explantation of the S-ICD and corresponding lead, followed by the implantation of the CRT-D in the pectoral region with corresponding transvenous leads. This strategy would most likely be more cumbersome and inefficient for the healthcare system. Therefore, upgrading from a conventional ICD is preferable and makes patients in whom during follow-up an upgrade becomes necessary unsuitable for an S-ICD implantation. Based on the results of the current study, approximately 5% of the patients underwent CRT upgrade and would consequently be considered unsuitable for an S-ICD implantation. However, with expanding indications for CRT-D, a higher proportion of patients will be eligible for initial CRT-D implantation or CRT-D upgrade and become unsuitable for an S-ICD implantation.[21,22]

ICD or S-ICD

Conventional ICDs are associated with specific complications that might be overcome with an S-ICD. For instance, several complications associated with transvenous leads, such as not reaching vascular access, pneumothorax and lead dislodgement, can be avoided with the implantation of an S-ICD. Though, it should be noted that these complications do not occur frequently and that S-ICDs might have their own unrevealed implantation related complications.[23] Another suggested advantage of S-ICDs over conventional ICDs is the preservation of venous access for other uses (ie, central line, etc). It has been reported that transvenous system implantation is frequently associated with venous lesions and accordingly with total venous obstruction in approximately 3.6% of the patients.[24] Finally, it is suggested that the removal of failed leads is more difficult and dangerous in patients with a transvenous system. On the other hand, recent reports indicate that transvenous leads can be removed with high success rates and low concomitant adverse events. It should however be noted that the risk for adverse events during the removal of an S-ICD lead compared with the removal of conventional ICD leads is currently lacking.
Even though there might be certain advantages for an S-ICD compared with a conventional ICD in patients that can be considered suitable for such a device, it should be kept in mind that current data regarding S-ICDs are scarce and true comparisons regarding efficacy, safety and cost-effectiveness with conventional ICDs cannot (yet) be made. Consequently, conclusions regarding the potential benefits of an S-ICD would currently be preliminary and therefore should be carefully drawn.

S-ICD suitability and future perspectives

Patients who remain free from the combined endpoint of ATP, development of an atrial and/or right ventricular pacing indication or the necessity for an upgrade to a CRT device

are those who are most likely to benefit of the suggested advantages of an S-ICD. Based on the results of this study, it can be concluded that the patients most likely to benefit from an S-ICD have a primary prevention indication with a relative good condition and no evidence of electrical dyssynchrony. Moreover, it should be noted that primary prevention ICD recipients with a monogenetic congenital heart disease are also likely to benefit from an S-ICD implantation.

Although the present study demonstrates that a large proportion of currently implanted ICD patients would be suitable for an S-ICD, the future role of an S-ICD remains to be identified. Will it become the first choice defibrillator in those patients proven to be suitable for an S-ICD, or will the S-ICD only be indicated for smaller groups of patients with for instance unfavourable vascular anatomy, recurrent device and/or lead infections, and young patients who require life-long defibrillator back-up? In our opinion, the important determinant factors hereof will be the device costs, expected device longevity and especially the proportion of S-ICD related complications. As this study is only a primary assessment of suitability, future studies should investigate these issues, preferably in a randomised controlled setting.

Study limitations

There are several limitations to this analysis assessing the suitability for an entirely subcutaneous ICD system. Since this is a retrospective single centre study, ascertainment bias could have influenced the results. Also, ICD tachycardia therapy programming was not homogeneous since in the minority of the patients, ICD settings were adapted when clinically indicated. Moreover, it should be emphasised that a pace burden > 20% in the current study considered as the development of a pacing indication is an arbitrarily chosen cut-off value which may influence the results. Furthermore, besides the combined endpoint (ie, pacing indication, appropriate ATP without subsequent shock and/or device upgrade), other parameters such as posture or vascular anatomy potentially influencing the feasibility of a device implantation were not assessed. Another limitation of this study is that all patients were considered suitable for defibrillation with an S-ICD. Although current data do not indicate that there is a proportion of patients not suitable for defibrillation using this new device, it should be acknowledged that this issue should be explored in more detail in future studies.[6,25,26] Furthermore, in the current study, CRT-D implantation was done according to the then existing guidelines, and therefore changes in these guidelines could not be accounted for. [11,12] Finally, the preference of the patient for the implantation of a conventional ICD or an S-ICD system, an important factor in decision making, was also not included in the present analysis.

CONCLUSIONS

At 5 years after ICD implantation, approximately 60% of the patients do not reach the combined endpoint of ATP, development of an atrial or right ventricular pacing indication or the necessity to undergo an upgrade to CRT-D. Based on those results, these patients would have been suitable for implantation of an S-ICD instead of a conventional ICD that depends on transvenous leads. Additionally, baseline clinical factors have been identified for the selection of patients suitable for an S-ICD implantation.

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