

Complications related to elective generator replacement of the subcutaneous implantable defibrillator

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Aims

To guarantee uninterrupted function of the subcutaneous implantable cardioverter-defibrillator (S-ICD), the pulse generator needs to be surgically replaced before the battery is depleted. The risks related to this replacement substantially impact long-term outcome for S-ICD recipients, as the majority will undergo one or several of these procedures in their lifetime. We aim to describe the procedural characteristics of the replacement procedure and to provide an insight in the complications associated with these replacements.

Methods and results

In this retrospective analysis, data from replacement procedures and follow-up visits were collected from all patients who underwent elective S-ICD generator replacement in our tertiary centre from June 2014 until November 2019. Original device position was assessed using the PRAETORIAN score. Complications were defined as those requiring surgical intervention, systemic antibiotic treatment, or device extraction. Seventy-two patients were included, with a median follow-up of 1.9 years (IQR 0.6–3.3 years) after replacement. Battery depletion occurred after 5.9 ± 0.7 years. The pulse generator was repositioned in patients with a PRAETORIAN score ≥ 90 to minimize the defibrillation threshold. Although there was an increase in impedance compared to the implant procedure, first shock conversion rate during defibrillation testing was 91.4% with a success rate of 100% after multiple attempts. Two patients developed a complication after, respectively, 9 and 21 months, resulting in a complication rate of 1.4% per year.

Conclusion

With a median follow-up of 1.9 years, this study shows a low complication rate after S-ICD replacement, with a first shock conversion rate of 91.4%.

Keywords

Subcutaneous implantable cardioverter-defibrillator • Pulse generator replacement • Battery longevity • PRAETORIAN score • Shock impedance • Complication rate

Introduction

Vascular access issues and lead failures associated with transvenous leads have initiated the development of the subcutaneous implantable cardioverter-defibrillator (S-ICD).¹ The S-ICD has since emerged as a valuable alternative to the transvenous ICD (TV-ICD) and should

be considered in patients with an indication for ICD therapy without the need for bradycardia or anti-tachycardia pacing, according to the current guidelines.² To guarantee uninterrupted function, the pulse generator needs to be surgically replaced before the battery of the device is depleted, as ICD therapy is often a lifelong therapy. For the first generation S-ICDs, the battery longevity is estimated by the

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What's new?

- This study shows no procedure-related complications after elective subcutaneous implantable cardioverter-defibrillator (S-ICD) replacement, and an overall complication rate of 1.4% per year.
- Although high voltage impedance increases over time, first shock conversion rate of the S-ICD remains high (91.4%).
- The PRAETORIAN score might be a useful tool to determine the need for repositioning during S-ICD replacement, in order to minimize defibrillation threshold and ensure successful defibrillation.

manufacturer to be ~5 years, which means that early S-ICD patients are currently facing their first elective pulse generator replacements.³ The complications related to these replacements are crucial to take into account when considering (continuation of) ICD therapy, as they may undermine long-term outcome of these patients. For TV-ICDs, several studies have reported important risks related to generator replacements, and consecutive replacements have been shown to double the risk of surgical re-interventions. In these studies, the most frequently reported complication was infection requiring antibiotic therapy or device extraction.^{4–6} Conversely, there are little data available for S-ICD replacements. An earlier retrospective study by our study group reported a complication rate of 3% after elective S-ICD generator replacement, but their follow-up ended shortly after the replacement procedures were performed.⁷ To help clinicians weigh the benefits against the disadvantages of S-ICD therapy, it is essential to gain more knowledge on long-term complications after elective S-ICD generator replacement. We aim to describe the procedural characteristics of the pulse generator replacement as performed in our large tertiary centre and to provide a preliminary insight in the long-term complications associated with our first elective S-ICD generator replacements.

Methods

Study design

In this retrospective data analysis, we aim to describe the procedural characteristics of the S-ICD replacement procedure and to present the complications associated with elective S-ICD generator replacement. All data were collected from patient files. The need for informed consent was waived by our local Medical Ethics Committee.

Study subjects

The cohort in this study consists of every patient who underwent an elective S-ICD generator replacement between June 2014 and November 2019 in the Amsterdam University Medical Centers, location AMC. All patients had a Class I or II indication for ICD therapy and received an S-ICD because of ineligibility for TV-ICD treatment or patient and/or physician preference. Patients undergoing generator replacement for other reasons than battery depletion and patients participating in ongoing S-ICD studies were excluded from this study. All patients were regularly seen in the outpatient clinic following our local hospital schedule.

Complications were defined as those requiring surgical intervention, systemic antibiotic treatment, or device extraction.

PRAETORIAN score

The PRAETORIAN score was developed using computer modelling data on factors that raise the defibrillation threshold in S-ICD recipients. This scoring tool, which uses the routine post-procedural chest radiograph, takes three components of S-ICD implant position into consideration: position of the S-ICD generator, sub-coil adipose tissue, and sub-generator adipose tissue. The score roughly correlates with the defibrillation threshold in Joules and varies from low (<90) to intermediate (90–150) and high (≥ 150). Details of the PRAETORIAN score and its retrospective validation are published elsewhere.⁸

Pulse generator replacement procedure

All implant and replacement procedures were performed by a single experienced S-ICD implanter. Procedures were performed using local and general anaesthesia. The pocket was opened using the same incision as the initial implant. In every patient, the chest X-ray after implant was carefully reviewed and in case of an intermediate or high PRAETORIAN score (≥ 90), the implanting physician could choose to reposition the pocket more posteriorly during the replacement procedure in order to minimize the defibrillation threshold. During defibrillation testing (DFT), ventricular fibrillation was induced using a single 50-Hz alternating current burst. The programmed shock output during DFT was 65J or lower with a standard polarity. If the first shock failed to terminate the ventricular arrhythmia, the programming of the S-ICD was switched to reversed polarity. Further action in case of ≥ 2 failed shocks during DFT was per physician's discretion.

Statistical analysis

Continuous data are presented as median with interquartile range or as mean with standard deviation, depending on the distribution of the data. Dichotomous data are presented as proportions. Battery longevity was calculated as the time from implant until generator replacement procedure. Complication rate per year was calculated by dividing the total number of complications by the total person-years. Statistical analysis was performed in IBM SPSS version 25.

Results

A total of 72 patients underwent elective generator replacement due to battery depletion, after an average of 5.9 ± 0.7 years. The patients in this cohort were young, with a preserved left ventricular function of $50 \pm 12\%$, and limited comorbidities (Table 1). The majority of patients was implanted using a two-incision technique (65%). After the replacement procedure, they were followed-up for a median of 1.9 years (IQR 0.6–3.3 years, 139.7 person-years). The majority of patients had a low PRAETORIAN score after initial implant (89%). In the remaining cases ($n = 5$), the pocket would be positioned more posteriorly if this improved the PRAETORIAN score. An example of improvement of the PRAETORIAN score after pulse generator repositioning during replacement is shown in Figure 1.

Defibrillation testing

Nine patients were ineligible to undergo DFT, due to the use of local anaesthesia ($n = 6$) or discontinuation of anti-coagulation in patients with atrial fibrillation or left ventricular thrombus ($n = 3$). Ventricular fibrillation was successfully induced in 58 of the 63 patients (92%)

during DFT. The first shock of the S-ICD effectively terminated the arrhythmia in 53 of the 58 patients, resulting in a first shock success rate of 91.4%. Three of the five patients with a failed first shock had a successful second DFT shock. Defibrillation testing was successfully

repeated the following day after two failed shocks in one patient, without the need for repositioning. In the final case, DFT was suspended because of air leakage of the laryngeal mask. After consulting the anaesthesiologist, further testing was abandoned. Of 48 patients, both the shock impedance of the DFT during implant and replacement procedure were available. A Wilcoxon signed rank test showed that the mean shock impedance during replacement was significantly higher than during implant (86 ± 28 vs. $77 \pm 26 \Omega$, $Z = -3.794$, $P < 0.001$, Figure 2). The increase in impedance was not significantly different between patients with a successful first shock during DFT and patients in whom the first shock during DFT failed (10 ± 15 vs. $12 \pm 34 \Omega$, $P = 0.85$). Procedural characteristics of the replacement procedure and DFT are presented in Table 2.

Table 1 Patient characteristics

	N = 72
Age at replacement (years), mean \pm SD	46 \pm 15
Follow-up after replacement (years), median (IQR)	1.9 (0.6–3.25)
Male, n (%)	44 (61)
LVEF (%), mean \pm SD	49.6 \pm 11.6
Implanted using the two-incision technique, n (%)	47 (65)
ICD Indication, n (%)	
Primary indication	44 (61)
Secondary indication	28 (39)
Clinical disease, n (%)	
Ischaemic cardiomyopathy	11 (15)
Non-ischaemic cardiomyopathy	7 (9)
Genetic arrhythmic disease	39 (54)
Congenital heart disease	3 (4)
Idiopathic VF	10 (14)
Other	2 (3)
NYHA functional class, n (%)	
Class I	61 (85)
Class II	9 (13)
Class III	2 (3)
PRAETORIAN score at implant, n (%)	
Low	64 (89)
Intermediate	4 (6)
High	1 (1)

LVEF, left ventricular ejection fraction; IQR, interquartile range; NYHA, New York Heart Association; SD, standard deviation; VF, ventricular fibrillation.

Long-term outcome

In this cohort, there were no procedure-related complications. Two patients had a device-related complication after, respectively, 9 and 21 months. With 139.7 person-years, this results in a complication rate per year of 1.4% (95% CI 0.4–5.7%). Both complications concerned the pocket of the pulse generator. The first patient contacted the outpatient clinic with complaints of pain around the pocket during movement of the left arm. The pocket appeared swollen and showed some minor discoloration. Laboratory results showed no indication for infection. The cardiologist concluded that there was imminent pocket erosion and a pocket revision was performed a few days later. During this revision, the S-ICD was removed and placed in a newly created pocket underneath the serratus anterior muscle (SAM), also known as a submuscular position.⁹ This resulted in visibly less pressure on the skin and the patient remained pain-free during the remainder of his follow-up. The second patient presented to the outpatient clinic after he noticed yellow fluid being excreted from the pocket, almost two years after the replacement procedure. This happened after he had fallen onto his S-ICD during household chores, after which a haematoma formed around the generator. After the haematoma resolved, the pocket remained painful and the skin

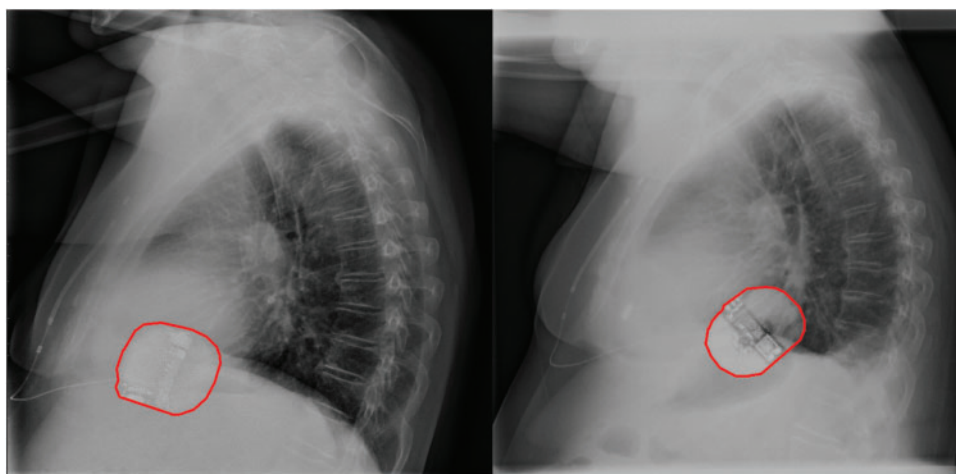


Figure 1 Improvement of the PRAETORIAN score from 120 (intermediate score) to 60 (low score) by repositioning of the pulse generator (red) during replacement procedure.

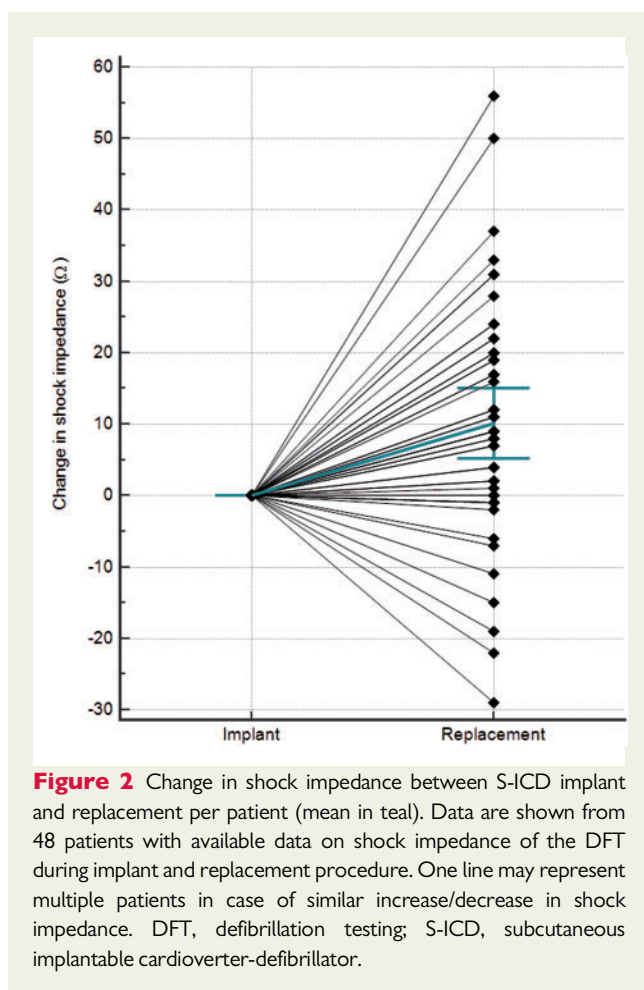


Figure 2 Change in shock impedance between S-ICD implant and replacement per patient (mean in teal). Data are shown from 48 patients with available data on shock impedance of the DFT during implant and replacement procedure. One line may represent multiple patients in case of similar increase/decrease in shock impedance. DFT, defibrillation testing; S-ICD, subcutaneous implantable cardioverter-defibrillator.

Table 2 Practical aspects of replacement procedure

Battery longevity (years), mean \pm SD	5.9 \pm 0.7
Procedural time (min), mean \pm SD	38 \pm 13
Defibrillation testing, n (%)	
Successful first shock	53 (91.4)
Unsuccessful first shock	5 (8.6)
Unable to induce VF	5 of 63 (7.9)
Shock impedance during implant, mean \pm SD	77 \pm 26 Ω
Shock impedance during replacement, mean \pm SD	86 \pm 28 Ω

SD, standard deviation; VF, ventricular fibrillation.

became tenuous, leaving the S-ICD generator visible. It was decided that this patient needed a S-ICD generator and lead extraction. He was prophylactically treated with systemic antibiotics, although there were no clinical signs of infection and the cultivation from the pocket turned out to be negative for micro-organisms. The S-ICD was re-implanted after 3 months, during which he wore a LifeVest for the prevention for sudden cardiac death.¹⁰ During the re-implant procedure, the pocket was created underneath the SAM, which resulted in a stable situation. In both cases, there were no complications during follow-up.

Discussion

This study describes the procedural characteristics and outcomes after S-ICD replacement for battery depletion. The main findings of this analysis are the high first shock success rate during DFT and low complication rate during subsequent follow-up. Since some patients are prone to undergo multiple generator replacements during their lifetime, these data regarding the safety of this procedure are of importance.

Replacement procedure

Our results regarding battery longevity are similar to the results of previous studies,^{7,11} which is longer than projected by the manufacturer.³ Next generations S-ICDs are expected to have an advanced longevity, which will result in fewer replacement procedures. During DFT, we found an increase in shock impedance between implant and replacement procedure, possibly caused by device encapsulation or fibrotic tissue.¹² Recently, Rudic *et al.* showed a DFT success rate of 80% after generator replacement in a cohort with an overall higher PRAETORIAN score. They attribute this relatively low DFT success rate to the increase in shock impedance between implant and replacement procedure.¹³ According to Ohm's law, a higher shock impedance results in a lower electrical current draw and has previously been associated with ineffective defibrillation.^{14,15} However, with a similar increase in shock impedance as Rudic *et al.*, we showed a first shock success rate of 91.4% during DFT. Our results correspond with the first shock success rate after first S-ICD implant, as shown in the IDE and EFFORTLESS studies.^{16,17} This high first shock success rate could be explained by our overall low PRAETORIAN score, suggesting that implant position is even more predictive for defibrillation success than shock impedance. The retrospective validation of the PRAETORIAN score confirmed this.⁸ We therefore strongly recommend implanting physicians to carefully review the chest X-rays and to consider to reposition the pulse generator during replacement procedure to minimize the defibrillation threshold and increase the effectiveness of the S-ICD.

Device-related complications

The S-ICD replacements as described in this study will be the first of many, especially since large ICD trials have demonstrated that the majority of the patients has a life expectancy of more than five years after they have been implanted with an ICD.^{18,19} Due to expanding treatment options for chronic heart failure, it is likely that this mismatch between patient longevity and device longevity will continue to grow. Although next generation S-ICDs are expected to have an advanced battery longevity, this discrepancy will possibly result in patients undergoing multiple generator replacements during their lifetime. For transvenous devices, the complications related to these replacement procedures have been extensively analysed. Large trials have shown that the major complication rate after transvenous device replacement ranged between 4.0% and 5.8%,^{6,20} with the most common complications being infections. In this cohort, no lead-related complications occurred and only one patient was treated with systemic antibiotics following S-ICD pulse generator replacement. The prevention of infectious complications has been one of the main reasons for the development of an extracardiac ICD, and our results seem to confirm its effectiveness. Furthermore, the lack

of any immediate peri-procedural complication is remarkable. Although the sample size of this study is too small to estimate a reliable complication rate, the complication rate seems reassuringly low. The complications in this cohort were related to the subcutaneous implant position and the size of the device. In both cases, the solution was to reposition the generator to a submuscular position. Although it has been described to be a more painful procedure,⁹ repositioning the pulse generator to a submuscular position could be a proper alternative for patients with a history of pocket-related complications.

Limitations

This study has several limitations. The single-centre, single-implanter, and non-randomized design of this study comes with inherent limitations. Our hospital protocol and long-standing experience with S-ICD procedures might differ from others and therefore results may not be translatable to other centres. Moreover, the studied population comprised younger patients with a better left ventricular ejection fraction than seen in most ICD studies and the risk of complications may not apply to older patients with more comorbidities.

Conclusion

This study shows a complication rate of 1.4% per year after S-ICD replacement, which is lower than after TV-ICD replacement. Using the PRAETORIAN score to reposition the pulse generator during replacement could help implanters to achieve a high first shock conversion rate.

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Data availability

The data underlying this article cannot be shared publicly due to the General Data Protection Regulation. The data will be shared on reasonable request to the corresponding author.

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