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DEVICES

Long-term follow-up of the two-incision implantation technique for the subcutaneous implantable cardioverter-defibrillator

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Abstract

Introduction: The two-incision implantation technique of the subcutaneous implantable cardioverter-defibrillator (S-ICD) was introduced as an alternative to the standard three-incision approach by omitting the superior parasternal incision. Thereby, complications may be prevented. Short-term follow-up demonstrated the safety and efficacy of the two-incision technique. However, long-term results are lacking.

Methods: This retrospective study included patients implanted between February 2009 and June 2020. Patients were divided into a group of patients who were implanted with the standard three-incision technique and a group who were implanted with the two-incision technique. Outcomes were defibrillation impedance and efficacy and complications requiring intervention.

Results: A total of 268 patients were included (age 42.4 ± 16.6 years, 35.4% female, BMI 25.1 ± 4.5 kg/m^2). Thirty-one patients underwent S-ICD implantation with the three-incision technique and 237 patients with the two-incision technique. First shock efficacy during defibrillation testing was 93% in the three-incision group versus 94% in the two-incision group (P = .69), and shock impedance was 85 versus 68 ohms (P = .04). First shock success was 75% versus 76% for spontaneous episodes (P = 1.00). Complication-free survival at 5-year follow-up in the three-incision group was estimated at 0.96 (95% CI 0.90-1.00) versus 0.98 (95% CI 0.96-1.00) in the two-incision group (P = .20) and for inappropriate shocks at 5-year 0.77 (95% CI 0.63-0.94) versus 0.83 (95% CI 0.77-0.89, P = .30), respectively.

Conclusion: Five-year follow-up in this S-ICD cohort showed similar complication rates and effectiveness of two-incision technique compared to the three-incision

Abbreviations: CI, confidence interval; DFT, defibrillation testing; EIT, electrode insertion tool; ICD, implantable cardioverter-defibrillator; S-ICD, subcutaneous implantable cardioverter-defibrillator; VF, ventricular fibrillation

technique. This technique offers physicians a less invasive and more simplified implantation procedure for the S-ICD, with a better cosmetic result.

KEYWORDS
implantable cardioverter-defibrillator, implantation technique, subcutaneous implantable cardioverter-defibrillator

1 | BACKGROUND

Implantable cardioverter-defibrillators (ICDs) have demonstrated to reduce mortality in patients at increased risk for sudden cardiac death.[1–3] The subcutaneous ICD (S-ICD) was introduced as a less invasive treatment option that could overcome transvenous lead-related complications, including pneumothorax, endocarditis, cardiac perforation, and lead dislocations.[4–6]

The S-ICD is implanted according to labeling with three incisions, one lateral pocket incision and two parasternal incisions for lead positioning.[6] These parasternal incisions are a potential source of discomfort and infection.[7] Therefore, our group previously reported on a new implantation technique for the S-ICD, which omits the superior parasternal incision.[8] In this preliminary report of 39 patients, short-term safety and efficacy of the two-incision technique were demonstrated. However, long-term follow-up data of safety were lacking.

We hypothesized that the two-incision technique could be associated with fewer infections and a better cosmetic result, while not compromising the safety and efficacy of the S-ICD. The purpose of this study was to evaluate long-term follow-up data of the two-incision S-ICD implantation technique on clinical outcomes and compare this with patients who were implanted with the labeled three-incision technique.

2 | METHODS

2.1 | Study population

We conducted a retrospective single center cohort study between February 2009 and June 2020. All consecutive patients who were implanted in our hospital were included, except patients participating in the PRAETORIAN trial.[9] Patients between February 2009 and October 2010 were implanted with the labeled three-incision technique and after October 2010 with the two-incision technique (described below). The need for informed consent was waived by the institutional review board, because of the observational nature of the study.

2.2 | Two-incision implantation technique

The two-incision S-ICD implant technique has been described previously.[8] In short, the difference compared to the labeled three-incision implant technique comprises the positioning of the parasternal part of the subcutaneous lead. An 11Fr peel-away sheath is placed over the shaft of the electrode insertion tool (EIT) and tunneled approximately 14 cm superior of the Xiphoid incision, after which the peel-away sheath is advanced over the EIT. The EIT is removed, and the peel-away sheath is left in its subcutaneous position. The electrode is inserted into the subcutaneous sheath, and then the sheath is peeled away leaving the electrode in place.

Implantation of the S-ICD was performed under a combination of local anesthesia using lidocaine and conscious sedation in the catheterization laboratory or operating room by one implanter (RK). All patients were routinely evaluated prior to discharge, 2 weeks and 2 months postimplant and thereafter semiannually in the ICD clinic. Unscheduled visits were documented and used for evaluation.

2.3 | Periprocedural defibrillation threshold testing and follow-up

Defibrillation testing (DFT) was performed with a single ≤65 J shock after ventricular fibrillation (VF) induction with 50 Hz stimulation. In case of first shock failure, additional conversion tests were performed. A successful defibrillation test was defined as conversion to sinus rhythm or atrial fibrillation after shock delivery within 5 seconds.

All patients were routinely followed-up in the outpatient clinic after device implantation and were screened for complications such as (in) appropriate shocks, infections, and lead dislocations. Additionally, all visits that were not part of the standard follow-up protocol were documented. Complications were defined as any untoward event requiring medical or surgical intervention for correction. Inappropriate shocks were defined as shock therapy delivered on anything other than ventricular tachycardia or VF.

2.4 | Statistical analysis

Continuous data were tested for normality and reported as mean ± SD or medians with corresponding interquartile ranges (25%, 75%) and compared between groups using the Student's *t*-test or the Mann-Whitney *U* test. For discrete variables, percentages are calculated and compared with Fisher's exact test. Estimated event-free (complications and inappropriate shocks) survival in both groups (three-incision versus three-incision) was assessed by Kaplan-Meier analysis, and differences between strata were compared using the log-rank test. A two-sided *P* value of <.05 was considered to be statistically significant for all analyses. Statistical analysis was performed in R version 3.2.2, R Foundation for Statistical Computing, Vienna, Austria.

TABLE 1 Baseline characteristics

Characteristics	Three-incision (N = 31)	Two-incision (N = 237)	*P*-value
Age (mean±SD)	39 ± 17	42 ± 17	.23
Female (N, %)	11 (35)	84 (35)	1.00
BMI (median, IQR)	23 (20, 26)	25 (22, 28)	.04
LVEF (median, IQR)	51 (40, 57)	48 (30, 58)	.47
QRS duration (ms)	100 (89, 112)	98 (90, 108)	.62
Previous transvenous implant (%)	2 (6)	35 (15)	.35
Diabetes mellitus (%)	1 (3)	15 (6)	.77
Hypertension (%)	9 (29)	41 (17)	.19
Atrial fibrillation (%)	2 (6)	26 (11)	.73
Dyslipidemia (%)	1 (3)	22 (9)	.42
Primary prevention (%)	21 (68)	147 (62)	.69
Diagnosis			.65
iCMP (%)	6 (19)	51 (22)	
Non-iCMP (%)	6 (19)	41 (17)	
Genetic (%)	15 (48)	87 (37)	
iVF	3 (10)	34 (15)	
Congenital (%)	1 (3)	8 (3)	
Other (%)	0 (0)	14 (6)	
Therapy zones programming			
Lower rate conditional zone	190 (190, 200)	200 (180, 200)	.65
Upper rate conditional zone	230 (220, 230)	250 (250, 250)	<.01
Sensing vector postimplant			.72
Primary (%)	14 (45)	8)	
Secondary (%)	12 (39)	92 (39)	
Alternate (%)	5 (16)	31 (13)	
Follow-up months (median, IQR)	115 (92, 120)	38 (18, 70)	<.01

Values are given as n (%), mean ± SD, or median (interquartile range [IQR]).
Abbreviations: BMI, body mass index; eGFR, estimated glomerular filtration rate; iCMP, ischemic cardiomyopathy; LVEF, left ventricular ejection fraction.

3 | RESULTS

3.1 | Patient characteristics

A total of 268 S-ICD patients were implanted with an S-ICD in our hospital between February 2009 and June 2020, of which 31 with the three-incision technique and 237 with the two-incision technique. The baseline characteristics in both groups were similar, except for one aspect of ICD programming (upper rate of the conditional zone) and follow-up duration (Table 1).

TABLE 2 Procedural outcomes during S-ICD implantation

Procedural outcomes	Three-incision (N = 31)	Two-incision (N = 237)	*P*-value
DFT-test performed (N, %)	30 (97)	211 (89)	.33
First shock success DFT (N, %)	29 (93)	198 (94)	.69
Shock impedance (median, IQR)	85 (67-90)	68 (59-83)	.04

3.2 | Clinical follow-up

Complete follow-up was available for all but 18 patients that were transferred to other ICD clinics closer to their homes. The median follow-up duration was 115 (interquartile range 92-120) and 38 (interquartile range 18-70) months for patients implanted with the three-incision technique and the two-incision technique respectively ($P < .01$).

3.3 | Implantation procedure and testing

In 96% of the patients in the three-incision group, a defibrillation test was performed, versus 89% in the two-incision technique group, and the first shock was successful in 93% and 94% of patients, respectively ($P = .69$). In the 14 patients with a failed first shock during defibrillation testing, the second shock proved to be successful. The shock impedance was significantly higher in the three-incision group with 85 Ω (interquartile range 67-90) versus 68 Ω (interquartile range 59-83) in the two-incision group ($P = .04$). Defibrillation testing was not performed in 27 patients for a variety of reasons: LV thrombus or atrial fibrillation without anticoagulation (n = 14), repeated failed VF induction (n = 6), high risk as perceived by implanting physician (n = 4), and pregnancy (n = 3). Procedure time was available in 10 patients (32%) in the three-incision group and 163 patients (69%) in the two-incision group. Mean procedural time was significantly longer in the three-incision group with 103 ± 43 minutes versus 59 ± 24 minutes in the two-incision group ($P = .01$). Table 2 shows the procedural outcomes during S-ICD implantation comparing the two techniques.

3.4 | Lead complications and revisions

There was one lead complication that required intervention in the three-incision group and none in the two-incision group. The lead complication in the three-incision group that required intervention was a lead dislocation, 3 months after implantation. This patient was implanted before the suture sleeve to secure the lead to fascia at the xiphoid incision was introduced. There were no dislocations and no lead-related complications in the two-incision group. In the two-incision group, there were no dislocations or complications directly related to the lead. However, three patients in this group required

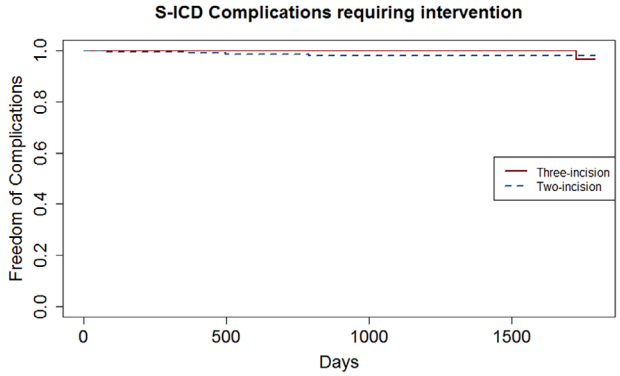

FIGURE 1 Kaplan-Meier of complication free survival for the three-incision group and two-incision group, log-rank test $P = .80$ [Color figure can be viewed at wileyonlinelibrary.com]

repositioning of the lead, all of whom had had a failed defibrillation test. One patient had oversensing with the lead in the standard left parasternal position, which was successfully repositioned to a right parasternal position. The second patient had repeated failed DFTs. To overcome the high defibrillation threshold in this obese patient, both the lead and the pulse generator were repositioned closer to the chest wall, which solved the high threshold. The last patient had lead failure due to Twiddler syndrome. Notable is that the parasternal part of the lead did not dislocate despite excessive mechanical stress that resulted in lead failure.

3.5 | Other complications and infection

Complication-free survival at 5-year follow-up was estimated at 0.96 (95% confidence interval [CI] 0.90-1.00) in the three-incision group and 0.98 (95% CI 0.96-1.00) in the two-incision group ($P = .80$) (Figure 1). During follow-up, there were 15 infections, three (9.7%) in the three-incision group versus 12 (5.1%) in the two-incision group ($P < .001$) (Table 3). The majority of these infections (one in the three-incision group and eight in the two-incision group) comprised simple wound problems, which were either controlled with local antibiotics or with a wait-and-see strategy. Of the 13 complications in the three-incision group and 37 in the two-incision group, a total of six complications (46.2%) in the three-incision group required medical or surgical intervention versus 12 complications (32.4%) in the two-incision group ($P = .50$).

3.6 | Appropriate and inappropriate shocks

A total of 42 spontaneous VT/VF episodes were treated in the cohort, four in the three-incision technique group and 38 in the two-incision technique group, with similar first shock efficacy ($P = 1.00$), 75% and 76%, respectively. Inappropriate shocks occurred in 39 patients, eight in the three-incision group and 31 in the two-incision group (Table 3) with an inappropriate shock-free survival rate at 5 year follow-up

TABLE 3 Clinical outcomes of S-ICD therapy

Clinical outcomes	Three-incision (N = 31)	Two-incision (N = 237)	*P*-value
First shock efficacy spontaneous episodes (N, %)	3/4 (75)	29/38 (76)	1.00
Inappropriate shocks* (N, %)	8 (26)	31 (13)	.10
Device-related complications (N, %)	13 (42)	37 (16)	.001
Infection	3	12	
Erosion	2	4	
Hematoma	1	3	
Lead complications	1	0	
Failed DFT	0	3	
Inadequate sensing	0	2	
Battery insufficiency	1	0	
Other complications	5	13	
Complications requiring intervention (N, %)	6 (46)	12 (32)	.50

*First inappropriate shock.

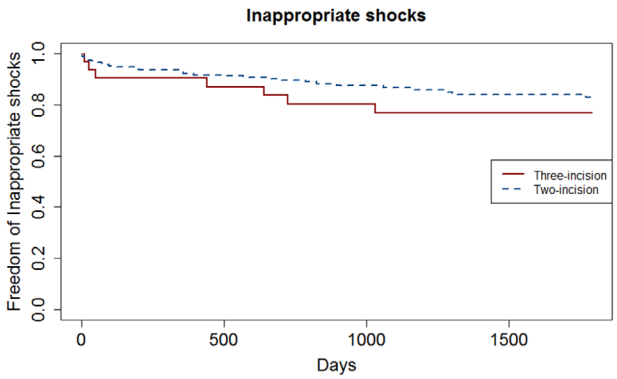

FIGURE 2 Kaplan-Meier of inappropriate shock free survival for the three-incision group and two-incision group, log-rank test $P = .30$ [Color figure can be viewed at wileyonlinelibrary.com]

of 0.77 (95% CI 0.63-0.94) versus 0.83 (95% CI 0.77-0.89, $P = .30$) (Figure 2).

3.7 | Extractions

The entire system, pulse generator and lead, was extracted in 32 patients of whom 24 (75%) were implanted with the two-incision technique. In the online supplemental material, a video of a lead extracted with the two-incision technique that was implanted for 6 years can be found.

4 | DISCUSSION

4.1 | Main findings

The main finding of this single-center study is that in consecutive, unselected patients who are implanted with the two-incision technique results are similar with respect to long-term clinical outcomes such as defibrillation testing, appropriate and inappropriate therapy, and infections. Importantly there were no lead dislocations in the two-incision technique group during a maximum follow-up duration of 9.6 years, indicating a very stable lead position. In one case with Twiddler syndrome resulting in medial migration of the pulse generator and subsequent lead failure,[10] the parasternal half of the lead did not dislocate despite excessive mechanical stress.

Interestingly, shock impedance of the first shock during defibrillation testing was significantly lower in the two-incision group. We speculate that this is the result of the growing experience of the implanting physician, resulting in implantation of the lead and pulse generator directly onto the fascia, rather than within the subcutaneous adipose tissue.[11] Adipose tissue, as well as a too anterior placement of the generator, has been demonstrated to increase the defibrillation threshold of the S-ICD.[12] These factors are incorporated into the noninvasive PRAETORIAN score, which predicts the chance of successful conversion testing and provides feedback on implantation technique.[13]

The superior parasternal incision for implantation of the lead is a potential source of infection and discomfort. It is often visible wearing normal clothing and considered, especially by female patients, to be cosmetically disturbing. The cosmetic result of the two-incision technique may therefore be considered superior. In our experience, it makes the procedure less invasive and simple.

4.2 | Limitations

This study has several important limitations. It is a nonrandomized study, however patients were unselected and the implantation technique depended solely on the time period of implantation. Moreover, there were similar baseline characteristics, with exclusion of programming of the upper limit of the conditional zone. This study reflects the practice in a single, highly experienced center. The three-incision group includes the earliest experience with the S-ICD, and the two-incision group can be considered as the stable part of the learning curve.

5 | CONCLUSION

Long-term follow-up in this S-ICD cohort showed safety and effectiveness of the two-incision technique. This technique offers physicians a less invasive and more simplified implantation procedure for the S-ICD.

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REFERENCES

1. Moss AJ, Zareba W, Hall WJ, et al. Prophylactic implantation of a defibrillator in patients with myocardial infarction and reduced ejection fraction. *N Engl J Med*. 2002;346:877-883.
2. Moss AJ, Hall WJ, Cannom DS, et al. Improved survival with an implanted defibrillator in patients with coronary disease at high risk for ventricular arrhythmia. Multicenter automatic defibrillator implantation trial investigators. *N Engl J Med*. 1996;335:1933-1940.
3. Bardy GH, Lee KL, Mark DB, et al. Amiodarone or an implantable cardioverter-defibrillator for congestive heart failure. *N Engl J Med*. 2005;352:225-237.
4. Burke MC, Gold MR, Knight BP, et al. Safety and efficacy of the totally subcutaneous implantable defibrillator: 2-year results from a pooled analysis of the IDE study and EFFORTLESS registry. *J Am Coll Cardiol*. 2015;65:1605-1615.
5. Lambiase PD, Barr C, Theuns DA, et al. Worldwide experience with a totally subcutaneous implantable defibrillator: early results from the EFFORTLESS S-ICD registry. *Eur Heart J*. 2014;35:1657-1665.
6. Bardy GH, Smith WM, Hood MA, et al. An entirely subcutaneous implantable cardioverter-defibrillator. *N Engl J Med*. 2010;363:36-44.
7. Olde Nordkamp LR, Dabiri Abkenari L, Boersma LV, et al. The entirely subcutaneous implantable cardioverter-defibrillator: initial clinical experience in a large Dutch cohort. *J Am Coll Cardiol*. 2012;60:1933-1939.
8. Knops RE, Olde Nordkamp LR, de Groot JR, Wilde AA. Two-incision technique for implantation of the subcutaneous implantable cardioverter-defibrillator. *Heart Rhythm*. 2013;10(8):1240-1243.
9. Olde Nordkamp LR, Knops RE, Bardy GH, et al. Rationale and design of the PRAETORIAN trial: A prospective, RAndomizEd comparison of subcuTaneOus and tRansvenous ImplANtable cardioverter-defibrillator therapy. *Am Heart J*. 2012;163:753-760.e2.
10. Kooiman KM, Brouwer TF, Van Halm VP, Knops RE. Subcutaneous implantable cardioverter defibrillator lead failure due to twiddler syndrome. *Pacing Clin Electrophysiol*. 2015;38:1369-1371.
11. Knops RE, Brouwer TF, Barr CS, et al. The learning curve associated with the introduction of the subcutaneous implantable defibrillator. *Europace*. 2016;18:1010-1015.
12. Heist EK, Belalcazar A, Stahl W, Brouwer TF, Knops RE. Determinants of subcutaneous implantable cardioverter-defibrillator efficacy: a computer modeling study. *JACC Clin Electrophysiol*. 2017;3:405-414.
13. Quast ABE, Baalman SWE, Brouwer TF, et al. A novel tool to evaluate the implant position and predict defibrillation success of the subcutaneous implantable cardioverter-defibrillator: The PRAETORIAN score. *Heart Rhythm*. 2019;16:403-410.

SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

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