Intraoperative Defibrillation Testing of Subcutaneous Implantable Cardioverter-Defibrillator Systems—A Simple Issue?

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Background—The results of the recently published randomized SIMPLE trial question the role of routine intraoperative defibrillation testing. However, testing is still recommended during implantation of the entirely subcutaneous implantable cardioverter-defibrillator (S-ICD) system. To address the question of whether defibrillation testing in S-ICD systems is still necessary, we analyzed the data of a large, standard-of-care prospective single-center S-ICD registry.

Methods and Results—In the present study, 102 consecutive patients received an S-ICD for primary (n=50) or secondary prevention (n=52). Defibrillation testing was performed in all except 4 patients. In 74 (75%; 95% CI 0.66–0.83) of 98 patients, ventricular fibrillation was effectively terminated by the first programmed internal shock. In 24 (25%; 95% CI 0.22–0.44) of 98 patients, the first internal shock was ineffective and further internal or external shock deliveries were required. In these patients, programming to reversed shock polarity (n=14) or repositioning of the sensing lead (n=1) or the pulse generator (n=5) led to successful defibrillation. In 4 patients, a safety margin of <10 J was not attained. Nevertheless, in these 4 patients, ventricular arrhythmias were effectively terminated with an internal 80-J shock.

Conclusions—Although it has been shown that defibrillation testing is not necessary in transvenous ICD systems, it seems particular important for S-ICD systems, because in nearly 25% of the cases the primary intraoperative test was not successful. In most cases, a successful defibrillation could be achieved by changing shock polarity or by optimizing the shock vector caused by the pulse generator or lead repositioning. (*J Am Heart Assoc*. 2016;5:e003181 doi: 10.1161/JAHA.115.003181)

Key Words: defibrillator testing • device complications • implantable cardioverter-defibrillator, subcutaneous • sudden cardiac death

T he implantable-cardioverter defibrillator (ICD) is an established therapy for primary and secondary prevention of sudden cardiac death.[1,2] The totally subcutaneous implantable defibrillator (S-ICD; Boston Scientific) has been introduced as a new alternative to the conventional transvenous defibrillator system. The obvious advantages of this system are marketed as a minimization of lead complications and systemic infections. This innovative system can particularly be considered in patients with congenital heart disease,[3] other rare entities impeding transvenous lead implantation,[4] or electrical heart disease.[5,6] The early results of the worldwide Evaluation oF FactORs ImpacTing CLinical Outcome and Cost EffectiveneSS (EFFORTLESS) registry suggested an appropriate system performance. Occurrence of arrhythmic events and inappropriate shocks resembled those reported for conventional transvenous ICD systems.[7] These results were confirmed in the 2-year follow-up of the same cohort.[8] Common problems in the S-ICD patient population requiring surgical revision or changes in device settings are lead migration, inappropriate sensing due to muscular noise, and T-wave oversensing.[9–13] Ineffective shocks have also been described previously.[14]

The results of the recently published Shockless IMPLant Evaluation (SIMPLE) trial question the value of perioperative defibrillation testing in individuals undergoing ICD implantation.[15] In this single-blinded, randomized, multicenter noninferiority trial, routine defibrillation testing at the time of implantation did not improve shock efficacy or reduce arrhythmic death.[15] The lack of long-term experience with the S-ICD system and the described cases of ineffective shock deliveries underline the necessity of intraoperative defibrillation testing in S-ICD recipients. Thorough data on

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intraoperative defibrillation testing in these patients are not yet available. Thus, in the present study, the single-center experience of 102 consecutive patients undergoing intraoperative defibrillation tests was systematically evaluated.

Methods

The study conforms to the Declaration of Helsinki and later amendments and was approved by an institutional review board. Patients gave informed consent for S-ICD implantation and testing. Between July 2010 and June 2015, 102 S-ICD systems were implanted at our institution. These consecutive patients were retrospectively analyzed. Patient baseline characteristics are summarized in Table 1. The left parasternal position of the shock coil with the pulse generator positioned over the sixth rib in the left mid-axillary line was recognized as the optimal configuration.[16] All patients underwent a standardized intraoperative defibrillation test. Before induction of ventricular fibrillation by using a DC burst for 4 seconds, the detection rate was lowered to a minimal value of 170 bpm. The first shock energy was programmed to 65 J, resulting in a safety margin of at least 15 J. In case of an ineffective first shock delivery, the second shock energy was programmed to 80 J in reversed polarity. An ineffective second shock delivery would have required external defibrillation. An ineffective first shock required further tests in either reverse polarity or after repositioning of the subcutaneous lead and/or the pulse generator. Data are presented as percentages including 95% CI. Left ventricular ejection fraction (LVEF) and body mass index (BMI) are presented as mean±SD.

Table 1. Baseline Characteristics

Age, y	41±16
Male sex, n	68 (67%)
Coronary artery disease, n	13 (13%)
Dilated cardiomyopathy, n	16 (15%)
Electrical heart disease, n	21 (20%)
Hypertrophic cardiomyopathy, n	21 (20%)
Congenital heart disease, n	6 (6%)
Valvular heart disease, n	8 (8%)
Idiopathic ventricular fibrillation, n	9 (9%)
Other, n	9 (9%)
Primary prevention, n	50 (49%)
Secondary prevention, n	52 (51%)
LVEF, %	52±14%
BMI, kg/m^2	26.3±5.1

BMI indicates body mass index; LVEF, left ventricular ejection fraction.

Results

Induction of Ventricular Fibrillation and Effectiveness of First Shock Delivery

One hundred of 102 consecutive S-ICD recipients underwent intraoperative defibrillation testing. In 1 patient, defibrillation test not done because of fibrotic adhesions on a dialysis catheter, while another patient was not tested because of severe comorbidities. Two of these 100 patients were not inducible despite numerous attempts with DC bursts of different lengths.

In 74 (75%; 95% CI 66–83%) of 98 patients, ventricular fibrillation was effectively terminated by the first programmed internal shock. In 24 (25%; 95% CI 22–44%) of 98 patients, the first internal shock was ineffective and further internal or external shock deliveries were required (Figures 1 and 2A).

Ineffective Shock Delivery

In 14 of 24 patients with ineffective first shock of 65 J, further defibrillation with reversed polarity and the same energy was effective (Table 2). Therefore, the first shock was programmed with reversed polarity in these patients. In 6 patients with ineffective first shock of 65 J, further defibrillation attempts with reversed polarity and maximum energy were not effective. These patients underwent a fluoroscopic examination in which a potential for improvement of the shock vector was diagnosed. Therefore, repositioning of the sensing lead and/or the pulse generator under fluoroscopic control was performed. In 4 of these patients, the can was moved to a more cranial position (Figure 2B), while in 1 patient, the can was positioned more caudal. In 1 additional patient, the sensing lead was moved to a right parasternal position. In 4 additional patients with ineffective first shock, further attempts with reversed polarity and increased shock energy (either 70 or 80 J) effectively terminated ventricular fibrillation. In 2 of these patients, ventricular fibrillation could not be further induced for a second test. Therefore, further intraoperative tests were impeded. In the other 2 patients, fluoroscopic examination revealed an ideal position of the sensing lead and the pulse generator. Therefore, a decreased safety margin of <10 was accepted in these 4 patients.

Discussion

In the present study, in a significant proportion of S-ICD recipients who underwent routine intraoperative defibrillation testing, the first shock of 65 J did not effectively terminate ventricular fibrillation. In most cases, either programming of a reversed shock polarity or repositioning of the sensing lead solved this problem and resulted in successful defibrillation.
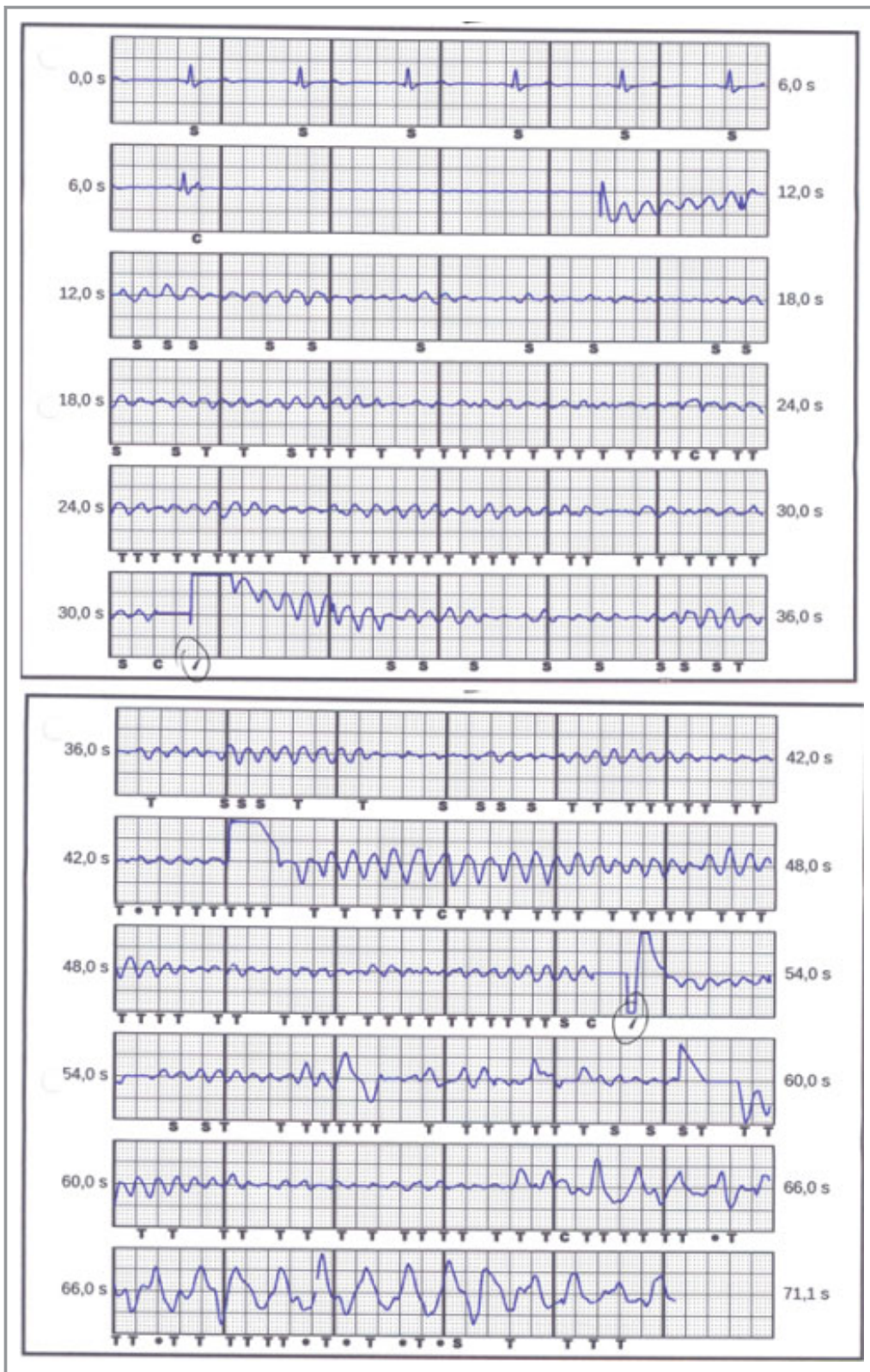
Figure 1. Representative example of an ineffective shock delivery during intra-operative defibrillation test: 2 ineffective internal shocks. Ventricular fibrillation was subsequently terminated by external defibrillation.
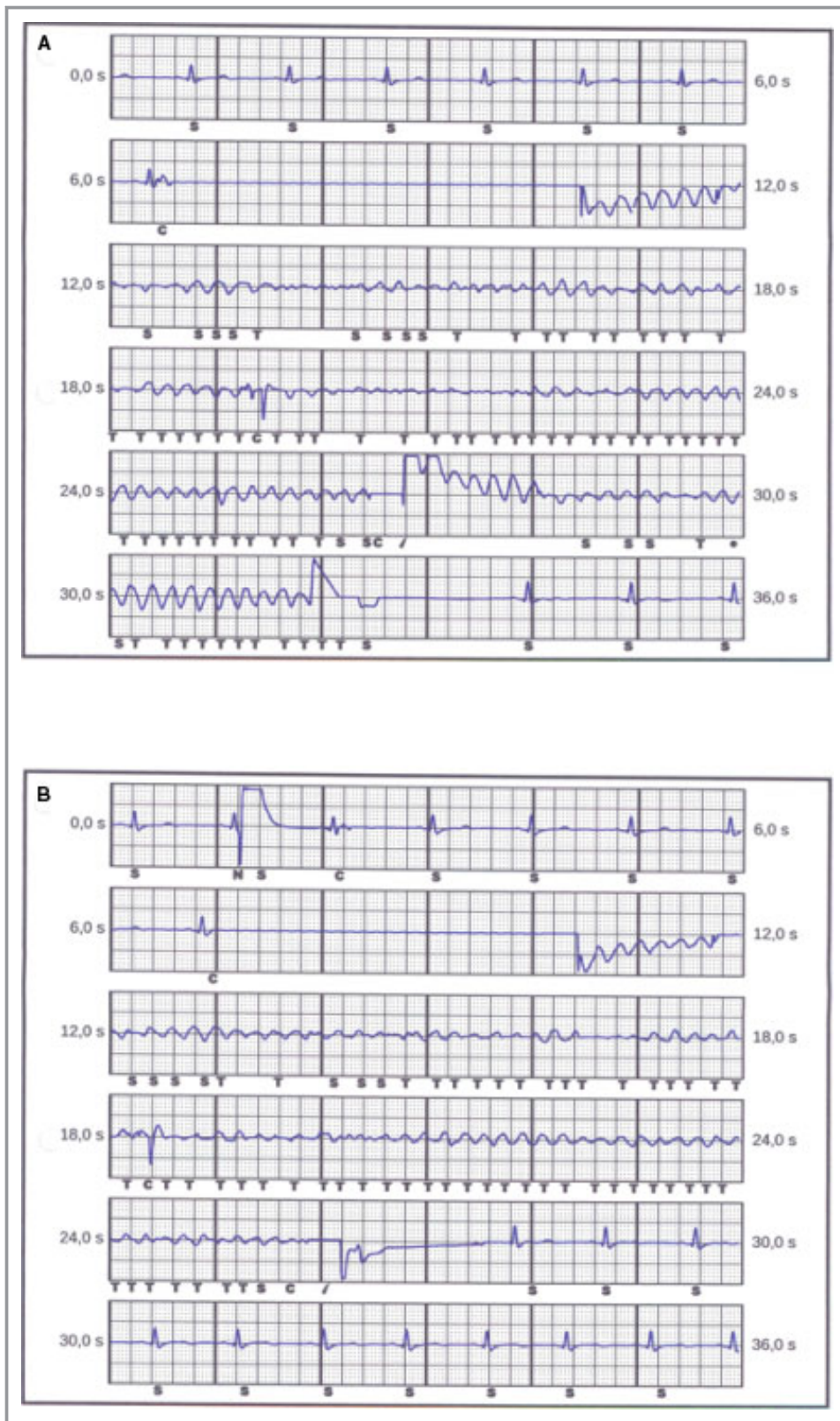
Figure 2. A, Another ineffective internal shock in the same patient after programming of reversed polarity without altering the position of the pulse generator and subsequent external defibrillation. B, Example of an effective internal shock delivery during defibrillation testing in the same patient after repositioning of the pulse generator in a more cranial position.

Table 2. Results of Intraoperative Defibrillation Testing (n=98)

Successful first defibrillation test	74 (75%)
Successful test with reversed shock polarity	14 (15%)
Successful test after lead repositioning	1 (1%)
Successful test after pulse generator repositioning	5 (5%)
Safety margin <10 J	4 (4%)

However, in a small percentage of these patients, a reduced safety margin of <10 J had to be accepted. With regard to the recently published results of the SIMPLE trial that questions the clinical value of routine defibrillation testing in patients receiving conventional transvenous ICD,[15] the results of the present study underline that defibrillation tests are currently necessary to evaluate system functionality.

Defibrillation Testing in Patients With Transvenous ICD Systems

Routine defibrillation tests in patients with the use of modern conventional ICD systems are almost always effective in the first programmed shock configuration.[17] In a study that included 1530 ICD recipients, only 3.9% did not meet the 10J safety margin criterion. After programming of reversed shocking polarity, lead repositioning, or addition of a subcutaneous array, a 10-J safety margin could be achieved in all patients.[17]

In the SIMPLE study, ICD implantation without defibrillation testing was not inferior to intraoperative defibrillation testing regarding long-term efficacy of the ICD or total mortality. These results were judged as rather robust by the authors and could simplify the implantation procedure of transvenous ICD systems in the future. Of note, an increased mortality rate compared with other ICD studies was described in the SIMPLE population.[18,19] This aspect was attributed to the fact that the patient population in the SIMPLE study presented many comorbidities. However, small patient groups that might have a higher risk for ineffective shock deliveries such as patients with hypertrophic cardiomyopathy might not be sufficiently encompassed in this study. The results of the NO Regular Defibrillation testing In Cardioverter Defibrillator Implantation (NORDIC-ICD) trial, also randomized, further underlined that intraoperative defibrillation testing during routine left-sided ICD implantation does not improve defibrillation efficacy.[20,21]

Ineffective Shock Deliveries of the S-ICD System

Ineffective shock deliveries have been described in the literature. These episodes can also occur in patients who undergo successful intraoperative defibrillation testing.[14] The cited cases mostly resulted in subsequent system explantation and implantation of a transvenous ICD. In case of defibrillation threshold problems, comparable positions of the subcutaneous lead—as described in the present study—have been suggested previouslye.[22] These attempts to improve the shock vector can only be minimal because complex repositioning manoeuvers are impeded by the rather strict localization of the S-ICD system. Further, other possible interventions to improve shock efficacy that are available in transvenous ICD systems, such as implantation of a subcutaneous array, cannot be used.

Limitations

The present study is a single-center experience of intraoperative defibrillation testing of S-ICD systems with a small sample size compared with former multicenter trials with transvenous ICD systems. Of note, the patient population fundamentally differs from patients in former trials because in the present study mostly young patients with channelopathies and patients who underwent extraction of transvenous ICD systems as a results of infections received S-ICD systems, while the majority of ICD recipients in previous studies consists of older patients with ischemic or nonischemic heart disease. Further, predictors of successful termination of ventricular fibrillation could not be identified because of the limited sample size. This aspect represents an important area of future research.

Conclusion

The results of the present study underline that in a significant proportion of S-ICD recipients ineffective shock deliveries may occur during routine intraoperative defibrillation testing. In the majority of these cases, the shock vector could be improved by programming a reversed shock polarity or repositioning of the sensing lead or the pulse generator. These results imply that ineffective shock deliveries are more common in S-ICD patients than in patients with conventional transvenous ICDs. In addition, revision of programmed shock polarity of repositioning of the lead or pulse generator is often necessary to ensure adequate system functionality. Therefore, the recently published study data most likely cannot be directly transferred to S-ICD recipients and patients who receive these innovative devices should still be tested during the implantation procedure.

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Disclosures

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