Acute human defibrillation performance of a subcutaneous implantable cardioverter-defibrillator with an additional coil electrode

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BACKGROUND The subcutaneous implantable cardioverter-defibrillator (S-ICD) delivers 80 J shocks from an 8 cm left-parasternal coil to a 59 cm^3 left lateral pulse generator (PG). A system that defibrillates with lower energy could significantly reduce PG size. Computer modeling and animal studies suggested that a second shock coil either parallel to the left-parasternal coil or transverse from the xiphoid to the PG pocket would significantly reduce the defibrillation threshold.

OBJECTIVE The purpose of this study was to acutely assess the defibrillation efficacy of parallel and transverse configurations in patients receiving an S-ICD.

METHODS Testing was performed in patients receiving a conventional S-ICD system. Success at 65 J was required before investigational testing. A second electrode was temporarily inserted from the xiphoid incision connected to the PG with an investigational Y-adapter. Phase 1 (n = 11) tested the parallel configuration. Phase 2 (n = 21) tested both parallel and transverse configurations in random order.

RESULTS This study enrolled 35 patients (28 males (80%); mean age 51 ± 17 years; left ventricular ejection fraction 40% ± 15%; body mass index 26 ± 4 kg/m^2; prior myocardial infarction 46%; congestive heart failure 49%; cardiomyopathy 63%). Compared to the conventional S-ICD system, mean shock impedance decreased for both parallel (69 ± 15 Ω vs 86 ± 20 Ω; n = 33; $P < .001$) and transverse (56 ± 14 Ω vs 81 ± 21 Ω; n = 20; $P < .001$) configurations. Shock success rates at 20, 30, and 40 J were 55%, 79%, 97%, and 25%, 70%, 90% for parallel and transverse configurations, respectively. Defibrillation threshold testing was well tolerated with no serious adverse events.

CONCLUSION Adding a second shock coil, particularly in the parallel configuration, significantly reduced the impedance and had a high likelihood of defibrillation success at energies ≤40 J. This may enable the development of a smaller S-ICD.

KEYWORDS Defibrillation; Subcutaneous; Human; Electrodes; Implantable cardioverter-defibrillator

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Introduction

The subcutaneous implantable cardioverter-defibrillator (S-ICD) system has been shown to be a safe and effective alternative to transvenous ICD (TV-ICD) systems for patients at risk for sudden cardiac death.[1–3] The key advantage of the S-ICD over the TV-ICD is that it is completely subcutaneous with no leads inserted in the heart chambers or vasculature. The S-ICD system therefore avoids most issues associated with TV-ICD and has been shown to reduce long-term lead-related complications.[4,5]

The S-ICD system consists of an electrode and a pulse generator (PG; EMBLEM, Boston Scientific, Marlborough, MA). The electrode is inserted subcutaneously along the left sternal margin from a ~2 cm incision in the left paraxiphoid region using a tunneling tool and peelable sheath. The PG is placed in a subcutaneous or intramuscular pocket on the posterolateral aspect of the left thorax from a lateral incision along the fifth or sixth intercostal space. The proximal end of the electrode is tunneled subcutaneously from the xiphoid incision to the PG pocket. The defibrillation shock is

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delivered between the left parasternal shock coil and the PG (see Figure 1A).

A potential factor limiting S-ICD usage is the size of the PG. Critical mass theory suggests that a minimum of 4 V/cm must be achieved across 95% of the heart for successful defibrillation, and to accomplish this with an S-ICD system placed outside the rib cage requires more energy compared with systems with leads inside the heart.[6] The S-ICD system delivers 80 J shocks from a 59 cm^3 PG, while typical ICDs deliver ~40 J shocks from an ~30 cm^3 PG. New technology will allow some reduction in S-ICD size, but significant size reduction will require PGs that deliver less energy. This in turn requires new electrode designs and shock vectors that have lower defibrillation energy requirements compared to current S-ICD systems. Computer modeling studies and an animal study suggested that significant reduction in S-ICD energy requirements might be achieved via a simple adaptation using a second electrode, inserted either parallel to the first or in transverse direction from the xiphoid toward the PG (Figures 1A and 1B).[7,8] The purpose of this acute feasibility study was to assess the defibrillation efficacy of these dual electrode approaches in patients receiving an S-ICD system.

Methods

This study enrolled patients scheduled to receive a conventional S-ICD system for standard indications at 4 clinical sites experienced in S-ICD implantation. Patients believed to be at high risk for complications related to the insertion of a second

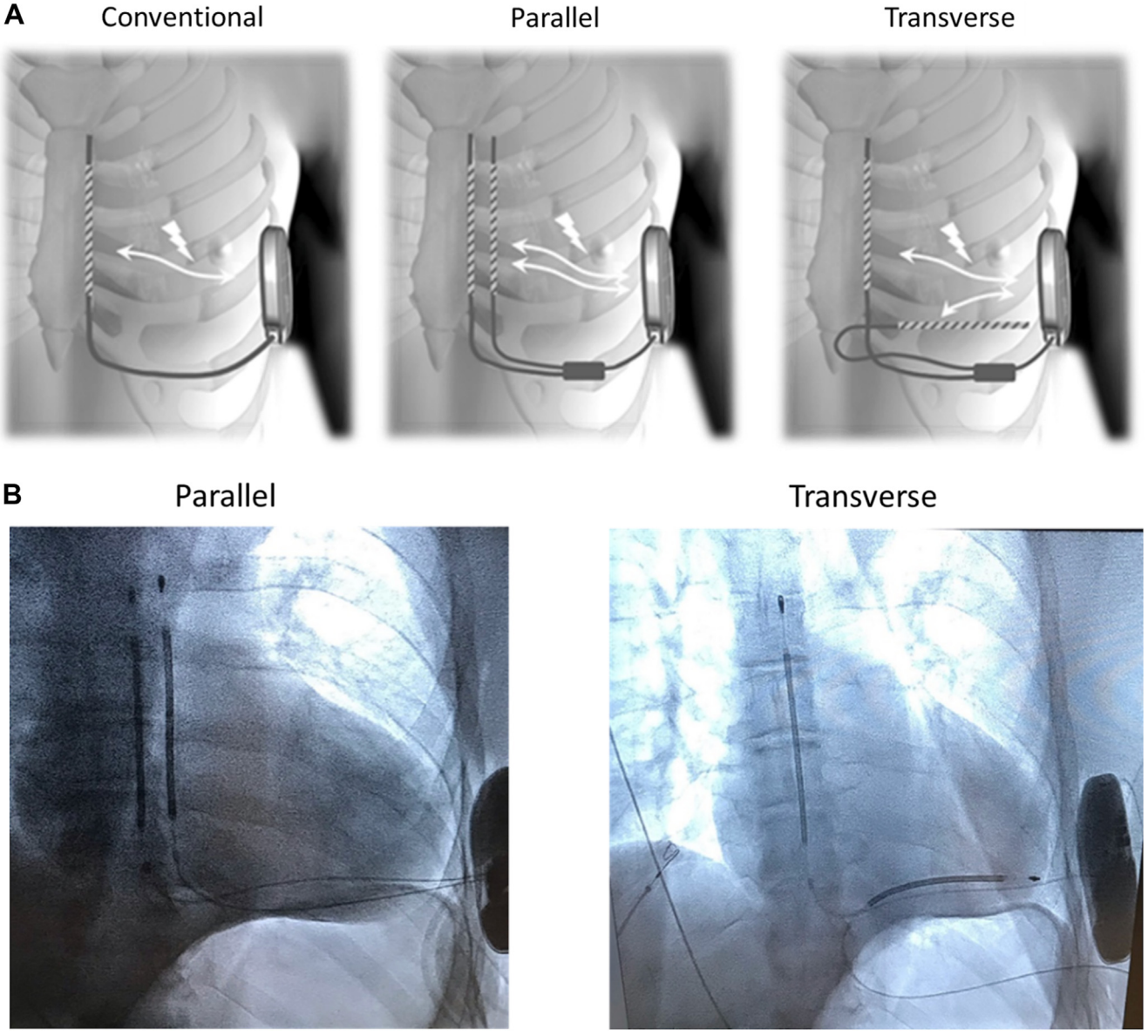

Figure 1 **A:** Subcutaneous implantable cardioverter-defibrillator (S-ICD) shock configurations. The conventional S-ICD configuration was a single left parasternal electrode and S-ICD pulse generator, as used for all current S-ICD systems. Parallel and transverse configurations added a second coil electrode for testing of new dual electrode configurations in this study. **B:** Fluorographic images of 1 tested patient, showing parallel and transverse electrode locations.

electrode, additional ventricular fibrillation (VF) conversion testing, stroke, or infection were excluded as evidenced by factors including unusual chest anatomy, left ventricular ejection fraction $< 20\%$, unstable heart failure/heart transplant list, body mass index > 35 kg/m^2, hypertrophic cardiomyopathy, atrial fibrillation or flutter within 4 weeks of the procedure, infection in the past 30 days, dialysis, insulin-dependent diabetes, or immunosuppressive therapy. A complete list of inclusion and exclusion criteria may be found here (ClinicalTrials.gov identifier NCT03802110). The study conformed to the principles of the 2013 Declaration of Helsinki and was approved by the relevant competent authority and ethics committees.

The procedure began with the implantation of the conventional S-ICD system (model 3401 or 3501 EMBLEM electrode, and EMBLEM model A209, or EMBLEM MRI A219 pulse generator, Boston Scientific) using standard methods. Before any investigational testing, successful VF conversion at 65 J with the conventional S-ICD system was required (a failed 65 J shock was a safety criterion to discontinue in-procedure acute testing). VF was induced with 50 Hz from the S-ICD PG. If the first shock delivered by the PG at 65 J failed for any reason, the patient was excluded from investigational testing since electrode repositioning and/or additional testing may have been needed to ensure safe implantation. After verification of successful conversion at 65 J with the conventional S-ICD system, investigational testing began with the temporary insertion of a second electrode (model 3401 or 3501, Boston Scientific) from the same paraxiphoid incision using the same introducer and sheath tools (Figure 1). For the parallel configuration, the second electrode was inserted just lateral to the first electrode with $\sim$1 cm of separation. For the transverse configuration, the electrode was inserted from the paraxiphoid incision toward the PG pocket while keeping the shock coil as anterior as possible. Fluoroscopy was used to document electrode locations and ensure neither electrode touched the other or touched the PG. Both electrodes were connected to the PG with an investigational Y-adapter (model 3598, Boston Scientific) to facilitate VF induction and shock testing. The investigational Y-adapter was designed to allow both shock coils to be electrically common while limiting sensing to only the first 3401 or 3501 electrode (see Figure 2).

The study was conducted in 2 phases to gain initial experience and help ensure safety. In phase 1 (Figure 3A), only the parallel configuration was tested. Starting energy was 50 J, with subsequent tests at 65, 40, 30, and 20 J depending on shock success or failure. Only 1 test shock was delivered per VF induction, and failed test shocks were followed by either an 80 J shock from the S-ICD or an external shock. This sequence required up to 3 additional VF inductions for phase 1 testing. A test shock was considered successful if a return to sinus or a nonshockable rhythm occurred within 5 seconds of the test shock. In phase 2 (Figure 3B), both parallel and transverse configurations were tested in random order. Starting energy was reduced to 30 J with a subsequent test at either 40 J or 20 J. This more efficient testing method

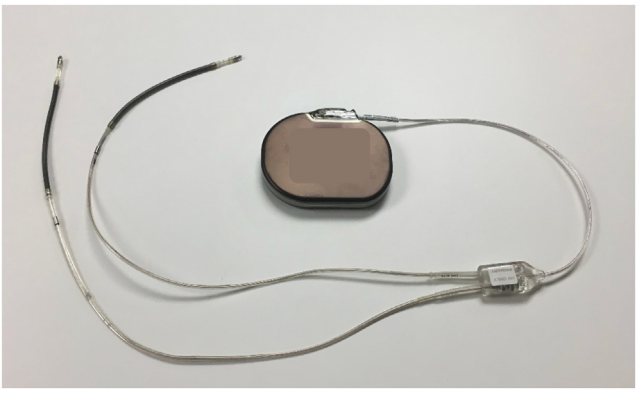

Figure 2 Photograph illustrating how the dual electrode configurations tested in the study were realized using an EMBLEM subcutaneous implantable cardioverter-defibrillator (S-ICD), an investigational Y-adapter, and 2 S-ICD electrodes.

(2 VF inductions per shock configuration) enabled testing of both dual-electrode configurations in the same patient.

In addition to the 65 J success requirement for the conventional S-ICD system before beginning investigational testing, the protocol included several other safety precautions that required testing to be discontinued if (1) any rescue shock failed, (2) time from VF induction to PG shock delivery was $>$25 seconds, (3) hemodynamic instability, (4) excessive bleeding, (5) or any other unexpected clinical or system-related event. After testing was completed, the second electrode and investigational Y-adapter were removed, and conventional S-ICD system implantation was completed via standard procedures. A patient's active participation in the study ended at the completion of acute testing, but the sites were required to report any adverse events within 3 months of the procedure. Either a 3-month visit or phone call plus chart review was required to help ensure reporting of late-occurring adverse events.

Given the exploratory nature of this study, sample size was not driven statistically. However, it was estimated that a minimum of 20 patients with complete test data (per configuration) would provide an $\sim$10% margin of error for an expected conversion rate of 95% at the highest energy level tested. Parallel configuration test data from phases 1 and 2 were combined. Demographic information for patients beginning the test procedure was expressed as either a count (percentage) of the total of patients or mean $\pm$ SD. Shock impedances were reported as mean $\pm$ SD and compared using a paired Student t test. Conversion success was expressed as percent success (with 95% confidence interval) at each energy test level (ie, 20, 30, and 40 J). While we did not perform full step-down to failure defibrillation threshold (DFT) tests, we computed mean $\pm$ SD for the lowest successful energy and compared parallel and transverse configurations using the Wilcoxon signed-rank test. The duration for experimental testing was calculated from the beginning of the insertion of the second electrode to the last VF induction and expressed as mean $\pm$ SD. Fluorographic images were retrospectively analyzed to determine

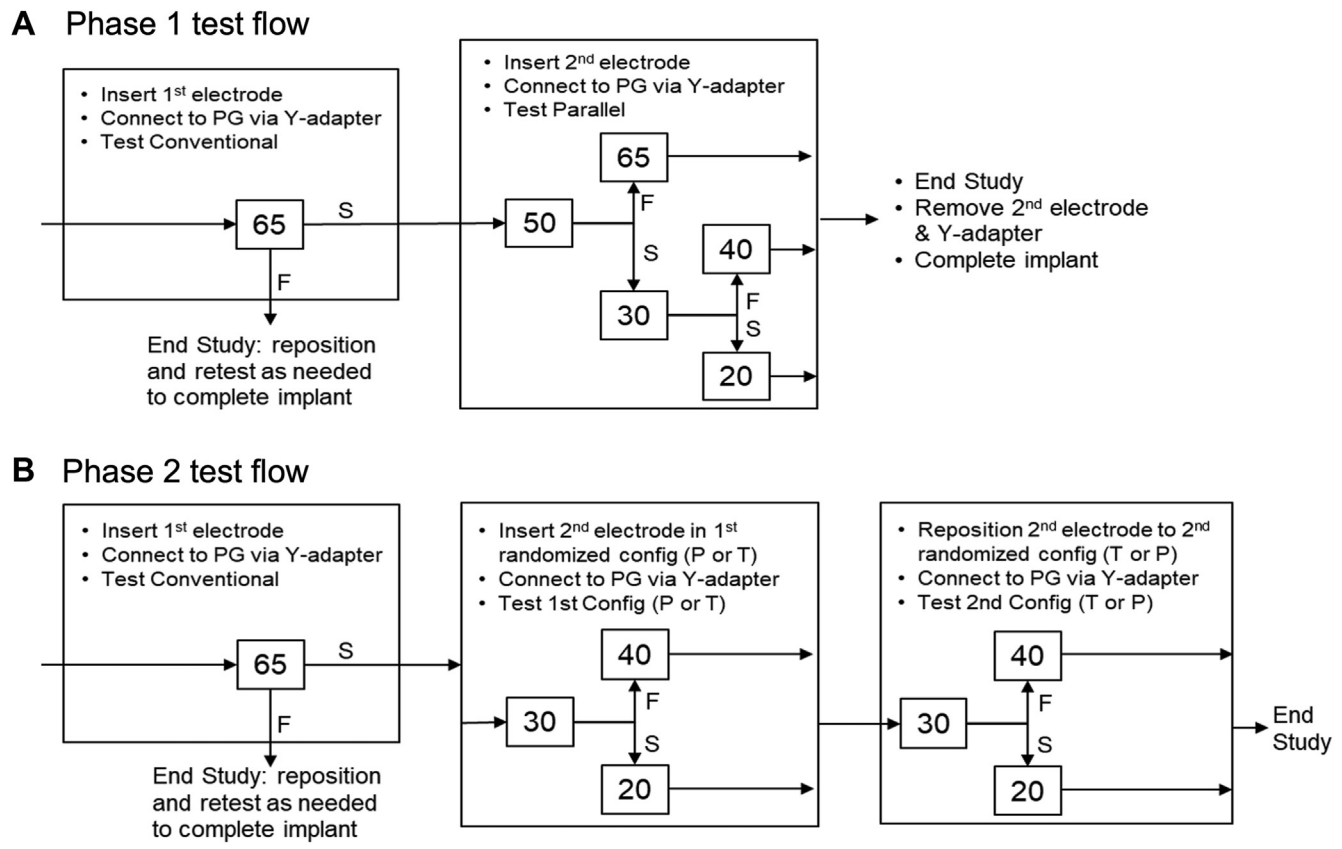

Figure 3 Flowcharts illustrating the sequence of testing used in the study: (**A**) phase 1 testing in the first 11 patients and (**B**) phase 2 testing in the subsequent 24 patients. P = parallel; PG = pulse generator; T = traverse.

spacing and orientation relationships between the first and the second electrode.

Results

Forty-two patients at 4 investigational sites in the Netherlands were enrolled between November 2018 and December 2021. Seven patients were withdrawn before S-ICD implantation because they were discovered to not meet inclusion or exclusion criteria, they withdrew consent, or the study had been suspended by the sponsor to make protocol changes. The characteristics and medical history of the 35 patients who began implant testing are presented in Table 1. Patients were representative of an S-ICD population, although as typical, they were younger and had higher left ventricular ejection fraction and fewer comorbidities than a TV-ICD population. Patient characteristics did not differ between phase 1 and phase 2, except that there were 6 diabetic patients in phase 2 vs none in phase 1 and 9 patients in phase 2 were receiving an aldosterone antagonist vs none in phase 1.

Thirty-three of 35 patients (94%) who began the procedure had successful VF conversion with the conventional S-ICD system on their first attempt at 65 J and progressed to investigational testing. Phase 1 testing of the parallel configuration began in 11 patients, was completed in 10, and added 14 ± 3 minutes (range 11–18 minutes) to the implant procedure. Phase 2 testing began in 24 patients, yielded nearly complete data in 23, and was completed in 20. There were 3 patients who could not reliably be induced into VF in the transverse configuration, so testing was not completed in these patients. Testing both parallel and transverse configurations in phase 2 added 21 ± 4 minutes (range 17–28 minutes) to the procedure.

Efficacy

The addition of a second electrode in either the parallel or the transverse configuration significantly reduced the shock impedance compared to the conventional S-ICD system (Figure 4). The parallel configuration had a 22% lower mean impedance than did the conventional S-ICD system (69 ± 15 Ω vs 86 ± 20 Ω; n = 33; $P < .01$), and the transverse configuration impedance was 32% lower than did the conventional S-ICD system (56 ± 14 Ω vs 81 ± 21 Ω; n = 20; $P < .01$). The shock impedance for the transverse configuration was also 16% lower than that for the parallel configuration (56 ± 14 Ω vs 66 ± 14 Ω; n = 20; $P = .04$).

Shock success rates (±95% confidence levels) at 20, 30, and 40 J were 55% ± 17%, 79% ± 14%, 97% ± 6% and 25% ± 19%, 70% ± 20%, 90% ± 13% for the parallel and transverse configurations, respectively (Figure 5A). The mean lowest successful energy tested was similar for both configurations (parallel: 27.0 ± 8.8 J; transverse: 31.5 ± 9.3 J). Figure 5B shows the pairs of the lowest successful energies for the 20 patients in phase 2 who completed testing

Table 1 Patient characteristics for the 35 patients who began testing in this study

Characteristic	Value
Age at the time of enrollment (y)	51 ± 17
Gender: male/female	28 (80)/7 (20)
Height (cm)	180 ± 9
Weight (kg)	84 ± 15
Left ventricular ejection fraction (%)	40 ± 15
Cardiovascular disease history	
Any cardiovascular disease	32 (91)
Hypertension	13 (37)
Coronary artery disease	11 (31)
Myocardial infarction	16 (46)
Congestive heart failure	17 (49)
NYHA class I	2 (6)
NYHA class II	15 (43)
Cardiomyopathy	22 (63)
Genetic heart disease	4 (11)
Valvular heart disease	4 (11)
Hyperlipidemia	14 (40)
Noncardiovascular disease history	
Any noncardiovascular disease	10 (29)
Diabetic	6 (17)
COPD	1 (3)
Stroke	1 (3)
TIA	1 (3)
GI bleed	1 (3)
Cardiac surgery history	
Any cardiac surgery	14 (40)
Angioplasty	12 (34)
Stent	10 (29)
CABG	6 (17)
Valve surgery	1 (3)
Arrhythmia history	
Atrial flutter/atrial fibrillation	2 (6)
NSVT	6 (17)
Ventricular fibrillation	9 (26)
Medications at the time of enrollment	
ACE/ARB	21 (60)
β-Blocker	25 (71)
Antiarrhythmic agent	0 (0)
Aldosterone antagonist	9 (25)

Values are presented as mean ± SD or n (%).

ACE = angiotensin-converting enzyme; ARB = angiotensin II receptor blocker; CABG = coronary artery bypass graft; COPD = chronic obstructive pulmonary disease; GI = gastrointestinal; NSVT = nonsustained ventricular tachycardia; NYHA = New York Heart Association; TIA = transient ischemic attack.

in both configurations. The lowest successful energy was higher for the transverse configuration than for the parallel configuration in 10 patients (50%), equal in 8 patients (40%), and lower in 2 patients (10%).

Spacing between the 2 electrodes in the parallel configuration was 11 ± 3 mm overall and decreased from phase 1 (14 ± 3 mm) to phase 2 (10 ± 5 mm) because of learning curve and request by the study sponsor for closer spacing. Spacing did not have a relationship to either shock impedance or shock efficacy. In the transverse configuration, the proximal end of the transverse shock coil was 39 ± 11 mm inferior and 35 ± 20 mm lateral to the proximal end of the left parasternal

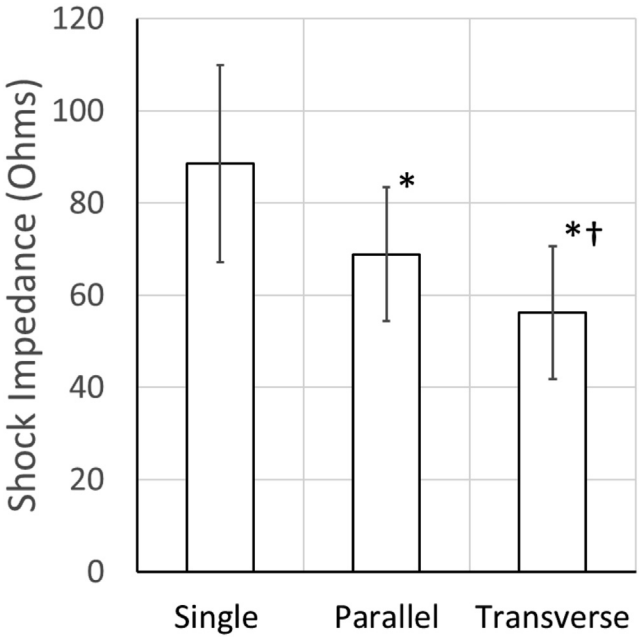

Figure 4 Shock impedance results displayed as mean ± SD. *$P < .01$ vs conventional and †$P < .04$ vs parallel.

shock coil. Again, distances between coils did not have a relationship with shock impedance or shock efficacy.

Safety

Investigational testing was well tolerated. Of the 2 patients who failed initial 65 J testing with the conventional S-ICD system, 1 underwent electrode repositioning and subsequent VF conversion success without any issues. The other patient who failed at 65 J proved extremely difficult to convert requiring chest compressions and several external and 80 J S-ICD shocks before conversion, but subsequently the patient recovered completely. The S-ICD system was removed, and at a later date the patient also failed multiple 40 J shocks during TV-ICD system implantation. One additional patient had a single rescue shock that failed during investigational testing, and per the protocol design, the testing was discontinued with no clinical consequences. Atrial fibrillation and/or atrial flutter occurred at some point during testing in 4 patients. Two resolved spontaneously and 2 were converted to normal sinus by external cardioversion near the end of the implant procedure. There were no instances of hemodynamic instability, bleeding, or other unexpected adverse events.

During 3-month follow-up, there were a few adverse events that have been previously described and are expected after S-ICD implantation.[1,4,5] These included 2 superficial infections that resolved without surgical intervention, 2 hematomas that resolved without intervention, 2 patients reported pocket pain after discharge, 1 allergic reaction possibly due to antibiotics, 1 edema during follow-up treated with diuretics, 1 paroxysmal atrial fibrillation treated with ablation, and 3 patients with inappropriate shocks. None occurred at a rate higher than expected.

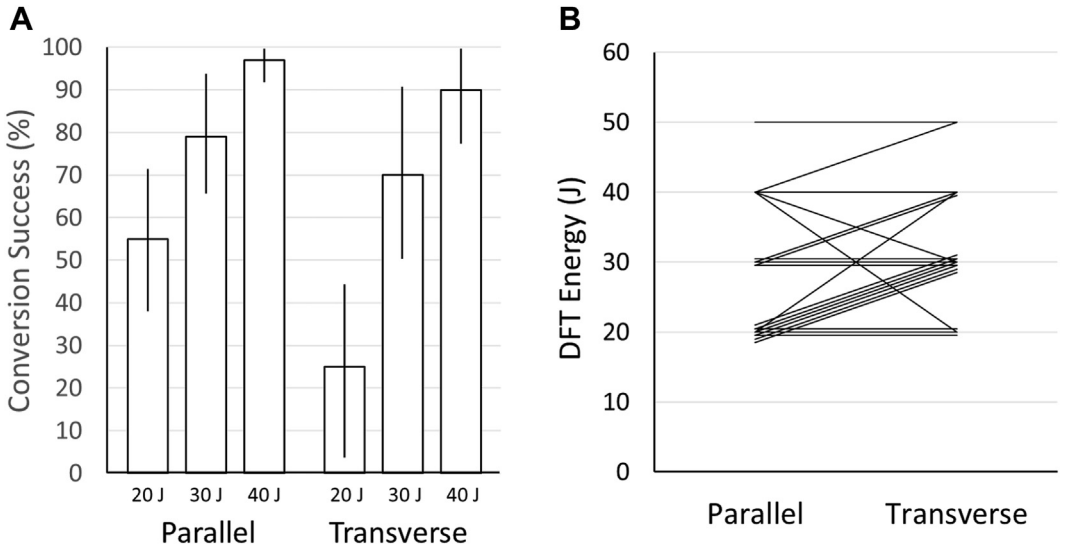

Figure 5 Defibrillation results. **A:** Percent defibrillation success (±95% confidence interval) at 20, 30, and 40 J for both the parallel configuration (n = 33 patients) and the transverse configuration (n = 20 patients). DFT = defibrillation threshold. B: Pairs of the lowest successful energies for the 20 patients in phase 2 that completed testing in both configurations.

Discussion

Key findings

This study demonstrates that inclusion of a second shock coil to the S-ICD system yields a high rate of defibrillation success at energies of ≤40 J. The use of a dual-coil electrode system could therefore enable the development of a significantly smaller S-ICD PG. The mechanism of action is likely related to reduction in shock impedance, especially in the parallel configuration. However, impedance is not the only factor as the transverse configuration had a lower impedance but trended toward requiring higher energies. Computer modeling suggests that a second electrode in the transverse configuration that extends too far laterally and close to the PG may be less efficacious since too much current flows from the second electrode to PG, thereby missing the heart.[7] Inclusion of a second electrode also helps ensure that at least 1 electrode will be deep along the facial plane and/or traverses through less fat, both of which have previously been shown to be associated with improved defibrillation success.[6,9–11]

Prior work

The concept for the addition of a second parallel electrode was derived from previous TV-ICD systems that incorporated a subcutaneous array electrode that used multiple coils tunneled subcutaneously and spaced apart to create a system of electrodes that spanned a large area of the left thorax (sometimes referred to as "phantom area"). Clinical studies showed that the subcutaneous array electrode reduced shock impedance and significantly reduced DFT.[12] The concept for the transverse design was derived from the desire for a simpler implant, whereby both shock coils could be included on a single electrode body, similar to dual-coil TV-ICD leads. Clinical studies have also shown that dual-coil TV-ICD leads provide lower DFTs than do single-coil leads.[13] Both parallel and transverse configurations were assessed in a computer model of human defibrillation that suggested that DFTs could be ∼50% lower for either the parallel or transverse configurations compared to the conventional S-ICD system with a single left parasternal electrode system.[7] The parallel configuration was also assessed in vivo in a swine model that suggested a more moderate reduction in DFT of ∼15%–20%.[8] However, swine anatomy is considerably different from that of humans, so this human feasibility study was necessary to assess true defibrillation performance.

Given the feasibility nature of this study, direct comparison of single- and dual-coil systems was not the objective and true DFTs were not obtained (ie, no tests <20 or >40 J in phase 2). Therefore, it is not possible to estimate how much energy reduction from single- to dual-coil systems was obtained, but some comparisons to prior studies may be informative. Bardy et al[14] reported mean DFTs of 32.5 ± 17.0 and 36.6 ± 19.8 J for 2 series of 78 and 49 patients, respectively. In the present study, using the lowest energy that converted VF yielded means of 27.0 ± 8.8 and 31.5 ± 9.3 J for the parallel and transverse systems, respectively. The lowest successful energy tested in the present study likely overestimates DFT because of the fairly large number of successes at 20 J and lack of testing at lower energies.

Biffi et al[15] reported on a series of 308 patients implanted at 28 sites who were uniformly tested for conversion success at an energy of 40 J. Overall conversion success with 40 J was 84%. The 97% and 90% success at 40 J for parallel and transverse configurations, respectively, seen in this study suggest better efficacy, but the numbers of patients tested were small and were not a true all-comers population. Data from Quast et al[16] suggest that when implanting an S-ICD following specific implant criteria, high success rates at low energies can be achieved even with the conventional single shock coil

system. Thus, one might envision future S-ICD implants beginning with a single coil and adding a second coil in a smaller subset of patients only in specific situations.

Clinical relevance

The data from this study support the development of a smaller, lower-energy S-ICD system; however, the clinical acceptance of such a system depends on several factors. The first factor is the size of the S-ICD PG. The size/volume of high-voltage capacitors used to deliver the shock are directly proportional to the maximum energy the PG must deliver. Energy and charge time also affect the size and voltage required for the device's battery. Current S-ICD systems are 59 cm^3 and deliver 80 J at ~1350 V peak in a charge time of ~8 seconds using a 9 V battery system. For comparison, ICDs are typically ~32 cm^3 and deliver an ~40 J shock at ~700 V in a charge time of ~8 seconds using a 3 V battery. The present study, showing high success at 40 J, suggests that a device with a maximum energy of ~50 J may be feasible, and while not as small as a TV-ICD, it would be significantly smaller than current S-ICDs, perhaps $\leq$40 cm^3.

A second factor influencing clinical acceptance is how a dual shock coil S-ICD system is implemented. Providing a Y-adapter similar to that used in this study is an obvious, but perhaps least favorable, option. A more favorable approach might be to create a PG with 2 ports in the header to allow the optional use of a second electrode. This would provide flexibility to allow the implanter to determine what is best for an individual patient. A new electrode with 2 shock coils on the same body might be the most attractive option for many.

Finally, one must also consider the implant workflow and need for VF conversion testing. In today's clinical practice, TV-ICDs are most often implanted without a VF conversion test because of the results of the Shockless IMPLant Evaluation study.[17] S-ICD implantation procedures typically include a VF conversion test, but the need for such testing is currently under study in the Prospective Randomised compArative trial of subcutanEous implanTable cardiOverter-defibrillatoR ImplANtation with and without DeFibrillation Testing study and favorable results would be expected to significantly reduce VF testing during S-ICD implantation procedures.[18] However, VF conversion testing might still be prudent for a lower energy S-ICD system as is also the case for recently introduced extravascular systems. Future clinical preferences—particularly choice of small, lower-energy PG with VF testing vs conventional S-ICD system with no VF testing—are unclear and could significantly affect the viability of new S-ICD systems.

Limitations

The results of this study must be considered with respect to some potential limitations. The sample size was relatively small, and the investigators at the 4 sites were highly experienced in S-ICD implantation. Per the protocol design, patients thought to be at higher risk were prospectively excluded, and testing was discontinued in 2 patients who failed conversion at 65 J with the conventional single electrode system. Performance of a dual shock coil system would have been interesting to assess in these 2 patients, but the study was designed conservatively for safety and to fit within the established implant workflow. Another limitation is that we did not assess the possible risks associated with lead-lead interactions and the possible implications of shorting between the 2 coils or between the transverse coil and the PG. This possible risk was mitigated using fluoroscopy to ensure that the coils did not touch each other or the PG. Future product designs would need to assess this interaction and mitigate risks accordingly. Finally, we did not directly compare the defibrillation efficacy of conventional single-coil systems with that of dual-coil systems in this study. Two patients who failed initial testing at 65 J did not contribute dual-coil data, and true step-down to failure DFTs were not obtained, so there is potential for bias in both directions and it is difficult to compare our results to prior studies.

Conclusion

Adding a second shock coil to the conventional S-ICD system significantly reduced the impedance and had a high likelihood of defibrillation success at energies $\leq$40 J, particularly in the parallel configuration. This may enable development of a smaller, lower-energy S-ICD PG; however, clinical viability is also dependent on parameters other than defibrillation efficacy like implant workflow and the need for VF conversion testing.

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