BRIEF REPORT

Short- and long-term patient-reported outcomes of subcutaneous implantable cardioverter-defibrillator therapy: Results from the RHYTHM DETECT Registry

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Introduction

There is increasing interest in assessing the quality of life (QoL) and psychosocial well-being of patients with an implantable cardioverter-defibrillator (ICD).[1] Patient acceptance refers to the patient's psychological adjustment to the device, along with perceived benefits in biopsychosocial functioning, as assessed by tools such as the Florida Patient Acceptance Scale (FPAS).[2] The subcutaneous implantable cardioverter-defibrillator (S-ICD) is an alternative to the traditional transvenous ICD. Although the recent ATLAS (Avoiding Transvenous Leads in Appropriate Subjects) trial showed that S-ICDs reduce lead-related complications, the devices may lead to increased early postoperative discomfort.[3] This study aimed to assess the pain experienced by patients during S-ICD implantation under current clinical settings and to examine their device acceptance during follow-up.

KEYWORDS Acceptance; Anesthesia; Implantable defibrillator; Pain; Serratus anterior plane block; Subcutaneous (Heart Rhythm O2 2024;5:474–478)

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Methods

Study design

Patients who underwent S-ICD (Boston Scientific Inc., Natick, MA) implantation from 2020 to 2022 were prospectively enrolled at 11 centers (ClinicalTrials.gov Identifier: NCT02275637). All patients signed an informed consent that had been approved by each institutional review board. Based on physician's discretion, the pulse generator was placed in either a subcutaneous or an intermuscular pocket.[4] Procedures were conducted with patients under standard sedation (intravenous midazolam or propofol at dosage personalized for each patient) and local anesthesia, or use of ultrasound-guided serratus anterior plane block (SAPB).[5] At the end of the implantation or when patients were able to respond, they rated their pain intensity using a 10-point visual analog scale. In addition, both dynamic (on sitting, coughing, or moving the arm) and static (rest) pain levels were assessed 6 hours postprocedure.[6] Twelve months postimplantation, device acceptance was evaluated using the FPAS with its 4 domains[2]: return to function (RTF), device-related distress (DRD), positive appraisal (PA), and body image concerns (BIC).

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KEY FINDINGS

- Subcutaneous implantable cardioverter-defibrillator implantation in contemporary practice is associated with minimal discomfort.
- The serratus anterior plane block technique offers reduced perioperative pain levels compared to conventional local anesthesia, enhancing the overall implantation experience.
- During follow-up, favorable acceptance of the subcutaneous implantable cardioverter-defibrillator is observed across different ages, genders, and body habitus.

Statistical analysis

Quantitative variables are given as mean ± SD if normally distributed or as median [25th–75th percentile] in the case of skewed distribution. Categorical variables are given as percentages. Mann–Whitney nonparametric test was used to assess intergroup variability. Multiple linear regression was used to identify variables associated with pain intensity and device acceptance. $P < .05$ was considered significant.

Results

Study population and S-ICD implantation

One hundred forty-nine consecutive patients underwent S-ICD implantation and were enrolled in the study (Table 1). Mean procedural time was 57 ± 15 minutes. No operative complications were reported. Pain intensity during and after the implantation procedure is shown in Figure 1. Lower pain intensity values were recorded during the implantation procedure in the SAPB group, and the difference in dynamic pain intensity between the groups persisted at 6 hours. Among baseline clinical and implantation variables, the only factor independently associated with lower pain intensity during implantation was SAPB adoption (coefficient –1.27; SE 0.35; $P < .001$) on linear regression analysis.

Follow-up

After 12 months, episodes of ventricular fibrillation were appropriately detected and treated in 3 patients (2%), and inappropriate therapies were delivered in 5 patients (3%). Device-related complications occurred in 2 patients (1%) (1 developed indication for bradycardia pacing, 1 system infection). Overall, 10 patients (7%) had the combined endpoint of complications or delivered ICD therapies.

Acceptance of S-ICD

FPAS scores at 12 months and the 4 domains are shown in Figure 2. Figure 2 also shows the score stratified by age, gender, body habitus, etiology, anesthesia/analgesia approach, defibrillation test, and device-related complications and/or therapies delivered. Patients who underwent SAPB showed better FPAS, as did those who did not undergo the defibrillation test. Multiple regression analysis of baseline and implantation variables confirmed the association of SAPB (coefficient 3.22; SE .39; $P = .034$) and omission of the defibrillation test (coefficient 6.39; SE 2.55; $P = .013$) with better FPAS.

Table 1 Baseline clinical parameters and implantation variables (N = 149)

Male	129 (87)
Age (y)	53 ± 13
Body mass index (kg/m^2)	27 ± 4
LV ejection fraction (%)	39 ± 14
Cardiomyopathy	
Ischemic/Nonischemic dilated	108 (72)
Hypertrophic	6 (4)
ARVC	5 (3)
Congenital	3 (2)
Channelopathies/other	
Idiopathic ventricular fibrillation	10 (7)
Brugada syndrome	11 (7)
Other	6 (4)
Chronic kidney disease	12 (8)
Diabetes	22 (15)
Intermuscular pocket	140 (94)
Serratus anterior plane block	103 (69)
Defibrillation test performed	72 (48)

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

ARVC = arrhythmogenic right ventricular cardiomyopathy; LV = left ventricle.

Discussion

Our findings suggest minimal discomfort associated with S-ICD implantation. Previous studies have confirmed the efficacy and safety of the S-ICD.[7] The ATLAS trial highlighted S-ICD's capacity to reduce lead-related complications without compromising shock efficacy.[3] However, it hinted at a potential tradeoff with increased postoperative pain due to the bulkier design of S-ICD compared to traditional ICDs. In contrast, our study recorded lower perioperative pain levels compared to the S-ICD arm of the ATLAS trial, aligning with the ICD arm. We attribute this finding to the innovative intermuscular implantation method and widespread adoption of the SAPB technique, which is known for its efficacy in reducing pain and procedural durations over conventional local anesthesia.[5,8] Our data further support the benefits of SAPB, with sustained pain reduction up to 6 hours postprocedure, potentially enhancing the overall implantation experience. Body image concerns can impact patient well-being and QoL, along with the potential psychological effects of ICD shocks.[9,10] Utilizing the FPAS, we observed favorable acceptance of the S-ICD across age, gender, and body habitus. Positive sentiment toward the device from both sexes is significant given their susceptibility to body image concerns.[11] Similarly, favorable FPAS scores among younger patients, who often receive an S-ICD, are crucial because they are more prone to device-related distress.[12,13] Evidence regarding patient-reported outcomes becomes pertinent following positive clinical endpoint results[3,7] and favorable QoL outcomes

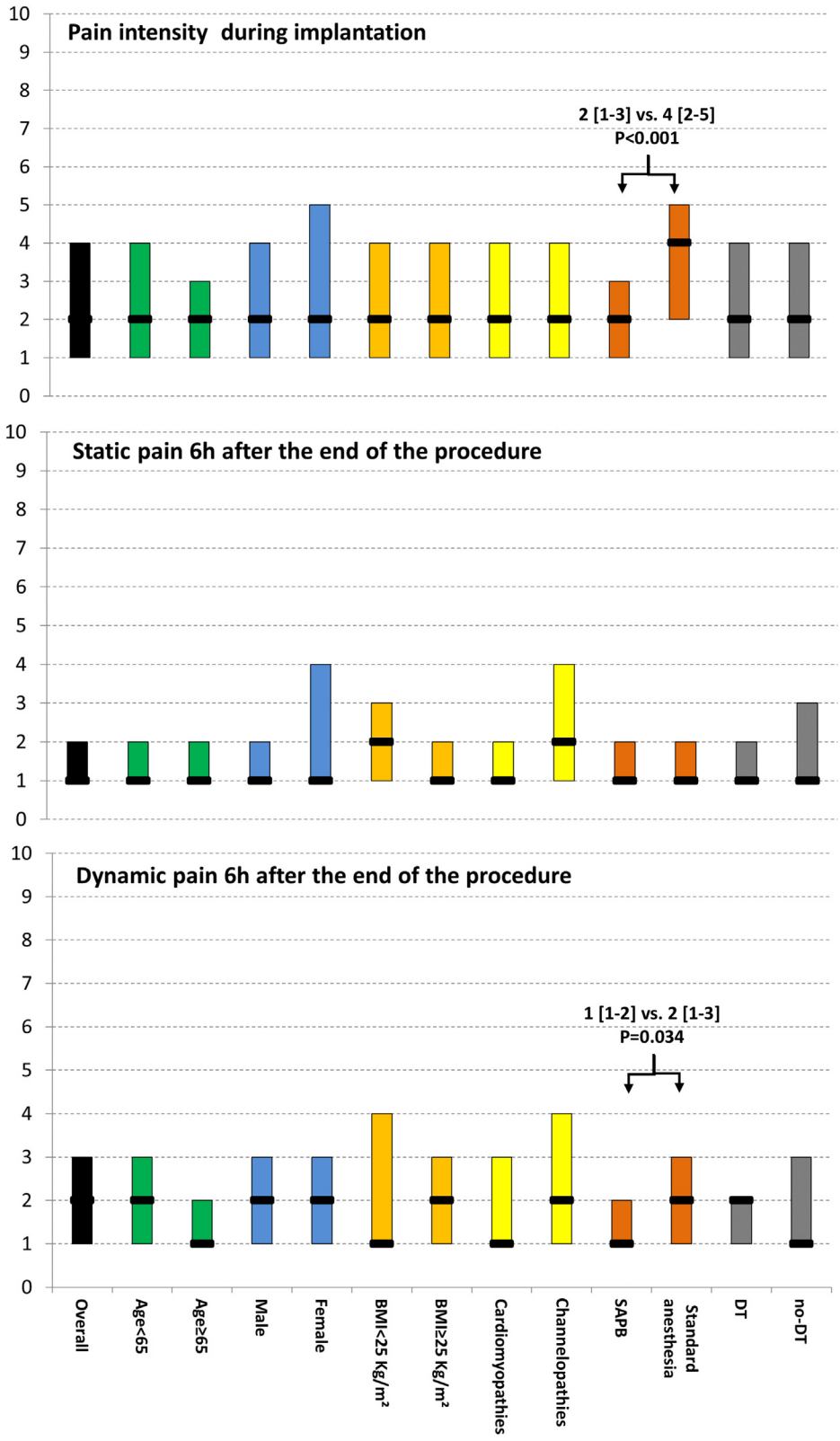

Figure 1 Pain intensity (median with 25th–75th percentiles) during and after the implantation procedure on a scale of 0 (no pain) to 10 (worst imaginable pain).

among S-ICD patients.[14] Our results align with a previous study that compared S-ICD acceptance with that of transvenous ICDs.[15] Notably, S-ICDs demonstrated good acceptance, particularly in heart failure patients. Moreover, a recent study on the extravascular ICD reported comparable FPAS scores,[16] although our patients had lower body mass index and thus a potentially higher risk of body image concerns. The contemporary intermuscular approach promises optimal

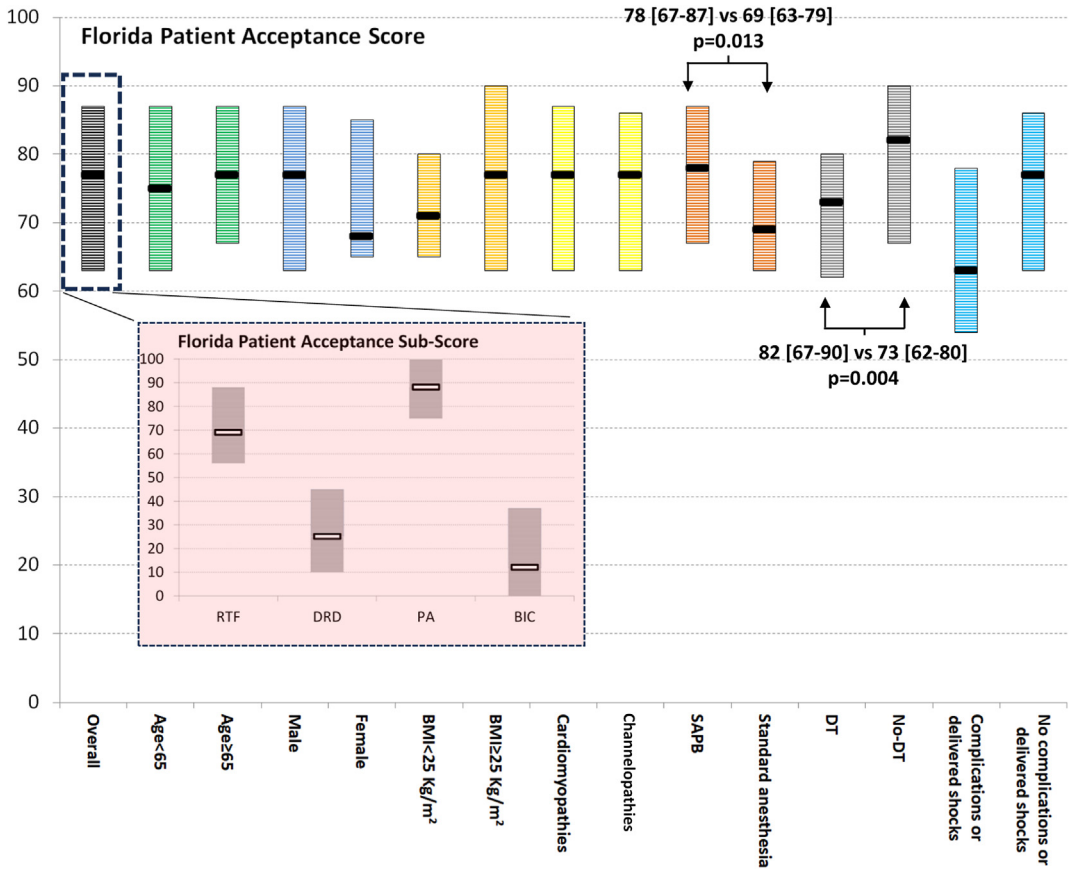

Figure 2 Return to function (RTF), device-related distress (DRD), positive appraisal (PA), body image concerns (BIC), and the final Florida Patient Acceptance Scale (FPAS) (median with 25th–75th percentiles). Higher scores on RTF and PA indicate better acceptance, whereas elevated scores on DRD and BIC indicate poorer acceptance. BMI = body mass index; DT = defibrillation test.

device positioning, reduced shock impedance, and fewer complications.[4,17,18] Improved device acceptance was noted among patients undergoing SAPB, suggesting a positive link between implantation experience and therapy acceptance. Notably, SAPB, conducted before device implantation, often does not require continuous presence of an anesthesiologist. Decreased reliance on anesthesiologist involvement is evident, partly due to declining frequency of defibrillation test in current clinical practice,[19] which was omitted in 52% of our patients. This trend is expected to persist, particularly in ongoing randomized trial results.[20] Our findings support this trend, showing improved acceptance when the defibrillation test was omitted. Simplified procedures, perceived as less invasive and risky, likely enhance patient acceptance, thus underscoring the importance of refining device implantation techniques continuously.

Study limitations

Major limitations of the study include its nonrandomized nature, small sample size, and subjective endpoints. Consecutive patient enrollment aimed to minimize selection bias, but et variable use of shared decision-making may have influenced therapy acceptance. The absence of a control group (ie, transvenous ICDs) limits the interpretation of results within available therapeutic solutions.

Conclusion

S-ICD implantation in contemporary practice is associated with minimal discomfort. SAPB offers reduced perioperative pain levels compared to conventional local anesthesia. Furthermore, S-ICD demonstrates favorable acceptance during follow-up, even among patients with potential psychological distress.

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Authorship: All authors attest they meet the current ICMJE criteria for authorship.

Patient Consent: Participants provided written informed consent for data collection and analysis.

Ethics Statement: The study protocol was carried out in accordance with Declaration of Helsinki guidelines and was approved by the Institutional Review Board.

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