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Subcutaneous vs Transvenous Implantable Cardioverter-Defibrillators: A Brief Review of the Current Landscape

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Introduction

Implantable cardioverter-defibrillators (ICDs) have demonstrated remarkable effectiveness in preventing sudden cardiac death in patients who are at high risk of ventricular arrhythmias.[1] Transvenous ICDs (TV-ICDs) have been the standard design for decades, but they may cause major device-related complications in up to 3% of recipients.[2] These complications, such as pneumothorax or cardiac perforation with tamponade, are primarily related to the leads and can occur during implantation; in addition, long-term complications, including lead endocarditis or malfunction, may appear. The subcutaneous ICD (S-ICD) was developed as an extravascular device with the aim of preventing sudden cardiac death while reducing the risks and complications associated with transvenous leads.[3]

The PRAETORIAN trial was the first prospective, randomized, head-to-head trial to compare the performance of S-ICDs and TV-ICDs.[4] The trial's hypothesis was that the S-ICD is noninferior to the TV-ICD with respect to major ICD-related adverse events, including inappropriate shocks, ICD-related complications requiring intervention, and lead-related complications. Secondary end points included death and appropriate shocks. A total of 849 patients older than 18 years of age with primary or secondary indications for ICD therapy across the European Union and the United States were enrolled in PRAETORIAN. Patients requiring pacing therapy and patients for whom S-ICD vector screening failed were excluded.

The PRAETORIAN trial demonstrated that after a median follow-up of 49.1 months, the S-ICD was noninferior to the TV-ICD with respect to major ICD-related adverse events. The primary end point was observed in 15.1% of patients with S-ICDs and in 15.7% of patients with TV-ICDs; however, there was a significantly lower rate of lead-related complications in the S-ICD group (1.4%) compared with the TV-ICD group (6.6%).[5] Mortality rates, infections requiring device extraction, and device-related complications did not notably differ between the groups. Although not statistically significant, there was a trend toward more inappropriate shocks in the S-ICD group, mainly because of cardiac oversensing, while inappropriate shocks in the TV-ICD group were more commonly triggered by supraventricular arrhythmias. These findings suggest that the devices differ in the types of complications they present, with the S-ICD having fewer complications that require intervention but a potentially greater rate of inappropriate shocks. Further results are expected as follow-up continues for another 4 years.

The ATLAS trial was a prospective, randomized, head-to-head trial that compared the rate of major lead-related complications between the S-ICD and the TV-ICD for 6 months following implantation.[6] This study enrolled

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503 patients ranging from 18 to 60 years of age, including patients with conventional indications for ICD and patients with inherited cardiac arrhythmias or cardiac disorders that predisposed them to a heightened risk of lead-related complications.

At 6 months after implant, serious lead-related complications were found in 4.8% of patients with TV-ICDs compared with 0.4% of patients with S-ICDs, demonstrating the S-ICD's superiority and a remarkable 92% reduction in serious lead-related complications. Major lead-related complications included pneumothorax, cardiac perforation, tamponade, and lead dislodgement. Though no significant differences were observed in the number of inappropriate shocks, there was a slightly higher trend in risk associated with the S-ICD (2.7% per year vs 1.2% per year), which was attributed to the oversensing of T waves. The efficacy of ICD therapy, as measured by the rate of unsuccessful first shocks, was found to be comparable between the 2 devices. Additional randomized controlled trials are needed to assess the efficacy of appropriate shock and the rates of inappropriate shock for the S-ICD and the TV-ICD.

Troubleshooting High Defibrillation Thresholds in S-ICDs

Determining factors affecting defibrillation threshold with S-ICD can be challenging. The location of the device or lead and the amount of subcoil and sub–pulse generator adipose tissue are crucial in determining shock efficacy. Adipose tissue is a poor electrical conductor and can hinder defibrillation efficacy if it is present between the device and the chest.[7] An internal observation of 188 defibrillations in 170 patients at the Michael E. DeBakey Department of Veterans Affairs Medical Center in Texas demonstrated that a high shock impedance (>100 Ω) is a strong predictor of ineffective defibrillation thresholds. In such cases, repositioning the pulse generator deeper into the pocket or tunneling the lead closer to the sternal fascial plane may be necessary (Fig. 1). In patients with "ideal" S-ICD placement, the defibrillation threshold is likely to have a clinically significant safety margin with the 80-J S-ICD regardless of whether the patient has a normal or a dilated heart.

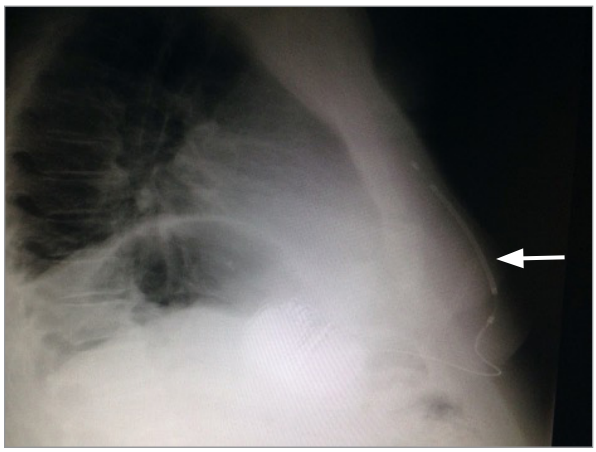

Fig. 1 Chest radiograph, lateral view, shows suboptimal lead placement. The ventral lead position (arrow) results in high shock impedance (>100 Ω) because of the presence of adipose tissue between the lead and the sternum.

Abbreviations and Acronyms

ICD	implantable cardioverter-defibrillator
S-ICD	subcutaneous implantable cardioverter-defibrillator
TV-ICD	transvenous implantable cardioverter-defibrillator

Conclusion

Based on current evidence, S-ICDs have a lower risk of lead-related complications than and a similar effectiveness at preventing sudden cardiac death as TV-ICDs. The S-ICD may present a small excess risk of inappropriate shocks and a possible benefit regarding long-term survival, but longer follow-up is needed to confirm these hypotheses. Subcutaneous defibrillators can be considered an alternative to TV-ICDs for patients requiring ICD placement without a pacing indication, especially for young patients with inherited heart rhythm disorders or patients at a higher risk of lead-related complications or infections.

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