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INVITED EDITORIAL

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The wearable cardioverter-defibrillator—Improving comfort and reaching towards noise immunity

The wearable cardioverter-defibrillator (WCD) has high shock conversion rates, but its efficacy in clinical practice tends to be degraded by patient noncompliance. Reduced wear time may have neutralized the results of the Vest Prevention of Early Sudden Death Trial (VEST).[1] The reasons for patient reluctance to continue with this device revolves around two issues: wear discomfort and frequent false alarms that are not only a nuisance but may interrupt sleep and generate anxiety. The study by Poole et al.[2] in this issue reports the function of a novel WCD platform that aimed to resolve these persistent problems. The results are impressive. Improved comfort yielded a median daily use time of 23 h per day. The false alarm rate decreased to 0.00075 per patient day. These results, meeting the prespecified goals of the study, represent a significant advance over contemporary technology and are attributable to improvements in garment structure and sensing algorithm.

The garment was redesigned, following inputs from athletic and fashion clothing designers. A light breathable fabric was selected. Two styles were tailored for the different sexes. Patient experience (an important factor measured in the trial) was positive, yielding strong scores, notably without any sex difference. Significantly, more than three-quarters of the patients crossing over from the commercially available WCD to the test device expressed greater satisfaction with the novel garment.

The function of the proprietary algorithm is well described by the authors in their report. The study enrolled implantable cardioverter-defibrillator (ICD) patients, thereby permitting comparison of WCD diagnostics with retrieved intracardiac electrograms in each individual. Crucially, there were no false negatives, that is, no missed ventricular tachycardia/ventricular fibrillation (VT/VF) events, validating results of preclinical testing (99% sensitivity for VF and 98.4% for VT). Misclassifications of SVTs were *fewer* with the novel WCD which uses electrocardiogram segments rather than the beat-to-beat basis for ICD detection (of ICD detected 131 inappropriate detections only one of these resulted in a false positive by the WCD diagnostic algorithm). These results show that cutaneous, as well as subcutaneous sensing systems, are at least noninferior to the gold standard of intracardiac discriminators.[3] Significantly, the number of noise detection events with the WCD remained high but the incidence of false alarms was very low. Thus, among 159 non-VT/VF episodes, 153 were noise-related, but only three triggered shock alarm markers (i.e., false positives). This may be puzzling at first. The basis for this is the introduction of intermediate filters in the diagnostic pathway which apply advanced signal processing techniques and machine learning functions, resulting in 95% rejection of nonshockable rhythms. The algorithm's staged approach to analysis resulted in only a tiny minority of non-VT/VF WCD events going on to trigger an alarm, thus almost achieving noise immunity.

Certain limitations need to be acknowledged. The study enrolled only patients who could be fitted with the garment. Possibly some individuals may have a suboptimal fit despite the versatility of its design. The study was designed to compare to the commercially available WCD but the trial was not a randomized comparison between these technologies. ICD programming was not standardized except for a monitor zone >150 bpm. Patient alarms and therapies were disabled- it is conceivable that these would contribute to attrition in compliance in real-world use. Although the garment was restructured to provide "superior electrode" contact using non-adhesive conductive metal integrated into the cushioned fabric, noise events were still generated. This is a persistent challenge with garment-related electrodes.[4] The algorithm "learns" a patient's QRS. The impact on its function when a patient's rhythm shifts between intrinsic to paced rhythm are relatively unknown. This is important since, among the inappropriate detections that occurred, some were because of paced complexes with low QRS amplitude. In the presence of noise, this condition presents an additional challenge for the noise filtering algorithm to identify true QRS complexes. This was only a 30-day study with intensive training and weekly phone calls to reinforce compliance. Long-term results are unknown (noting that compliance decreased linearly over time in the VEST trial[1]). Although there were no missed VT/VF episodes, there were very few such events to assess (expected with "delayed" detection[5]). Therapies were not tested—therefore the question of whether the novel device performs as well as the commercially available WCD remains. However, other data indicate shock efficacy.

In summary, the current results demonstrate substantive improvements in WCD technology. We look forward to translation into improved clinical outcomes.

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