A Novel Wearable Cardioverter Defibrillator with Reduced False Alarm Rate

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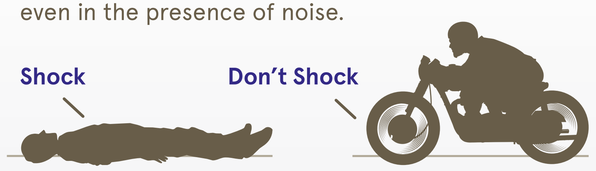
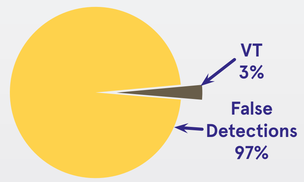
Background

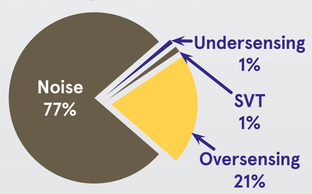
- Wearable Cardioverter Defibrillators (WCDs) provide temporary protection from ventricular arrhythmias.
- WCDs must shock VF and rapid VT even in the presence of noise.



- WCDs sometimes may inappropriately provide a shock alarm to a patient who is not in VT/VF (a false alarm). If not diverted by the patient, this could lead to an inappropriate shock.
- Previous studies have shown that most WCD detections are false.[1]



- Unlike ICDs, previous WCD studies have shown that false detections are mainly due to noise.[1]



- For the only commercially available WCD, false detections (false alarms) occur approximately every 3 days.[2,3]
- Frequent WCD alarms may increase patient anxiety and decrease compliance.
- Kestra Medical Technologies has developed a new algorithm and WCD system designed to increase noise immunity and reduce the false alarm rate.

Purpose

The purpose of this study was to assess the false alarm rate and sensitivity of a WCD prototype and algorithm.

Methods

To evaluate our algorithm and WCD system, we undertook two studies:

False Positive Rate Study

- Outpatients fitted with a prototype WCD
  - Inclusion criteria: Adults (age ≥ 18) with LVEF <= 40%.
- ECGs recorded continuously for approximately two days during normal daily activities.
- Diagnostic performance of the algorithm was assessed using the recorded ECGs.
- False alarms were defined as any arrhythmia detection without an adjudicated VT/VF rhythm.
- The false alarm rate was calculated as the total number of patient-days of recording time/number of false alarms.
- Poisson distribution was used to calculate 95% confidence limits.

Sensitivity Study

ECG segments (10 – 20 seconds long) were:

- Collected from EP labs, emergency medical systems, and publicly available databases.
- Annotated by clinical experts to confirm VT/VF rhythm and heart rate.
- Analyzed by new algorithm, giving shock/no-shock results.
- Sensitivity is defined as 100 X (# True Positive Detections/ # Segments).
- 95% confidence interval was adjusted to account for clustering.

Results

False Positive Rate Study

Baseline Characteristics	
Participants (male)	50 (60% male)
Age (mean +/- SD)	58 +/- 14 years
Percent overweight (BMI > 25)	78%

Study Results	
Total time of wear in study:	82.2 patient-days
Number of true VT/VF episodes in study	0
Number of false alarms	0
False alarm rate (days/alarm)	**27 (lower 95% C.I. limit)**

The WCD and algorithm provided no false alarms, giving 95% confidence that the true alarm rate is less than once every 27 patient days. This compares favorably to previous studies.

Sensitivity Study

	Rapid VT	VF
Number of Segments	141	199
True Positive Detections	139	197
False Negative Detections	2	2
Sensitivity (95% C.I.)	**98.6% (95.8-100%)**	**99.0% (97.6-100%)**

Comparative Data

Comparative Study Baseline Characteristics	LifeVest® WCD 3000[2]	Duncker et al[3]
Participants (male)	13 (69% male)	355 (70% male)
Age (mean, range)	56 +/- 11 years	57 +/- 15 years
Percent overweight (BMI > 25)	n.r.	n.r.

Comparative Study Results		
Total time of wear in study:	735 patient-days	25,660 patient-days
Number of true VT/VF episodes in study	4	16
Number of false alarms	214	7,030
False alarm rate (days/alarm)	**3.4**	**3.6**

Limitations of This Study

- Single site, limited number of patients, limited time of wear, prototype device.
- Performance should be prospectively tested with an independent dataset.
- Further studies are required to assess the WCD performance in actual use.

Conclusion

The novel WCD and algorithm provides a very low false alarm rate while maintaining a high sensitivity for VT/VF.

Conflicts:
J. Sullivan: Employment; Significant; Kestra Medical Technologies, Inc.
K. Branch: Other Research Support; Modest; Kestra Medical Technologies, Inc.
L. Gustavson: Employment; Significant; Kestra Medical Technologies, Inc.
A. Stewart: Employment; Significant; Kestra Medical Technologies, Inc.
P. Breske: Employment; Significant; Kestra Medical Technologies, Inc.
R. Rowbotham: Employment; Significant; Kestra Medical Technologies, Inc.
J. Kim: Employment; Significant; Kestra Medical Technologies, Inc.
J. Poole: Other Research Support; Significant; Kestra Medical Technologies, Inc.

References:
1) Schuhmann et al., "Experience with the wearable cardioverter defibrillator (WCD) in high risk cardiac patients from a German single center cohort", HRS 2016 Abstract
2) LifeVest® Model 4000 Operator's Manual, ZOLL PN 20B0048, pages 7-5,7-6
3) Duncker et al., "Real-world experience of 355 consecutive patients with a wearable-cardioverter defibrillator – Single center analysis, EHRA 2017 Abstract