#AHA23

SAFETY AND EFFICACY OF THE JEWEL, A NOVEL PATCH WEARABLE CARDIOVERTER DEFIBRILLATOR: RESULTS FROM THE JEWEL IDE STUDY

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On behalf of the Jewel IDE Investigators

DISCLOSURES

Sponsored by Element Science, Inc, San Francisco, California

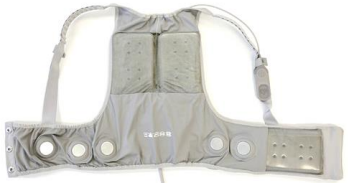
Consulting or other relationships:

- Medtronic
- Volta Medical
- S4 Medical
- Abbott Medical
- Element Science

BACKGROUND: TRADITIONAL WCDS

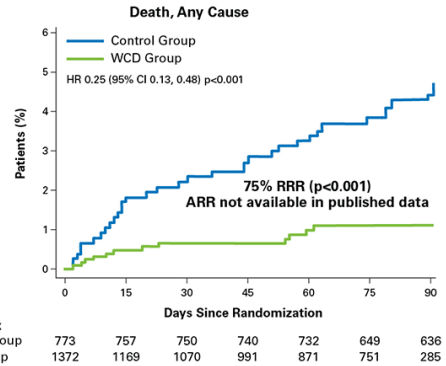
Currently available WCDs have mixed results in clinical trials

lifevest.zoll.com

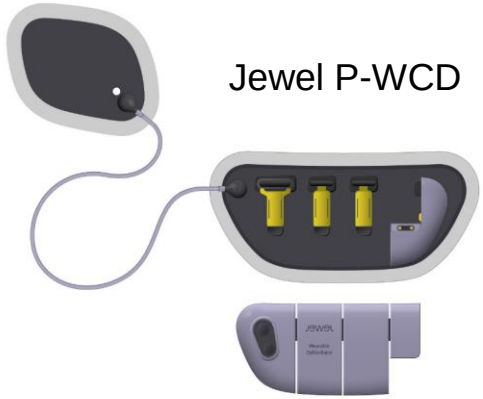


kestramedical.com

When subjects who wore the WCD included, there was a survival benefit



Primary endpoint no survival difference between control and device groups



Jewel P-WCD

THE JEWEL IDE STUDY

Can the Jewel safely and effectively monitor, detect, and terminate shockable rhythms?

Objectives	Demonstrate safety & effectiveness of Jewel P-WCD • Primary Endpoints: Efficacy: <2 inappropriate shocks per 100 patient-months Safety: <15% patients with clinically significant cutaneous adverse device effects (ADEs) • Secondary Endpoints: successful shocks, compliance
Design	• Multi-center, prospective single-arm
Sample Size	• n = 290 patients (early stopping point at 179)
Wear Time	• Up to 180 days
Clinical Sites	• 70 enrolling locations across the US

PATIENT SELECTION & ANALYSIS

Enrolled adult patients at risk for SCA who were indicated for a WCD

Fitted with the Jewel for anticipated prescription period determined by physician, up to a maximum of 180 days

Analysis

- All outcome events were adjudicated by an independent Clinical Events Committee
- Patient compliance was assessed using time-stamped data recorded by the Jewel

Inclusion Criteria

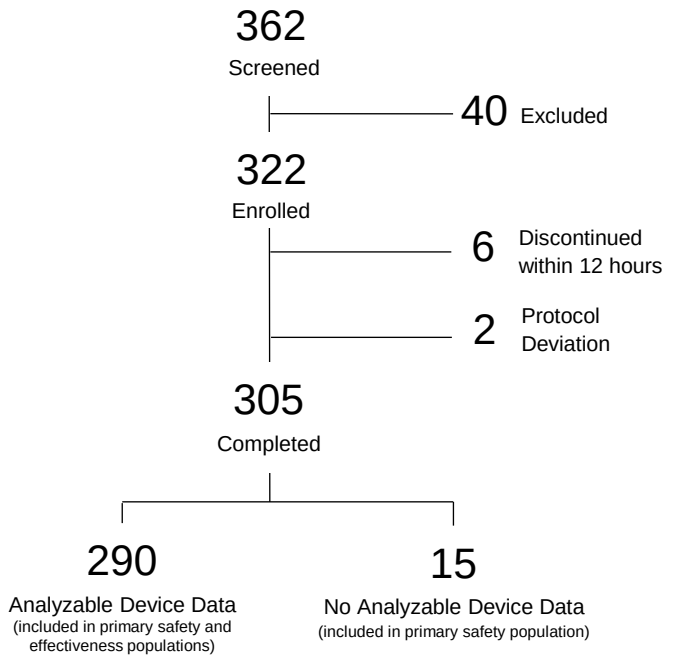
- LVEF ≤40% with diagnosis of either acute MI, ICM, NICM, or myocarditis OR
- Contraindication to receiving ICD, had an ICD removed, or refused ICD OR
- ICD implantation delayed due to COVID-19 infection or exposure-related risks

Exclusion Criteria

- Life expectancy <1 year
- Existing ICD or unipolar pacemaker
- Clinically significant valve disease likely to require surgery within 1 year
- Planned CABG within 6 months
- ESRD
- Discharge to SNF >7 days
- Deficit that would impair ability to interact with Jewel
- Dextrocardia
- Body circumference <27in or >56in
- Allergic to medical adhesives or hydrocolloids
- Active skin breakdown
- Pregnancy

ENROLLMENT DEMOGRAPHICS

Participant demographics typical of the population indicated for WCDs



Demographics	(N=305)
Age, Mean ± SD	57.9 ± 13.3
Age, Median [Min, Max]	60.0 [21.8, 88.7]
Female, n (%)	92 (30.2%)
Not Hispanic or Latino, n (%)	293 (96.1%)
Race: White	220 (72.1%)
Race: Black or African American	74 (24.3%)
Race: Asian	4 (1.3%)
Mean Body Mass Index (kg/m2)	30.0 ± 6.7

WCD Indication	(N=305)
Non-Ischemic Cardiomyopathy	**107 (35.1%)**
Temporary Contraindication to ICD	**80 (26.2%)**
Ischemic Cardiomyopathy	52 (17.0%)
Acute Myocardial Infarction	42 (13.8%)
- NSTEMI	15 (35.7%)
- STEMI	27 (64.3%)
Patient refuses ICD	12 (3.9%)
ICD Removal	5 (1.6%)
Long-Term Contraindication to ICD	4 (1.3%)
Myocarditis	2 (0.7%)
ICD Implant Delayed	1 (0.3%)

9 patients remained active at time of data analysis

PRIMARY ENDPOINTS

Efficacy: Inappropriate Shock Rate

Prespecified Goal:

<2 inappropriate shocks per 100 patient-months

Result:

0.36 per 100 patient-months (upper 98% CI 1.53)

Details on shocks adjudicated as inappropriate

Rhythm Adjudication	Investigator Assessment	CEC Adjudication	Outcome
SVT with underlying LBBB	Appropriate	Inappropriate	ICD implant
Sinus tachycardia	Inappropriate	Inappropriate	EF improvement and study exit

Safety: Rate of Significant Cutaneous Adverse Effects

Prespecified Goal:

<15% patients with clinically significant cutaneous adverse device effects (ADEs)

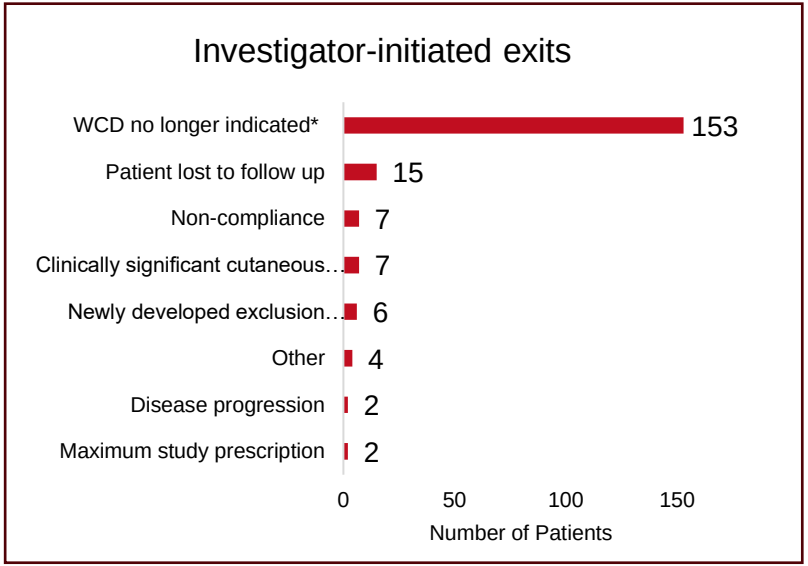
Result:

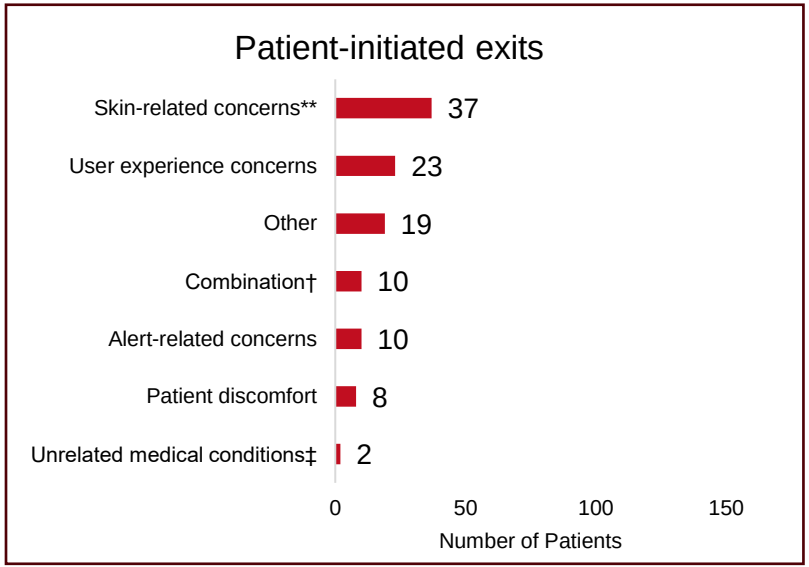
Clinically significant cutaneous ADE rate: 2.30%
(upper one-sided 98% confidence interval [CI]: 4.80)

No device-related deaths or serious adverse events

STUDY COMPLETION

Most patients exited after WCD was no longer indicated

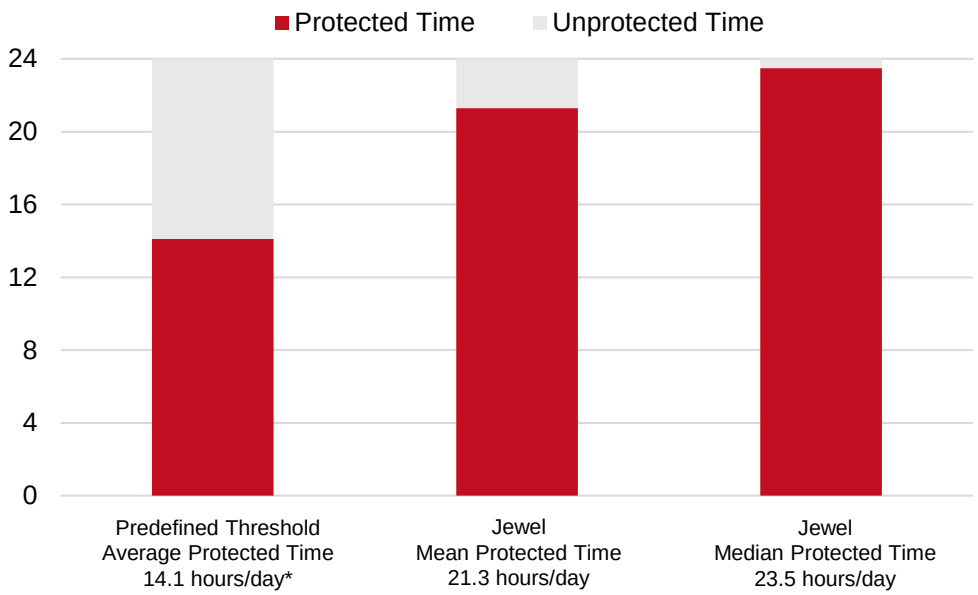




* Reasons WCD no longer indicated include EF improvement (6 patients), ICD implantation (70 patients), other PI determination (77 patients)
** Of the skin-related ADEs, 2.3% resulted in investigator-initiated exits and 7.5% resulted in patient-initiated exits

SECONDARY ENDPOINT: PATIENT COMPLIANCE

Jewel patients had a median compliance of 97.8% (IQR: 86.1%, 99.7%)



91.0% of patients wore the Jewel for longer than the prespecified threshold of 14.1* hours per day.

Days Worn

Mean ± SD: 59.3 ± 45.0

Median (Q1, Q3): 49 (23, 90)

Low False Alarm Rate

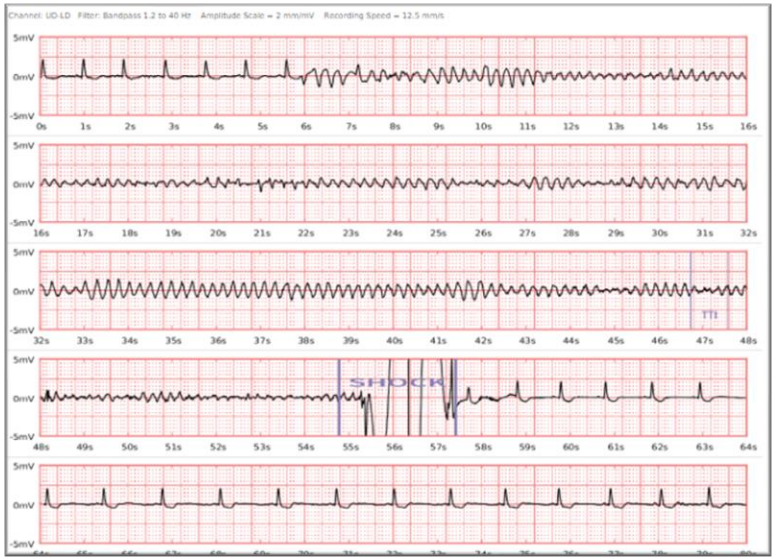
61.7% had no alarms

88.9% had < 1 alarm per day

*Average protected time as reported in the VEST trial: J.E. Olgin, et al. NEJM (2018) 379:1205-1215

SECONDARY ENDPOINT: SUCCESSFUL SHOCKS

8 adjudicated successful conversions (prespecified goal ≥1 successful VT/VF conversion)



Rhythm Adjudication	Investigator Assessment	CEC Adjudication	Outcome
Polymorphic VT/VF	Appropriate	Appropriate	Received ICD
Polymorphic VT/VF	Appropriate	Appropriate	Received CRT-D
VT	Appropriate	Appropriate	Received ICD
Pleomorphic VT	Appropriate	Appropriate	Received ICD
Coarse VF	Appropriate	Appropriate	Received ICD
Polymorphic VT	Appropriate	Appropriate	Received ICD
Coarse VF / Polymorphic VT	Appropriate	Appropriate	Received ICD
Monomorphic VT	Appropriate	Appropriate	Received ICD
Polymorphic VT/VF	Appropriate	Appropriate	Device removed in hospital

There were no deaths in the study population

CONCLUSIONS AND DISCUSSION

Jewel is a promising alternative to traditional WCDs

- Safe and effective
  - High number of patient saves
  - No deaths or serious AEs
- High patient compliance
  - Low false alarm rate
  - Well tolerated for extended prescription durations

KEY TAKE-AWAYS

The patient-centric design of the Jewel P-WCD drove improved wear-time compliance versus traditional WCDs.

As a result of improved compliance and increased protection time, there were a high number of patient saves and no deaths in the Jewel IDE Study.

The Ohio State University
Central Baptist
Brigham and Women's Hosp
St. Bernard Heart and Vasc
Baptist Health Cardiology
Northwell Health
NorthShore Medical Group
St. Thomas Research Inst
North Mississippi MC
University of Iowa
Medstar Georgetown
Parkview Health
University of Louisville
TriHealth Heart Institute
University of Mississippi
Hartford Hospital
Inova Fairfax Hospital
Johns Hopkins
Massachusetts General Hosp
Novant Health
Piedmont Hospital
Methodist Le Bonheur
Virginia Cardiovascular Spec
Northwestern University
ACRC Trials
New York Presbyterian
Montefiore Medical Center
Emory University
Crystal Run Healthcare
Methodist Hospital
Columbus Cardiology
Every patient

THANK YOU

American Heart Association.

Scientific Sessions

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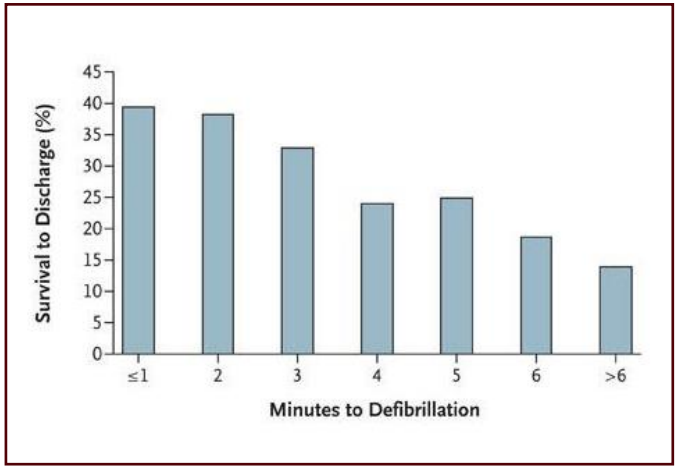
SCA IS A SIGNIFICANT ISSUE

Impact of delayed defibrillation[2]



EMS averages 7-14 minutes to arrive on scene after a 9-1-1 call has been made[3]

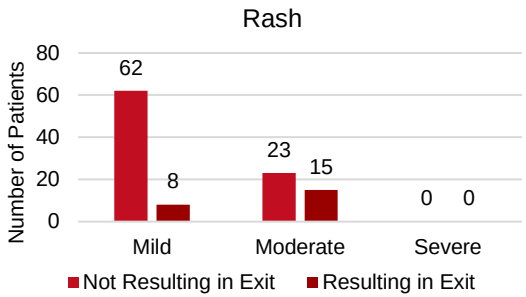
Indications and Recommendations for WCD Therapy

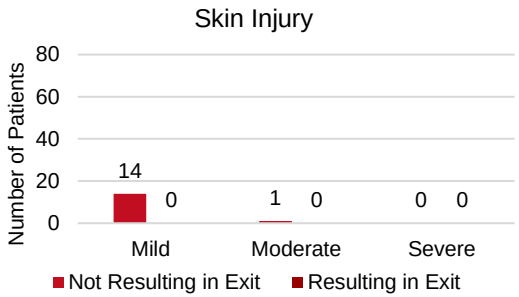
Indication	Class	Level of Evidence
Use of WCDs is reasonable when there is **a clear indication for an implanted/permanent device accompanied by a transient contraindication or interruption in ICD care** such as an infection	IIa	C
Use of WCDs is reasonable as a **bridge to more definitive therapy** such as cardiac transplantation.	IIa	C
Use of WCDs may be reasonable when there is concern about a **heightened risk of SCD that may resolve over time or with treatment** of left ventricular dysfunction; for example, in ischemic heart disease with recent revascularization, newly diagnosed nonischemic dilated cardiomyopathy in patients starting guideline-directed medical therapy, or secondary cardiomyopathy (tachycardia mediated, thyroid mediated, etc) in which the underlying cause is potentially treatable.	IIb	C
WCDs may be appropriate as **bridging therapy in situations associated with increased risk of death in which ICDs have been shown to reduce SCD** but not improve overall survival such as within 40 d of MI.	IIb	C

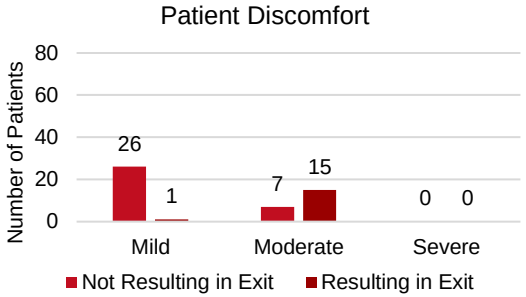
AHA guidelines recommend Wearable Cardioverter Defibrillator (WCD) high risk of SCA when clinical improvement is anticipated or if ICD is contraindicated

[1] Meiso Hayashi. Circulation Research (2015) 116(12):1887-1906, DOI: 10.1161/CIRCRESAHA.116.304521
[2] PS Chan, et al. NEJM (2008) 358:9-17, DOI: 10.1056/NEJMoa0706467
[3] Howard Mell, et al. JAMA Surgery (2017) 152(10):983-984, DOI: 10.1001/jamasurg.2017.2230

ADVERSE DEVICE EFFECTS







The majority of ADEs did not result in patient exit

- 175 (57.4%) of participants experienced no ADEs
- Of those reporting an ADE, only 24 (7.87%) exited due to the ADE