VEST and Interpretation of a Randomized Controlled Trial

Fariha Hasan MBBS , Haris Riaz MD

PII: S0002-9343(18)30547-3
DOI: 10.1016/j.amjmed.2018.05.040
Reference: AJM 14714

To appear in: *The American Journal of Medicine*

Received date: 27 March 2018
Revised date: 29 May 2018
Accepted date: 29 May 2018

Please cite this article as: Fariha Hasan MBBS , Haris Riaz MD , VEST and Interpretation of a Randomized Controlled Trial, *The American Journal of Medicine* (2018), doi: 10.1016/j.amjmed.2018.05.040

VEST and Interpretation of a Randomized Controlled Trial

Fariha Hasan MBBS[1], Haris Riaz MD[2]

[1] Dow Medical College, Pakistan

[2] Heart and Vascular Institute, Cleveland Clinic, Cleveland, Ohio

Corresponding author:

Haris Riaz MD

Fellow, Department of Cardiovascular Medicine,
Cleveland Clinic, Ohio
Phone: 216-644-7103
Email: riazh@ccf.org

Article type: Editorial

Conflict of interest: None (for both authors)

Funding sources : None

Both the authors were involved in the manuscript writing and had access to the data.

Randomized controlled trials (RCTs) form the highest level of evidence and well done RCT's with rigorous methodology help inform clinical decision making. Therefore, the conduct and application of RCT's assumes paramount importance in the contemporary era of evidence based medicine. Patients entrust the physicians with their life to partake in the RCT's and thereby transparent interpretation of RCT's is a moral obligation on the physicians.

The recent session of the American College of Cardiology (held at Orlando, Florida in March 2018) was marked by a buzz around the presentation of the much awaited Vest Prevention of Early Sudden Death Trial (VEST) study (1). This is the largest randomized investigation on a wearable defibrillator and hence the enthusiasm of the scientific community was understandable. The notion behind the study was that the current professional guidelines recommend a duration of at least 90 days for medical optimization prior to implantation of an implantable cardioverter defibrillator (ICD) in patients with myocardial infarction and ejection fraction below 35%. This theoretically creates a period where patients are left “unprotected” from sudden cardiac death. Therefore, a wearable defibrillator appears to be an attractive strategy to mitigate the risk of sudden cardiac death in this duration.

The study did not reveal any significant differences in the primary end point, namely reduction in the sudden cardiac death (1.6 versus 2.4%, p=0.18) and should hence be interpreted as negative. There was a statistically significant signal in the secondary end point of all-cause mortality (3.1 versus 4.9%, p=0.04). This signal could be driven solely by chance or by better care and follow up of patients wearing the vest or by some yet unidentified factor and should hence be

considered as hypothesis generating only. Why would a wearable defibrillator whose function is to reduce sudden cardiac death reduce all-cause mortality and not sudden cardiac death? Statistical differences in secondary end point of a clinical trial is not uncommon. For instance, in the VEST study, four patients had stroke in the control group and none in the wearable device group had stroke, a finding that also reached statistical significance (p=0.01). Despite these results, both the company and investigators claimed in both the conference and subsequent media press releases that the device reduces total mortality and hence should be considered in the management of patients with myocardial infarction and reduced ejection fraction. The commentary on the American College of Cardiology's website was entitled "VEST: Wearable Cardioverter-Defibrillator Reduces Total Mortality, Not Sudden Deaths Post MI". If the effect size of this intervention are as tremendous as the investigators and the company are proposing, full results of the study should be made available to the public and physicians as swiftly as possible. Until that is done, we have no evidence to support the idea that the use of wearable cardioverter defibrillators have any clinical relevance other than increasing the risk of rash and itching.

Reference:

1. Presented at the American College of Cardiology Annual Scientific Session (ACC 2018), Orlando, FL, March 10, 2018