CLINICAL VIGNETTE

External Defibrillator as a Bridge to Implantable Device

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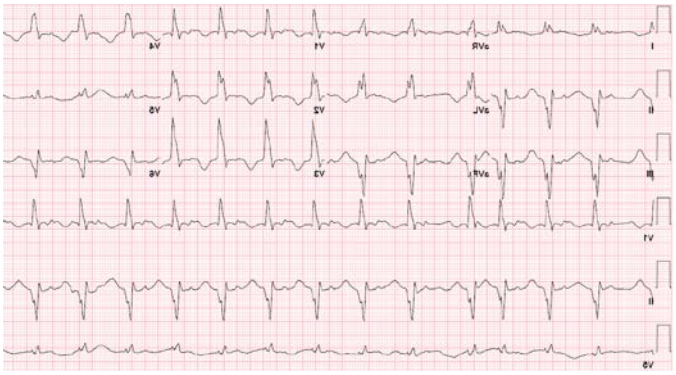
Case Report

A 76-year-old man presented with a 3-month history of progressive fatigue, dyspnea, orthopnea, paroxysmal nocturnal dyspnea, and peripheral edema. He denied angina and syncope. Physical examination was suggestive of acutely decompensated heart failure. His electrocardiogram (EKG) below showed sinus rhythm, premature atrial contractions, right bundle branch block, left axis deviation, and Q waves concerning for anteroseptal myocardial infarction (MI).



The patient was hospitalized for further diagnostic evaluation and management. His blood tests were notable for elevated troponin. Echocardiogram showed biventricular dysfunction with left ventricular ejection fraction of 20-25% and multiple regional wall motion abnormalities. He was initiated on cardiac medications, including aspirin, beta blocker, ACE inhibitor, statin, and diuretics. On telemetry, he had frequent ventricular ectopic beats and runs of non-sustained ventricular tachycardia. Coronary angiography showed single vessel CAD with chronic occlusion of LAD near its ostium and minimal collaterals. Cardiac MRI revealed partial-thickness viability involving his myocardium in the septum, anterior wall, and apex.

After careful review of his test results as well as consultation with CT surgery and interventional cardiology, it was felt that coronary revascularization might improve his ventricular function. However, there was a clinical concern that LV systolic dysfunction may persist after revascularization. The patient underwent 2-vessel CABG with LIMA to LAD and saphenous vein graft to diagonal artery. He was discharged in a stable condition with a wearable external defibrillator to protect against sudden cardiac death. At 3 months after revascularization and optimal medical therapy, repeat echocardiogram showed persistent LV systolic dysfunction with EF 30-35%. He had stable NYHA class II heart failure symptoms. He was then referred for implantable cardioverter-defibrillator (ICD).

Discussion

Ventricular arrhythmias are a common cause of death in the early post-MI period. In the VALIANT trial, 14,609 patients with left ventricular (LV) dysfunction or heart failure after acute MI were observed to have a 1.4% rate of sudden cardiac death (SCD) during the first month following MI.[1] This rate increased to 2.3% for patients with LV ejection fraction ≤30%. Other studies have shown similar rates; a community-based cohort of 2,997 patients from Olmsted County, MN showed a 1.2% 30-day risk of SCD.[2] Pooled analysis of 3,104 patients with either LV ejection fraction <40% or frequent ventricular ectopy on monitor showed SCD rate of 8 per 100 patient-years following MI.[3] There are multiple factors associated with increased risk of SCD, including frequent ventricular ectopy or non-sustained ventricular tachycardia, reduced LV function, reduced heart rate variability, T-wave alternans, late potentials on signal-averaged ECG, and inducible sustained ventricular tachycardia during electrophysiology study.[4] However, it remains challenging to predict which patients are at greatest risk for sudden death following an ischemic event.

One treatment option to prevent arrhythmogenic death after MI is the use of an ICD. Implantation of an ICD for primary prevention of SCD is recommended in guidelines for most patients with LV ejection fraction <35% despite optimal medical therapy. However, despite the overall mortality benefit observed with ICDs in patients with increased risk of SCD, multiple trials have shown no mortality benefit for early ICD placement following MI. In the DINAMIT trial, 647 patients with reduced ejection fraction and reduced heart rate variability between 6 and 40 days following acute MI were randomized to receive either optimal medical therapy or optimal medical therapy along with ICD placement.[5] In the IRIS trial, 898 patients with acute MI in the past 5-31 days with reduced LV function and either an elevated resting heart rate or non-sustained VT were randomized to optimal medical therapy with or without ICD placement.[6] While both trials showed a reduction in SCD with ICD placement, this was offset by an increased rate of non-cardiac death, possibly secondary to device-related complications, and ultimately demonstrated no overall mortality benefit for early ICD placement. In addition, many post-MI patients show significant improvement in ejection fraction in the first

few months following revascularization, and consequently might no longer meet criteria for primary prevention ICD. Therefore, current guidelines for primary prevention ICD placement following acute MI recommend waiting 40 days if no revascularization was performed, and 3 months if patients undergo acute revascularization.

To address the increased risk of SCD immediately following acute MI or in other high-risk patients for whom an ICD is temporarily contraindicated, the medical device company Zoll developed the LifeVest, a wearable cardioverter-defibrillator (WCD) consisting of 3 defibrillation pads, 4 sensing electrodes, and a programmable defibrillation unit incorporated into a patient-worn vest. Should the device detect a ventricular arrhythmia, it alerts the wearer by vibrational alerts followed by audible alerts and voice prompts prior to delivering up to five 150J biphasic shocks. This process can be aborted at any time by the user through a manual response button designed to minimize the risk of inappropriate shocks. While WCDs have not been studied as extensively as ICDs, several trials have demonstrated efficacy of WCDs in terminating VT/VF.[7-9] These devices may offer potential benefit for high-risk patients during the "window period" following MI, for patients with nonischemic cardiomyopathy who have not yet been treated with optimal medical therapy, or for other high-risk patients with temporary contraindications to ICD placement, such as ongoing infection.

A large retrospective observational study by Epstein *et al.*, reviewed data from 8,453 patients with recent MI and LV ejection fraction <35%, who were prescribed a LifeVest between 2005 and 2011, and wore the device for at least 15 minutes.[10] Of these patients, 133 (1.6%) received at least 1 appropriate shock for a total of 309 shocks over 146 discrete events, successfully terminating either VT or VF on 252 occasions. Of the remaining shocks, 41 were not successful, 9 resulted asystole, 1 each resulted in SVT and VT, and the results of 5 shocks were undetermined. Of the 133 patients who received at least 1 appropriate shock, 121 (91%) survived the initial event. On 3 occasions, the LifeVest failed to detect a ventricular arrhythmia due to either slow rate or signal artifact; each of these episodes resulted in patient death. Of the patients who received an appropriate shock, 106 (79.7%) had an LVEF <30%. Seventy-five percent of shocks were delivered in the first 30 days following MI, and 96% were delivered in the first 90 days following MI. For patients who received a successful appropriate shock, the 1-year mortality was 29%, similar to that found in the DINAMIT trial (30%). In addition to the 309 appropriate shocks delivered, 114 inappropriate shocks were delivered to 99 patients over 102 discrete events, for an overall rate of 0.006 inappropriate shocks per patient per month. The majority of these were due to noise artifact, electrical oversensing, detection of atrial arrhythmias, and non-sustained VT. Aside from immediate pain and discomfort, there were no other reported adverse effects from these inappropriate treatments. The authors therefore conclude that a WCD can protect patients from SCD during the acute period following MI, allowing time to differentiate those patients who will ultimately have ventricular recovery from those who will remain at higher risk and benefit from ICD placement.

The Vest Prevention of Early Sudden Death Trial (VEST) was published in 2018.[11] It is a randomized prospective trial which enrolled patients with an acute MI and LV ejection fraction 35% or less, comparing WCD plus guideline-directed medical therapy versus a control group who received guideline-directed medical therapy alone. In this randomized trial, WCD showed a trend, although statistically not significant, in reducing the primary outcome of arrhythmic death during the first 90 days after MI. Interestingly, there was a statistically significant reduction in the secondary endpoint of all-cause mortality (3.1 vs 4.9%; P = .04), favoring the WCD group. The exact mechanism for this benefit has not been established, and question remains whether arrhythmic deaths were correctly adjudicated in the study. In addition, suboptimal adherence to wearing the device may have attenuated the benefit of WCD as the wear-time with the device was lower than anticipated. Of the 25 patients in the device group with adjudicated sudden death, 16 were not wearing the device at the time of death.

In conclusion, ventricular tachyarrhythmias portend a poor outcome in patients with ischemic cardiomyopathy and LV ejection fraction less than 35%. A shared decision-making approach is needed to consider WCD as a potential temporary life-saving therapy, while acknowledging the limitations of current medical evidence, harm due to inappropriate shocks, and frequent device alarms. In a motivated patient who is at high risk, such as our patient with recent MI, impaired ventricular function, and frequent ventricular ectopy, WCD can be considered as a bridge to either recovery or permanent device implantation.

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