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Mitigating Post-Extraction Risk:

Is it Worth the inVESTment?*

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Implantable cardioverter-defibrillators (ICDs) are implanted in patients estimated to be at high enough risk for sudden cardiac death (SCD) to warrant lifetime device therapy, along with its potential risk for complications. When infection complications require ICD system extraction, reimplantation is often deferred to allow completion of antibiotics and clearance of the infection. This population may be particularly vulnerable to risk for SCD, and a wearable cardioverter-defibrillator (WCD) may offer temporary protection in the event of ventricular tachycardia or fibrillation (VT/VF).

The study by Ellenbogen et al. (1) in this issue of *JACC: Clinical Electrophysiology* reports outcomes of 8,058 patients who wore a WCD after ICD device extraction for infection. Of these 4% experienced VT/VF events. Although first-shock success rate was not reported, 24-h survival was 93% in patients with VT/VF and 94% in patients who were shocked for VT/VF. Fatal asystole occurred in 0.7%. Overall, 12.2% of patients died (mean follow-up, 88 days; median time of WCD use, 50 days).

The authors note that of patients who wear the WCD, this population had the highest incidence of WCD events in a prior study (2). With 4% experiencing VT/VF events, translating to a 10% annualized risk of events, this study confirmed the high risk of this population. Prior studies reported WCD-appropriate shock rates of 0% to 3% in patients with newly diagnosed nonischemic or ischemic cardiomyopathy or early after myocardial infarction or coronary revascularization over similar durations of use (2–4). Thus, the period after extraction for infection is a particularly vulnerable period with high early rates that decline with time, reinforcing observations that event rates are highest post-cardiac events,

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including after myocardial infarction or coronary revascularization. Extraction or the infection with attendant high inflammatory and stress burdens may be a similar stimulant of cardiac events.

Patients with device infections are at known high risk for mortality, and this study reported overall mortality of 12.2% with mean follow-up <3 months, whereas other large reviews of survival with WCD use report 93% to 99% survival over similar time periods (2,5,6). Although the current study did not determine cause of death, presumably a significant proportion succumbed to noncardiac causes, including factors related to the infection. Similar to other risk periods, delaying ICD implantation with a WCD bridge in patients without pacing dependence may be viewed as allowing survival of the fittest to manifest before ICD reimplantation.

The 24-h mortality of 7% in patients with VT/VF brings to question whether WCD shocks or delay of shocks contributed to early demise. WCD therapies may be delayed to 1 min after detection, and antitachycardic pacing is not available. However, the death rate within 24 h of an appropriate shock was comparable with the 11% rate reported in SCD-HeFT (7), suggesting that outcomes after the delay in therapy delivered by a WCD may not be different than that after potentially faster therapy delivered by an ICD. Indeed, long-term survival after WCD use has been reported to be comparable with that in patients receiving a first ICD (2), and shock avoidance may be beneficial, as shown in MADIT-RIT (8).

So who should receive a WCD for bridging after ICD explantation for infection? The American Heart Association Scientific Advisory on WCD therapy for prevention of SCD lists a class IIa recommendation (level of evidence C) that WCD use is reasonable when there is a clear indication for an implanted permanent device but with a transient contraindication or interruption in ICD care (3). The high risk seen in this cohort supports this recommendation, but a WCD may not be always mandated. In the absence of randomized clinical trials, the decision to bridge with a WCD is dependent on clinical correlations. In surveys taken from the manufacturer's databases, it should be recognized that the patients covered with a WCD are a selected cohort. Patients with primary prevention ICDs and no recent shocks were likely deemed to be of lower risk, less likely to be bridged with a WCD, and thus unlikely to be represented by the current study. Without pacing capabilities, a WCD cannot be used to bridge pacemaker-dependent patients, who need to be reim-planting before hospital discharge after clearance of cultures. Patients who demonstrate cardiac resynchronization therapy dependence, or those at very high risk for VT/VF requiring shocks, should probably also be considered for early ICD reimplantation, if possible. However, it is the latter group that may be difficult to predict in the absence of data. Nevertheless, high-risk secondary prevention patients with recent shocks, requirement for antitachycardia pacing, or who have been observed to require post-shock pacing may best be served by reimplanting ICDs early.

Finally, WCDs are limited by lack of pacing capabilities and lack of randomized data. The rate of fatal asystole in the current report was 0.7% and in an earlier survey was 0.6% of which 74% died (2). The manufacturer of the WCD has seen a remarkable growth in use of the WCD, and it is time to consider adding at least post-shock antibradycardia external

pacing, as the subcutaneous ICD has developed, and perhaps to include shorter detection times in the algorithms. Also, the entire field would gain clarity as to the benefits of WCD therapy, beyond that gained from mining of the manufacturer database, if randomized clinical trials could be supported, especially to clarify use in high-risk gap periods, when ICDs are not yet indicated. One such trial after acute myocardial infarction is ongoing (VEST [Vest Prevention of Early Sudden Death Trial; NCT01446965]). The high-risk post-extraction patient now well demonstrated by Ellenbogen et al. (1) to be at very high risk would not be well suited to randomization. However, other potential cohorts believed to be at heightened risk for SCD and who received a class IIb recommendation for WCD therapy (3) are appropriate populations that are in need of study. These include patients in whom risk may reduce over time or in whom ICD implantation is not yet indicated, such as those with recent coronary revascularization, newly diagnosed heart failure, or other secondary cardiomyopathies (3). Moreover, the demonstration of long-term tolerance to this noninvasive therapy in some patients in the current report supports randomized longer term studies of certain high-risk cohorts at high risk for transvenous ICDs, such as patients on hemodialysis.

In summary for patients who undergo extraction of an ICD for infection, if ICD reimplantation is deferred, event rates suggest that a bridging WCD vest is worth the investment. However, there are areas that remain difficult for clinicians to recommend use or nonuse of this therapy. What is most needed are investments in randomized trials to clarify benefits of WCD use in other groups for which rationale for use remains deficient. It is also time to bring the option of external pacing capabilities to the WCD, which might reduce patient deaths from fatal asystole.

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