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An entirely subcutaneous implantable cardioverter-defibrillator

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The authors report the results of two short-term trials of a temporarily inserted subcutaneous ICD electrode system, followed by two trials of long-term subcutaneous ICD implantation of a fully functional system.

The use of implantable cardioverter–defibrillators (ICDs) is a class I therapy for the prevention of death from ventricular arrhythmia; however, there are still many complication, mainly associated with transvenous lead insertion, including pneumothorax, hemothorax, and cardiac tamponade. Methods and results: All study participants satisfied standard criteria for ICD implantation and provided written informed consent.

The last trial involved 55 patients who underwent implantation in New Zealand and Europe between December 2008 and February 2009. The authors identified candidates for subcutaneous ICD implantation among the patients who were referred for ICD implantation.

The inclusion criterion was a class I, IIa, or IIb indication for ICD therapy. Exclusion criteria were an estimated glomerular filtration rate of less than 30 ml per minute, a requirement for antibradycardia pacing, a history of ventricular tachycardia at rates slower than 170 beats per minute, and documented ventricular tachycardia known to be reliably terminated with antitachycardia pacing. The primary end point was successful immediate conversion of two consecutive episodes of induced ventricular fibrillation, each with a single 65-J shock. The subcutaneous ICD system that tested consisted of a 3-mm tripolar parasternal electrode (polycarbonate urethane 55D), which was connected to an electrically active pulse generator. The electrode was positioned parallel to and 1 to 2 cm to the left of the sternal midline, and the pulse generator was positioned over the sixth rib between the midaxillary line and the anterior axillary line.

A conditional discrimination zone incorporating a feature-extraction technique can be programmed between rates of 170 and 240 beats per minute to distinguish supraventricular tachycardia from ventricular tachycardia and avoid inappropriate treatment of the former. After 10±1 months and 46 patient-years of follow-up, 54 of 55 patients (98%) were alive. One death from renal failure occurred 6 months after device implantation in an 84-year-old patient.

A pocket infection developed in two patients; pocket revision was performed in one patient, and the other elected to discontinue defibrillator therapy. There were no cases of

pocket erosion. No lead fractures developed in any patient, and no generator migration occurred. Minor lead migration was noted during follow-up in two patients. A total of 12 episodes of spontaneous ventricular tachycardia were detected and successfully treated in three patients, including 1 episode after the above-mentioned software revisions. ❑

CONCLUSION

The goal of developing a subcutaneous ICD was to overcome some of the problems that are associated with transvenous leads in conventional ICDs.

Such a device could potentially reduce or eliminate some problems, such as failure to achieve vascular access, intravascular injury, and lead failure and replacement.

Additional potential benefits include the preservation of venous access for other uses and the avoidance of radiation exposure during fluoroscopy. These benefits would be especially important for young patients, in whom leads may fail during the decades that therapy is needed. In addition, there are inherent limitations of this device design. Although transient post-shock pacing is available, the subcutaneous ICD cannot provide long-term pacing. It is therefore not an alternative to transvenous ICDs when antibradycardia pacing is required.

Also, the subcutaneous ICD is not designed to treat patients with ventricular tachycardia at rates slower than 170 beats per minute. The lack of capability to provide antitachycardia pacing may be a limitation in patients with frequent, recurrent, monomorphic ventricular tachycardia. ❑

Comment on a paper:
GH Bardy, WM Smith, MA Hood et al – An Entirely Subcutaneous Implantable Cardioverter-Defibrillator...,. *N Engl J Med* 2010; 363:36-44