Defibrillation threshold testing and neurologic outcome

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ABSTRACT

Implantable cardioverter defibrillator (ICD) implantation is a common approach in patients at high risk of sudden cardiac death. Verification of defibrillation efficacy by defibrillation threshold (DFT) testing during ICD implantation is the current standard. Traditionally, a safety margin of at least 10 J between the maximum output of the pulse generator and the energy needed for defibrillation has been used because early studies indicate that lower safety margins were associated with high rates of failed defibrillation and sudden cardiac death. Improvements in ICD and lead technology result in marked reductions in defibrillation thresholds and more stable thresholds long term. Despite these improvements, some patients still require system modification during implantation to obtain an adequate safety margin. During DFT testing multiple induction of ventricular fibrillation cause brief transient episodes of cerebral ischemia. These repeated short episodes of circulatory arrest with global cerebral ischemia have been associated with changes in cerebral oxygen uptake and cerebral electrical activity. In addition, minor neurologic injury can occur after ICD implantation and defibrillation testing. This finding needs to be examined in further research. *(Anadolu Kardiyol Derg 2007: 7 Suppl 1; 47-9)*

Key words: implantable cardioverter defibrillator, defibrillation threshold testing, cerebral ischemia, neurologic outcome

The implantable cardioverter defibrillator (ICD) has become a standard therapy for a variety of patient groups (1). The assessment of defibrillation (DFT) efficacy at the time of implantation has long been the standard and required procedure (2, 3). Documentation of DFT efficacy provides the system's ability to sense, detect, and defibrillate ventricular fibrillation (VF). Different protocols are available for DFT testing (2, 4-6). Traditionally, a safety margin of at least 10 J between the maximum output of the pulse generator and the energy needed for defibrillation has been used because early studies indicate that lower safety margins were associated with high rates of failed defibrillation and sudden cardiac death (7, 8). Subsequently, some investigators showed that monophasic defibrillation thresholds can increase over time with transvenous lead systems (9, 10). In selected patient, this increase required reoperation. Improvements in ICD technology permitted the routine active pectoral implantation of devices. Such active pectoral pulse generators, in combination with biphasic waveforms, result in marked reductions in DFT's and more stable thresholds long term (9, 11). The Low Energy Safety Study (LESS) examined whether the 10-J safety margin still was necessary using pectoral defibrillators with active can, biphasic shock waveforms (12). The main results of the study showed that a 4 to 6 J of safety margin above the DFT ++ is adequate for safe implantation of modern ICD systems.

A follow-up study of the LESS trial found that first shock conversion success for spontaneously occurring tachyarrhythmias at rates>200 beats/min was 92% in the full cohort versus 89% in the subgroup of patients whose VF induction test was successful with a first 14 J shock. The differences was not statistically significant (13). In another reanalysis of the LESS data, Higgins et al. (14) investigated whether a single successful 14 J shock was as good as the currently accepted standard of two successful shocks at ≤17 J. The gold standard for comparison was three successful shocks at ≤21 J. The study analyzed the results of 611 ICD recipients completed a rigorous VF induction test scheme that begun with 14J and continued until the energy that succeeded three times without a failure was determined (DFT ++). The positive predictive accuracy for the 91% of patients in whom the first 14J shock succeeded was virtually identical to the positive predictive accuracy for the commonly used criteria of two successes at ≤17J (99.1% vs 99%) and slightly higher than the positive predictive accuracy for two successes at ≤21J. One may reasonably conclude that, in this study, a single 14 J shock certainly was not inferior to two shocks at 17J or 21J. Although, this criterion appears to be a reasonable strategy to allow implantation with a single VF induction in the vast majority of ICD recipients, abandoning traditional ICD testing in favor of a single 14 J shock is not accepted universally. Limited DFT testing for 10 J safety margin or abbreviated step-down protocols may be recommended in most patients (15). Today, most studies of new ICD systems required documentation of a 10 J safety margin (3, 16).

Recently some experts have begun to question the necessity of ICD testing (17). They noted that the probability of a high DFT threshold and a failed implant is a quite small with modern biphasic ICDs and the majority of ventricular arrhythmias treated by ICD are ventricular tachycardias (VT). In addition, they proposed that abandoning ICD testing might facilitate greater access to ICD therapy by permitting device implantation by those with reduced training requirements. Even with modern biphasic ICDs, inade-

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quate safety margin (>10 J) has been reported in up to 6.2% of patients during initial testing (3). With some form of system modification, an adequate safety margin (≥10J) can be established in the majority of these cases. In one retrospective analysis (16), Pires and Johnson compared the outcome of ICD recipients who underwent DFT testing, defibrillation safety margin testing, or no testing. Included in this study were 835 consecutive patients who received transvenous devices. One hundred twenty nine (15.5%) had intraoperative DFT testing, 503 (60.2%) had limited defibrillation safety margin testing, and 203 (24.3 %). In this analysis, the success of the first delivered shocks against VT/VF was similar for DFT (91%), safety margin testing (91%), and no testing (92%) groups; and the second shocks terminated the remaining episodes in all three groups. Successes of sudden-death free survival rates were similar in the three groups, however, the overall long-term survival rate was significantly lower in the no-testing group.

Until long-term follow up data regarding the safety and efficacy of defibrillator implantation in large group of patients, in whom DFT testing is not performed, are available, implantation testing should be considered standard procedure at the time of implantation.

During DFT testing multiple inductions of VF and shocks cause brief, transient episodes of cerebral ischemia (18). These repeated short episodes of circulatory arrest with global cerebral ischemia have been associated with changes in cerebral oxygen uptake and cerebral electrical activity (19, 20). In addition, a disturbance in blood-brain barrier function occurs early in the course of cerebral ischemia, and neuron specific enolase (NSE) which is cytoplasmic protein of cerebral origin can leak in blood (21, 22). Neuron specific enolase is a known marker of ischemic brain damage and has a high predictive value for neurocognitive deficits and neurologic outcome after cardiac arrest, stroke and cardiac surgery (23-26). In recently published studies, significant increases in serum NSE have been detected after repeated brief cardiac arrest during ICD procedure (22, 27). Dworshcak et al. (22) have determined the NSE serum level before, immediately postoperatively and 2 hours postoperatively in 45 patients undergoing ICD implantation (22). Serum NSE level significantly increased from baseline to 2 hours after surgery in all ICD patients. In the subgroup of ICD patients with an extended observation period, NSE reached its maximum level between 6 hours after surgery and the end of the 24-hour observation period, after which evaluation was terminated . In contrast, NSE levels were not increased in 11 pacemaker (PM) patients who served as controls. Similar results have been reported by Weigl et al (27). They have studied 42 patients undergoing ICD (n=21) or PM insertion (n=21) and serum NSE levels have been determined at the same time period mentioned in the previous study. Serum NSE levels increased over time in the ICD group, whereas it remained at baseline level in PM patients. It was shown that the increase of NSE values after ICD implantation were significantly associated with the number of shocks and the cumulative time in circulatory arrest (22). Also, the combined results of these studies support the hypothesis that the increase of this biochemical marker of cerebral injury seems to be associated with deteriorating neurocognitive function. However, previous studies, in which neurologic injury and cognitive function after ICD implantation were assessed, have reported heterogeneous results (28, 29).

Adams et al. (28) performed preoperative and postoperative neurologic and cognitive assessments in eight patients having 5.5±5.7 episodes of VF (28). These patients were managed with general anesthesia. While transient electroencephalographic abnormalities were revealed, no significant deterioration in postoperative neuropsychometric function was detected. None of the patients exhibited a new neurologic deficit. In contrast to these results, Murkin et al. (29) reported cognitive dysfunction and minor neurologic deficits after ICD implantation under general anesthesia. In that study, mean 12±6 episodes of VF were induced intraoperatively. Methodological differences may account for the different results observed in these patients.

In conclusion, with the current evidence, DFT testing still remains in part of routine ICD implantation. Minor neurologic injury can occur after ICD implantation and defibrillation testing. This finding needs to be examined in further research.

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