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Incidence of ineffective safety margin testing (<10 J) and efficacy of routine subcutaneous array insertion during implantable cardioverter defibrillator implantation☆

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ABSTRACT

The purpose of this study was to assess (1) the incidence of safety margin testing <10 J (SMT) and (2) the efficacy/safety of routinely adding a subcutaneous array (SQA) (Medtronic 6996SQ) for these patients.

Patients with SMT smaller than a 10-J safety margin from maximum output were considered to have very high readings and underwent SQA insertion. These patients were compared with the rest of the patients who had acceptable SMT (≥10 J).

A total of 616 patients underwent ICD implantation during the analysis period. Of those, 16 (2.6%) had SMT <10 J. By univariate analysis, younger age, and non-ischemic cardiomyopathy, were all significant predictors of SMT <10 J ($p < 0.05$). In all 16 cases, other methods to improve SMT prior to array insertion were attempted but failed for all patients: reversing shock polarity (n = 15), removing the superior vena cava coil (n = 14), reprogramming shock waveform (n = 9), and repositioning right ventricular lead (n = 9). Addition of the SQA successfully increased SMT to within safety margin for all patients (32 ± 2 versus 21 ± 3 J; $p < 0.001$). Follow-up (mean 48.1 ± 21 months) was available for all patients with SQA, only 2 cases with inappropriate shocks due to atrial fibrillation had to be noted. None of the patients experienced complications due to SQA implantation.

SMT <10 J occur in about 2.6% of patients undergoing ICD implantation. SQA insertion corrects this problem without procedural/mid-term complications.

☆ The results of the study were presented as a poster presentation at the 120th German Society of Internal Medicine annual meeting in Wiesbaden, April 2014.

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Introduction

The implantable cardioverter defibrillator (ICD) is widely accepted for primary and secondary prevention of severe life-threatening ventricular tachyarrhythmia. The Heart Rhythm Society updated appropriate use criteria for ICD therapy [1], however the incidence, risk factors, and management of safety margin testen <10 J (SMT) during implantable cardioverter defibrillator (ICD) testing are not well known.

The first small study in 1995 [2] and more previous studies [3,4] have demonstrated that additional insertion of a subcutaneous array (SQA) reduces mean defibrillation thresholds (DFT) of 20%–60%, depending on the electrode model used.

The purpose of this study was to assess the efficacy/safety of routinely adding a subcutaneous array (Medtronic 6996SQ) for patients with SMT <10 J during implantable cardioverter defibrillator (ICD) testing.

Methods

All consecutive patients undergoing initial ICD placement or generator replacement from January 2007 to December 2009 were analyzed in this retrospective, single-centre analysis.

Postimplantation ICD test protocol

Devices of all 4 important international companies (Biotronic, Medtronic, St. Jude Medical, Boston) were implanted. They were implanted in the catheter laboratory by 5 experienced invasive cardiologists. In all patients adequate ventricular sensing (≥9 mV) and pacing threshold (≤1 V) was confirmed. In the absence of absolute contraindications (eg thrombus formation in the left atrial appendage (LAA) or the left ventricle (LV)), an intra-operative ICD testing was routinely performed to prove a correct sensing, processing, shock delivery and termination of an induced VF. Our protocol for intra-operative ICD testing required at least one induction of VF with successful first shock terminating VF at a safety margin of at least 10 Joule (J) below the maximum output of the implanted device. If the first shock was not successful, a second shock at the maximum output of the device was delivered. In case this shock was still not successful an external defibrillation with 360 J biphasic shock was added. Patients with the need of a second shock at the maximum output or an external defibrillation to terminate induced VF were considered as ineffective SMT and were included in our study. Further management of these patients included intra-operative right ventricular lead reposition or an ICD-system modification such as addition or subtraction of the superior vena cava (SVC) shock coil and polarity reversal, respectively. In case the SMT was still ineffective, the implantation of a subcutaneous electrode array, considered to be the most effective method for reducing defibrillation threshold, was planned.

Subcutaneous electrode array Medtronic 6996SQ

The subcutaneous array electrode Medtronic 6996SQ consists of a single defibrillating coil of 25 cm length and has a diameter of 7.5 F, and an electrical cord ending with a 3.2 mm connector type DF-1. Total length of the electrode is 41 cm or 58 cm. That system is connected to the SVC socket of the implanted ICD. If a dual-coil intravascular lead is used, the subcutaneous electrode may be connected through the Y-connector to the SVC socket together with the proximal coil of the intravascular lead.

Implantation procedure of the 6996SQ electrode

The patient was lying flat, with the left upper limb abducted and an additional support under the left scapula. Local anesthesia was applied in the ICD pocket and along the designed course of the subcutaneous electrode. An incision was made in 10 cm distance of the ICD pocket. A stainless steel tunneling tool (6996ST provided by the manufacturer together with the electrode) with a dedicated sheath on was shaped appropriately and introduced via the small incision and further into the subcutaneous tissue along the chest wall, and towards the region below the inferior angle of the left scapula. Then the tunneling tool was removed and the electrode with an introducer inside was inserted into the sheath. Following that, the sheath was removed with a dedicated slittering tool, and the electrode itself was sutured in the pocket in a manner typical for intravascular leads. The electrode was tunneled from the incision into the ICD pocket and connected to the SVC socket of the ICD. Ideally the electrode along its course remained in the projection of the chest, and its end is located as close to the vertebral column as possible. In case of right sided ICD implantation the procedure itself does not differ from left sided implantations; however, the final tunneling to the ICD pocket has to be performed across the thorax and the end of the SQ array is located much more lateral because of the limited length of the array (Fig. 1).

Statistical analysis

The study group consisted of all patients with SMT <10 J, whereas the control group included all patients who did not develop this problem. Continuous variables were reported as mean value ± standard deviation or median and interquartile ranges (25th–75th percentiles) where appropriate. Categorical variables were presented as absolute (n) and relative (%) frequencies. Normal distribution of variables was assessed using the D'Agostino-Pearson omnibus normality test. Comparisons of continuous variables were made with the appropriate two-sample test; Student-t-test in cases where the variable was normally distributed. Otherwise, the Kruskal–Wallis test was used to identify risk factors for ILM. A probability value of $p \leq 0.05$ was considered statistically significant. Statistical analysis was performed using the GraphPad Prism version 6.02 for windows (GraphPad Software, La Jolla, California, USA).

Results

A total of 1221 patients underwent heart rhythm device implantation during the study period. Out of 632 analyzed ICD-recipients, 16 (2.5%) had no intra-operative defibrillation

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