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Original research article

Occurrence of implantable cardioverter-defibrillator therapy in clinical practice

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ABSTRACT

The landmark trials MADIT II, SCD-HeFT, and COMPANION in 2002–2005 years have reported their positive results to sudden cardiac death reduction. Since that time the indications for the use of implantable cardioverter-defibrillators (ICDs) have substantially broadened. The occurrence of appropriate ICD therapy differs in the individual trials. We were retrospectively analyzing the occurrence of ventricular tachycardia/ventricular fibrillation (VT/VF) from ICD remote monitoring database (Biotronik Home Monitoring TM, www.biotronik-homemonitoring.com). No significant difference was found between subgroups divided by the implantation indication, the programmed ventricular stimulation, the aggressivity of programmed ventricular stimulation protocol, left ventricular ejection fraction, ICD types, percentage of right ventricular pacing, diabetes mellitus, renal dysfunction and gender. VT/VF occurred statistically significantly more often in patients with non-sustained VT on the preimplant Holter monitoring report in patients with primary preventive indication for postinfarction coronary artery disease but not in primary preventive indication for non-ischemic dilated cardiomyopathy. We observed higher VT/VF occurrence in patients with preimplant syncope or presyncope even higher than in patients after cardiopulmonary resuscitation. There was a visible trend for higher VT/VF occurrence in patients with positive programmed ventricular stimulation especially with less aggressive protocol and in patients with left ventricular ejection fraction of 30% and less. Authors found the preimplant nonsustained ventricular tachycardia (NSVT) on Holter monitoring as the only independent predictor of VT/VF occurrence.

Introduction

The landmark trials MADIT II, SCD-HeFT, and COMPANION, conducted in the years 2002–2005, have reported positive results to sudden cardiac death reduction [1–3]. Since that time, the indications for the use of implantable cardioverter-defibrillators (ICDs) have substantially broadened.

Implantable cardioverter-defibrillators implantation rate varies very much between different countries and continents.

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There is a stabile trans-Atlantic difference of over 10 years. The average implantation rate in Western Europe is 155 per million people [4], in contrary to the US, where it ranges up to 833 per million people [5]. It is still suggested that ICDs are under-utilized on both sides of the Atlantic when compared to guidelines.

The ICD implantation rate in the Czech Republic reached around 335 per million people in 2014 [6].

The occurrence of appropriate ICD therapy differs in the individual trials. ICD remote monitoring database enables a user-friendly data system for ICD therapy analysis in the clinical practice.

Methods

Data from ICD remote monitoring database (Biotronik Home Monitoring TM, www.biotronik-homemonitoring.com) were retrospectively analyzed. Only data of ICDs monitored for 2 years after first implantation were utilized for the analysis. ICDs deactivated for any reason within the analyzed period were discarded. The occurrence of appropriate ICD therapy was described. Possible predictors of the ICD therapy occurrence were analyzed.

Subgroups

For the analysis, the patients were divided into several groups:

1. by the implantation indication: SP (secondary preventive, that means patients after documented hemodynamically significant ventricular tachycardia VT or fibrillation VF), PP (primary preventive with coronary artery disease, that means patients after myocardial infarction with low left ventricular ejection fraction LVEF ≤35%), and DC (primary preventive in patients with non-ischemic dilated cardiomyopathy with LVEF ≤35%). Primary preventive implants from other reasons were discarded.
2. by the programmed ventricular stimulation (as a part of electrophysiological study) result: PVS+ (inducible VT/VF during PVS, performed by maximum 3 extrastimuli into paced rhythm 120–160 per minute) and PVS− (non-inducible VT/VF). In PVS+ subgroup, divided by the PVS aggressivity: PVSagg (aggressive protocol, defined as the inducibility in 140 ppm and 2 extrastimuli or 160 ppm and 1–3 extrastimuli) and PVSnonagg (nonaggressive protocol, defined as the inducibility in 120 ppm or in 140 ppm and 1 extrastimuli). The extrastimuli coupling interval was not lower than 200 ms.
3. by the Holter monitoring result (in PP and DC indication subgroups only): NSVT+ (patients with non-sustained ventricular tachycardia of 4 and more premature beats, NSVT, in Holter monitoring) and NSVT− (patients without NSVT), in all primary preventive patients and separately for PP and DC indication: PP-NSVT+, PP-NSVT− (patients with resp. without NSVT in PP indication subgroup), DC-NSVT+, and DC-NSVT− (patients with resp. without NSVT in DC indication subgroup).
4. by the LVEF: EF30 (patients with LVEF ≤ 30%) and EF31 (patients with LVEF ≥31%).
5. by the ICD type: VR (single-chamber ICD), DR (dual-chamber ICD, including biventricular ICDs without functional left ventricular lead), and HF (biventricular ICD). In VR and DR subgroups, the average right ventricular pacing percentage (VP%) was compared between ICDs with resp. without ICD therapy. In the same subgroups, VT/VF therapy occurrence was compared between ICDs with VP % of 40% and higher (VP%40 subgroup) versus VP% below 40% (VP%39 subgroup).
6. By the concomitant diseases: by the diabetes mellitus presence: DM+ (patients with diabetes mellitus DM) and DM− (patients without DM); by the renal insufficiency defined by serum creatinine level above 150 μmol/l = 2 mg/dl: CRI+ (patients with high serum creatinine level) and CRI− (patients with low creatinine level).
7. by the gender: M (males) and F (females).
8. according to the preimplant symptomatology: ASYMP (without pre/syncope), SYNC (syncope or presyncope), and CPCR (patient after cardiopulmonary resuscitation).

Statistics

All data are presented as mean values ± standard deviation for continuous variables and as percentages for categorical variables. The Kaplan–Meier analysis with a log-rank test was used to compare the occurrence of ICD therapy. The association between potential risk factors and ICD therapy was analyzed via a univariate logistic regression model. For the parameters with the potential predictive power (providing at least $p < 0.10$ in univariate logistic regression), a multivariate model was used. Results with p-value <0.05 are considered statistically significant. The statistical package used was SAS Software.

Results

Since April 2008 till June 2015, 187 ICDs after first implantation were activated for remote monitoring (Biotronik Home Monitoring system). The 2-year monitoring period was available for 147 ICDs. Reasons for deactivation during first 2 years were the following: death (23), heart transplantation (10), non-compliance (5), premature reimplantation (1) and transmission problems (1). Demographic and preimplant data of analyzed ICDs are mentioned in Table 1. There was no statistical difference in the demographic data.

At least one episode of detection of VT/VF occurred in 57 (38.8%) of the ICDs during 24-month follow-up. VT/VF occurrence in the individual subgroups is displayed in Table 2.

Difference between indication subgroups

VT/VF was detected in 32.8–44.8% in individual subgroups. ICDs in secondary preventive indication had non-significantly higher occurrence of VT/VF ($p = 0.3278$), as seen in Table 2 and Fig. 1.

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