Effectiveness Evaluation of ICDs Implanted in the Right Side vs. Left Side

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Abstract

Background
The implantation of ICDs left pectorally is the conventional normal practice, but pathological reasons may obly to insert the devices on the right side. The aim of our evaluation was to define the outcome of right-sided implantation (n=52) on defibrillation effectiveness in comparison to the left-sided ICD implantation (n=210).

Methods
A cohort of patients received standard therapy for primary or secondary prevention of sudden cardiac death (SCD) in patients with the structural cardiac disease, lay open to the ICD-DR implantation. The 262 individuals who had all the inclusion criteria were comprised in the assessment.

Results
The defibrillation threshold testing (DFT), at the end of implantation showed that the mean energy to revert a programmed induced sustained ventricular tachycardia/ventricular fibrillation was 33.4±6.3 J for the patients that had the ICD implanted on the right side, and 23.9±5.3 J for the ones that presented the ICD positioned on the left side, P<0.0001. However the mean and the sum of shock events recorded by ICD during 1 year of monitoring, according to the side of ICD implantation, did not show any difference.

Conclusions
Our results show that ICD implantation on the right side caused an elevated DFT in comparison to the left side insertion. This study also reported that there is no difference regarding safety and effectiveness about the amount of appropriate and inappropriate shock therapies, the mean and the sum of shock events recorded by ICD during 1 year of monitoring, according to the side of ICD implantation.

Keywords: Ventricular arrhythmia; Automatic implantable cardioverter-defibrillator; Right-sided implantation; Intraoperative test.

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Introduction
Implantation of automatic implantable cardioverter-defibrillators (ICD) in subjects with elevated danger for life threatening ventricular arrhythmias is the normal therapeutical technique [1]. The implantation of ICDs left pectorally is the conventional normal practice, which has significantly enhanced at the time by the progress of new ICD leads, shock algorithms, high energy defibrillators, and fast energy supply succeeding the introduction of new compeers of capacitors. Yet, pathological reasons like thrombosis, infection and reckless leads on the left side may obly to insert the devices on the right side, as well upgrade systems from the pacemaker to ICD previously implanted on the right side. With growing implantations of ICDs, the number of system revisions due to lead dysfunction and/or infections will rise and the number of rights sided implantations will upsurge successively. The consistency of devices implanted on the right pectoral side remnants controversially debated. The few studies presenting right-sided implants have totally set up important higher thresholds as matched to devices inserted on...
left pectoral site, but none of the studies have reported of failing initial intraoperative tests [2-8]. The aim of our evaluation was to define the outcome of right-sided implantation on defibrillation effectiveness in comparison to the left-sided ICD implantation.

Materials And Methods

Study design

This prospective study was conducted at the Department of Cardiac Artificial Stimulation and Cardiac Surgery of the Hospital e Clínica São Gonçalo, São Gonçalo, Rio de Janeiro, Brazil in partnership with Elisabethenhien Krankenhaus, Linz, Austria. A cohort of patients received standard therapy for primary or secondary prevention of sudden cardiac death (SCD) in patients with the structural cardiac disease, lay open to the ICD-DR implantation in accordance with the “Guidelines for Implantable Electronic Cardiac Devices of the Brazilian Society of Cardiology” [9].

Patients were followed for one year after the implant procedure. Inclusion criteria were the following: (i) individuals with structural cardiac illness and ICD implant warning for primary or secondary avoidance of SCD; (ii) left ventricular ejection fraction ≤ 35%; (iii) subjects who are providing documentation not showing cardiac ischemia previously ICD implant evinced by myocardial scintigraphy at rest and during stress, by cardiac magnetic resonance imaging at rest and during stress, or coronary angiography; (iv) upgrade from pacemaker to ICD system implantation. Exclusion criteria were the following: (i) ischemic cardiac disease; (ii) LVEF > 35%; (iii) nonexistence of structural cardiac disease; (iv) valvar heart disease that might lead to arrhythmias; (v) left atrial or ventricular thrombi were to decrease the hazard of embolization regrading to the intraoperative testing procedure; (vi) patients necessitating epicardial defibrillator patches also were left out as they were not treated with endocardial defibrillator leads.

The goal line of our evaluation was to define the outcome of right-sided implantation on defibrillation effectiveness in comparison to the left-sided ICD implantation. The enrollment of the patients began in January 2011 and ended in January 2016. We enrolled 262 patients that meet the criteria to receive an ICD. They were followed for one year after the implant procedure. The patients were evaluated 15 days after ICD implantation to observe the pocket, the site of the surgical incision, and to adjust the device programming. Fifteen days later, the patients returned for further evaluation (one month after ICD implantation). The data were obtained from the day of the device implant to 12 months after implantation. Subsequently, patients were evaluated every 3 months till the complete total period of follow-up. At each follow-up visit, we achieved a record (stored on a USB device and then transferred to a computer) of the ICD memory data that has accumulated since the last reset of memory. The occurrence and duration of therapy events were recorded.

Statistical analysis

All patients enrolled were included in the analysis. The results were expressed as the mean and standard deviation (mean ± SD) in the case of normal distribution and as median with interquartile range otherwise. Statistical tests were all of two sides. Comparisons between the two paired values were performed by paired t-test in case of a Gaussian distribution or, alternatively, with the Wilcoxon test. The comparisons between more than two values paired values were performed by analysis of variance for repeated measures ANOVA or Kruskal-Wallis test, as appropriate, complemented by a post hoc test. Frequencies were compared with x2 or Fisher’s exact tests. P values <0.05 were considered significant. Correlations between two variables were performed by Pearson in the case of a Gaussian distribution or, alternatively, with the Spearman correlation test. Kaplan-Meier analysis was performed to determine the probability of success, assessed as the percentage of patients free of therapies. Differences in free survival therapies were evaluated with the log-rank/Mantel-Haenszel test. The Cox regression analysis was applied to explore triggering factors of ATP and shock events. All statistical analyzes were performed using the program Graphpad Prism v 7.0 (Graphpad software, La Jolla, CA, USA).

Results

Patients

The 262 individuals who had all the inclusion criteria were comprised in the assessment. The baseline features divided into two groups according to the side of ICD implantation, are displayed meticulously in Table 1.

Therapy events

The acute defibrillation threshold testing (DFT), at the end of implantation showed that the mean energy to revert a programmed induced sustained ventricular tachycardia/ventricular fibrillation was 33.4±6.3 J for the patients that had the ICD implanted on the right side, and 23.9±5.3 J for the ones that presented the ICD positioned on the left side, P<0.0001 (Figure 1). Table 2 shows the mean and the sum of shock events recorded by ICD during 3 months till the complete total period of follow-up. At each follow-up visit, we achieved a record (stored on a USB device and then transferred to a computer) of the ICD memory data that has accumulated since the last reset of memory. The occurrence and duration of therapy events were recorded.
time of follow-up, 11 individuals bearing the ICD implanted on the right side (21%) experienced inappropriate shock events, and 24 patients bearing the ICD implanted on the left side (11%) received inappropriate shock therapy, P=0.0677, by log-rank/Mantel-Haenszel test (Figure 3).

Discussion
We demonstrated that an ICD implantation on the right side caused an elevated DFT in comparison to the left side insertion. This study also showed that there is no difference regarding the amount of appropriate and inappropriate shock therapies, the mean and the sum of shock events recorded by ICD during 1 year of monitoring, according to the side of ICD implantation.

Markewitz and colleagues [12] confirmed that the DFT in a two-lead system was lower when the proximal coil was positioned in the left subclavian vein than when it was located in the SVC. Our finding that the right-sided DFT is augmented in bipolar systems is consistent with this statement, given that right-sided vascular access requires an SVC location in single lead systems, and favors such a place in two-lead systems. Likewise, in a study by Epstein and colleagues [13] right-sided implant of biphasic non active can systems occasioned a high DFT in those systems that lacked subcutaneous leads. These authors also suggested that the boost in DFT resulted from a defibrillating electrical field that was minus auspiciously dispersed over the myocardium due to the anatomical limitations of right-sided venous access. We demonstrated that despite the benefit of a large surface area, right-sided active can DFTs were significantly increased matched with the left-sided implant. An acceptable ventricular sensing of >6 mV and a pacing threshold of <1 V @ 0.5 ms were succeeded in all subjects, prior to testing. As all our patients reached these values, we must question whether right ventricular stimulation threshold alone has sufficient proof for suitable device function [14]. The inappropriate shock events were triggered by any kind of supraventricular tachycardia or atrial fibrillation with high conduction to the ventricles, as well some sustained noising in one or both intra-cardiac channels. However, no difference was reported regarding the amount of appropriate and inappropriate shock therapies, the mean and the sum of appropriate and inappropriate shock events recorded by ICD during the 12 months of follow-up, according to the side of ICD implantation, demonstrating that the implant of ICD in any side is safety for the patients.

Limitations
Although our data showed favorable results about the effectiveness of the ICDs implanted in the left side, our group of patients was small. This relatively small sample size can be seen as a limitation.

Conclusion
Our results show that ICD implantation on the right side caused an elevated DFT in comparison to the left side insertion. This study also reported that there is no difference regarding safety and effectiveness about the amount of appropriate and inappropriate shock therapies, the mean and the sum of shock events recorded by ICD during 1 year of monitoring, according to the side of ICD implantation.

Conflict of Interests
The authors declare no conflict of interest.

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