Inappropriate shocks for ICD patients – single- vs dual-chamber devices

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A - Research concept and design, B - Collection and/or assembly of data, C - Data analysis and interpretation,
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Abstract

Background: Single-chamber (VR-ICD) and subcutaneous (S-ICD) implantable cardioverter-defibrillators are effective to protect patients against sudden death but expose them to higher risk of inappropriate shocks (IS). Auricchio A. et al. performed a meta-analysis of 16 studies to estimate the annual first IS rate among patients implanted with VR-ICD or S-ICD and determine the factors influencing IS. In this article we refer to and briefly comment on the results of this meta-analysis.

In the second part of this article, we focus on the comparison of single- and dual-chamber devices according to IS rate.

Results: Use of dual-chamber ICDs increases the expense and peri-procedural complications without reducing IS or improving the quality of life.

The article "Inappropriate shocks in single-chamber and subcutaneous implantable cardioverter-defibrillators: a systematic review and meta-analysis" was intended by the authors to assess the annualized rate of appropriate and inappropriate shocks (IS) in single-chamber (VR-) and subcutaneous (S-) implantable cardioverter-defibrillators (ICDs) [1].

A systematic research of PubMed (Medline), Embase and Cochrane Library was performed to identify articles with VR-ICD or S-ICD IS rates published up to July 2015. The systematic review and meta-analysis were conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement.

The final population for the meta-analysis included 6470 patients with 14 696 patient-years cumulative follow-up and came from 16 studies – 13 were VR-ICD studies and 3 were S-ICD studies. Thirteen studies were prospective and 3 studies were retrospective. Five of 16 studies reported the percentage of VR-ICD or S-ICD patients with AF.

This study showed a relatively constant annual appropriate shock rate of 5.8% (95% CI 5.3– 6.3, I2=0.0%) and an

annual IS rate of 6.4% (95% CI 5.1–7.9, I2=90.1%), which later progressively decreased over time, and significantly dropped to 1.9% in one of the more recent studies (PainFree SST). The meta-regression model found that studies with longer mean follow-up had lower annualized IS rates. The annualized IS rate was estimated to decrease by a factor of 0.76 (95% CI 0.60–0.95, P= 0.02) for each additional year of mean follow-up.

In our opinion, the advantage of this study is that the authors did not focus on proving that transvenous technology is superior to subcutaneous technology or one ICD brand is better than another one. The analysis demonstrates that the IS rate, independently of the implantation approach used and manufacturer, decreased over time. Due to the fact that IS are painful, may worsen the cardiac function, and cause discomfort and anxiety for the patient, this is very important information for both the patient and the doctor. Additionally, it reduces the cost of hospitalization associated with IS.

The great advantage of this study is that the authors examined how IS rates differ by ICD programming (with vs. without a ventricular tachycardia [VT] zone) and by device type (VR-ICD vs. S-ICD). It was demonstrated that use of S-ICDs and a VT zone programmed on were not associated with a significantly increased change in risk.

Unfortunately, progressive reduction in IS rates has not been related to a similar remarkable reduction in the annualized appropriate shock rate. The conclusion is that, despite major advances in heart failure therapy and patient management over the last decade, the risk of repeated life-threatening arrhythmias in VR-ICD patients has mostly remained unchanged. Additionally, a significant association between ICD shock and mortality has been demonstrated, although the level of association seems to be stronger for appropriate shocks.

The disadvantage of this study is that the appropriate and inappropriate rates were calculated without including many factors that may have an impact on them.

Firstly, the 16 studies used for the meta-analysis had different inclusion/exclusion criteria; hence the results cannot be interpreted unambiguously. It is worth noting that apart from the lower age criterion (≥18 years of age), studies with >100 patients with single chamber/subcutaneous devices and studies with >6 months of follow-up, the other criteria are not clearly specified. There was some heterogeneity in the studies with respect to patient population and criteria for ICD implantation.

Moreover, the process of ICD implantation is unknown, and therefore we do not know about possible complications, which obviously have a significant impact on the subsequent functioning of the ICD and the frequency of IS. The time of implantation is also unknown.

Additionally, age, co-morbidities and other risk factors, which may have influenced the use of ICD, cannot be accounted for.

What is more, IS rates appear to be influenced by factors that include the technology configuration, device programming, and rhythm discrimination algorithms. Several important factors which influenced IS rate (e.g. remote monitoring, AF) were not reported for all studies.

Finally, despite many advantages of the research, I think that due to the lack of proper selection of criteria, it can only provide an approximation of appropriate/inappropriate rates and trends.

Of course, we can assume that the IS rate is actually falling over the years – this is because more modern equipment and programming devices are used, implantations are less invasive and shorter, and the operators are more experienced. However, to be able to state it conclusively, it is important that future research includes the medical history of the patient, implantation process and device configuration data.

In clinical practice, many patients who undergo placement of an implantable cardioverter-defibrillator (ICD) for primary prevention of sudden cardiac death receive dual-chamber devices. Many clinicians believe in the superiority of dual-chamber over single-chamber devices in reducing the risk of inappropriate ICD shocks. But is it really true?

Peterson Pamela N., Greenlee Robert T., Go Alan S., et al. identified patients receiving a single- or dual-chamber ICD for primary prevention who did not have an indication for pacing from 15 hospitals. The primary outcome was time to first inappropriate shock. Among 1042 patients without pacing indications, 54.0% (n=563) received a single-chamber device and 46.0% (n=479) received a dual-chamber device. In a propensity-weighted analysis, device type was not significantly associated with inappropriate shock (hazard ratio, 0.91; 95% confidence interval, 0.59–1.38 [P=0.65]), all-cause hospitalization (hazard ratio, 1.03; 95% confidence interval, 0.87–1.21 [P=0.76]), heart failure hospitalization (hazard ratio, 0.93; 95% confidence interval, 0.72–1.21 [P=0.59]), or death (hazard ratio, 1.19; 95% confidence interval, 0.93–1.53 [P=0.17]) [2].
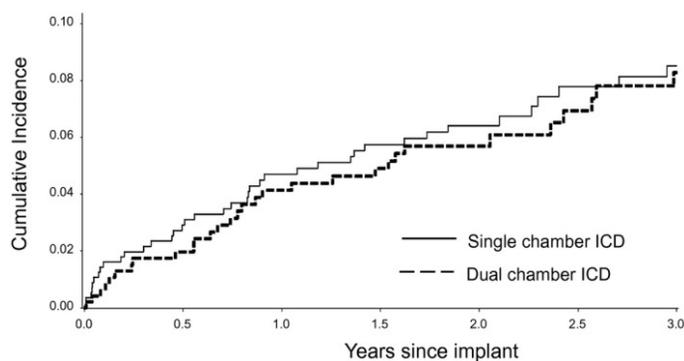
Cumulative incidence curves of time to each outcome by device type. ICD indicates implantable cardioverter-defibrillator[2].

The conclusion is that there is no association between the use of a dual-chamber defibrillator compared with a single-chamber device with respect to the risk of inappropriate shocks, hospitalization, or death.

The clinical implication is, because of higher costs and known higher risks associated with dual-chamber devices, there is no point of their use in patients receiving a primary prevention ICD where there is no indication for pacing.

There were also some limitations of this study. Programming of devices was not standardized and follow-up was

limited to 3 years. Thirdly, the authors did not capture lead or generator revisions. Within the follow-up time, patients may have undergone lead or generator revisions, including upgrades from single- to dual-chamber devices or to cardiac resynchronization therapy. However, propensity score weighting should mitigate this concern. Similarly, the data are observational and residual confounding by unmeasured confounders cannot be fully excluded despite the ability to account for a wide range of measured potential confounders.

Between 2002 and 2012, the DAI-PP registry consecutively enrolled 1258 SC- and 1280 DC-ICD recipients at 12 French medical centers. The devices were interrogated at 4- to 6-month intervals during outpatient visits, with a focus on the therapies delivered. The study endpoints were incidence of appropriate therapies, ICD-related morbidity, and deaths from all and from specific causes. The mean age of the SC- and DC-ICD recipients was 59 ± 12 and 62 ± 11 years, respectively (P< 0.0001). The rates of periprocedural complications were 12.1% in the DC- vs. 8.8% in the SC-ICD groups (P= 0.008). Over a mean follow-up of 3.1 ± 2.2 years, pulse generators were replaced in 21.9% of the DC- vs. 13.6% of the SC-ICD group (P< 0.0001). The proportions of patients treated with ≥1 appropriate therapies (24.7 vs. 23.8%) and ≥1 inappropriate shocks (8.4 vs. 7.8%), and all-cause mortality (12.4 vs. 13.2%) were similar in both groups[3].

The conclusion is that DC-ICDs were associated with higher rates of peri-implant complications and generator replacements, whereas the survival and rates of inappropriate shocks were similar between groups.

The programming of ICDs influences inappropriate shock rates. Inappropriate ICD shocks are associated with increased mortality. They also impair patients' quality of life, increase hospitalizations, and raise health-care costs. However, when optimal programming is utilized, inappropriate shocks are rare in primary prevention patients with both single- and dual-chamber ICDs [4].

Nearly 80% of inappropriate ICD shocks are caused by supraventricular tachycardia[5].

There are no criteria for selecting single- or dual-chamber ICDs in patients without a pacing indication. However, the presented studies show that using a dual-chamber device is not associated with lower risk of inappropriate shocks, but may have more peri-procedural complications and higher cost of implantation.

No benefit over single-chamber ICDs was observed. The routine use of dual-chamber ICDs increases the expense without reducing inappropriate shocks or improving the quality of life[4].

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