

Inappropriate Shocks in Patients with ICDs: Single Chamber versus Dual Chamber

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Abstract

Background: Despite the technological evolution of the implantable defibrillator, one of the questions that remains is the possible benefit of the dual chamber versus single chamber implantable cardioverter defibrillator (ICD) in reducing inappropriate shocks.

Objective: To evaluate which type of device provides fewer inappropriate shocks (dual chamber versus single chamber) in patients with implantable cardioverter defibrillators (ICDs).

Methods: Meta-analysis of randomized studies published in the literature comparing dual-chamber implantable cardioverter defibrillators to single chamber devices which have been known to cause, as an evaluated endpoint, inappropriate shocks.

Results: The dual-chamber implantable cardioverter showed no benefit in reducing the number of inappropriate shocks. In fact, the opposite was shown. In the analysis of fixed effects, the association tended to favor single-chamber implantable cardioverter defibrillators (OR = 1.53, CI 95%: 0.91-2.57), despite the absence of statistical significance ($p = 0.11$). We highlight the heterogeneity observed in the results ($I^2 = 53\%$), which motivated a replication of the analysis using a model of random effects. However, significant differences remained in the occurrence of inappropriate shocks in both groups (OR = 1.1, 95% CI: 0.37-3.31; $p = 0.86$). To complement the analysis, we proceeded to perform sensitivity analysis, which showed that the exclusion of a study resulted in the lowest heterogeneity observed ($I^2 = 24\%$) and the association with inappropriate shocks significantly favored the single chamber cardioverter defibrillator (OR = 1.91; 95% CI: 1.09–3.37; $p = 0.27$).

Conclusions: It was determined that there was no clear evidence of superiority of any of the devices evaluated. (Arq Bras Cardiol. 2013;101(2):141-148)

Keywords: Implantable Defibrillators / utilization; Shock; Meta-Analysis.

Introduction

Although the Implantable Cardioverter Defibrillator (ICD) is effective in diagnosing and treating ventricular tachyarrhythmias, inappropriate shocks continue to be the major clinical problem for patients who have the device implanted¹. About one-fourth to one-third of ICD patients experience inappropriate shocks², the consequences of which can include pain, anxiety, discomfort, serious psychological complications, ventricular tachyarrhythmias induced by the inappropriate shock and early depletion of the ICD battery^{3,4}. The clinical importance of this problem has made it necessary to develop new discrimination

algorithms with the objective to increase the specificity in detecting arrhythmias while maintaining sensitivity⁵.

In theory, the Dual Chamber ICD (DR) should be capable of discriminating tachyarrhythmias more effectively than the Single Chamber ICD (VR), since the addition of the atrial electrocatheter provides additional information on the heart rhythm and atrial frequency, as well as on atrial-ventricular synchrony. Studies show a clear benefit of the ICD DR versus the ICD VR in discriminating tachyarrhythmias, thus achieving a reduction in inappropriate shocks^{3,6,7}. However, other studies with the same objective show little or no advantage on the part of the ICD DR⁸⁻¹⁰.

Thus, it becomes necessary to determine whether the discrimination algorithms of the ICD DR significantly reduce the number of inappropriate shocks when compared to the ICD VR.

To this end, a systematic review and a meta-analysis of randomized studies comparing the performance of the ICD DR with the ICD VR were performed, with attention paid to the ability to discriminate tachyarrhythmias culminating in the application of inappropriate shocks.

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Methods

Study Design

A systematic review and a meta-analysis were performed, including published literature detailing the number of inappropriate shocks delivered by ICDs, which were randomized into ICD DR or ICD VR. The description of the methods is based on the work of the PRISMA group¹¹.

Research strategy

In order to locate all studies discussing ICD VRs versus ICD DRs with respect to inappropriate shocks, various procedures were developed. We started by performing a search by keyword, with no restriction of dates, on electronic databases such as: PubMed, B-On, Elsevier Science, Science Direct and Web of Science. The search employed the search filter for human research, utilizing the following terms: ("Implantable cardioverter defibrillator" OR "ICD" OR "Implantable Cardioverter-defibrillators" OR "implantable defibrillator") AND ("Dual-chamber ICD" OR "dual-chamber ICD" OR "dual-chamber device" OR "dual-chamber pacemaker defibrillator" OR "DC-ICD device") AND ("single-chamber ICD" OR "Single-chamber ICD" OR "single-chamber device" OR "SC-ICD device") AND ("Inappropriate shocks" OR "Inappropriate ICD interventions" OR "Inappropriate therapies" OR "Inappropriate implantable cardioverter-defibrillator discharges" OR "inappropriate therapy" AND "Clinical Trial[ptyp]" OR "Randomized Controlled Trial[ptyp]"). The search was performed in October 2011.

Articles identified in this way were then analyzed, looking for new references contained therein that could be researched. The references of articles read in full were also used as sources of articles.

Additionally, we performed a direct search in specialty magazines: *Europace*, *New England Journal of Medicine*, *Journal of the American College of Cardiology*, *Circulation*, *European Heart Journal*, *Journal of Cardiovascular Electrophysiology* and *Heart Rhythm*.

Selection of studies

The selection of studies included two phases: the first was the analysis of the title and the summary of potential studies found during the search of the databases. For this phase we used a standardized form Figure 1.

Two independent reviewers classified the studies, deciding whether or not to include them. When the summary of the study did not provide enough information to determine inclusion or exclusion, the reviewers moved on to the next phase. The second phase involved a complete analysis of the full study. Again, two independent reviewers classified the studies, deciding on their inclusion or exclusion.

Statistical treatment and data analysis

The statistical analysis was performed using the MetaView module of the statistical software Review Manager Version 5.0 (Copenhagen, The Nordic Cochrane Centre, The

Cochrane Collaboration, 2008), by means of models of fixed and random effects. Heterogeneity was assessed using Cochran's Q test and was complemented by the I², which indicates the degree of variability between studies, providing a measure of heterogeneity.

Results were analyzed as dichotomous variables. To do this we calculated Odds Ratios (OR) and Confidence Intervals of 95% (CI 95%). The criterion for statistical significance used was p value ≤ 0.05. For continuous variables, the difference of pondered averages was calculated (random effect model) with the corresponding CI 95%. If necessary, the original data were transformed into logarithmic bases that followed a normal distribution or scales that presented similar properties. If needed, the continuous variables could be subdivided for dichotomous analysis.

Results

Included studies

After searching the selected databases, 1,330 studies were selected for analysis, of which 403 remained after exclusion of duplicate studies. Of these, 370 studies were excluded after review of title and abstract. The remaining 33 articles were analyzed in full, although it was not possible to obtain two of these articles (one because it had not yet been published). In the end, five articles were selected for analysis, although only one of them had the values required to perform the meta-analysis. The other four authors were contacted so that they could provide the necessary items from the studies; only one of the authors failed to respond to our request. Thus, four studies were included. The flowchart of the literature review is shown Figure 2.

Qualitative results

This meta-analysis included four randomized studies comparing the occurrence of inappropriate shocks in ICD VR versus ICD DR. The studies are the DATAS¹², the Detect Supra Ventricular Tachycardia (Detect SVT)⁷, the Prevention of INAPProPriaTe Therapy (PINAPPs)¹⁰, and the study by Deisenhofer et al. study⁸.

The characteristics and the design of the studies included are summarized in Table 1.

This meta-analysis represents a total of 886 patients. Of these, 17.6% had a single-chamber ICD implanted (ICD VR) and 82.4% had a dual-chamber ICD implanted (ICD DR); among the 730 patients with an implanted ICD DR, 53.6% were randomized to remain with the DR group and 46.4% with the VR group. The clinical characteristics of the study participants included are shown in Table 2.

The mean age of the patients was between 59 and 65 years, and more than 78% were men. All studies included patients with an ejection fraction (EF) ≥ 30%, and most patients had coronary artery disease (CAD). There were no differences in baseline clinical characteristics between patients randomized to ICD VR or ICD DR.

Study reference: _____

Selection level (check where applicable):
Title _____ Abstract _____ Text _____

Selection Criteria:

Patients
Do the study patients meet implementation criteria for ICD ? Yes/No
Are the study patients older than 18 years of age? Yes/No
Are the study patients free of chronic atrial fibrillation (AF)?Yes/No

Intervention
Is there a group of patients with ICD DR? Yes/No

Control
Is there a group of patients with ICD VR or programmed as VR? Yes/No

Events
Were there repeated inappropriate shocks? Yes/No
Were there quantified shocks? Yes/No

Design
Is it a randomized study? Yes/No

Action: (Include only if ALL previous answers have been YES):
Included _____ Excluded _____ For decision by consensus _____

Figure 1 - Selection Sheet for potential articles for the meta-analysis. ICD DR: dual chamber cardioverter defibrillator; ICD VR: single chamber cardioverter defibrillator; ICD: cardioverter defibrillator; CRT-D: cardiac resynchronization therapy and defibrillation; CRT-P: cardiac resynchronization therapy.

The programming for detection of arrhythmias was similar in both groups (392 ± 24 ms for ICD VR versus 413 ± 57 ms for ICD DR). All studies included were randomized. In most of the studies, the main objective was the comparison of the incidence of inappropriate therapies in patients with ICD VR versus ICD DR^{8,10} in some studies this was part of a combined objective^{6,12}. The Detect SVT study had inappropriate detection as its main objective, which was the second objective in the PINAPP study. All studies excluded patients with permanent atrial fibrillation (AF), sinoatrial (SA) node dysfunction, atrioventricular blockage or any other indication for the implantation of a permanent pacemaker.

To convey the distribution of inappropriate shocks included in the meta-analysis, Table 3 was prepared.

From the point of view of representativeness, the two randomization groups were equivalent, with 56% of the patients randomized to the ICD VR group and 44% to the ICD DR group. The global predominance of inappropriate shocks was 7.4%, being slightly higher in the ICD DR group (9.7%) in relation to the CDI VR group (5.6%).

Inappropriate shocks according to analysis by patient

When data from all studies were pooled using the fixed-effect model Figure 3, there was not a statistically significant difference in the risk of occurrence of inappropriate shocks between the ICD DR and ICD VR (OR = 1.53; CI95%: 0.91 - 2.57, $p = 0.11$), despite the identification of a larger number of patients with inappropriate shocks in ICD DR. From the analysis of heterogeneity, our attention was drawn to the I^2 results of 53%. The graphical analysis of the distribution of the results of the studies included is very expressive of this heterogeneity, reinforcing the need for caution in interpreting the overall results obtained.

To minimize the effect of this heterogeneity, we proceeded to perform an analysis of random effects, as demonstrated in Figure 4. As can be seen, there were no significant differences in the occurrence of inappropriate shocks in both groups. Heterogeneity remained evident in the I^2 analysis of 53% and the asymmetric distribution of the studies in graphical terms.

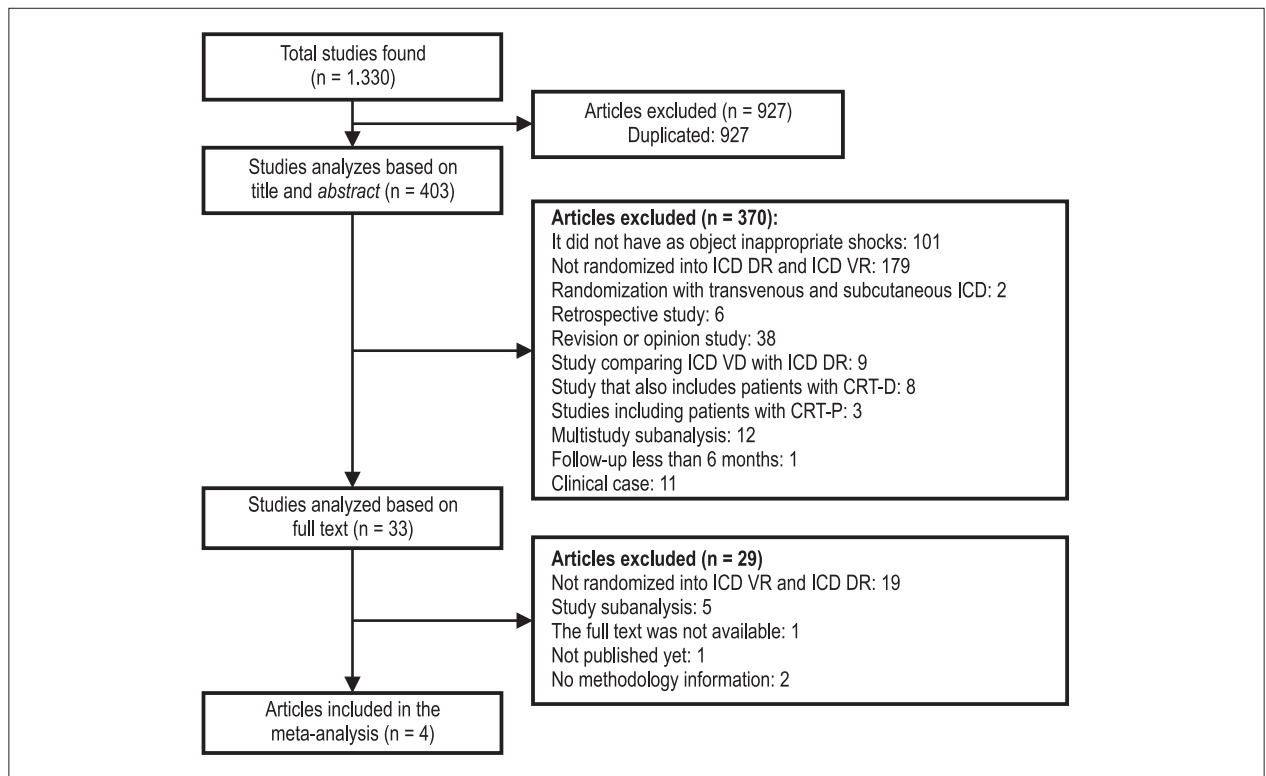


Figure 2 - Systematic Review Flowchart. ICD DR: dual chamber cardioverter defibrillator; ICD VR: single chamber cardioverter defibrillator; ICD: cardioverter defibrillator; CRT-D: cardiac resynchronization therapy and defibrillation; CRT-P: cardiac resynchronization therapy.

Table 1 - Characteristics and design of the studies

Studies	DATAS	Detect SVT	PINAPP	Deisenhofer						
Year	2008	2006	2004	2001						
Population	Randomized into 3 arms : ICD VR; ICD DR and ICD DR programmed as VR	All DR	All DR	Randomized VR and DR						
Study design	Parallel with crossover at arm DR	Parallel	Parallel	Parallel						
Type of concealment	No concealment	Simple concealment	No concealment	No concealment						
Endpoint	All causes of death; invasive interventions; hospitalizations of CV cause; inappropriate shocks; sustained AT > 48 hours	Inappropriate detection of SVT	Inappropriate therapies for atrial arrhythmias	Inappropriate therapies and complications of ICD						
Months of follow-up	15.7 months	6 months	12 months	7 months						
N	IICD VR	3334	1111	111-Stimulate in VR	400	199	60	29	92	45
	IICD DR		112		201		31		47	

ICD VR: single-chamber cardioverter defibrillator; ICD DR: dual-chamber cardioverter defibrillator; VR: single chamber; DR: dual chamber; SVT: supraventricular tachycardia; CV: cardiovascular; AT: atrial tachycardia.

To evaluate the impact of statistical heterogeneity, focused on the impact of excluding each study, we analyzed the sensitivity of the data (Table 4).

It was observed that heterogeneity remained significant ($I^2 > 20\%$) in all of the analyses performed, with the exclusion of the DATAS study which is on the threshold

of heterogeneity ($I^2 = 24\%$) with an OR = 1.91 (CI 95%: 1.09 - 3.37, $p < 0.05$), revealing a statistically significant association of the ICD DR with a higher risk of inappropriate shocks. This trend was present in all partial analyses, except for the reanalysis excluding the Detect SVT study, which produced an OR = 0.7 (95% CI: 0.28 - 1.75) without statistical significance.

Table 2 - Clinical characteristics of the included studies

Studies	DATAS	Detect SVT	PINAPP	Deisenhofer
Average age	64	65	59	61
Males (%)	84	80	78	90
Coronary disease (%)	85	81	78	67
EJ (%)	36	32	30	-
History of AT (%)	-	29	25	11
Medication	Amiodarone (%)	-	25	32
	Beta blockers (%)	-	6	57
	Digoxin (%)	-	-	17

EJ: Ejection fraction; AT: Atrial Tachycardia.

Table 3 - Distribution of inappropriate shocks in the meta-analysis population, according to the type of device

	ICD DR		ICD VR	
	n/N	%	n/N	%
Patients	391/886	44	495/886	56
Shocks	38	9,7	28	5,6

ICD DR: dual-chamber cardioverter defibrillator; ICD VR: single-chamber cardioverter defibrillator; n: number of patients with inappropriate shocks; N: total sample.

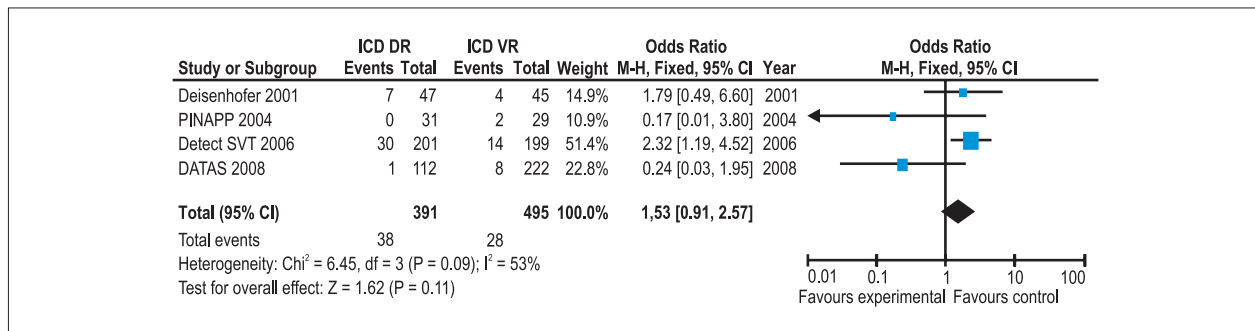


Figure 3 - Forest Plot representing the model analysis of fixed effect model in the evaluation of the list of patients carriers of dual chamber cardioverter defibrillator versus single chamble cardioverter defibrillator in the occurrence of inappropriate shocks.

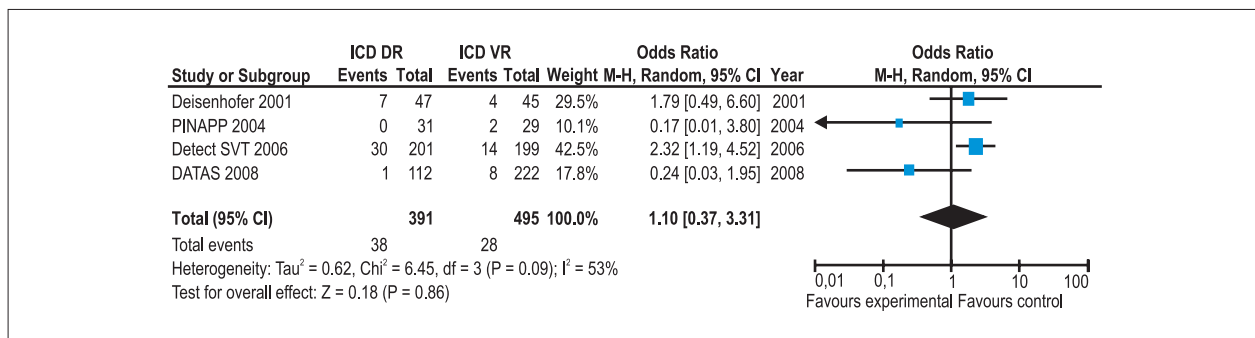


Figure 4 - Forest Plot representing the model analysis of random effect in the evaluation of the list of patients. ICD DR: dual chamber cardioverter defibrillator; ICD VR: single chamber cardioverter defibrillator.

Table 4 – Study sensitivity analysis

Studies	OR	CI	X ²	I ² (%)
Deisenhofer	1.49	0.85-2.61	0.04	69
PINAPP	1.7	0.99-2.9	0.12	52
Detect SVT	0.7	0.28-1.75	0.15	47
DATAS	1.91	1.09-3.37	0.27	24

OR: Odds Ratio; CI: Confidence Interval; X²: chi-square; I²: heterogeneity.

Discussion

There was no benefit in terms of reducing the number of inappropriate shocks in the ICD DR compared with the ICD VR, contrary to the prediction originally outlined. Actually, it was possible to show a slight tendency to an increase of inappropriate shocks in the ICD DR compared to the number of shocks in the comparison group. In the included studies, 9.7% of patients with an ICD DR received inappropriate shocks, compared to 5.6% of patients with an ICD VR (or device programmed to act as such). Therefore, considering the analysis of fixed models, the OR corresponding to the occurrence of inappropriate shocks between ICD DR and VR was 1.53 (95% CI: 0.91 - 2.57, $p = 0.11$), indicating a slight tendency towards a benefit with the ICD VR, although without statistical significance. Given the high heterogeneity documented in this analysis, the evaluation was replicated using a random effect model, resulting in an OR of 1.10 (95% CI: 0.37 - 3.31, $p = 0.86$), and we found no significant association between the type of ICD and the occurrence of inappropriate shocks. We must highlight the fact that, despite the lack of statistical significance in both analyses, the OR somewhat favored the ICD VR, keeping in mind all due cautions that the statistics require in reading this result. Nevertheless, the results are clear in showing the lack of benefit of the ICD DR in relation to the DCI VR in this specific context.

The main justification for failure of superiority of the ICD DR in some studies included in this meta-analysis is a problem with atrial sensing, with this being the prevailing cause of incorrect detections of the ICD DR resulting in inappropriate shocks^{13,14}. In Deisenhofer et al's⁸ study, for example, problems with atrial sensing were the cause of 38 of the 51 inappropriate shocks which occurred in patients with the ICD DR. Atrial sensing problems represent from 41% to 75% of the inappropriate therapies in the oldest studies included in this meta-analysis^{8,10}. In the Detect SVT⁷ study, the importance given to atrial sensing resulted in far-field sensing of the R wave or oversensing of the R wave, with a value less than 3% in the ICDs programmed to act as a DR. Of all the discrimination errors in the ICDs programmed as DRs, only 5% were counted as atrial sensing errors⁷.

It was found that in the most recent studies, there are fewer numbers of inappropriate shocks and therapies caused by problems with atrial sensing, perhaps due to improvements in the sensing filters achieved by ICD manufacturers, which were called for by Deisenhofer et al⁸ in their 2001 study.

A curious aspect that resulted from the sensitivity analysis, which was recommended in order to determine the high level of heterogeneity shown in the global statistical analysis, was that the exclusion of the DATAS study from the analysis resulted in the lowest coefficient of heterogeneity ($I^2 = 24%$) and was associated with an OR of 1.91 (95%CI: 1.09 - 3.37, $p < 0.05$), clearly favoring the ICD VR and thus indicating a risk of inappropriate shock 91% higher than in the ICD DR group. This homogeneity in the results stemming from the exclusion of the DATAS study may be due to the temporal context in which the clinical trials were developed, as well as the state of the technological evolution of the ICD, in addition to the way in which each study was conducted. In fact, with the DATAS study being the most recent study of all, this study involved devices at the most current level of technological development, which might explain its contribution to the heterogeneity identified in the several models of analysis undertaken. On the other hand, one must consider that in the DATAS study, all of the implanted ICDs contained algorithms for the prevention of atrial tachycardia (AT) and atrial fibrillation (AF) which, as we know, are the main causes of inappropriate shocks. Currently, patients with ICDs have a high prevalence of atrial tachyarrhythmias. It has been shown that 20% of patients develop AF before ICD implantation and, during the time that the ICD is implanted, 50% of the patients go on to develop AF¹⁵. Atrial anti-tachycardia functions (prevention algorithms and atrial ATP) available in ICDs implanted in the DATAS study have been shown to be effective in preventing and terminating atrial tachyarrhythmias quickly, as reported in the study by Ricci et al¹⁶, who demonstrated efficiency in the termination of AT (> 71%) and AF (36%) in a one-year follow-up period. It must be further highlighted that in the DATAS study, two or more episodes of inappropriate shocks were defined as "inappropriate shock", with the justification that the first inappropriate shock could signal the need for reprogramming of the ICD, which might then prevent subsequent inappropriate shocks¹². Therefore, the total number of inappropriate shocks registered is not the actual number reported, thus underrating the true number of shocks experienced which may have a direct influence on the results obtained, skewing results in an unpredictable direction.

It should be noted that, in order to demonstrate the superiority of the ICD DR in relation to the ICD VR, the programming was not optimized for each patient, which

could be considered a failure. Several studies have already demonstrated this fact^{17,18}, with improvements in atrial detection and in morphology algorithms. In the studies included in this meta-analysis, one could not determine if the programming for each patient had been appropriate, although changes and adjustments in programming were reported as clinical variations in the patients.

In a few brands currently on the market, the discrimination algorithms are not applied during the redetection of tachyarrhythmias, which may cause an increase in inappropriate shocks. However, in the studies included in the meta-analysis, there was no information regarding this characteristic present in some brands, or if they are connected to redetection.

Study limitations

This meta-analysis included a large number of patients; however, there was a significant heterogeneity among the studies included. This heterogeneity may be due to differences in the technological devices used in the different studies, related to the different time periods in which each study was conducted. However, some of the algorithms used by the different manufacturers at the time of the studies included in the meta-analysis had undergone improvements and modifications. The most current ICDs, for example, may discriminate the type of tachyarrhythmia in conjunction with morphological algorithms, based on atrioventricular intervals, even though some of the algorithms used in this analysis are also used in the current brands of ICDs. The inclusion of studies conducted in different years (2001, 2004, 2006 and 2008) resulted in technological differences in the ICDs, which may explain the fact that the DATAS study (the most recent study) is the only one to show clear evidence of a reduction in inappropriate shocks in the ICD DR, as opposed to what was found in the other studies. However, the definition of inappropriate shocks in this study could have resulted in an underestimation of the same, with unforeseeable consequences for the analysis.

Another potential limitation may have been the influence of publication bias. It is not possible to completely eliminate this type of bias, although in an extensive search its effect may be minimized. Despite the fact that one might have

used visual analysis of funnel plots, the usefulness is limited due to the limited number of studies included.

Another limitation is the impossibility of obtaining 1+1 data from the study, which could reinforce the results obtained from the meta-analysis, taking into account the large number of patients that participated in that study (n = 102).

Conclusion

The overall conclusion of this meta-analysis is that there is a lack of clear evidence regarding the superiority of any of the therapeutic alternatives analyzed, although we documented a consistent tendency towards fewer inappropriate shocks in the ICD VR. This issue should be reviewed in future randomized and larger prospective studies. On the other hand, the proportion of patients with inappropriate shocks still persists at unacceptable levels, despite all of the sophisticated algorithms and the steady progress and improvement of technology. These findings increase the urgency to develop strategies to minimize this event, given the dramatic impact it can have on the quality of life of patients with ICDs.

Author contributions

Conception and design of the research, Acquisition of data, Analysis and interpretation of the data, Statistical analysis, Writing of the manuscript and Critical revision of the manuscript for intellectual content: Gonçalves JF, Pereira T.

Potential Conflict of Interest

No potential conflict of interest relevant to this article was reported.

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Study Association

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