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Standardized programming to reduce the burden of inappropriate therapies in implantable cardioverter defibrillators - Single centre follow up results

U. Boles [a, b, *], E.E. Gul [a], L. Fitzgerald [b], F. Sadiq Ali [a], C. Nolan [c], K. Aldworth-Gaumond [a], D.R. Redfearn [a], A. Baranchuk [a], B. Glover [a], C. Simpson [a], H. Abdollah [a], K.A. Michael [a]

[a] Heart Rhythm Service, Division of Cardiology, Kingston General Hospital, Queen's University, Ontario, Canada
[b] Cardiology Department, Midland Regional Hospital Mullingar (MRHM), Ireland
[c] Heart and Vascular Centre, Mater Private Hospital, Dublin, Ireland

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ABSTRACT

Background: Current algorithms and device morphology templates have been proposed in current Implantable Cardioverter-Defibrillators (ICDs) to minimize inappropriate therapies (ITS), but this has not been completely successful.
Aim: Assess the impact of a deliberate strategy of using an atrial lead implant with standardized parameters; based on all current ICD discriminators and technologies, on the burden of ITS.
Method: A retrospective single-centre analysis of 250 patients with either dual chamber (DR) ICDs or biventricular ICDs (CRTDs) over a (41.9 ± 27.3) month period was performed. The incidence of ITS on all ICD and CRTD patients was chronicled after the implementation of standardized programming.
Results: 39 events of anti-tachycardial pacing (ATP) and/or shocks were identified in 20 patients (8% incidence rate among patients). The total number of individual therapies was 120, of which 34% were inappropriate ATP, and 36% were inappropriate shocks. 11 patients of the 250 patients received ITS (4.4%). Of the 20 patients, four had ICDs for primary prevention and 16 for a secondary prevention. All the episodes in the primary indication group were inappropriate, while seven patients (43%) of the secondary indication group experienced inappropriate therapies.
Conclusions: The burden of ITS in the population of patients receiving ICDs was 4.4% in the presence of atrial leads. The proposed rationalized programming criteria seems an effective strategy to minimize the burden of inappropriate therapies and will require further validation.

1. Introduction

Inappropriate therapies (ITS) from implantable cardioverter-defibrillators (ICD) lead to significant morbidity either from the painful delivery of shocks or from the pro-arrhythmic potential [1]. Prior studies suggest that 15–28% of anti-tachycardia therapies may be inappropriate [2]. Measures to reduce inappropriate shocks, including an empiric ablative strategy, have been shown to reduce morbidity [3].

It seems intuitive that device specialists should also refine ICD programming to minimize ITS, as this is the least invasive option. Inappropriate therapies occur more frequently in patients having supraventricular arrhythmias, particularly atrial fibrillation, or in younger patients who achieve higher sinus tachycardia rates and may represent up to 12.1% of ITS [4]. We contend that the use of dual chamber devices improves the algorithmic differentiation of atrial from ventricular arrhythmias, but does not completely resolve problem [5].

In this study, we evaluated the burden of ITS affecting a heterogeneous population of recipients of ICDs, with dual chamber (DR) ICD or biventricular ICD (CRTD) defibrillators with current recommended programming standards.

2. Methods

This is a retrospective single centre analysis. We examined the

* Corresponding author. Heart and Vascular Department, Mater Private Hospital, Dublin, Ireland.
E-mail address: bolesu@tcd.ie (U. Boles).
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overall device therapies (defined as ATP and/or high voltage (HV) shock) in a cohort of 250 patients implanted with either DR ICDs or CRTDs. Indications for the implants were both primary and secondary, and had a follow up period of 41.9 ± 27.3 months. Follow up was conducted at two months in the first visit, then six-monthly intervals afterwards in our devices clinic. Physicians were to follow current guidelines for pharmacologic therapy if required.

2.1. End point

Inappropriate ICD therapy was defined as all device therapy delivered (by ATP or HV) for sinus tachycardia, atrial fibrillation, atrial flutter, or regular supraventricular tachycardia. Evaluate the impact of a standardized programming regimen on patients.

2.2. Rhythm discrimination

All events associated with therapy were classified as appropriate or inappropriate. Inappropriate therapy was classified as any therapy delivered in a rhythm that was not a true ventricular arrhythmia.

The supraventricular tachycardia was classified as atrial tachycardia (AT) if the atrial near field electromyograms (EGMs) measured as regular. If the variability of the atrial cycle length was more than 50 ms with a rapid atrial rate (<200 ms) recorded, it was diagnosed as atrial fibrillation (AF). A paroxysmal supraventricular tachycardia (either AVNRT/AVRT) or AT was inferred depending on the response to ATP (VAV or VAAV response respectively) [6].

All recorded events with stored EGMs were reviewed independently by two electrophysiologists and by a third reviewer in the case of disagreement. The empiric programming strategy was considered in all devices to minimize inappropriate therapies illustrated in (Table 2–A and 2-B).

2.3. Exclusion criteria

Patients with ITS due to non-arrhythmic episodes e.g. over sensing or detection of non-physiological “noise” were excluded from the analysis. This study was therefore streamlined to evaluate the use of ICD programming to discriminate supraventricular tachycardia (SVT) from ventricular arrhythmias. We excluded patients without atrial leads from the analysis. The atrial lead has been successfully demonstrated to lower the inappropriate shock rate of dual/triple-chamber ICD group when compared to the single-chamber ICD group according to PainFree SST trial [7].

2.4. Proposed device programming

In Table 2–A and 2-B, we proposed our centre and institutional board approved programming based on reviewing all the guidelines on large prospective trials for ICD programming. A proven optimal programming approach would adopt a simple therapy prescription, reduce inadvertent programming errors and reduce shock related morbidity, thereby improving therapy outcomes. The available sources for programming as per manufacturer were PROVE trial for St Jude Medical (SJM - now Abbott) [8]; PAINFREE II for Medtronic [7]; MADIT- RIT trial for Boston Scientific devices [9]; and general consensus of the American Heart Association (AHA) recommendations [10,11]. All these proposed programming parameters discussed and adjusted in conjunction with manufacturers continuous collaborations.

2.5. Statistical analysis

The quantitative variables with normal distribution are presented as a mean and SD. The other variables (qualitative) are represented as a percentage. Statview version 5.0 for Windows (SAS Institute Inc. Cary, NC, USA) was used for statistical analysis.

3. Results

In total, we implanted 250 devices of them 165 were DR ICDs and 85 were CRTDs. Cohort classification according to device indication and all therapies are shown in Fig. 1.

We identified 39 events (giving a total of 120 therapies) in 20 patients. Inappropriate therapies “ITS” were identified in 11 patients. We presented the characteristics and baseline demographics of ITS group in Table 1. We focused our study and data analysis on the identified 20 patients who received device therapies.

According to indication of device implantation in our cohort of those 20 patients; we had four devices implanted for a primary indication (n = 2 DR ICD and n = 2 CRTD), while the remaining 16 patients had ICDs implanted for a secondary indication (n = 8 DR ICD and n = 8 CRTD). See Table 1 & Fig. 1

The event rate of the patients that received therapies in regards to the whole cohort was 8% (20/250 patients) over a 41-month period, with an average of 0.95 events per month (39 events/41 months) for the whole cohort.

However, Sub analysis of the 20 patients that received therapies identified that 100% (n = 4/4) patients in the primary prevention group had ITS for a SVT. In secondary prevention group (n = 16), 44% (n = 7/16) of patients had ITS (Fig. 2), whilst the remaining 56% (n = 916) had appropriate therapies for ventricular tachycardia (VT). The overall incidence of ITS delivered in both primary and secondary prevention group was 4.4% (11/250 patients) in comparison to the whole study cohort.

According to the type of therapies delivered, were 120 in total; we found 76 sequences of ATP and 44 HV shocks (High volt shocks). Out of these, inappropriate therapies included 26 ATP sequences (34.2%) and 16 (36.4%) HV shocks (Fig. 2)

4. Discussion

Implantable defibrillators have improved survival in patients at risk of sudden cardiac arrhythmia [6,12]. They have also impacted on the quality of life for patients with heart failure [13]. Despite advances in ICD development and advanced programming, ITS have not been fully overcome. Sinus tachycardia in younger individuals is especially challenging due to the sinus tachycardia rates approaching the tachycardia detection intervals, as are supraventricular arrhythmias, such as AF [14]. The delivery of inappropriate shocks has been linked to decreased survival and increased morbidity, and measures to reduce this phenomenon are imperative [15]. The presence of an atrial lead has demonstrated success in PainFree SST trial with lower inappropriate shock rates of the dual/triple-chamber ICD group when compared to single-chamber ICD group [7]. This accounts for better discrimination of SVT and therefore a lower incidence of ITS.

In our heterogeneous cohort (both primary and secondary) we proposed programming parameters that coalesce the most common programming trials tailored as device manufacturer specifications to minimize ITS.

Our study population entailed a cross section of heterogeneous patients with a predominance of patients with secondary indications for ICD implantation (80%). The remaining 20% had a primary indication. Only four patients implanted with a primary indication for an ICD received inappropriate therapies with EGM analysis revealing underlying AF or AT. Keruz et al. showed a higher incidence of ITS in patients having an ICD for a primary indication (range between 9 and 15%), however in our study its 1.8% [16].

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