Programming implantable cardioverter/defibrillators and outcomes

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Abstract

Implantable cardioverter-defibrillators are complex technical devices with a multitude of programming options for the physician. In recent years, numerous randomized trials have been performed to define the optimal programming strategies and have provided valuable insights, especially in primary prevention patients. This article provides an actual overview on the existing evidence on the most important programming features for accurate detection and therapy of ventricular arrhythmias.

Introduction

Implantable cardioverter-defibrillators (ICDs) can prevent sudden cardiac death in patients implanted for primary and secondary prevention. However, inappropriate shock deliveries, most commonly caused by supraventricular tachycardia (SVT), remain a major challenge. Appropriate as well as inappropriate ICD shock delivery is, besides the immediate pain and increase in the rate of hospitalisations, associated with a relevant burden of chronic anxiety and depression [1,2]. In addition to a potentially lower quality of life, appropriate as well as inappropriate shocks are associated with increased mortality [3–7]. The frequently mentioned influence of several shock deliveries on the longevity of ICD generators seems to be insignificant [8–10].

Two major options determine the initiation and the characteristics of ICD therapies: the tachycardia detection settings and the type of therapy delivered, that is, antitachycardia pacing (ATP) or high voltage shocks.

In recent years, several important randomized studies have tried to define the ideal programming approach for accurate rhythm detection and the reduction of inappropriate and appropriate ICD shocks. The major findings focussed on ATP therapy,—even rapid ventricular tachycardia, (which was previously widely regarded as too dangerous) — prolonged detection intervals, ventricular detection rate, and dual chamber tachycardia detection mode. Regrettably, there is as yet no published consensus on the form of a therapeutic guideline on the most appropriate programming of ICDs. Furthermore, in the light of the existing evidence, some common default settings of ICD manufacturers should be questioned, for example, numbers of intervals to detect tachyarrhythmias or sustained rate duration.

The current article will provide an update on the state of evidence for modern ICD programming and focus on different strategies to prevent ICD shocks for ventricular as well as supraventricular tachyarrhythmia in order to reduce morbidity.

Antitachycardia pacing for fast ventricular tachycardia

Generally, fast ventricular tachycardias (FVTs) are regarded as more dangerous. Traditionally, they have been treated by primary shock delivery.

The PainFree I and II trials showed the effectiveness and safety of the application of ATPs (2 sequences of 8-pulse burst pacing train at 88% of the ventricular tachycardia (VT) cycle length) before shock delivery even on FVT with a heart rate of 188-250 beats per minute (bpm) [11,12]. Concerns about efficacy, risk of VT acceleration, and delay of shock therapy have not been confirmed, especially not in modern generation ICDs. In the randomized PainFree II trial, VT acceleration, episode duration,

syncope, and sudden death were similar between arms. With "ATPonFastVT", the efficacy and safety of two sequences of ATP to terminate FVTs has been demonstrated [13]. Prolongation to a 15-pulse ATP in the ADVANCE-D trial proved to be as effective and safe as the 8-pulse ATP, but was not superior [14]. ATPs for FVT are also effective in cardiac resynchronisation therapy defibrillator (CRT-D) patients. There was no difference between biventricular and right ventricle-delivered ATP in the general population [15]. Programming more than 2 ATP attempts for FVT resulted in only a small increase in successful termination of VT [16]. There is some evidence that burst-ATP is more effective for FVT rates of 188-250 bpm than ramp-ATP [17]. All of the above mentioned studies used burst pacing as the primary ATP attempt.

As shown in Figure 1, ATP was successful from between two-thirds and nearly three-quarters of ventricular episodes in all randomized trials.
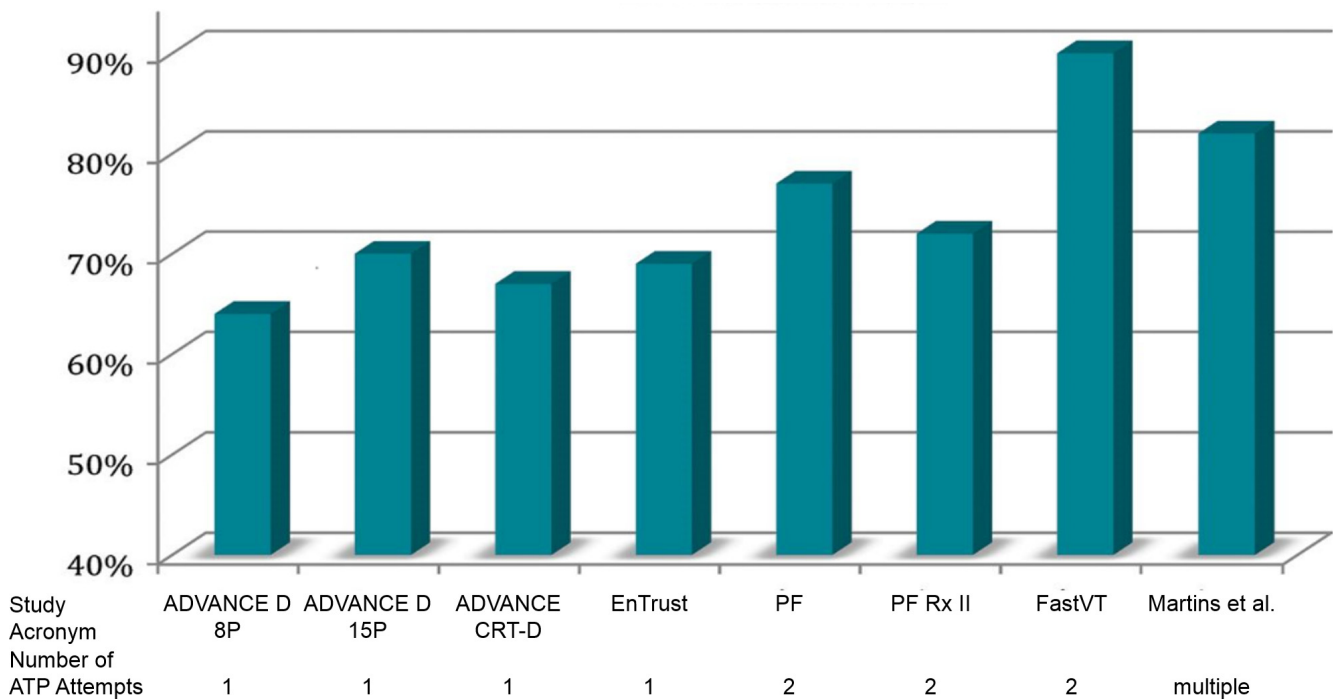
Detection intervals
It has been shown that appropriate ICD therapy delivery exceeds the incidence of sudden cardiac death in control populations by two or three to one [18]. This is partly due to treatment of non-sustained ventricular arrhythmias. Several studies analysed whether increasing the number of intervals of detection (NID) is effective in reducing the burden of unnecessary "appropriate" ICD interventions.

The PREPARE trial evaluated this approach (FVT ≥182 bpm, 30/40 NID) in a non-randomized manner with a cohort of primary prevention patients compared to a historical control group (NID 18/24) and described a significant decrease in ICD interventions for SVT as well as for VT [19]. The RELEVANT study confirmed this finding (12/16 vs. 30/40 NID) for the first time in non-ischemic cardiomyopathy (NICM) patients with CRT-D [20]. The MADIT-RIT followed a similar concept with a delayed therapy (60 sec delay at 170-199 bpm, 12 sec delay at 200-249 bpm, and a 2.5 sec delay at ≥250 bpm) and proved its effectiveness in patients with ICDs or CRT-D devices for primary prevention defibrillator therapy [3]. Recently, the large scale randomized ADVANCE III trial confirmed the superiority of a 30/40 interval detection (compared to 18/24) in patients for primary and secondary prevention, including both ischemic (ICM) and non-ischemic cardiomyopathy

Figure 1. Antitachycardia pacing (ATP) success rates in selected randomized trials

Study Acronym	ADVANCE D 8P	ADVANCE D 15P	ADVANCE CRT-D	EnTrust	PF	PF Rx II	FastVT	Martins et al.
Number of ATP Attempts	1	1	1	1	2	2	2	multiple

Percentage of successful termination of ventricular tachycardia by antitachycardia pacing in different trials and the maximal number of programmed ATP attempts.
ADVANCE D 8P, 8 pulses burst ATP; ADVANCE D 15P, 15 pulses burst ATP; ADVANCE CRT-D, ADVANCE CRT-D study; EnTrust, EnTrust clinical study; PF, PainFree; PF Rx II, PainFree Rx II study; FastVT, ATPonfastVT study. (Adapted according to Schwab JO [38])

(NICM) [21]. The earlier published PREPARE-Trial reported one death, probably related to the study programming [19]. This case was an initially untreated slow VT in the monitor zone which later accelerated to ventricular fibrillation (VF) and was terminated with the sixth high voltage shock therapy. However, in this non-randomized study, there was a trend of reduced mortality in the treated group. The above mentioned MADIT-RIT, ADVANCE III, and RELEVANT trials did not find any association between prolonged arrhythmia detection and increased mortality.

Detection rate
In the non-randomized ALTITUDE REDUCES observation study, the lowest risk of appropriate and inappropriate shock was associated with detection rates ≥200 bpm [22]. In MADIT-RIT, the setting of a high cut-off rate (heart rate of ≥200 bpm combined with a 2.5 sec delay before initiation of therapy) compared with conventional programming (2.5 sec delay at 170-199 bpm and a 1 sec delay at ≥200 bpm) reduced the first occurrence of inappropriate shocks by nearly 50% [3]. Because patients with documented permanent or persistent atrial fibrillation, a major risk factor for inappropriate therapies, were excluded from this study, the benefit of high cut-off programming may be influenced by the inclusion criteria [23, 24].

The DECREASE study, presented at the American Heart Association (AHA) 2013 meeting, tested a "progressive" ICD programming (187/min for VT and 240/min for VF) against a more conventional programming feature (171/min for VT and 214/min for VF) in a primary prevention ICD population with dual and single chamber ICD devices, CRT-Ds and both ischemic and non-ischemic cardiomyopathy. The higher detection rate resulted in a significant reduction of inappropriate (13% *vs*. 6%) and appropriate (15% *vs*. 9%) therapy deliveries (ATP + shock) [25]. These results support the concept of using higher VT and VF detection rates with up to 240 bpm (cycle length 250 ms). This would include additional activation of all SVT discriminators.

In the recently published PROVIDE trial, a combination of higher detection rates, longer detection intervals, empiric ATP and optimized SVT discriminators reduced the 2-year ICD shock rate to 12.4% compared with 19.4% with conventional programming [6]. However, the annual inappropriate shock rate of the study arm (5%) in this trial was higher than in the DECREASE study (2%). The majority of inappropriate shocks in the PROVIDE study were triggered by SVTs [6]. This difference may be explained by the upper limit of SVT discrimination (214 bpm).

It was reported that using the "sustained rate duration" algorithm accounted for 18% of inappropriate ICD therapies [26]. This algorithm can overrule SVT discrimination by enforcing ICD therapy delivery, irrespective of the type of ongoing tachycardia, after a discrete amount of time (e.g. a default setting of 3 mins). Although almost all ICD manufacturers provide this programming feature, it has no significant value in modern ICD programming and should not be applied at all.

It can be summarized that both long detection intervals and increased detection rates for VT/VF are safe. Raising the detection rate of the ICDs not only decreases the rate of false detection with this inappropriate therapy of SVT but also reduces the number of detected VT episodes that do not need ICD intervention.

Subcutaneous ICDs, which are not equipped with the ATP feature, seem to present an increased risk of inappropriate ICD shocks, compared to ICDs with the above mentioned programming. A dual zone programming with activation of SVT discrimination in these devices resulted in a reduced shock rate [27].

Special attention has to be paid to young individuals with primary electrical diseases (e.g. Brugada or long QT syndrome). A single detection zone with a VF zone starting at 230 bpm, including a long detection interval to avoid treatment of self-terminating VTs or Torsades de pointes tachycardia is recommended. In patients with bradycardia induced ventricular tachycardia syndromes (e.g. LQT- Type 3), atrial pacing may be used with a sufficiently high lower rate limit [28].

Detection mode
For a long time, there has been controversy about whether dual chamber (DC) ICDs are superior to single chamber (SC) ICD tachycardia detection. Concerns have been raised that the implantation of DC ICDs might increase complication rates and, with this, mortality in comparison to SC ICDs [29,30]. However, other factors that reflect an impaired cardiac condition may influence the choice of ICD device type. This can be the presence of atrial fibrillation or the need for anti-bradycardia pacing.

Friedman *et al.* showed that DC detection significantly decreases inappropriate detection of SVTs compared with SC programming [31]. In the non-randomized ALTITUDE REDUCES study, dual-zone programming was associated with a reduction in the incidence of appropriate and inappropriate shocks, but only for detection rates <200 bpm [22]. Other studies found no benefits or only small benefits for DC defibrillators [32–34].

The recently presented OPTION-Trial is the first large prospective randomized study that questions whether DC tachycardia detection algorithms reduce the risk of inappropriate shocks in comparison to SC detection [35]. The study used two ATP sequences followed by shocks at tachycardia rates of 170-200 bpm, and only one ATP setting with subsequent shock delivery for tachycardia rates above 200 bpm. The patient follow-up lasted 27 months. DC discrimination (combined with algorithms to minimize ventricular pacing) significantly reduced the risk of first inappropriate shocks to 4.3%, compared to 10.3% in the SC detection group. The annual incidence of inappropriate shocks (2.6% in DC ICDs) was similar when compared to patients in the MADIT-RIT trial, but much lower than in several earlier large-scale trials that reported inappropriate shock rates of up to 11% [3,5,6,19,23,31,32,36].

The DECREASE study also showed an additional benefit for DC detection vs. SC detection, when combined with progressive detection settings to reduce inappropriate shocks [25].

### Impact of ICD shocks on mortality
The connection between appropriate shocks and mortality is well known and might be explained in part by the fact that worsening heart failure promotes the occurrence of VT/VF and consecutively shock delivery. Thus, appropriate ICD shocks probably indicate a risk of heart failure rather than induce heart failure *per se* [5]. A harmful effect of inappropriate ICD shocks on mortality has also been discussed after MADIT II [23,37]. Worsening heart failure, besides increasing the incidence of ventricular arrhythmias, may also lead to more atrial fibrillation and sinus tachycardia that produces inappropriate shock delivery.

However, only appropriate and inappropriate shocks were associated with increased mortality, whereas appropriate and inappropriate ATP was not. The prognostic relevance of the significant reduction in inappropriate and appropriate ATP by high rate programming remains unclear. Concerning the prognosis , the difference between ATPs and shocks has been confirmed by a 2010 meta-analysis (Figure 2) [4].

In the above mentioned studies, neither the use of ATP for FVT nor the prolongation of detection intervals or higher cut-off rates of the VT/VF settings resulted in an increase of syncope events. The MADIT-RIT as well as the PROVIDE study showed that optimization of ICD programming

Figure 2. Differences in effects of electrical therapy type for ventricular arrhythmias on mortality
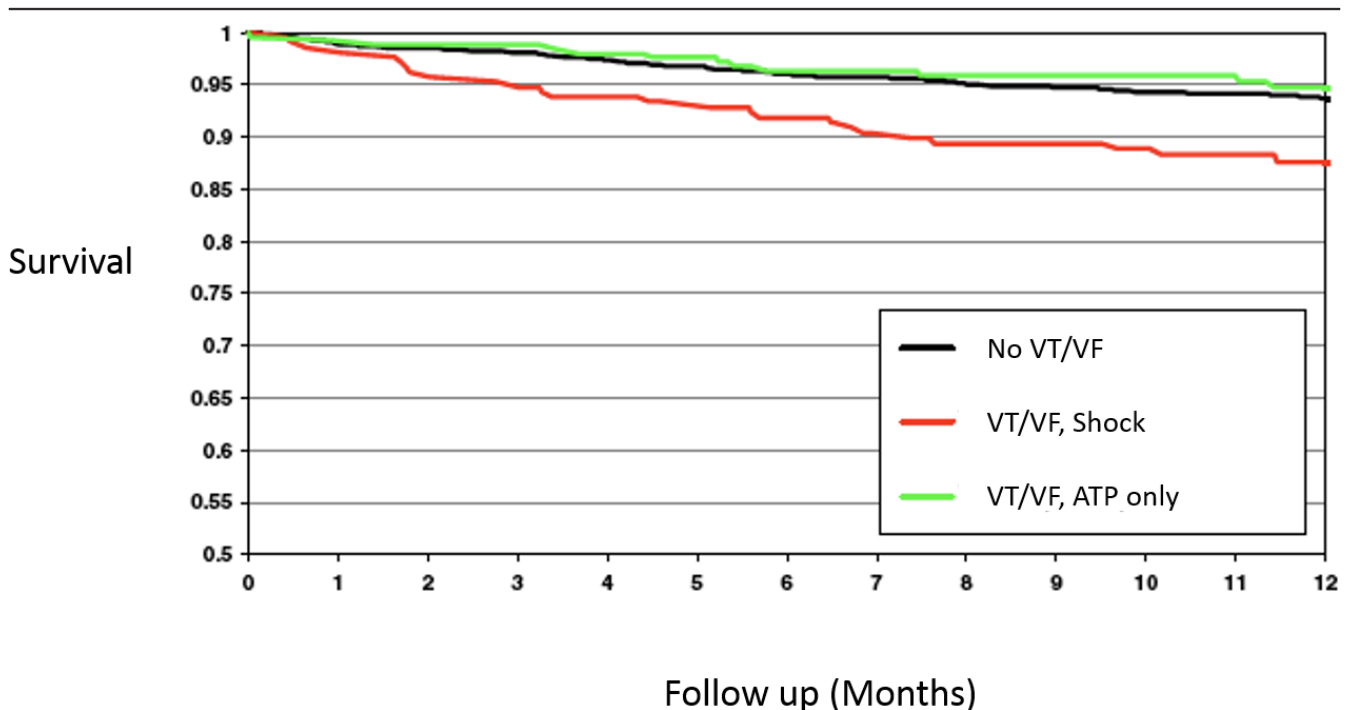
Survival rates by ventricular rhythm and therapy type. Survival among patients who received appropriate defibrillator shocks was significantly worse than among patients with no ventricular tachycardia/fibrillation or among patients treated with ATPs only. The latter groups showed a similar survival. ATP, antitachycardia pacing; VT, ventricular tachycardia; VF, ventricular fibrillation (Adapted according to Sweeney *et al.* [4])

with consecutive reduction of inappropriate shocks was associated with a significant reduction in total mortality. In contrast, the risk of overall mortality in the OPTION and DECREASE studies, which also showed a significantly reduced occurrence of inappropriate shocks, was not reduced. The reason for this remains to be established, but may be due to the different patient populations studied.

In summary, the impact of inappropriate shocks as well as high numbers of ATP on mortality is not completely understood. However, despite the questionable negative effect of inappropriate shocks, every effort should be made to reduce inappropriate ICD intervention by applying new algorithms with prolonged detection intervals and higher VT cut-off rates.

Conclusion

Currently, modern ICD devices provide many antitachycardia programming features, which are able to reduce morbidity and, in some settings, mortality. The EMPIRIC trial failed to prove the superiority of a patient-specific, physician-tailored ICD programming to a standardized empiric ICD programming [36]. This was mostly due to the underuse of ATP therapy, which led to an excess in inappropriate ICD shocks in the physician-tailored cohort.

Particularly with primary prevention ICD indication, avoiding inappropriate and unnecessary shock delivery is mandatory.

In primary prevention patients, the risk of appropriate and inappropriate shocks can be safely reduced by a dual detection zone with VT detection rates above 188 bpm or even ≥200 bpm [3,11–13,22]. The VF zone with shock-only therapy may be programmed as high as 240 bpm, including activation of SVT discriminators [13].

We recommend the use of ATP as the first-line ICD intervention in a FVT-zone ranging from 188 to 240 bpm, preferably with one or two sequences of 8-pulse burst pacing train at 88% of the VT cycle length interval [11–17].

The prolongation of VT detection intervals (e.g. 30/40 NID) further reduces unnecessary ICD intervention due to self-terminating tachycardias without a higher risk of syncope [3,19–21].

The "sustained rate duration" algorithm does not add significant benefit to modern ICD programming and should be turned off by default.

In primary and secondary prevention, activation of DC algorithms seems to be helpful to reduce inappropriate shocks. But it is important to use optimal tachyarrhythmia discrimination, together with optimized anti-bradycardia settings, to avoid unnecessary ventricular pacing, especially in heart failure individuals.

We strongly support patient-adjusted ICD programming recommendations by the European Heart Rhythm Association (EHRA) as well as Heart Rhythm Society (HRS).

Abbreviations

ATP, antitachycardia pacing; bpm, beats per minute; CRT, cardiac resynchronisation therapy; CRT-D, cardiac resynchronisation therapy defibrillator, CRT-D; DC, dual chamber; FVT, fast ventricular tachycardia; ICD, implantable cardioverter/defibrillator; ICM, ischemic cardiomyopathy; NICM, non-ischemic cardiomyopathy; NID, number of intervals to detect; SC, single chamber; SVT, supraventricular tachycardia; VF, ventricular fibrillation; VT, ventricular tachycardia.

Disclosures

Acknowledgments

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