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New Ways to Avoid Unnecessary and Inappropriate Shocks

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1. Introduction

Implantable cardioverter-defibrillators (ICDs) reduce mortality by terminating ventricular arrhythmias (VAs), and it has become widely accepted that this is done by delivering shocks. From the initials of ICD therapy it is known that ICD shocks are associated with reduced quality of life. Most importantly, recent accumulated evidence indicates a clear association among shocks (appropriate and inappropriate) and increased risks of heart failure (HF) and death (Poole et al, 2008). Knowing that, one of our major objectives when dealing with an ICD patient has to be reducing shocks while keeping the certainty that all the VAs are adequately terminated.

When trying to reduce shocks our focus should be dual, inappropriate and unnecessary therapies. Inappropriate shocks are generally defined as those not delivered for ventricular tachycardia (VT) or fibrillation (VF), and may be due to oversensing (double counting of right and left ventricular depolarization, T-wave oversensing, noise, etc) or to atrial arrhythmias with rapid ventricular conduction. Unnecessary shocks are those that could have been avoided using other means of terminating the VT, namely antitachycardia pacing, or allowing the VT to spontaneously finish, in case of non-sustained episodes, prolonging the number of intervals needed to detect and initiate therapy.

Depending on the trial, only 3–35% of shocked episodes were sustained VT/VF that absolutely require a shock for termination. When considering the number of shocks delivered for SVT, T-wave oversensing (TWOS) and lead noise, primary prevention patients may experience more inappropriate shocks than shocks for VT/VF. This highlights the need for improved shock reduction strategies.

During this chapter we will review the most recent developments and algorithms to avoid inappropriate and unnecessary shocks.

2. Where do we stand now?

2.1 The problem of inappropriate and unnecessary shocks

ICD therapy has clearly shown its benefit in reducing sudden death and is now an accepted therapy, with increasing number of patients receiving a device. One of the most serious problems with this therapy is the rate of unnecessary and inappropriate shocks, that ranges between 10 and 25% on different studies (Figure 1), with the added limitation of many trials not reporting this data.

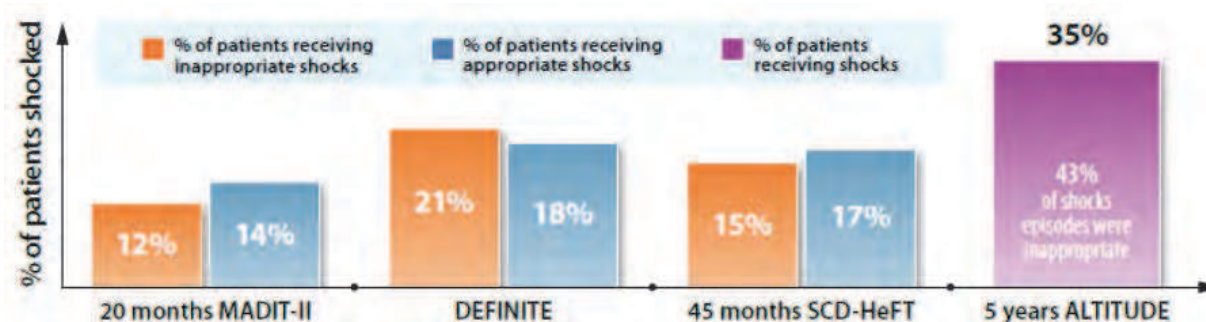


Fig. 1. Rate of inappropriate therapy (in orange) in some of the principal ICD trials.

Multiple studies have reported that ICD shocks are associated with several negative outcomes, both in the short term -such as increased troponin levels, decreased cardiac index or acutely reduced contractility-, as in the long term-increasing hospitalization rate or reducing quality of life. Inappropriate shocks might also be proarrhythmic in up to 10% of episodes and also reduce battery life.

Moreover, recent evidence indicates a clear association among appropriate shocks, inappropriate shocks, and increased risks of heart failure and death (Figure 2, reproduced from Poole et al, 2008). These data also demonstrates that the higher the number of shocks, the higher the death hazard ratio. An important corollary is that, even if it is impossible to completely avoid shocks, any reduction we obtain translates into lower hospitalization and death risk.

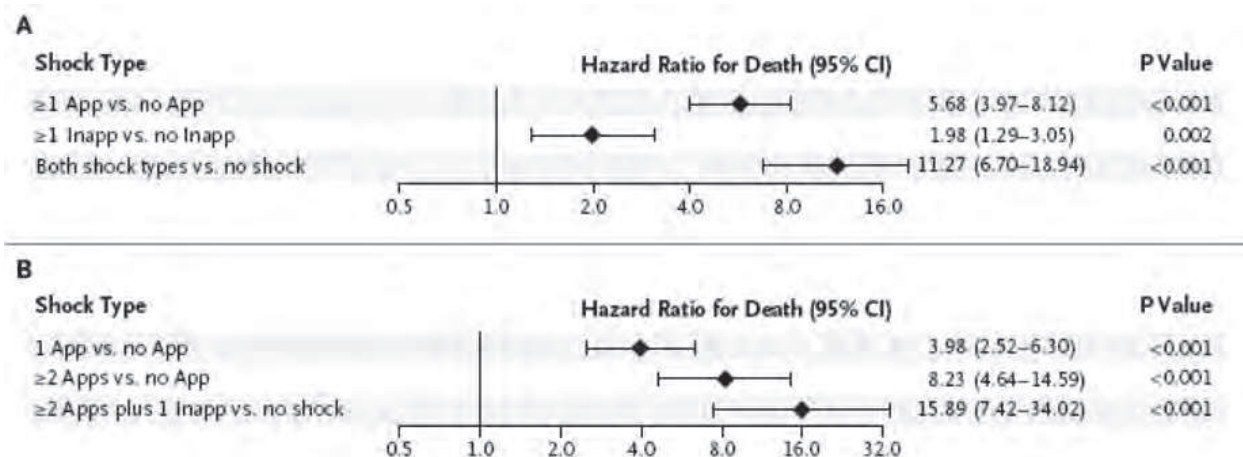


Fig. 2. Hazard Ratios for the association of ICD shock with the risk of death, according to shock type. Panel A shows the hazard ratios for the association of shock types (appropriate, inappropriate or both) with the risk of death. Panel B shows the adjusted hazard ratios for the risk of death according to the number of appropriate or inappropriate shocks.

From the SCD-HeFT we know that death from all causes was increased among patients who received an appropriate shock by a factor of nearly 6, with 30% of these deaths occurring within 24 hours after the first appropriate shock. After exclusion of these patients (in whom an appropriate shock was simply a harbinger of imminent death), appropriate shocks were still associated with a risk of death that was increased by a factor of 3. Data from MADIT II trial (Daubert et al, 2008) also clearly showed how shocks are associated with increased risk of all-cause mortality (by a factor of 3 after an appropriate ICD shock).

It is unclear whether this is due to the ventricular arrhythmia itself or to the shocks, but evidence is increasingly showing that ICD discharges are harmful per se. Pooled data from PainFREE I & II, EMPIRIC and PREPARE (Sweeney et al, 2010) has clearly shown the impact on survival depending on the type of therapy delivered by the ICD (Figure 3), demonstrating that antitachycardia pacing (ATP) termination of the VA can reduce the risk.

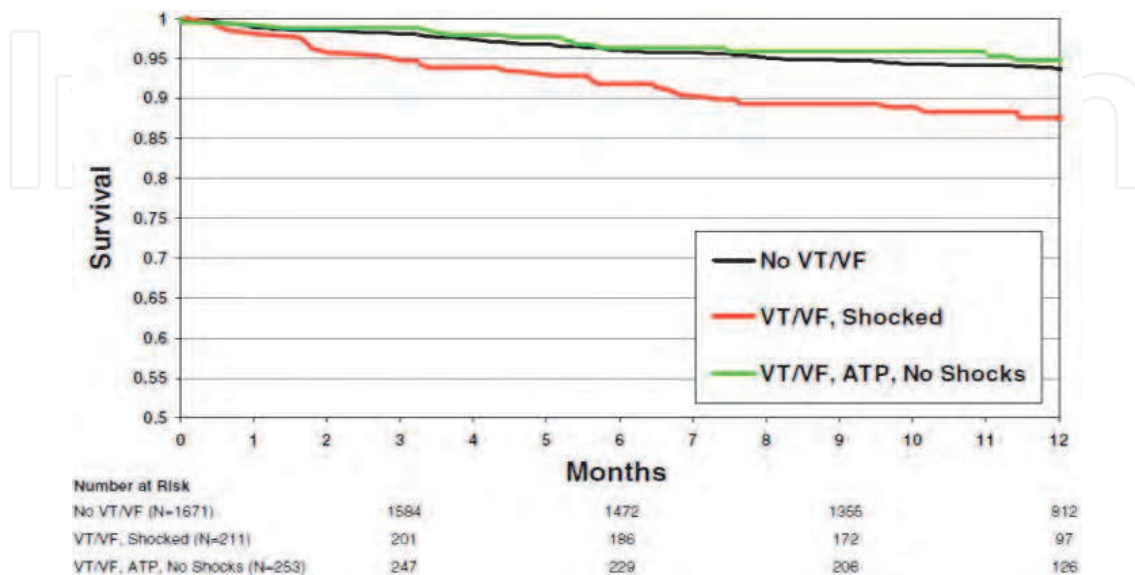


Fig. 3. Survival rates by rhythm and therapy type. Survival among patients treated only with ATP was identical to that in patients with no VT, whereas survival among patients who received shocks was significantly worse (reproduced from Sweeney et al, 2010).

An important issue to be considered is the high rate of inappropriate therapies in published studies, ranging from 10 to 25%. Benign events such as atrial fibrillation, supraventricular tachycardia (SVT), extra-cardiac noise, intracardiac oversensing, and nonsustained VT/VF are inappropriately treated with shocks by the ICD. Inappropriate therapy delivery remains the most frequent complication in patients with ICDs resulting in psychological distress, proarrhythmia, and battery life reduction. We could think that delivery of inappropriate shocks is something overcome in nowadays trials, but recent data from the MADIT II trial (Daubert et al, 2008) shows that one or more inappropriate shocks occurred in 83 (11.5%) of the 719 MADIT II ICD patients. Inappropriate shock episodes constituted 184 of the 590 total shock episodes (31.2%).

Atrial fibrillation was the most common trigger for inappropriate shock (44%), followed by supraventricular tachycardia (36%), and by abnormal sensing (20%). Due to the fact that the majority of inappropriate shocks are delivered because of a supraventricular rhythm incorrectly classified by the device (see Figure 4), nowadays most devices on the market contain some form of SVT discriminator.

Other causes of inappropriate therapy include oversensing of diaphragmatic potentials or myopotentials, T-wave oversensing, double or triple counting of intracardiac signals, lead fractures or header connection problems, lead chatter or noise, and electromagnetic interference. Strategies to reduce inappropriate therapy using device programming rely on the ability to distinguish supraventricular and atrial arrhythmias from ventricular tachycardia. Avoiding therapy for nonsustained ventricular arrhythmias and increasing the role of antitachycardia pacing to terminate ventricular tachycardia are key approaches to reducing shocks for ventricular arrhythmias.

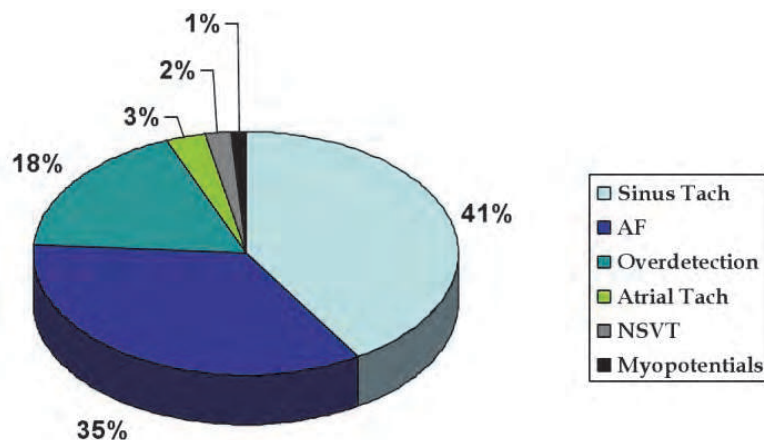


Fig. 4. Main causes of inappropriate shocks in ICD patients.

2.2 Algorithms to avoid inappropriate shocks

Although dual-chamber discrimination algorithms are frequently based on measurements of AV association, algorithms used in single-chamber ICDs focus on frequency-related tachycardia characteristics (beat-to-beat interval variability -rate stability- and abruptness of tachycardia initiation -onset-) and electrogram (EGM) morphology.

2.2.1 Sudden onset

Initially developed to avoid misclassification of sinus tachycardia as VT, the algorithm is based on the degree of prematurity of the first tachycardia cycle compared to the previous ones. If a tachycardia episode is declared, the device measures the RR intervals prior to the episode looking for the shortest RR interval. Then it compares this shortest RR interval with the RR interval initiating the episode. If the difference is above the programmed, the sudden onset criterion is satisfied. If the difference is below the programmed one, a non-sudden onset will be declared and therapy will be inhibited until the end of the sustained rate duration period if activated.

2.2.2 Stability

Measures the variability between RR intervals during tachycardia and was developed to avoid inappropriate shocks due to fast atrial fibrillation, a typically unstable rhythm. The device measures the stability during the programmed duration of the episode. If duration is satisfied, the mean difference in stability between consecutive RR intervals is compared to the programmed one. If stability is below the programmed one, the device declares the episode stable. If stability is above the programmed one, the device declares the episode unstable and therapy will be inhibited. Then it will continue to measure stability as long as the rate criterion is satisfied. If tachycardia becomes stable or the sustained rate duration period is satisfied, therapy will be initiated if the rate persists above the programmed cut-off rate.

Sudden onset carries a greater risk of error, since it analyses the rhythm only once upon initiation. In contrast, stability constantly reanalyzes the rhythm. These two algorithms have been traditionally underused due to concern of misclassification of a true VT as a non-shockable rhythm by the device, thereby continuously withholding a necessary therapy. However, several publications have demonstrated that programming sudden onset and stability detection criteria with a sustained rate duration safety net for triggering tachycardia

therapy results in appropriate device management in most patients with supraventricular and slow ventricular tachycardias (Brugada et al, 1998).

Recent data from the MADIT II trial (Daubert et al, 2008) showed that the stability detection algorithm was programmed less frequently in patients receiving inappropriate shocks (17% vs. 36%, $p: 0.030$), so we still have room to improve ICD programming by using consolidated algorithms.

2.2.3 Morphology algorithms

Morphology algorithms are the only single-chamber discriminators capable of distinguishing VT from abrupt-onset SVTs with regular V-V intervals, such as atrial flutter or atrial tachycardia. When integrated into dual-chamber algorithms, morphology algorithms may enhance discrimination of tachycardias with 1:1 AV relationships and detection of VT during atrial fibrillation (Swerdlow et al, 2002).

All morphology algorithms share general steps. (1) Create a template electrogram of baseline rhythm. (2) Construct a quantitative representation of this template. (3) Record electrograms from an unknown tachycardia. (4) Time align template and tachycardia electrograms. (5) Construct a quantitative representation of each tachycardia electrogram. (6) Compare the representation of each tachycardia electrogram with that of the template to determine the degree of morphologic similarity of the corresponding electrograms. (7) Classify each tachycardia electrogram as a morphology match or nonmatch with the template. (8) Classify the tachycardia as VT or SVT based on the fraction of tachycardia electrograms that match the template. The major differences among morphology algorithms are the electrogram source(s), methods of filtering and alignment, and waveform features used to compare tachycardia and template electrograms.

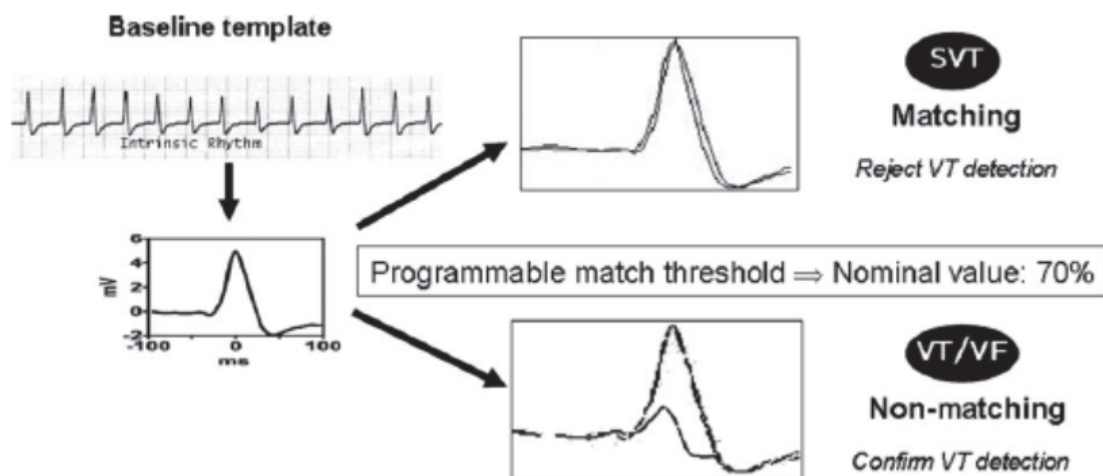


Fig. 5. Morphology analysis of tachycardia EGMs using the wavelet transform (Medtronic) The wavelet transform of the baseline rhythm template EGM is constructed and stored. When tachycardia is detected, each of the last eight tachycardia EGMs preceding detection is aligned with the template EGM. The wavelet transform of each EGM is performed and a match-percent score that describes the degree of morphological similarity to the template is calculated in real time. If the matching score is higher than the programmable threshold, VT is rejected. If the matching score is lower than the threshold, VT is confirmed and corresponding therapy initiated.

The Rhythm ID feature in Boston Scientific ICDs uses the vector timing and correlation algorithm -which incorporates both timing as well as morphological information- for supraventricular tachycardia discrimination. Clinical trials demonstrated high sensitivity and specificity of this feature in discriminating between ventricular tachycardia and supraventricular tachycardia. On detection of the unknown rhythm (when the ventricular tachycardia rate detection criteria is met), the vector timing and correlation algorithm compares the unknown rhythm beat-by-beat to a stored template of normal sinus rhythm. First, the algorithm aligns the signals coming from the near field and the far field EGMs. After that, the feature correlation coefficient computed over more than 8 points in the time-aligned signals is used for the comparison (see Figure 6).

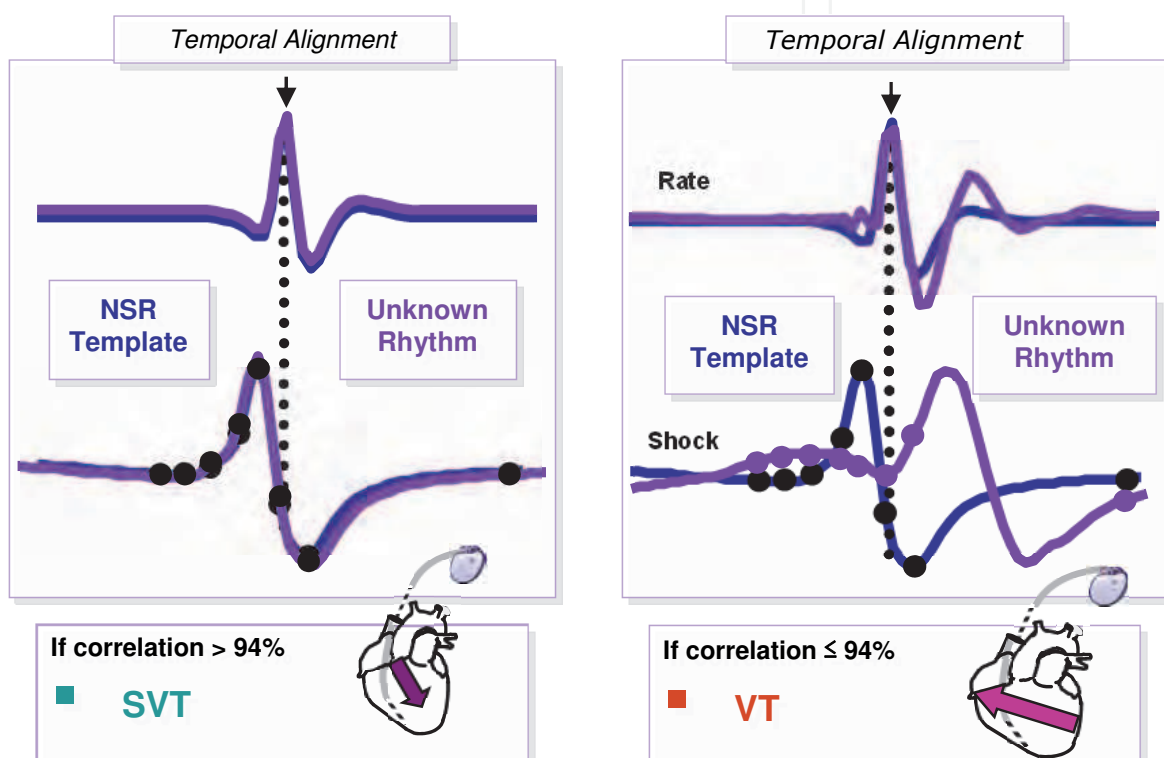


Fig. 6. Schematic representation of Rhythm ID algorithm functioning.

There are several limitations of morphology algorithms, such as:

- Truncation of EGMs that exceed the programmed range of the algorithm. Truncation both removed some electrogram features for analysis, and altered the timing of the highest peak used for alignment. It is, therefore, recommended to verify that recorded EGMs exceed 3 mV and are not clipped.
- Miopotential interference.
- Alignment errors: algorithm aligns electrograms in time based on their highest peaks. If an electrogram has two peaks of nearly equal amplitude, minor variation in their relative heights may result in an alignment error.
- Morphology algorithms may be applied in patients with baseline intraventricular conduction delays. However, rate-related aberrancy during rapidly conducted atrial fibrillation is likely to be misclassified.

As we stated in a recent publication (Toquero et al, 2009), probably morphology algorithms as an SVT discrimination criteria should be considered as an effective tool when used alone

but, in order to maximize the benefits, a lower limit of 500 ms and the concomitant use of other discrimination criteria or combination with a high rate time-out feature should be considered. When programming several discriminators together, the more we use the better the specificity for SVT but carries a greater risk of underdetecting VT, so once again we have to individualize and tailor the programming to each patient.

2.2.4 Dual chamber detection

Dual chamber devices allow for ventricular and atrial rate analysis during tachyarrhythmias, as well as establishing a relationship between them. As a concept, if the rhythm is faster in the ventricular chamber the device will deliver therapy. At the very beginning, it was expected a dramatic reduction of inappropriate shocks due to atrial tachyarrhythmias compared to single chamber devices, but finally it did not turn out to be that way due to atrial undersensing problems or difficulties programming the algorithm.

Evidence recently published (Ricci et al, 2009) shows that dual-chamber ICDs compared to single-chamber ICDs reduced the incidence of an endpoint composed by permanent AF, AF-related hospitalizations, and ICD shocks deemed inappropriate due to AF misclassification. So dual chamber detection helps to improve SVT discrimination but probably this is not enough to justify the implantation of a DDD device on this sole aim.

There are other algorithms intended to adequately discriminate SVT from true VT. Detailed description of PARAD+ from Sorin or SMART from Biotronik (using dual chamber discrimination) is beyond the aim of this chapter. Briefly, the PARAD+ combines several features of the tachyarrhythmia that are analyzed and inputted into a branching algorithm. It is the only algorithm that uses the chamber of acceleration to differentiate atrial from ventricular arrhythmias. It incorporates a feature termed VT long cycle, which monitors for longer intervals when the rhythm is classified as stable. Unlike VT, occasional longer RR intervals are common in rapid AF. SMART algorithm, like St Jude Devices, relies on a rate branch algorithm for discrimination. If the RR interval is shorter than the PP interval ($V > A$), the rhythm is considered VT.

For further description of different algorithms of several manufacturers, we strongly recommend the recent review by Mansour and Khairy, PACE 2011.

3. Ways to avoid shocks and new strategies

Even though it is plausible that shocks somehow have an adverse effect on myocardial function, this is unlikely to be a major factor. It is much more likely that the occurrence of a ventricular arrhythmia that causes a shock is signalling a meaningful change in the patient's clinical status. The important message is that the first occurrence of shocks is not a random event in an otherwise stable clinical course but a sign of clinical deterioration in the underlying disease process. Possible causes of shocks are to be considered, including a worsening of heart failure and myocardial ischemia.

There are several complementary ways to avoid both inappropriate and unnecessary shocks:

3.1 Optimize medical therapy, look for ischemia and other triggers, and early ablate clinical VTs

Antiarrhythmic medication is administered in patients with an ICD for a number of reasons. Most importantly, drug therapy can reduce or eliminate ICD shocks by suppressing

ventricular arrhythmias, or by slowing VT to such a degree that it can be terminated with programmed ATP. In addition to the suppression of such “appropriate” shocks, antiarrhythmic therapy may suppress the “inappropriate” shocks precipitated by supraventricular arrhythmias (primarily atrial fibrillation). In routine practice, adjunctive antiarrhythmic therapy is administered to between 49% and 69% of patients who have an ICD.

The Optimal Pharmacological Therapy in Cardioverter Defibrillator Patients (OPTIC) trial was a randomized clinical trial evaluating the efficacy of amiodarone plus β -blocker and sotalol versus β -blocker alone for reduction of ICD shocks (Connolly et al, 2006). In 412 patients studied, mainly secondary prevention, with a median follow up of 359 days, the authors demonstrated that shocks occurred in 41 patients (38.5%) assigned to β -blocker alone, 26 (24.3%) assigned to sotalol, and 12 (10.3%) assigned to amiodarone plus β -blocker (Figure 7).

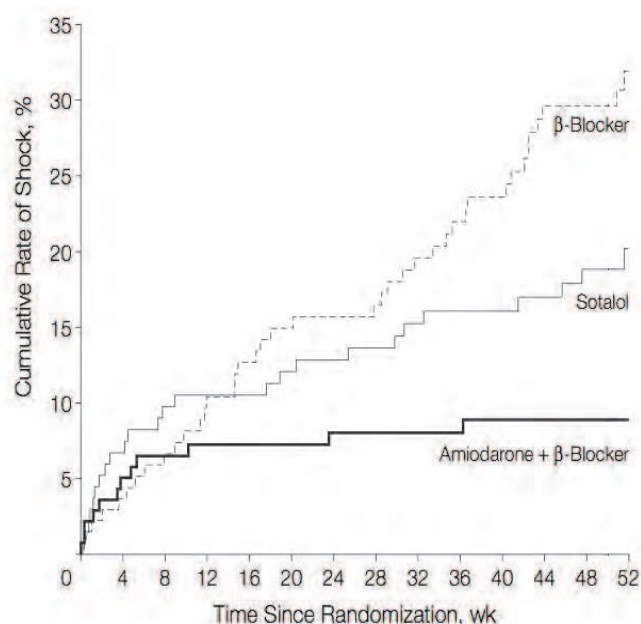


Fig. 7. Cumulative rate of shocks for the three treatment groups (β -blocker, Sotalol and Amiodarone+ β -blocker) by time since randomization (Reproduced from Connolly et al, OPTIC trial).

The OPTIC study applies primarily to ICDs placed as secondary prevention, in which sustained ventricular arrhythmias have been clinically observed. There are less data to support the use of antiarrhythmic agents in patients with prophylactic or primary prevention ICD therapy and this group appears to have less frequent need for such therapy; thus, empirical antiarrhythmic therapy cannot be recommended for this setting. For patients who receive an ICD for secondary prevention, one could argue for empirical initiation of amiodarone or sotalol. However, such pharmacological intervention has important trade-offs. Adverse lung and thyroid effects were common among patients receiving amiodarone over just 1 year, and it can be expected that toxicity would be even more common over longer follow-up. In the OPTIC study, these and other adverse effects resulted in the discontinuation of 18% of those patients receiving amiodarone and 24% of those patients receiving sotalol. As noted by the authors, most patients taking β -blocker alone will not receive an ICD shock and

could avoid the inconvenience, cost, and risk of antiarrhythmic therapy. At present, all patients with an ICD who tolerate such therapy should receive a β -blocker.

Amiodarone is known to be effective in the prevention of ventricular arrhythmias; however, SCD-HeFT itself finally put to rest the notion that amiodarone could improve survival among patients with heart failure. Addition of amiodarone or substitution with sotalol cannot be advocated for all patients and should be considered on an individual basis.

Triggers of VT include electrolyte abnormalities (e.g., hypokalemia, hypocalcaemia, and hypomagnesaemia), ischemia, inflammation, and sleep apnea. It can also be triggered by drugs (sympathomimetic agents, digitalis toxicity, drugs prolonging the QT complex, etc.). Hypokalemia is the most important arrhythmia trigger clinically, followed by hypomagnesaemia. Hyperkalemia may also predispose to VT and VF, particularly in patients with structural heart disease. Electrolyte disturbances and ischemia are frequent VT triggers in ICD patients with reduced ejection fraction and heart failure. The greater prognostic significance of appropriate ICD shocks in patients with ischemic heart failure makes revascularization another possible intervention; however, there are currently no prospective data to suggest that this will improve prognosis. So, when facing a patient receiving a shock, we should be aware of all the possible triggers of VTs, actively look for them and make every effort needed to control these triggers.

The Ventricular Tachycardia Ablation in Coronary Heart Disease (VTACH) study (Kuck et al, 2010) assessed the potential benefit of catheter ablation before implantation of a cardioverter defibrillator in 110 patients that were randomized to receive catheter ablation and an ICD or ICD alone. They showed that time to recurrence of VT or VF was longer in the ablation group (median 18 months) than in the control group (5 months). At 2 years, estimates for survival free from VT or VF were 47% in the ablation group and 29% in the control group. The authors conclude that prophylactic VT ablation before defibrillator implantation seemed to prolong time to recurrence of VT in patients with stable VT, previous myocardial infarction, and reduced LVEF and should therefore be considered before implantation of an ICD in such patients.

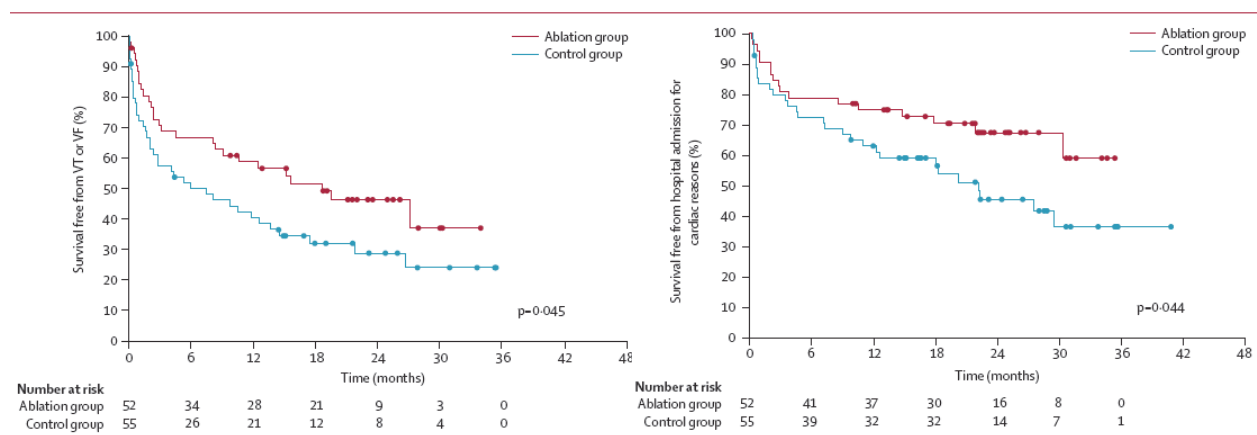


Fig. 8. Data from the VTACH trial. On the left, Kaplan Kaplan-Meier curves for survival free from VT or VF. On the right, estimates of survival free from hospital admission for cardiac reasons (Reproduced from V-TACH trial).

According to the latest guidelines of the American Heart Association, the American College of Cardiology, and the European Society of Cardiology, catheter ablation is indicated as adjunctive therapy in selected patients who have an ICD and who receive multiple shocks as a result of sustained ventricular tachycardia that is not manageable by reprogramming of the ICD or drug therapy.

Some evidence already exists on prophylactic ablation in ICD patients to prevent VTs and shocks. The SMASH-VT trial (Reddy et al, 2007) included 128 ischemic patients that were ICD implanted for spontaneous ventricular tachycardia or fibrillation. They were randomly assigned to defibrillator implantation alone or defibrillator implantation with adjunctive catheter ablation. Ablation was performed with the use of a substrate based approach in which the myocardial scar is mapped and ablated while the heart remains predominantly in sinus rhythm. During a mean follow-up of 22.5 ± 5.5 months, twenty one patients assigned to defibrillator implantation alone (33%) and eight patients assigned to defibrillator implantation plus ablation (12%) received appropriate ICD therapy. So the authors conclude that prophylactic substrate-based catheter ablation reduced the incidence of ICD therapy in patients with a history of myocardial infarction who received ICDs for the secondary prevention of sudden death.

3.2 Optimize device programming

3.2.1 Tailored programming for each patient

The first way to avoid inappropriate shocks is to program the device considering patient characteristics such as age, underlying myocardial pathology, primary or secondary indication and concomitant arrhythmias or, at least, risk of future development. For instance, previous investigations have demonstrated substantial differences in frequency, rate, and mechanisms of tachycardia observed in patients with ICDs implanted for primary versus secondary prevention indications. The primary prevention patient population has been reported to have a lower incidence of ventricular arrhythmias compared with secondary prevention patients. Consequently, a higher proportion of ICD therapies in primary prevention patients could be due to inappropriate detections and therapies primarily due to arrhythmias such as sinus tachycardia and atrial fibrillation.

3.2.1.1 Cut-off rates

ICD recipients with primary compared to secondary prevention indications experience faster ventricular tachyarrhythmias, with average rates of 200 versus 153 beats per minute (bpm), respectively. In contrast, clinical supraventricular tachycardia (SVT) usually ranges between 160 and 180 bpm. Also patients under antiarrhythmic drug therapy experience slower tachycardias. For patients with secondary prevention indications, a safety margin of 30–60 ms between the slowest spontaneous or induced VT and the cut-off rate has been recommended (Mansour and Khairy, 2011).

If the VT rate is unknown or if a primary prevention patient is receiving antiarrhythmic therapy, an empirically programmed rate of 150–160 bpm appears reasonable. A higher rate of 170–175 bpm could be used in youngest patients, typically suffering from channelopathies. Modern devices allow us to program different detection zones (Ventricular Fibrillation-VF, Fast Ventricular Tachycardia-FVT and Ventricular Tachycardia-VT). Depending on ICD indication we can select one, two or the three of them, with different detection criteria and therapies on each one. In certain patients could be interesting to program a detection zone with no therapy, using the device to monitor the occurrence of slow tachycardias.

Limiting the use of SVT discriminators for tachycardias of 188 bpm or slower results in inappropriate ICD therapy since 22–44% of SVTs conduct faster than 188 bpm. Since the majority of SVTs leading to ICD shock have rates less than 230 bpm some authors (Volosin et al, 2011) have proposed the use of SVT discriminators for rates up to 230 bpm. Our usual policy is to program it up to 220 bpm.

3.2.1.2 Timers to override discriminators

Sustained rate duration (SRD; Boston Scientific, Natick, MA, USA), High rate time out (HRT; Medtronic, Minneapolis, MN, USA), SVT time out (St. Jude Medical, St. Paul, MN, USA), and sustained VT (Biotronik GmbH, Berlin, Germany) are timers used to override discriminators. Once the programmed timer elapses, therapy is delivered even if it had been appropriately withheld.

The literature suggests that this safety feature is of little value, especially for dual chamber devices. A reasonable option could be to activate the overriding timer while extending its nominal duration (in our opinion to, at least, 3 min).

3.2.1.3 Detection time/intervals

Classifying an arrhythmia as sustained is a somewhat arbitrary balance between overtreating otherwise self-terminating arrhythmias and delaying therapy for potentially unstable arrhythmias. The trend has been toward programming longer detection times, due to the fact that nominal detection settings are likely excessively conservative, erring on the side of overtreating nonsustained VT.

Recent publications (Wilkoff et al, 2008) have shown that adequately programming detection criteria, increasing the number of RR intervals needed to detect the arrhythmia and thus allowing for non-sustained VTs to spontaneously terminate (30 of 40 beats on this study), reduce number of shocks without increasing risk of syncope or serious adverse events.

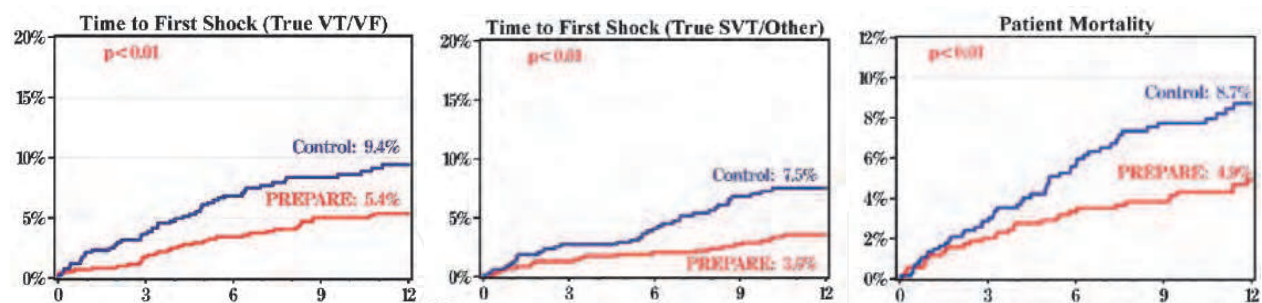


Fig. 9. Kaplan-Meier curves show the percentage of patients in each study cohort receiving a first shock during the first 12 months of follow-up due to: (left) true VT/VF; (middle) true SVT/other; on the right, Kaplan-Meier curves show the mortality rate (reproduced from Wilkoff et al, PREPARE study).

3.2.2 Improve correct detection

3.2.2.1 SVT discriminators

The main arguments against systematically enabling discriminators are their reliability and associated risks of underdetecting VT. With single chamber discriminators, underdetection occurs in 0–0.4% of VT episodes with stability, 0–2% with morphology, and 0.5–5% with

onset criteria. For dual-chamber devices, VT underdetection has been reported in 0.6–1% of events.

Discriminators appear most useful in patients with secondary prevention ICDs or under antiarrhythmic drug therapy, since lower programmed cut-off rates expose them to a higher risk of inappropriate therapy for SVT. We currently program discriminators up to a rate of 220 bpm with a high-rate timer along with discriminators. In Medtronic's most recent ICD model (Protecta™), the SVT limit is nominally programmed to 230 bpm within the VT zone. For Boston and Sorin devices, discriminators apply to the entire VT zone.

In the event of inappropriate VT detection, reported values of onset, stability, AV association, and/or morphology should be examined, when available, to guide further programming to optimize cut-off values.

3.2.2.2 Algorithms to avoid shocks due to noise or T wave oversensing

New algorithms capable of increasing specificity without affecting sensitivity for VT detection have been developed by different ICD manufactures. Oversensing of T-waves and noise due to lead problems (loose set-screw or lead fractures) are among the leading causes of noise-driven VF detection.

One of these new algorithms recently introduced is intended to reduce inappropriate shocks caused by fractures of implantable cardioverter-defibrillator leads (Swerdlow et al, 2008). This lead-integrity algorithm (LIA), which can be downloaded into presently implanted Medtronic implantable cardioverter-defibrillators, alerts the patient and/or physician when triggered by either abnormally high impedance or sufficient evidence of nonphysiological, rapid oversensing. Once the LIA is triggered, it sets the programmed number of intervals to detect (NID) at 30 of 40 intervals to reduce inappropriate shocks, an audible alert sounds immediately and every 4 hours thereafter, and transmits a wireless, internet-based alert if enabled. The authors demonstrated on 15970 patients with Fidelis leads and 95 other fractured leads that increasing the NID reduced inappropriate shocks and the LIA provided at least a 3-day warning of inappropriate shocks in 76% of patients.

A new T-wave discrimination algorithm by Medtronic analyzes the sensing electrogram for alternating patterns of amplitude and frequency content by comparing the standard sensing signal to a first-order difference signal that attenuates low-frequency content dominating T-waves. Other functions like SenseAbility available in St Jude Medical ICDs allows avoidance of TWOS by means of four key parameters: Threshold start, decay delay, maximum sensitivity and refractory periods (see Figure 10 for explanation). The algorithm adjusts the sensitivity setting based on intrinsic signals and changes sensitivity on every beat so it adjusts as the patient's intrinsic activity changes.

The new lead noise oversensing algorithm available in Medtronic devices analyzes the far-field EGM (e.g., right ventricular (RV) coil-can) in an amplitude measurement window centered around each event sensed on the near-field EGM (e.g., RV tip-RV ring). The concept behind RV Lead Noise Discrimination algorithm is that lead noise oversensing is typically isolated to the near-field EGM (RVtip-RVring sense channel). Therefore, a far-field electrogram signal (Can to RV coil or RV coil to superior vena cava -SVC-) is used to confirm that VT/VF senses on the near-field electrogram are not present on the far-field signal in the case of lead noise (see Figure 11). Oversensing due to a lead or connection problem is identified when the peak to peak amplitudes seen on the far field signal have a large disparity, indicating that these amplitude measurement windows are sensing both R-wave as well as absence of R-waves (isoelectric potentials).

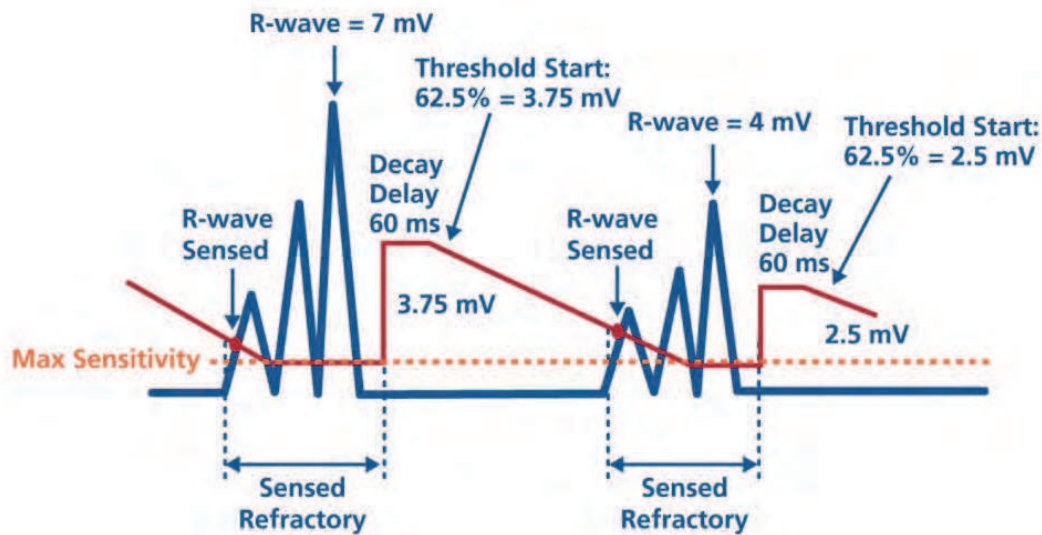


Fig. 10. SenseAbility algorithm: Threshold Start is a programmable percentage of the previous peak amplitude. Decay Delay “delays” the time before the linear decay occurs (60 ms on this example). Max Sensitivity defines the most sensitive level the ICD can reach.

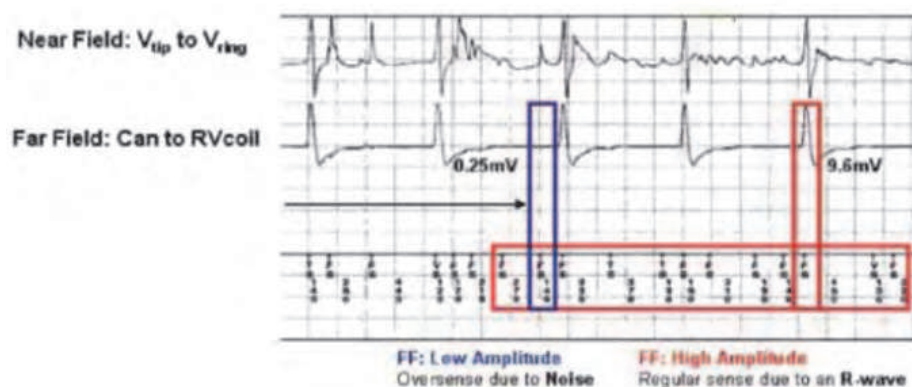


Fig. 11. Example of lead noise oversensing algorithm: Top line, near field EGM between tip to ring. Middle line, far field EGM between can to RV coil. Bottom line: marker channel. As the detection of noise continues, the algorithm withholds detection. Timeout is available to ensure that detection is not withheld for long periods of time.

3.2.3 Shock reduction strategies

Several recent publications have consistently demonstrated the usefulness of antitachycardia pacing and shock withholding for supraventricular rhythms, oversensing, and nonsustained ventricular tachycardia. During the following pages we will further discuss the evidence supporting this approach, as well as new developments incorporated in the newest devices to ensure correct VT diagnosis and delivery of shock only when needed.

3.2.3.1 Antitachycardia pacing

This function allows terminating VTs by pacing faster than the ventricular rate, thus blocking the re-entrant circuit sustaining the tachycardia. ATP is painless and much less

associated with atrial tachycardia induction. Nevertheless, it may accelerate the VT or even transform it into VF.

There are several different types of ATP, basically referred to as burst and ramps. Burst means that all the stimulation pulses given during the ATP maintain the same interval whereas ramp means that the pacing interval decreases from one beat to the following one (Figure 12).

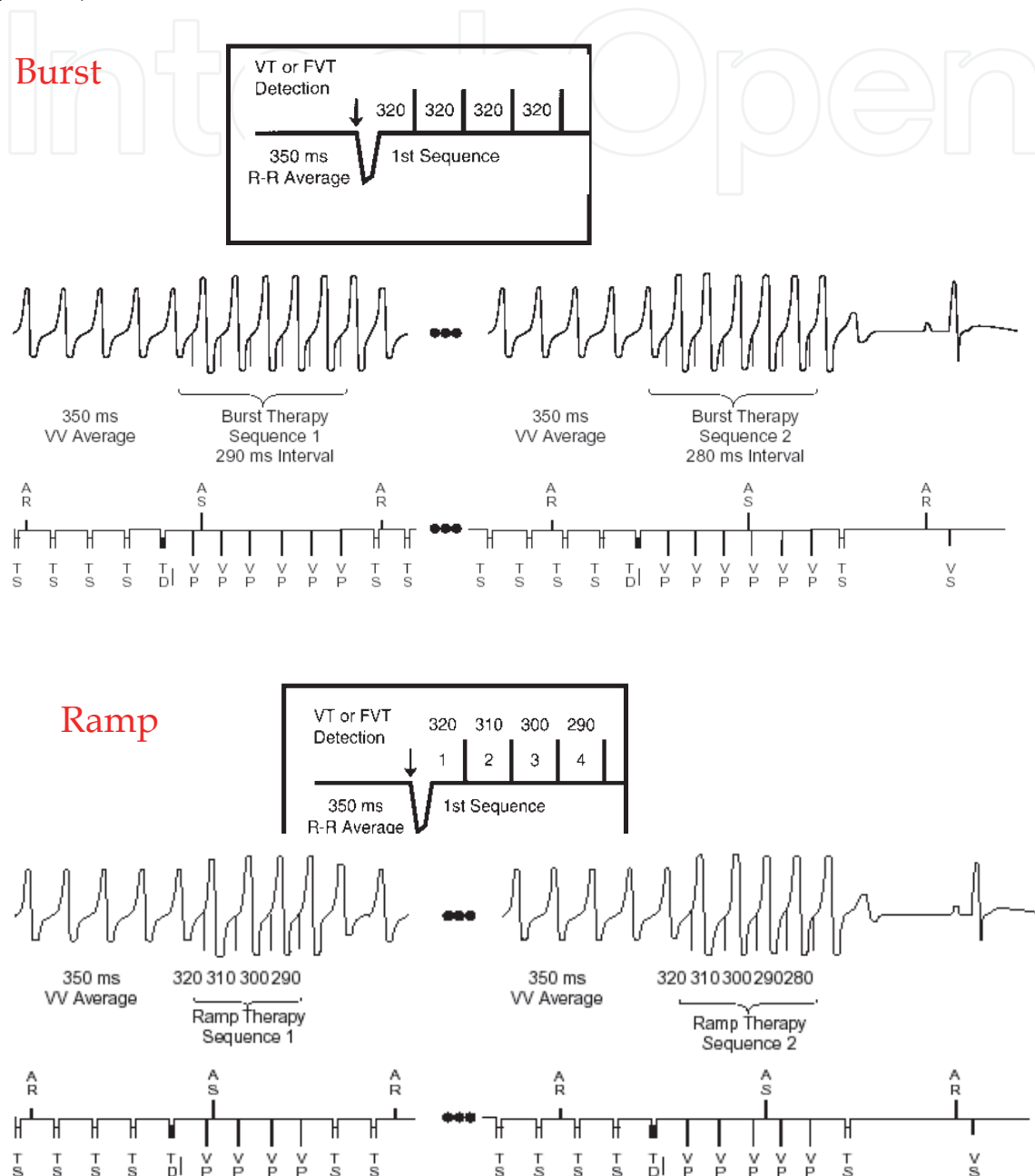


Fig. 12. Top. Burst pacing: after VT is detected, burst pacing is initiated. 2 sequences of 6 beats each are programmed, with a 91% coupling interval and 10 ms decrement between both. Bottom. Ramp pacing: only 2 sequences programmed, first one 4 beats, second one of 5. During ramp pacing, the 10 ms decrement programmed decreases each pacing interval in the same sequence.

ATP effectiveness is related to tachycardia cycle length, being higher in slower VTs and decreasing for VTs faster than 200 bpm (Ormaetxe-Merodio et al, 2008). Several publications have compared effectiveness and safety of both types of ATP, without finding statistically significant differences for slow VTs. Nevertheless, the PITAGORA ICD trial (Gulizia et al, 2009) randomized patients to one burst (eight stimuli, 88% of the cycle length) versus one ramp (eight stimuli, 91% cycle length) in the FVT zone (188–250 bpm). Bursts had a significantly higher success rate than ramps (72% vs 52%) for fast VTs, with a trend toward less acceleration (2.3% vs 7.4%).

There are some ICD models that memorize therapy effectiveness but it is known that failure of an ATP sequence does not predict subsequent failure. For Medtronic devices, in case it does not appear in four consecutive episodes, the device annulates it and, for the next episode, jumps directly to the next therapy programmed (Smart mode). Biotronik has a programmable option: ATP optimization. A successful ATP setting is memorized by the ICD and delivered as the first therapy for future events.

Concerning the number of pulses to use and stimulation rate, published data is scarce. Peinado et al, 1998, compared the efficacy and safety of different ATPs, namely 15 vs 7 pulses at rates of 91 vs 81% of tachycardia cycle length. They showed that for an isolated sequence of stimulation, burst pacing using 15 pulses was more effective than 7 pulses (78% vs 68%, $p: 0,01$) and stimulation rates of 91% of the tachycardia cycle length were better than 81% (80% vs 56%, $p<0,001$). So the authors conclude that ATP using 15 pulses at 91% of tachycardia cycle length was the most effective combination (87%, $p<0,001$ in comparison with the other ATP combinations).

Due to the scarce data we have concerning number of pulses to program, is our usual policy to program 10-12 pulses at 88-91% of tachycardia cycle length.

We can say that ATP in ICD recipients allows to successfully terminate 85-90% of VTs with cycle length higher than 320 ms, with a low acceleration rate (1-5%). Besides, these figures are applicable to different cardiomyopathies (ischemic and non-ischemic), confirming reentry as the most probable mechanism of these arrhythmias. 10 to 25% of ICD recipients present VTs with a CL lower than 320 ms. Even though effectiveness is lower than for slower VTs, there are published data supporting their use. In this way, Wathen et al 2001 (Pain-FREE trial), analyzed ATP results when using 2 burst of 8 pulses at 88% of tachycardia CL for VTs between 240 and 320 ms. Out of 442 studied episodes in 52 ischemic patients, 85% successfully terminated with the therapy, 90% with the first delivered burst. On top of that, a third therapy programmed in some patients by caring physician criteria successfully terminated 18 more VTs, rising global efficacy to 89%. With this stimulation protocol, VT acceleration rate was only 4%.

Several years later, Wathen et al published the Pain-FREE II trial (Wathen et al, 2004), comparing only one burst of 8 pulses at 88% with high energy shocks for VTs between 188 and 250 bpm. 1837 episodes were able for analysis, 73% of which corresponded to monomorphic fast VTs. ATP efficacy for VTs faster than 188 bpm was 81%, with an acceleration rate of only 2%. On the population randomized to receive shocks, 34% of episodes ended spontaneously and 66% required the programmed therapy. So, shock reduction by using ATP for fast VTs was 70% in this study. Mean duration of episodes was shorter in the ATP group ($10,7\pm 0,7$ vs $12,7\pm 0,8$ ms; $p<0,001$). There were no differences between groups in syncopal episodes. Another important finding in this study was the fact that the number of intervals to detect the tachycardia was prolonged to 18, compared to 12 for the Pain-FREE I. That reduced significantly the number of episodes that required

therapy, and settled the fundamentals for more recent studies investigating the results of prolonging the time to detect the tachyarrhythmia and start treatment.

Several smaller but more recent studies have also demonstrated that ATP is safe and effective for fast VTs termination. Following this evidence, most of the newest devices from different manufacturers offer the possibility of antitachycardia pacing delivery during ICD charging. The obvious advantage of ATP during charging is that, in case the VT terminates, the shock is avoided and, in case it does not, successful therapy is not delayed. One step forward is to deliver ATP even before initiating ICD charging. In case of success, not only shocks are avoided, but also battery depletion due to repeated charging thus prolonging ICD total life.

A less studied issue is the number of ATP attempts (burst or ramps) that are to be programmed. Published evidence shows that the majority of VTs ended with the first ATP, but is far from negligible the episodes terminated by the second or even the third attempt, not only for slow VTs but also for the fast ones. The main advantage of several ATPs programmed is avoiding shock delivery to terminate the episode. On the contrary, the risk is to prolong VT total duration, that could be dangerous depending on arrhythmia tolerance. So we have to tailor the therapy by programming different VT/FVT/VF zones and therapies on each, guided by cycle length and arrhythmia tolerability in each patient.

The PainFREE RX II (Pacing Fast VT REduces Shock ThERapies) and EMPIRIC (Comparison of Empiric to Physician-Tailored Programming of Implantable Cardioverter Defibrillators) trials demonstrated that specific VT and VF detection and therapy programming strategies reduced the frequency of shocked episodes. The use of detection algorithms designed to distinguish supraventricular and ventricular tachyarrhythmias and the use of ATP to terminate rapid VTs have been reported to be important components of programming strategies designed to optimize ICD programming and to reduce unnecessary shocks. Sweeny et al recently published that, combining the data of the studies PainFREE I & II, EMPIRIC and PREPARE, most ventricular episodes were potentially ATP-terminable VTs or FVTs, since ATP was able to terminate 92,4% of VT and 82,5% of FVT episodes attempted.

On the basis of this data, we think that programming the VT zone should include at least four ATPs, and for fast VTs, the weight of evidence suggests that at least one ATP sequence should be programmed for VTs between 188 and 250 bpm and that two sequences are superior to one.

3.2.3.2 Shock withholding for supraventricular rhythms, oversensing, and nonsustained ventricular tachycardia

The PREPARE (Programming of Detection and Therapy Parameters in ICDs Reduces Shock) trial was a prospective, cohort-controlled study that analyzed 700 patients with primary prevention indications for an ICD followed for 1 year. VT/VF was detected for rates ≥ 182 beats/min that were maintained for at least 30 of 40 beats. ATP was programmed as the first therapy for regular rhythms with rates of 182 to 250 bpm, and SVT discriminators were used for rhythms ≤ 200 bpm. The primary end point was a combined morbidity index, including incidence of device-delivered shocks, arrhythmic syncope, and untreated sustained symptomatic VT/VF. The authors demonstrated that programming strategies that prolong detection duration (30 of 40 ventricular beats), increase the heart rate threshold of tachycardia detection (182 beats/min), use

supraventricular detection discrimination algorithms and ATP, and encourage first shock termination of tachyarrhythmias can safely and substantially reduce the number of tachyarrhythmias subjected to shock therapy.

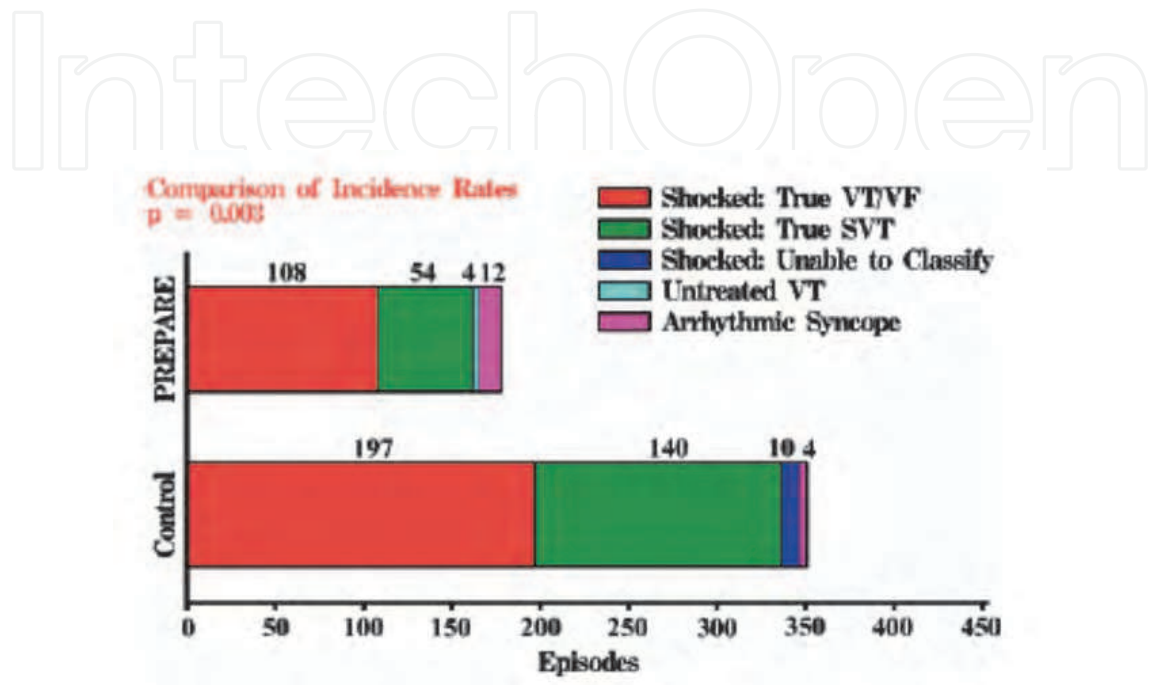


Fig. 13. Data from the PREPARE study. Both appropriate and inappropriate shocks were substantially reduced in the PREPARE study programmed patients. (Reproduced from Wilkoff et al, 2008).

The PREPARE study data clearly demonstrate that by waiting and permitting nonsustained and slower arrhythmias to self-terminate, there are fewer shocked and treated ventricular and SVTs.

New ways of further advancing our knowledge about how to avoid inappropriate and unnecessary shocks have been recently published (Volosin et al, 2011). The authors developed and validated a computer model using clinical data from other published ICD studies and nicely demonstrated how, by using the shock reduction strategies tested (see table 1), hypothetically were able to reduce the number of VT/VF shocked episodes in the SCD-HeFT ICD population by an estimated 59% (from 952 observed to 395 modelled shocks, probability of >0.999). The percentage of patients experiencing inappropriate shocks over 5 years was decreased by 15% (23.5–8.4%), and the number of shocks for non-VT/VF episodes was decreased from 423 to 77 (82% reduction).

Reducing Inappropriate Shocks
<ol style="list-style-type: none"> 1. Using SVT discriminators to cycle lengths of 260 ms or greater. 2. Longer detection time to allow more episodes to terminate spontaneously. 3. Enhanced T wave oversensing algorithm avoids shocks due to oversensed T waves. 4. Lead noise algorithm avoids shocks due to noise oversensing. 5. Combination of atrial and ventricular timing/pattern analysis (PR Logic) with electrogram morphology analysis (Wavelet). 6. Tachycardia detection rate cutoff.
Reducing Unnecessary Shocks
<ol style="list-style-type: none"> 1. ATP therapies to a cycle length of 240 ms. 2. Longer detection time to allow more episodes to terminate spontaneously. 3. New synchronization intervals to reduce shocks for nonsustained events. 4. Tachycardia detection rate cutoff.

Table 1. Strategies for reducing ICD Shocks tested by Volosin et al, 2011.

4. Conclusions

The number of unnecessary or inappropriate shocks is still not zero, which is the goal. ICD discharges have a negative impact on patient prognosis and quality of life, so every effort should be made by programming physicians and ICD manufacturers to reach this goal.

It has been suggested that the “out of box” settings for current ICD systems should be changed in light of the programming strategies shown in clinical trials to reduce shocks, and some manufacturers are already working on it. This may be worthwhile but, since there are so many patient specific issues to be considered, the important point is that the devices should be optimally programmed at implant, not how the devices are shipped.

The initial one-zone one-lead “shock box” approach has progressively become obsolete, as attention has increasingly turned toward avoidance of preventable shocks and inappropriate therapies for lead failure, SVT, and self-terminating tachyarrhythmias. ATP therapy should be systematically programmed, algorithms to discriminate from supraventricular rhythms are to be used and spontaneous episodes of VT have to be aggressively treated, with special consideration to ablation. Recently published evidence suggests that shock reduction strategies could and should be combined to reduce the incidence of unnecessary and inappropriate ICD shocks. New discrimination algorithms could significantly increase specificity without affecting sensitivity.

As in many other fields in Medicine and to the greatest extent possible, ICD programming should be guided by evidence based medicine and every effort should be made to translate this evidence to bedside by ICD programming physicians.

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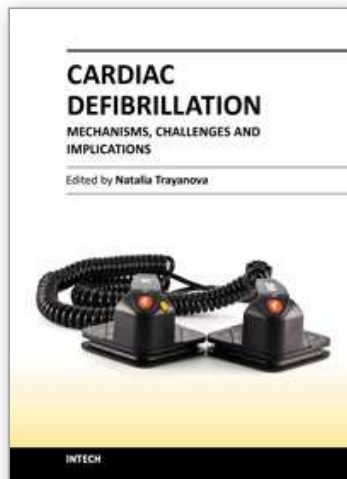
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Cardiac Defibrillation - Mechanisms, Challenges and Implications

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The only known effective therapy for lethal disturbances in cardiac rhythm is defibrillation, the delivery of a strong electric shock to the heart. This technique constitutes the most important means for prevention of sudden cardiac death. The efficacy of defibrillation has led to an exponential growth in the number of patients receiving implantable devices. The objective of this book is to present contemporary views on the basic mechanisms by which the heart responds to an electric shock, as well as on the challenges and implications of clinical defibrillation. Basic science chapters elucidate questions such as lead configurations and the reasons by which a defibrillation shock fails. Chapters devoted to the challenges in the clinical procedure of defibrillation address issues related to inappropriate and unnecessary shocks, complications associated with the implantation of cardioverter/defibrillator devices, and the application of the therapy in pediatric patients and young adults. The book also examines the implications of defibrillation therapy, such as patient risk stratification, cardiac rehabilitation, and remote monitoring of patient with implantable devices.

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