Progressive implantable cardioverter-defibrillator therapies for ventricular tachycardia: The efficacy and safety of multiple bursts, ramps, and low-energy shocks

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BACKGROUND The Heart Rhythm Society, the European Heart Rhythm Association, the Asia Pacific Heart Rhythm Society, the Latin American Heart Rhythm Society expert consensus statement on optimal implantable cardioverter-defibrillator programming recommends burst antitachycardia pacing (ATP) for the treatment of ventricular tachycardia (VT) up to high rates. The number of bursts is not specified, and treatment by ramps or low-energy shocks is not recommended.

OBJECTIVES We investigated the efficacy and safety of progressive therapies for VTs between 150 and 200 beats/min. After 3 failed bursts, we compared 3 ramps vs 3 bursts followed by a low-energy shock vs high-energy shock.

METHODS Using remote monitoring, we included monomorphic VT episodes treated with ≥1 burst.

RESULTS A total of 1126 VT episodes were included. A single burst was as likely to terminate VT between 150 and 200 beats/min as VT between 200 and 230 beats/min (63% vs 64%; $P=.41$), but was more likely to accelerate the latter (3.2% vs 0.25%; $P<.01$). For VT <200 beats/min, the likelihood of ATP success increased progressively (73% with 2 bursts, 78% with 3 bursts). Three additional bursts further increased VT termination to 89%, similar to the success rate with 3 additional ramps (88%; $P=.17$). Programming 6 bursts is associated with the probability of acceleration requiring shock of 6.6%. A low-energy first shock was less successful than a high-energy shock (66% vs 86%; $P<.01$) and more likely to accelerate VT (17% vs 0%; $P<.01$).

CONCLUSION Programming up to 6 burst ATP therapies for VTs 150–200 beats/min can avoid implantable cardioverter-defibrillator shocks in most patients. Ramp ATP after failed bursts were similarly effective. Low-energy shocks are less effective and more arrhythmogenic than high-energy shocks.

KEYWORDS Antitachycardia pacing; Implantable cardioverter-defibrillator; Primary prevention; Secondary prevention; Shock

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Introduction

The programming of an implantable cardioverter-defibrillator (ICD) directly influences the risk of inappropriate and avoidable shocks. Clinical trials have shown that strategies to reduce shocks are associated with reduced morbidity and mortality.[1–9] One such strategy is limiting detection and therefore therapies to fast ventricular tachycardia (VT) or sustained arrhythmia by programming a longer duration (12 seconds) or higher detection window (30 of 40).[6–8] Algorithms that aim to discriminate between VT and supraventricular tachycardia (SVT) through the onset or stability of the arrhythmia or analysis of the far-field signal can also reduce inappropriate therapies.[10] Far-field analysis can also be used to discriminate between ventricular arrhythmia and oversensing.[11] Finally, incorporating antitachycardia pacing (ATP) therapy has been shown to reduce the number of unnecessary and inappropriate shocks and to improve patient quality of life and device longevity.[1,2,4]

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These strategies have been found useful for both primary and secondary prevention.[6–9,12] The 2019 Heart Rhythm Society, the European Heart Rhythm Association, the Asia Pacific Heart Rhythm Society, the Latin American Heart Rhythm Society (HRS/EHRA/APHRS/LAHRS) expert consensus statement on optimal ICD programming offers manufacturer-specific recommendations on how to program an ICD "out of the box." For treatment of VT, programming at least 1 burst ATP therapy is recommended, followed by maximum-energy shocks.[13] While widely applied, parts of the consensus statement await validation as many recommendations are based on limited evidence. For instance, VT zones are recommended up to 230 or even 250 beats/min, the number of ATP bursts to program is not specified, and ramp ATP and low-energy shocks are not advised.[13]

At our center, progressive therapies have historically been used for VTs up to 200 beats/min. A Multicenter Automatic Defibrillator Implantation Trial: Reduce Inappropriate Therapy (MADIT-RIT) study showed that for VTs <200 beats/min, syncope is a rare event (1 syncope vs 33 nonsyncope).[12] This allows the ICD time to deliver multiple painless ATP therapies before delivering harmful shocks. We define progressive therapies as programming up to 6 ATPs (typically 3 bursts, followed by 3 ramps or by 3 bursts), followed by a low-energy shock before high-energy shocks (Figure 1). By analyzing VT episodes collected over the past decade through our remote monitoring center, we sought to explore the following questions: (1) Is a single burst of ATP as effective for VTs of 150–200 beats/min as it is for VTs of 200–230 beats/min? (2) What is the efficacy and safety of programming up to 6 bursts of ATP for VTs of 150–200 beats/min? (3) After 3 failed bursts, what is the efficacy and safety of programming 3 ramps compared with 3 more bursts? (4) What is the efficacy and safety of a low-energy shock vs a maximum-energy shock as first shock treatment of VT?

Methods

Study design

In this retrospective single-center study, we collected VT episode tracings via remote monitoring from all 5 major ICD vendors (Abbott, Abbott Park, IL; Biotronik, Berlin, Germany; Boston Scientific, Marlborough, MA; Medtronic, Minneapolis, MN; and MicroPort, Shanghai, China). Episodes were included if they demonstrated monomorphic VT at rates of 150–230 beats/min with at least 1 burst ATP therapy. For evaluations of progressive therapies, only VTs of ≤200 beats/min were considered. To limit the undue influence of clusters of episodes, additional episodes beyond 10 were not included in this analysis. Since nominal settings differ across manufacturers, we considered burst therapy as a succession of at least 8 pulses at a fixed interval and ramp therapy as a succession of at least 8 pulses at a decreasing interval. We considered a shock as low energy when the energy delivered was ≤15 J. Programming of the device parameters, including ATP parameters and shock energies, was left to the discretion of the treating physician. All patients gave written informed consent for the analysis of the data provided by remote monitoring, and patient information was deidentified before analysis of the episodes.

Analysis of episodes

Electrograms of all collected episodes were analyzed by device cardiologists. Besides VT episodes, "ventricular fibrillation" (VF) episodes were screened as they could represent monomorphic and organized VT and they were often treated with a burst of ATP before or during charging of the capacitors. Each episode was classified as *VT*, *VF*, *SVT*, *oversensing of physiological signals*, or *oversensing of noise*. When we were unable to make a definitive diagnosis, the episode was classified as *unknown*. Episode characteristics such as ventricular rate, the number and type of ATP (burst or ramp), and the number and energy of shocks were extracted. Each device therapy (ATP or shock) was classified as *successful* or *unsuccessful*. Up to 3 fast ventricular beats after ATP were allowed for it to be classified as successful. Additionally, therapy was classified as resulting in an acceleration of the VT when the ventricular cycle length decreased by at least 10 ms or VF was induced.

Statistical analysis

Categorical variables were expressed as absolute numbers and percentages; continuous variables were expressed as mean ± SD. P values <.05 were considered statistically significant. The probability of VT termination by successive bursts and ramps was calculated

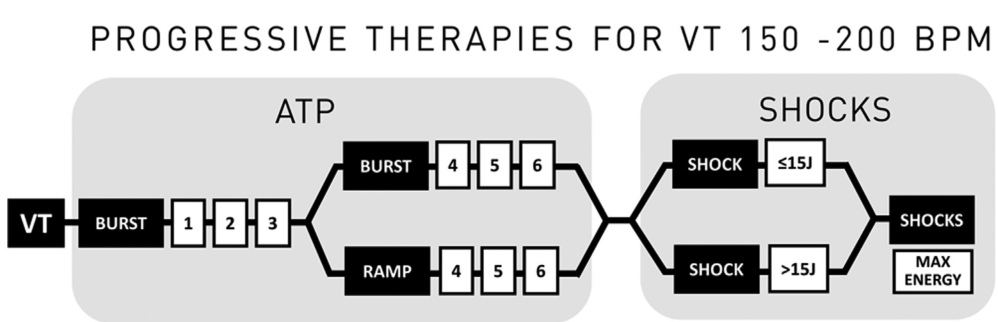

Figure 1 Flow diagram of progressive implantable cardioverter-defibrillator therapies for ventricular tachycardia (VT) of 150–200 beats/min. ATP = antitachycardia pacing.

using the Kaplan-Meier method and compared statistically using the log-rank test. The efficacy of ATP bursts in slower vs faster VTs, burst 1–3 vs burst 4–6 and ramp 4–6 accelerations, and low-energy vs high-energy shocks was compared using χ^2 tests. A generalized estimating equation analysis was also conducted to account for multiple episodes within a patient.

Results

Patient and episode characteristics

In total, 1775 patients with ICDs who transmitted episodes labeled as VT or VF to our remote monitoring center were screened. We received and analyzed 1877 episodes with therapies labeled as VT or VF transmitted by 480 patients (27%). Two hundred thirty-nine episodes were wrongfully classified by the ICD as VT or VF (12%); they were SVT (189 episodes [10%]), oversensing of noise (26 episodes [1%]), or oversensing of physiological signals (24 episodes [1%]). Seventy-five of these misclassified episodes (31%) showed inappropriate shocks (across 58 patients with a total of 147 inappropriate shocks). The annual inappropriate shock rate was 0.016. Nine episodes (<1%) were excluded because they could not be confirmed as VT with certainty. Of the confirmed VT episodes, 157 were excluded because they were too slow (<150 beats/min) and 107 were excluded because they were too fast (>230 beats/min). A total of 1126 episodes with confirmed VT of 150–230 beats/min with at least 1 burst ATP therapy were therefore included in the analysis. The demographic characteristics and device specifications of these 411 patients are summarized in Table 1.

Table 1 Demographic characteristics and device specifications of patients with implantable cardioverter-defibrillators and at least 1 verified ventricular tachycardia of ≥150 beats/min

Variable	Value
Patient demographic characteristics	
ICD patients with ≥1 VT episode (≥150 beats/min)	422
Age (y)	65 ± 14
Male sex	360 (85)
Primary indication	190 (45)
Ischemic heart disease	224 (53)
Left ventricular ejection fraction <35%	207 (49)
NYHA III or IV	137 (32)
Device type	
With atrial lead	295 (70)
With left ventricular lead	160 (38)
Abbott	98 (23)
Biotronik	110 (26)
Boston Scientific	64 (15)
Medtronic	128 (30)
MicroPort	22 (5)

Values are presented as mean ± SD or as n (%).

ICD = implantable cardioverter-defibrillator; NYHA = New York Heart Association; VT = ventricular tachycardia.

Efficacy of a single burst

There was no difference in single burst effectiveness for VTs of 150–200 beats/min (535 of 836 attempts successful [64%]) and of 200–230 beats/min (184 of 290 attempts successful [63%]) ($P=.41$). However, a single burst was more likely to accelerate faster VT (0.25% for VT of 150–200 beats/min vs 3.2% for VT of 200–230 beats/min; $P<.001$). There was no difference in single burst efficacy for VTs of 150–200 beats/min between patients with primary indication and those with secondary indication (66% vs 65%; $P=.81$), ischemic vs nonischemic etiology (64% vs 66% success; $P=.48$), male vs female sex (65% vs 65% success; $P>.99$), or left ventricular ejection fraction (LVEF) <35% vs LVEF ≥35% (64% vs 63% success; $P=.71$).

Efficacy of successive bursts and ramps in the VT zone of 150–200 beats/min

The probability of VT termination increased as more burst ATP therapies were delivered: 73% for 2 bursts (247 attempts), 78% for 3 bursts (166 attempts), 82% for 4 bursts (77 attempts), 86% for 5 bursts (45 attempts), and 88% for 6 bursts (22 attempts) (Figure 2). Successive bursts were more successful for patients with LVEF ≥35% than for patients with LVEF <35%: 93% vs 81% probability of VT termination after up to 6 bursts ($P=.001$). Other clinical characteristics had no effect on successive burst efficacy (primary vs secondary, ischemic vs nonischemic, and male vs female sex). For all patients, VT acceleration occurred at a rate of 0.7% per burst for bursts 1–3 (8 of 1180) and 1.8% per burst for bursts 4–6 (2 of 112) ($P=.2$ for bursts 1–3 vs bursts 4–6). The cumulative probability of VT acceleration requiring shock when programming 6 bursts was 6.6%. The cumulative probability of VT termination with ramp ATP after 3 bursts was 86.5% for 1 ramp (44 attempts), 89.3% for 2 ramps (24 attempts), and 90.6% for 3 ramps (17 attempts). After 3 failed bursts, programming 3 ramps was not significantly more successful in terminating VT as compared with 3 additional bursts ($P=.17$) (Figure 2). After 3 failed bursts, the risk of acceleration was 3.9% (3 of 76), not significantly different as compared with ramps 4–6 ($P=.36$). Considering all VT accelerations with ATP, 47% accelerated into faster

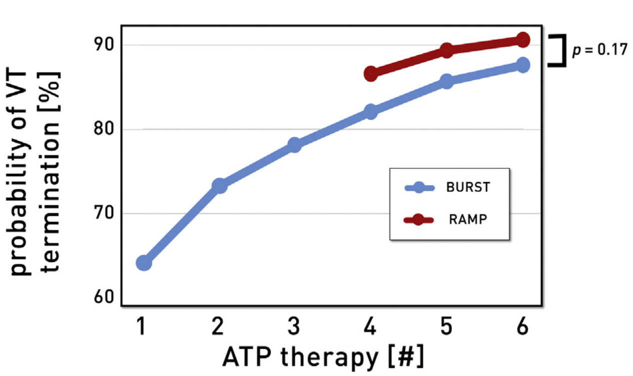

Figure 2 Probability of ventricular tachycardia (VT) termination by 3 bursts followed by either 3 additional burst (4–6) or ramp (4–6) antitachycardia pacing (ATP) therapies.

VT and 53% into VF. Thirteen percent of accelerations required >1 shock.

Low-energy vs high-energy shocks

A total of 86 episodes of confirmed VT of 150–200 beats/min and shock therapy were included in the analysis: 57 with a high-energy (>15 J) and 29 a with low-energy (≤15 J) first shock. Considering only the first shock, high-energy shocks were more successful at terminating the VT than low-energy shocks (81% vs 66%; $P<.01$) (Figure 3). Low-energy shocks accelerated the VT in 17% of cases, whereas no accelerations occurred with high-energy shocks ($P<.01$).

Discussion

In the present study, we evaluated the efficacy and safety of progressive ICD therapies by analyzing 1126 treated VTs sent to our remote monitoring center using all ICD vendors. Several important observations were made: (1) A single burst fails to terminate a third of VTs, <200 or >200 beats/min. (2) The cumulative rate of VT termination increases as more ATP therapies are delivered, which directly translates into an important reduction in shock therapy. However, each additional ATP therapy is associated with a risk of accelerating the VT, which must be weighed against its benefits. (3) Despite generally being considered to be more aggressive, ramp ATP therapies after failed bursts have similar efficacy and safety profiles to additional bursts. (4) Low-energy shocks are less effective at terminating VT and were associated with more accelerations when compared with high-energy shocks.

ICD programming has evolved a great deal in the last decade. We have learned that shocks intended for the treatment of VT may be harmful to the heart.[6] VTs may self-terminate, rendering shocks unnecessary, and delayed detection is now widely applied as in our patient cohort. An important culprit of shock harm is inappropriate therapy for SVT or oversensing. Many atrial arrhythmias occur within the 170–200 beats/min range, which is one of the major reasons why studies using higher cutoff rates show improved outcomes.[6,8] The correct detection of sustained VT is imperative, and major efforts are being undertaken to improve discrimination. Comparison of far-field (lead-to-can) morphology during VT with a template during sinus rhythm is an increasingly popular method as it may identify SVT without the need of an atrial lead but important differences exist in design and performance between the ICD manufacturers.[10] The far-field channel can also be helpful to avoid inappropriate treatment of oversensed events through comparison with the near-field channel (tip-to-ring/coil).[11] In our database, most treated VTs were <200 beats/min and there will always be a considerable group of patients that require ICD therapy for not-so-fast VTs. Our data support programming multiple burst ATP therapies for these patients, as this was associated with a consistent increase in VT termination. Importantly, benefits were seen with every additional burst, with success rates for VT termination for each additional burst between 14% and 27%. An inherent risk of programming more ATP therapies is that it could accelerate the VT. To enable weighing of the benefits against the risks of additional bursts, we plotted the net reduction in shocks by combining reduction of shock by successful bursts and induction of shocks through acceleration by bursts (Figure 4). While a single burst reduces shocks by 63%, programming 6 bursts reduces it by 81% (a further absolute decrease of 18%), despite the relative increase of accelerations. This is overall consistent with the results of a recent analysis of the shock-less cohort study, which showed that programming more than the nominal number of ATP sequences was associated with a lower occurrence of ICD shocks.[14] In this single-vendor study (Medtronic), treated episodes were not adjudicated to confirm the diagnosis of VT and the appropriateness of therapies delivered, burst and ramp therapies were combined, and VT accelerations were not examined. Nevertheless, our findings corroborate its results and further support the practice of empirically programming multiple ATP therapies, understanding that the device's ability to interrupt the VT circuit depends on various factors that remain

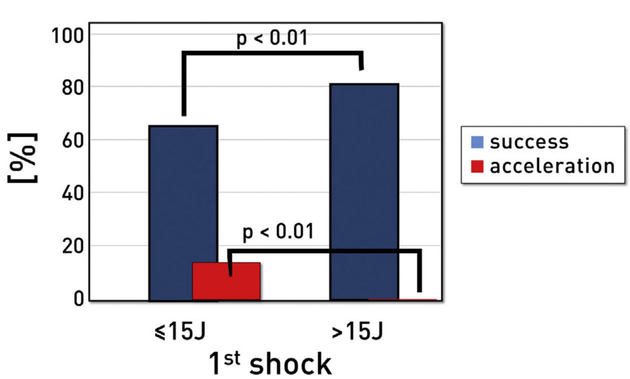

Figure 3 Percent successful termination and acceleration of ventricular tachycardia with low-energy (≤15 J) vs high-energy (>15 J) shocks.

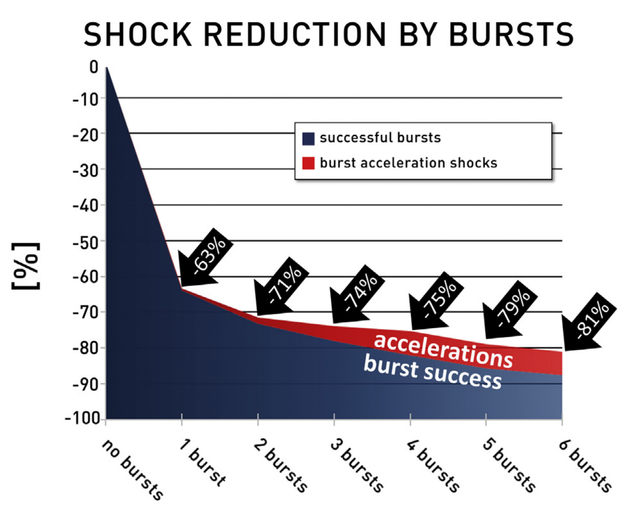

Figure 4 Probability of shock reduction for 0–6 bursts. A successful burst decreases the amount of shocks (*blue area*), but a burst that accelerates the ventricular tachycardia (VT) into a fast VT or ventricular fibrillation increases the amount of shocks (*red area*).

unaccounted for (eg, ventricular substrate, pacing location, and pacing intervals).

Our study identified a relatively low success rate for the first burst therapy relative to reports in previous studies (64% vs >75%, respectively).[3,4,15,16] This may be due to programming more prolonged detection of VT/VF in our patients, which avoids delivering ATP for self-terminating VT that would otherwise have been classified as "successful" therapy. Recent trials are indeed more in line with our results, such as the Avoid Delivering Therapies for Nonsustained Arrhythmias in ICD Patients III trial, which reports 52% ATP success in the long detection arm.[17]

Our results show that ramps had similar efficacy and safety profiles to bursts. This likely disproportionately discourages the use of ramp ATP, as ramps have historically been associated with VT acceleration. The Project for the Investigation and Treatment of Ventricular Arrhythmias: a General Observational Registry on Antitachycardia Pacing Efficacy (PITAGORA ICD) trial showed that a single burst was more successful at terminating fast VT (>188 beats/min) than a single ramp.[18] In our study focusing on less fast VTs between 150 and 200 beats/min, a strategy of an initial 3 bursts followed by up to 3 ramps instead of further bursts was not associated with a lower efficacy or a higher risk of VT acceleration.

Even when delaying detection and delivering multiple ATP therapies, some VTs will not terminate without shock therapy. Multiple potential benefits of programming a low-energy shock have been proposed, such as shorter charging times and reduced pain from the shock. More importantly, ICD shocks are associated with higher mortality, potentially by direct cardiac injury as evidenced by concomitant troponin release. Low-energy shocks may be less harmful to the heart; however, our results and previous studies show that low-energy shocks are less successful and more likely to accelerate the tachycardia than high-energy shocks.[19–21] These induced ventricular arrhythmia often show rapid signals of lower amplitudes, which may compromise the patient through an increased risk of undersensing. Furthermore, a failed first shock most often results in the need for a second shock, which subjects the myocardium to a higher summed injury and may prime the patient to the pain of an impending second shock, irrespective of its energy level.

Clinical implications

Our real-world findings serve to validate and refine the 2015 and 2019 HRS/EHRA/APHRS/LAHRS consensus statements. Currently, programming at least 1 burst is recommended, and our data suggest that programming up to 6 bursts in a VT zone between 150 and 200 beats/min is effective and safe. Programming ramps after failed bursts show a similar efficacy and safety profile. In keeping with the consensus statement, our study does not support programming low-energy shocks.

Limitations

Several study limitations should be considered when interpreting these results. First, the retrospective nature of this analysis renders it susceptible to inherent biases of such a study design. ICD programming was left to the physician's discretion and certain ICDs may automatically prioritize ramps or bursts according to previous outcomes, which may have influenced the results. Because of burst success, there was a limited number of VT episodes that required >3 bursts of ATP, thus limiting the precision of effect estimates in such cases. However, despite these limitations, the large sample size and range of programming across all major ICD vendors render our results representative of real-world practice and provide generalizable insights into the potential impact of progressive therapies. Finally, while additional bursts prevent shocks, they may favor syncope and we were not able to report the incidence of syncope. However, syncope is known to be rare below 200 beats/min; only a single syncope was reported in the MADIT-RIT trial (in a VT monitoring zone of 170–200 beats/min).

Conclusion

Programming up to 6 burst ATP therapies in a VT zone of 150–200 beats/min can avoid shocks in a substantial proportion of patients with ICDs. Ramp ATP therapies are not more effective than bursts. Low-energy shocks are less effective and more arrhythmogenic than high-energy shocks.

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