Novel ventricular tachyarrhythmia detection enhancement detects undertreated life-threatening arrhythmias

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BACKGROUND Ventricular tachyarrhythmias (VTA) with low and varying signal amplitudes and morphologies may not be successfully identified utilizing traditional implantable cardioverter-defibrillator algorithms.

OBJECTIVE Develop and validate a novel algorithm (VF Therapy Assurance, VFTA) to improve detection and timely delivery of high-voltage therapy (HVT) for these arrhythmias.

METHODS Arrhythmia detection was simulated on recorded VTA electrograms (EGMs) utilizing Abbott's Merlin.net database. EGMs where an HVT occurred only when VFTA was enabled, or where VFTA provided an HVT >30 seconds earlier than without VFTA, were readjudicated with physician review. As VFTA never prevents detection or therapy, EGMs where VFTA did not activate or alter HVT were not adjudicated.

RESULTS Among 564,353 recorded VTA EGMs from 20,000 devices, VFTA altered HVT in 105 EGMs from 67 devices. Physician adjudication determined that 81.9% (86/105) of these EGMs were true undertreated VTA episodes and would have received appropriate HVT with VFTA enabled. Furthermore, 65% of the episodes (56/86) were ventricular fibrillation, were polymorphic, did not self-terminate during the recording window, or were not amenable antitachycardia pacing. Of those, 87.5% (49/56) would not have elicited HVT without VFTA. Overall, VFTA provided new or earlier appropriate HVT in 0.27% (53/20,000) of devices with an increase in inappropriate HVT in 0.07% (14/20,000) devices.

CONCLUSION The VFTA algorithm successfully identifies VTA missed by traditional detection algorithms, owing to undersensed ventricular signals resulting in the rate falling below the programmed detection rate. The use of VFTA increases the likelihood of delivering life-saving HVT.

KEYWORDS Detection algorithm; Implantable cardioverter-defibrillator; High-voltage therapy; Undersensing; Ventricular tachyarrhythmia

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Introduction

Implantable cardioverter-defibrillators (ICDs) significantly improve survival in primary- and secondary-prevention patients, by effectively terminating life-threatening ventricular tachyarrhythmias.[1,2] Appropriate detection of tachyarrhythmias and subsequent therapy delivery requires reliable sensing of ventricular events (ie, R waves). Accordingly, ICDs employ dynamic sensing thresholds and refractory periods to enhance R-wave sensitivity and limit instances of sensing-related failures to treat life-threatening ventricular tachyarrhythmias.[3–6] Although rare, undersensing may still be observed with large variations in R-wave amplitudes and R-R intervals,[7] particularly during polymorphic ventricular tachycardia (PVT) and ventricular fibrillation (VF).

In addition, recent studies have demonstrated reduced morbidity and mortality with reductions in avoidable or inappropriate high-voltage (HV) therapy through extending detection intervals to allow for self-termination of ventricular tachyarrhythmia, or termination with use of antitachycardia pacing (ATP) therapy.[8–10] These findings led to a paradigm shift in ICD therapy programming away from more aggressive, shorter duration, and slower arrhythmia

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KEY FINDINGS

- Undersensing of ventricular tachyarrhythmias in implantable cardioverter-defibrillators (ICDs), even though rare, can be life-threatening.
- The VF Therapy Assurance (VFTA) algorithm enhances ICD therapy delivery in the context of low-amplitude signal detection during ventricular tachyarrhythmias.
- VFTA leverages the far-field discrimination channel to promptly identify and treat ventricular tachyarrhythmias for which high-voltage therapy would otherwise be delayed or deferred.
- The results of the simulation analysis demonstrate that VFTA can decrease time to treatment for potentially life-threatening arrhythmias without significantly increasing inappropriate high-voltage therapy.

detection to more conservative faster detection rate cutoffs and longer detection times.[11,12] Following these changes in recommended programming, several reports suggested that using generic programming of longer detection times and faster detection rates—with or without device undersensing—may lead to delayed or undelivered therapy for PVT or VF, regardless of device manufacturer.[13–15]

To mitigate this risk, a novel algorithm, "VF Therapy Assurance" (VFTA; Abbott, Sylmar, CA), has been developed that leverages far-field R-wave signals during a ventricular tachyarrhythmia episode to provide ICD therapy when near-field R-wave undersensing is confirmed. The objective of this study was to characterize the VFTA algorithm and demonstrate the performance of VFTA in reducing the number of undertreated ventricular tachyarrhythmias without significantly increasing inappropriate HV therapy delivery, while still maintaining physician preferred programming.

Methods

VFTA algorithm functionality

VFTA was designed as an enhancement module to the ventricular tachyarrhythmia detection and treatment suite of Abbott's Gallant™, Entrant™, and NeutrinoNXT™ ICD and cardiac resynchronization therapy defibrillator (CRT-D) devices, interacting with traditional ventricular tachycardia (VT)/VF detection, discrimination, and therapy features. The VFTA algorithm was developed based on Merlin.net database analysis of R-wave amplitudes and R-R interval variations observed during PVT and VF episodes, as captured by the far-field electrograms (EGMs) used for arrhythmia detection in Abbott ICDs. Devices and episodes were de-identified prior to analysis and thus the study does not fall under the purview of the institutional review board. The far-field EGM channel with SecureSense™ lead noise identification was designed to inhibit inappropriate therapy as a result of noise detected on the near-field EGM by identifying R-R mismatch between the 2 sensing channels. This algorithm is described in detail elsewhere.[16] However, R-R interval and amplitude variations in the far-field EGM signal were found to coincide with delayed ventricular tachyarrhythmia detection and treatment, as well as inappropriate episode termination during an ongoing arrhythmia. The VFTA algorithm aims to capitalize on the far-field EGM to promptly identify and treat tachyarrhythmias for which HV therapy would otherwise be delayed or deferred.

Figure 1 provides an overview of the VFTA algorithm logic. The VFTA algorithm enhances traditional tachyarrhythmia detection by determining whether HV therapy needs to be accelerated at 4 different checkpoints during an episode: (1) the number of intervals to detect (ITD) for 1 of the tachyarrhythmia rate zones is fulfilled (VT and VF) and rhythm discriminators indicate VT (only for VT); (2) a predefined number of intervals (45) since the beginning of a potential tachyarrhythmia episode is passed without reaching ITD (the VFTA monitoring period); (3) the number of intervals to redetect for 1 of the tachyarrhythmia rate zones is fulfilled; and (4) a new potential tachyarrhythmia episode is detected within a predefined number of intervals (15) after the end of a previously diagnosed tachyarrhythmia episode (the VFTA postepisode monitoring period). While primary detection of tachyarrhythmia episodes uses primary near-field V-sense channel, the VFTA algorithm makes its determination based on 2 undersensing criteria that are continuously monitored on the secondary far-field sensing channel. The undersensing criteria are (1) consecutive, low-amplitude R waves (<0.6 mV) and (2) excessively long R-R intervals on the far-field sensing channel (>2 seconds). These criteria are tracked using individual counters: the counter increases when low-amplitude R wave or long R-R interval is detected and is fulfilled when they are greater than a threshold at undersensing checkpoints. The counter can also be reset with consistent, normal R-wave amplitudes (>1 mV) to prevent brief sensing abnormalities triggering VFTA.

When criteria are fulfilled at any of the checkpoints, adjustments are made to detection, termination, redetection, and therapy parameters to provide HV therapy. Specifically, VFTA transitions arrhythmia detection to a single zone with a slower rate cutoff (add 100 ms to the slowest programmed therapy zone to a maximum of 400 ms), increases the number of binned sinus intervals required to terminate the episode from 5 to 7, and skips further ATP in favor of HV shock therapy (with certain exception of delivery of ATP while charging capacitors in preparation for delivery of HV shock). These adjusted parameters are not user programmable but are based on the programmed detection and therapy parameter values and remain in effect until the device determines that the ongoing episode has terminated. Certain detection-inhibiting algorithms, such as noise reversion and/or magnet reversion, disable VFTA for the ongoing episode.

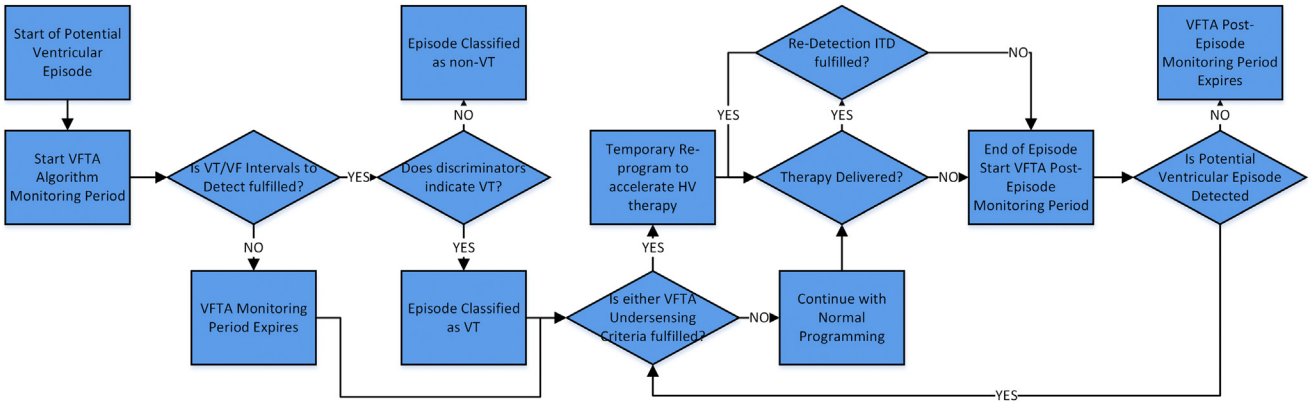

Figure 1 Algorithm logic flow of VF Therapy Assurance (VFTA). VFTA is activated upon initial detection of rapid ventricular signals and continues to monitor the rhythm until ventricular tachycardia or ventricular fibrillation diagnosis is made, at which point the algorithm automatically adjusts tachyarrhythmia settings to provide therapy. VF = ventricular fibrillation; VT = ventricular tachycardia.

VFTA undersensing checkpoints 1 and 3 follow the normal detection scheme. However, undersensing on the near-field V-sense channel or rates falling below the programmed detection rate may cause the device to delay detection or even declare episode termination (ie, End of Episode) while the ventricular tachyarrhythmia is still ongoing. Checkpoints 2 and 4 are designed to prevent delay in HV therapy delivery when arrhythmia ITD is not fulfilled or when there is erroneous episode termination.

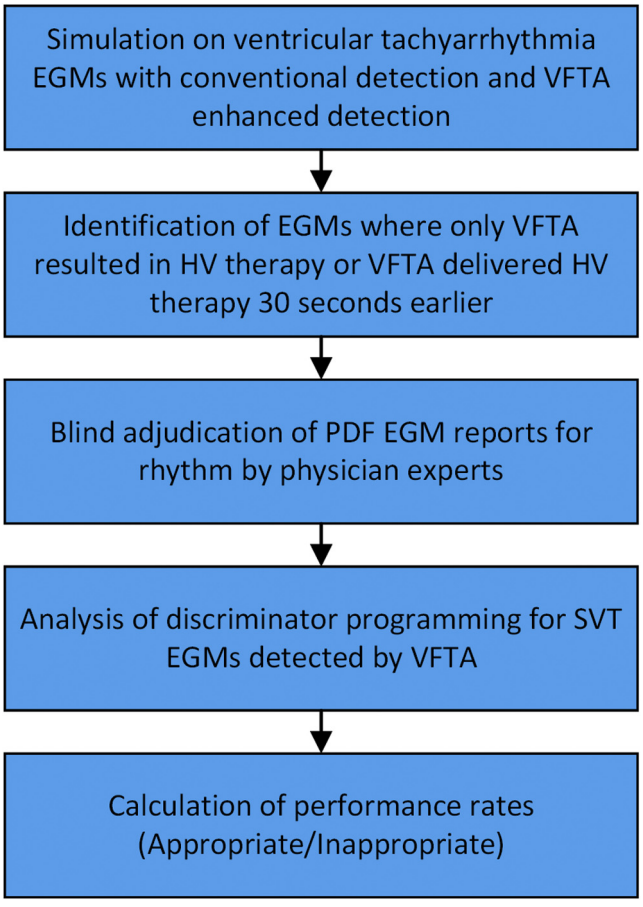

Figure 2 VF Therapy Assurance (VFTA) algorithm validation process. Validation of the VFTA algorithm is performed through a combination of electrogram (EGM) simulation and adjudication of tachyarrhythmia characteristics and device behavior. HV = high-voltage; SVT = supraventricular tachycardia.

VFTA algorithm performance

The clinical performance of VFTA was evaluated using ventricular tachyarrhythmia EGMs stored in Merlin.net from randomly selected Abbott ICDs (single-chamber, dual-chamber, and CRT) with SecureSense enabled. As non-self-terminating ventricular tachyarrhythmias may span several stored episodes and sufficient episode durations are required to accurately simulate detection, redetection, and delivery of therapy, multiple episodes from a single device that either overlapped in time or occurred sequentially were merged into a single, continuous episode (ie, overlapping EGM periods were cropped, while sequential EGMs were joined by aligning the last R wave of 1 EGM to the first R wave of the next EGM).

Computer simulations were used to model tachyarrhythmia detection, redetection, and therapy delivery, according to the unique, original programming of each device. Simulations were performed on all EGMs twice: once with VFTA disabled and once with VFTA enabled. As the outcome of therapy delivery cannot be ascertained, simulations were terminated simply upon delivery of HV therapy. An overview of the validation process is shown in Figure 2.

EGMs were flagged for manual physician readjudication if simulations showed that HV therapy was delivered (1) only when VFTA was enabled, or (2) at least 30 seconds earlier with VFTA enabled vs disabled. In other words, physician adjudication was performed for EGMs in which VFTA sufficiently altered delivery of HV therapy.

The readjudication process is shown in Figure 3. Each EGM report was classified by 3 physicians based on the rhythm at the time of VFTA detection and/or HV therapy delivery. Each EGM report was classified into 1 of 6 episode categories: PVT/VF, monomorphic VT (MVT), supraventricular tachycardia (SVT), normal sinus rhythm (NSR), noise, and oversensing. The majority decision was used for rhythm classification. However, if all physicians disagreed

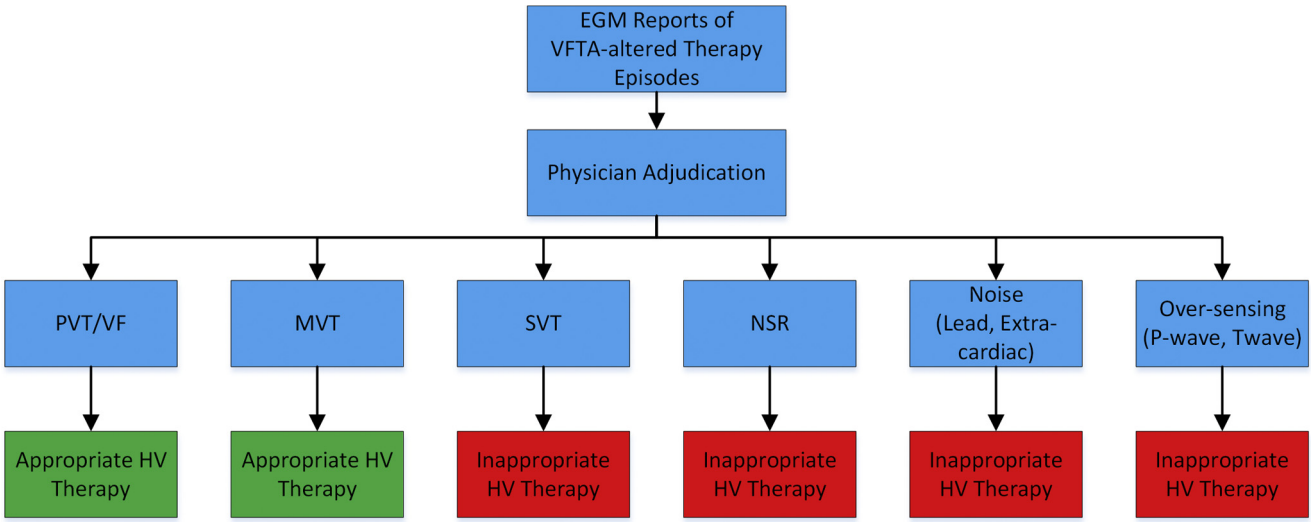

Figure 3 Adjudication process to determine appropriateness. Electrograms are classified into 6 rhythm types; each rhythm type corresponds to either appropriate or inappropriate high-voltage (HV) therapy. EGM = electrogram; MVT = monomorphic ventricular tachycardia; NSR = normal sinus rhythm; PVT = polymorphic ventricular tachycardia; SVT = supraventricular tachycardia; VF = ventricular fibrillation; VFTA = VF Therapy Assurance.

on the presenting rhythm, PVT/VF and MVT rhythms were classified as "ventricular arrhythmia" and all other rhythms (SVT, NSR, noise, oversensing) were classified as "non–ventricular arrhythmia".

Based on physician rhythm adjudication, EGM reports were classified as appropriate or inappropriate therapy episodes. Appropriate therapy episodes included episodes classified as PVT, MVT, VF, and "ventricular arrhythmia"; inappropriate therapy episodes included episodes classified as SVT, NSR, noise, and oversensing (Figure 3).

For episode-based calculations of positive predictive value (PPV), appropriate therapy episodes were classified as true-positive, while inappropriate therapy episodes were classified as false-positive. For device-based true-positive rate (TPR) calculations, devices with true-positive episodes are counted as true-positive and vice versa.

Exact binomial test executed in R (R Core Team, Vienna, Austria) was utilized in determining the 95% lower and upper confidence bound for increase in appropriate and inappropriate therapy resulted from the VFTA algorithm, respectively.

Results

Twenty thousand devices with stored tachyarrhythmia episodes were randomly selected from the Merlin.net database. These devices contributed a total of 564,353 merged VT/VF episode EGMs. Simulations identified 538 (0.1%) EGMs from 247 (1.2%) devices in which VFTA identified undersensing; of these, the VFTA algorithm either would have delivered therapy faster than without VFTA or delivered therapy that would have otherwise not been delivered in 105 (19.5%) EGMs from 67 (27.1%) devices (Figure 4A). VFTA did not significantly impact therapy delivery in the remaining 433 (80.5%) EGMs from 180 (72.9%) devices. These EGMs were not readjudicated, as no additional clinical risk or benefit would have been introduced by VFTA compared with conventional detection.

Results of physician adjudication are provided in Figure 4B. In summary, 39 episodes from 32 devices were adjudicated as PVT/VF; 43 episodes from 18 devices were adjudicated as MVT; 10 episodes from 6 devices were adjudicated as SVT; 4 episodes from 4 devices were adjudicated as oversensing; 5 episodes from 4 devices were adjudicated as noise; 4 episodes from 4 devices were adjudicated as ventricular arrhythmia; and no episodes were adjudicated as NSR or non–ventricular arrhythmia. These episodes and devices are categorized according to the methodology described above, and results are summarized in Figure 4C (1 device in the appropriate categorization exhibited episodes receiving both earlier and new therapy). In total, 86 episodes from 53 devices are appropriate and 19 episodes from 14 devices are inappropriate, producing an episode PPV of 81.9% (86/105) and a device TPR of 79.1% (53/67). This corresponds to an overall rate of 0.27% (53/20,000) of new or earlier appropriate HV therapy with VFTA. Exact binomial test indicates that the 95% lower confidence bound for appropriate HV therapy is 0.03%.

HV therapy is clinically important for 83% (44/53) of the devices with 65% (56/86) of the appropriately detected episodes. These episodes consist of VF, sustained PVT, or ATP ineffective VTs. A total of 86.4% (38/44) of these devices with 87.5% (49/56) episodes would have delivered HV therapy only when VFTA was enabled. In 15.9% (7/44) of these devices where appropriate HV therapy would have been delivered whether VFTA was enabled or not, therapy was delivered 124 ± 92 seconds earlier with VFTA enabled. HV therapy may be unnecessary for the remaining 17% (9/53) devices, as the tachyarrhythmia may self-terminate (1 episode) or may be terminated with ATP during charging (29 episodes), which is part of the therapy delivery of the VFTA.

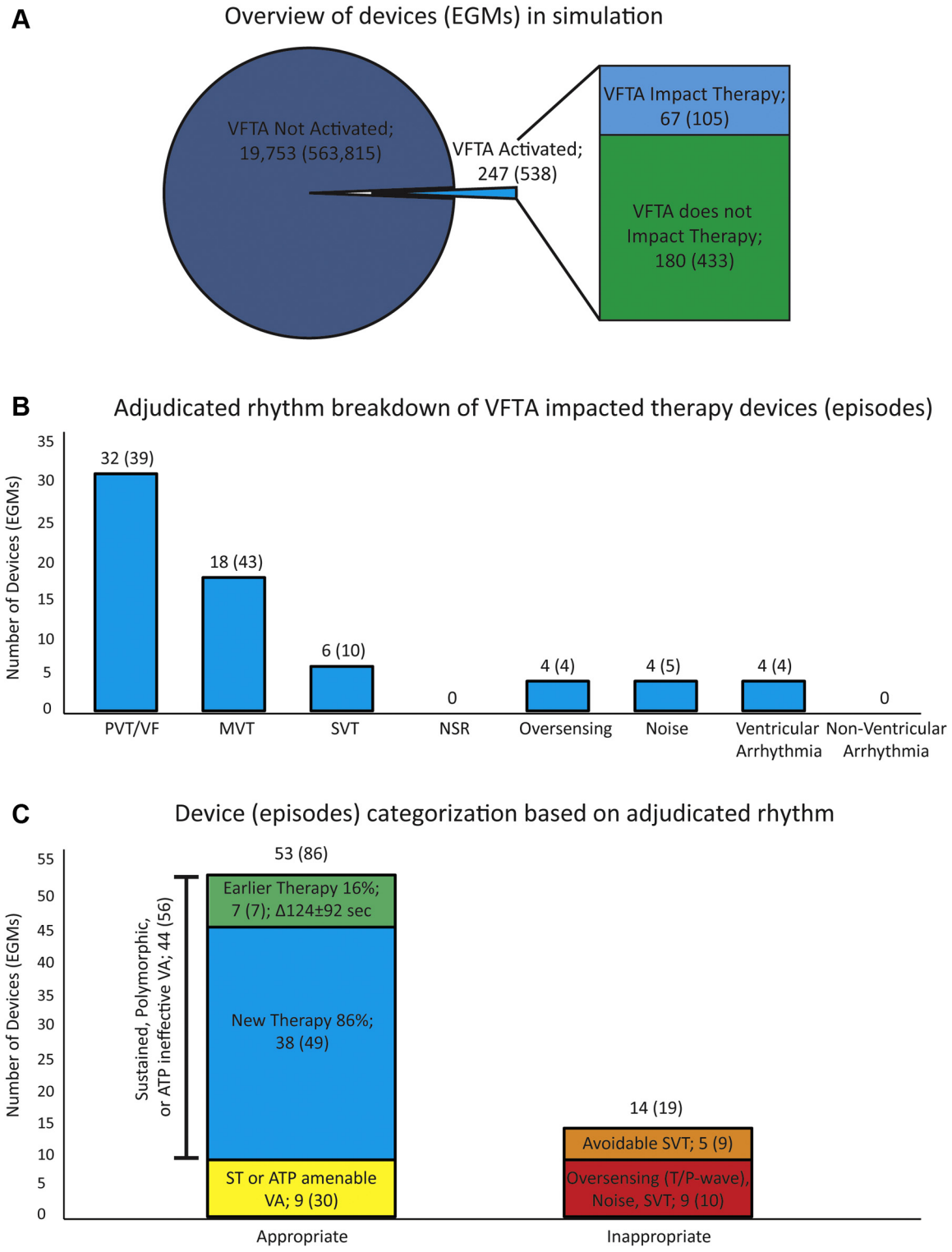

Figure 4 Episode and device data summary. A: A total of 19,753/20,000 devices did not activate VF Therapy Assurance (VFTA). Of the 247 devices that activated VFTA, 67 devices delivered therapy that otherwise would not have been delivered or delivered therapy earlier than would have otherwise occurred compared to without VFTA. B: Breakdown of adjudicated rhythm devices and episodes where VFTA was activated. C: Categorization of device and episode for appropriateness and further breakdown of episode/therapy type (1 device in the appropriate categorization exhibited episodes receiving earlier and new therapy). Numbers with parentheses indicate electrogram (EGM)/episodes, numbers without parentheses indicate device/patients. ATP = antitachycardia pacing; MVT = monomorphic ventricular tachycardia; NSR = normal sinus rhythm; PVT = polymorphic ventricular tachycardia; ST = self-terminating; SVT = supraventricular tachycardia.

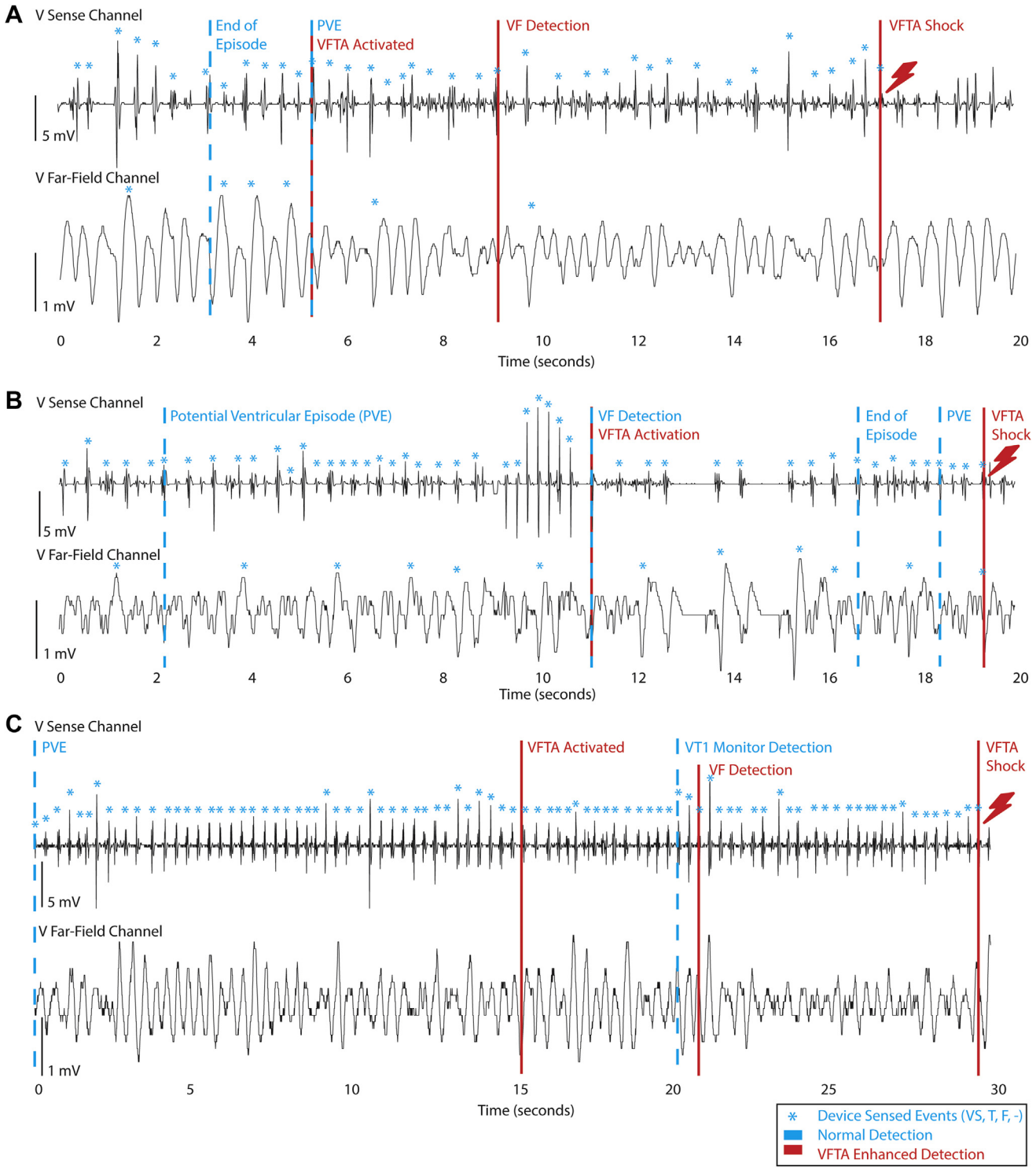

Figure 5 Example polymorphic ventricular tachycardia (PVT) / ventricular fibrillation (VF) episodes in which VF Therapy Assurance (VFTA) enhanced therapy delivery. **A:** VFTA activated during postepisode window, promptly providing high-voltage therapy (shock marker) Conventional detection incorrectly diagnosed the end of episode owing to brief slowing in the rhythm, preventing therapy from being delivered. **B:** VFTA activated at VF detection owing to low-amplitude far-field signals, providing therapy (shock marker). Owing to a few undersensed intervals and momentary slowing of the rhythm, conventional detection would have taken significantly longer to reach detection. **C:** VFTA activated after a prolonged period in potential ventricular episode, triggering a VF detection and providing therapy (shock marker), where conventional detection would have detected VT1 (monitor zone) owing to programming. Asterisks indicate device sense markers.

PVT/VF episode examples in which VFTA enhanced HV therapy delivery are illustrated in Figure 5. In Figure 5A, VFTA intervened when the required number of ITD were met in the presence of consistent low-amplitude intervals on the far-field channel, while the near-field channel has adequate sensing. In this case, VFTA prevented an "End of

Episode" diagnosis by increasing the required number of sinus intervals binned and promptly delivered HV therapy. In Figure 5B, the device had previously erroneously declared an "End of Episode" during an ongoing arrhythmia. VFTA intervened at the start of another potential ventricular episode owing to the lack of detected intervals on the far-field channel. In this postepisode redetection example, VFTA reduces criteria to detect VF, resulting in rapid diagnosis of VF and subsequent HV therapy delivery. Finally, Figure 5C illustrates VFTA intervention when there is a prolonged period of potential ventricular arrhythmia without episode detection; where conventional detection would have detected VT-1 (programmed to monitor), VFTA promptly provided HV therapy approximately 2 minutes earlier than without VFTA, which would have prevented degradation of the tachyarrhythmia.

The VFTA feature achieved these clinical improvements with an 18.1% (19/105) increase in rate of inappropriate therapy among physician-adjudicated EGMs. This corresponds to an overall rate of 0.07% (14/20,000) increase in inappropriate therapy delivery (noise oversensing: 4, physiologic oversensing: 4, and SVT: 6) with VFTA. Exact binomial test indicates that the 95% upper confidence bound for increase in inappropriate HV therapy is 0.1%.

Additional device programming analyses were performed on devices with episodes categorized as inappropriate therapy. These included 10 SVT episodes from 6 devices that were incorrectly diagnosed by rhythm discriminators. Four of 6 devices were found to have far-field morphology discriminators disabled, and in a fifth device, all discriminators were disabled. Therefore, in 5 out of 6 devices (9 out of 10 SVT episodes) improved arrhythmia discrimination may have been achieved simply by utilizing SVT discriminators.

In summary, the VFTA algorithm altered HV therapy in 0.34% (67/20,000) of devices with an 81.9% episode PPV and 79.1% device TPR. VFTA delivered HV therapy to 0.22% (44/20,000) of the devices that experienced at least 1 potentially undertreated ventricular tachyarrhythmia episode.

Discussion

To the best of our knowledge, this is the first demonstration of an algorithm developed specifically to provide an additional level of discrimination and detection of difficult-to-detect ventricular arrhythmias. The results of this computer-simulated analysis suggest that use of the VFTA algorithm enhances ICD therapy delivery in the context of low-amplitude signal detection during ventricular arrhythmias. The findings of this analysis indicate that VFTA has the potential to further improve ICD detection of ventricular tachyarrhythmias without significantly increasing the risk of inappropriate shocks.

Recently published literature suggests that delivery of HV shocks may affect mortality and quality of life in ICD patients.[9,10,17–22] As such, programming guidelines recommend faster detection rate cutoffs and longer detection times to reduce avoidable HV therapy. However, multiple reports have revealed that generic compliance with guideline-directed ICD programming recommendations, with or without undersensing, may lead to delayed, or in some instances even withholding, delivery of the HV therapy.[13–15,23] Moreover, postmortem studies suggest that mortality in ICD-implanted patients can be due to undertreated ventricular tachyarrhythmias.[13,18,24,25] It is well recognized that undersensing of ventricular signals (R waves) during VF in ICDs is a known limitation of the therapy.[7] While occasional undersensed events do not typically delay detection and treatment, the likelihood of this occurrence may be higher when longer detection times and/or faster detection rates are programmed. These occurrences are, so far, limited to very few patients, but the consequences are often catastrophic. These results demonstrate that the VFTA algorithm can prevent undertreatment caused by the combination of programming and undersensing by temporarily adjusting detection parameters in the presence of undersensing on the far-field EGM.

Undertreatment of arrhythmias may be under-reported owing to the episode storage logic employed by different manufacturers; VT/VF episodes may not be stored if a high enough rate is not sustained to meet detection criteria or may be overwritten by other episodes. Programming combined with R-wave undersensing can increase the rate of under-reported episodes, as no EGMs will be stored and available for review owing to lack of detection. By temporarily lowering the detection parameters, the VFTA algorithm can record, treat, and retain previously under-reported episodes.

Furthermore, arrhythmia detection and therapy delivery in ICDs typically rely on a set of timers and counters, which can be reset owing to brief undersensing or rate falling under programmed detection rate. This may cause significant delay in HV therapy. This delay can be detrimental to patient survival; a delay of more than 12 minutes resulted in 13% survival rate compared to 46% when HV therapy was delivered within 7 minutes.[26] The VFTA algorithm in this study facilitated HV therapy, on average, greater than 2 minutes earlier and prevented delays caused by counter and timer resets.

The VFTA algorithm may also allow for delivery in the monitor zone when activated, as the algorithm lowers the detection rate to the programmed slowest therapy zone with an additional 100 ms (to a maximum of 400 ms), as shown in Figure 5C. However, owing to the multiple undersensing criteria that VFTA must satisfy prior to activation, therapy delivery is most likely due to occasional undersensing causing the arrhythmia to fall into the monitor zone.

The study findings identified a small number of SVT episodes that were misdiagnosed as VT, leading to inappropriate therapy delivery with VFTA enabled. Analysis of these episodes suggests that inadequate discriminator programming resulted in incorrect rhythm diagnosis. Stroobandt and colleagues[14] demonstrated that SVT discriminators are crucial in reducing inappropriate therapy, with far-field morphology discriminator particularly effective. Programming of available discriminators, regardless of device manufacturer, is

recommended by expert guidelines and is key to reducing inappropriate HV therapy delivery.[11,12,27,28] Similarly, instances of inappropriate HV therapy for SVTs resulting from the VFTA algorithm may be reduced with appropriate programming of discriminators, further improving the episode PPV to 90.5% (95/105) and device TPR to 86.6% (58/67). Therefore, the VFTA algorithm is most effective when programmed with recommended rhythm discriminators.

Limitations

The algorithm validation used simulations of real-world recorded data and was not based on data from a prospective clinical study. However, owing to the relatively low incidence of these undertreated arrhythmias, the simulations outlined in this study were able to evaluate a much larger sample size, yielding statistically significant results. The EGM reports imposed another limitation related to physician review, as some reports had low fidelity, and others did not include pertinent patient information to help with the diagnosis. To address this limitation, multiple physicians were asked to blindly read-judicate the same EGM reports. Moreover, this approach in development and validation of device-based algorithms has been widely utilized.[29–31]

The algorithm only affected a very small number of devices (0.34%) and EGMs (0.019%) in this study owing to normally very effective sensing, detection, and treatment. Delay or withholding of HV therapy remains an infrequent but potentially life-threatening event. This study shows that the VFTA algorithm may lead to appropriate HV therapy in such events.

The current study analyzed the enhanced detection of undersensed tachyarrhythmias in cases where VFTA sufficiently altered HV therapy compared to conventional detection. As such, only EGMs (n = 105) where VFTA provided a new or earlier treatment (by more than 30 seconds) were adjudicated by physicians. This method precludes the ability to assess the improvement in the VFTA algorithm performance across all appropriate and inappropriate detections compared to the conventional algorithm, which would be appropriate for further statistical analysis such as net reclassification index.

Furthermore, the algorithm performance indicated a dependency on programming of SVT discriminators to reduce the risk of inappropriate shocks. However, this is a limitation shared across all ventricular tachyarrhythmia detection and therapy algorithms.

Additionally, while this study does not correlate sensed sinus R-wave amplitudes to VF signals, prior published findings have shown that even with large sinus R waves ($\geq$5 mV) at implant, there can be some undersensing of VF.[32] This is owing to the inherent nature of PVT and VFs given the dynamically changing ventricular signal amplitude and intervals, which can make them susceptible to undersensing, leading to delay or lack of HV therapy in rare scenarios. The VFTA algorithm enhances traditional detection algorithms with a novel discrimination criteria and acts as a safety net for patients that are at risk of undertreatment of VT/VF with poor outcomes.

Finally, a small number of ventricular tachyarrhythmias that were self-terminating MVTs or MVTs amenable to ATP also triggered VFTA. While these episodes are accurate ventricular tachyarrhythmia detections in the simulation analysis, HV therapy may not be clinically important. However, since VFTA does not alter the noncommitted nature of HV therapy and allows ATP while charging, the HV therapy provided by VFTA may still be avoided.

Despite these limitations, this study demonstrates the potential benefits of a novel algorithm that allows physician-preferred ICD programing while providing an additional safety net for patients implanted with ICDs. This algorithm closes a small but relevant gap in detecting and treating previously undertreated arrhythmias. The results of this study need to be validated and confirmed in additional prospective real-world studies where simulation is not used.

Conclusion

This study describes and validates the performance of a novel algorithm, "VF Therapy Assurance," designed to identify tachyarrhythmia episodes with potential undertreatment and reduce the risk of undertreatment without significantly increasing inappropriate HV therapy. The results of this study demonstrate that 0.22% of the patients implanted with ICD or CRT-D devices experienced at least 1 instance of an undertreated life-threatening ventricular tachyarrhythmia episode. The VFTA algorithm, when activated in these devices, will deliver HV therapy to 86% of patients who would have been otherwise untreated for potentially life-threatening arrhythmias.

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Authorship: All authors attest they meet the current ICMJE criteria for authorship.

Ethics Statement: Devices and episodes were de-identified prior to analysis and therefore this study does not fall under the purview of the institutional review board.

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