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Original Article

Evaluation of defibrillation safety and shock reduction in implantable cardioverter-defibrillator patients with increased time to detection: A randomized SANKS study

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ABSTRACT [1]

Background: The need for ways to minimize the number of implantable cardioverter-defibrillator (ICD) shocks is increasing owing to the risk of its adverse effects on life expectancy. Studies have shown that a longer detection time for ventricular tachyarrhythmia reduces the safety of therapies, in terms of syncope and mortality, but not substantially in terms of the success rate. We aimed to evaluate the effects of increased number of intervals to detect (NID) VF on the safety of ICD shock therapy and on the reduction of inappropriate shocks.

Methods: The present study was a prospective, multicenter, randomized, crossover study. Randomized VF induction testing with NID 18/24 or 30/40 was performed to compare the success rate of defibrillation with a 25-J shock and the time to detection. Inappropriate shock episodes were simulated retrospectively to evaluate a possibility of episodes avoidable at NID 24/32 and 30/40.

Results: Thirty-one consecutive patients implanted with an ICD or cardiac resynchronization therapy-defibrillator (CRT-D) were enrolled in this study. The success rate of defibrillation was 100% in both NID groups at the first shock. The time from VF induction to detection showed a significant increase in the NID 30/40 group (6.16 ± 1.29 s vs. 9.00 ± 1.31 s, $p < 0.001$). Among the 120 patients implanted with an ICD or CRT-D, 10 experienced 32 inappropriate shock episodes. The inappropriate shock reduction rate was 53.1% and 62.5% with NID 24/32 and 30/40, respectively.

Conclusions: The findings of this SANKS study suggest that VF NID 30/40 does not compromise the safety of ICD shock therapy, while decreasing the number of inappropriate shocks.

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1. Introduction

The implantable cardioverter-defibrillator (ICD) can prevent sudden cardiac death; however, recent studies have reported that ICD shock therapy, whether appropriate or inappropriate, may reduce the life expectancy of ICD recipients [1–3]. Inappropriate and unnecessary shock delivery is attributable to each ICD device's algorithm for detecting ventricular tachyarrhythmia (VTA). One algorithm detects VTA when a certain number of beats in the detection zone reaches the pre-programmed number of intervals to detect (NID). Many studies have explored ways to avoid inappropriate and unnecessary ICD shocks for fast ventricular

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[2] Mahito N, Xin Z, Naoshi I, et al. Evaluation of Defibrillation Safety with the increased Number of Sensing to Reduce Shocks for Ventricular Tachyarrhythmia in Japanese ICD Patients – SANKS STUDY. Venue of the 8th Tawara-Aschoff-Meeting; 2012.

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tachycardia (FVT). Some have reported that increasing NID and using antitachycardia pacing (ATP) effectively avoids inappropriate and unnecessary ICD shocks for FVT [4–10]. In the case of ventricular fibrillation (VF), increased NID may prolong the time to shock therapy and pose higher risks of hemodynamic deterioration and unstable VF waves, resulting in a higher number of undersensed VFs and higher defibrillation thresholds [11,12]. However, very few studies have evaluated the influence of prolonged time to shock therapy on the safety of ICD shock therapy. This SANKS study evaluated the effects of increased NID in the VF detection zone (VF NID) on the safety of ICD shock therapy and the number of inappropriate ICD shocks.

2. Material and methods

2.1. Study design

This SANKS study consisted of two aspects. One was a prospective, multicenter, randomized, un-blinded, crossover study to evaluate the safety of ICD shock therapy with increased VF NID in the VF detection zone. The other was a retrospective study to assess the possibility of reducing shocks with increased VF NID.

For the safety evaluation, we examined the defibrillation success rate, time from detection to termination, undersensing of VTA, and adverse events related to ICD shock therapy during induction testing. This study design is shown in Fig. 1. The subjects were patients eligible for implantation of a commercially available Medtronic ICD or cardiac resynchronization therapy-defibrillator (CRT-D) for primary or secondary prevention. At the time of implantation, subjects were randomly assigned to 1 of the 2 VF NID settings in a 1:1 ratio: (1) NID 18/24 (18 of the last 24 beats in the VF detection zone must meet a programmable threshold rate for the device to detect and treat) or (2) NID 30/40. During the first and second VF induction tests, the patients were crossed over to the other setting so that the safety of each NID setting could be evaluated. Inherently, VF NID 30/40 will take longer to detect an arrhythmia because it requires at least 16 more beats.

We also evaluated the possibility of shock reduction with prolonged detection duration, NID 24/32 or NID 30/40, by computer simulation retrospectively. This analysis used spontaneous shock episodes from a separate sample of subjects who previously received an ICD or CRT-D programmed to NID 18/24.

2.2. Participants

The study was conducted at three sites in Japan. Subjects enrolled for the safety evaluation met the following eligibility criteria: Class I or IIa recommendation for ICD or CRT-D implantation by the Guidelines for Non-Pharmacotherapy of Cardiac Arrhythmias (Japanese Circulation Society) [13]; a history of cardiac events; patients medically cleared to receive VF induction testing; and patients able to tolerate 25-J shocks at VF induction testing. For medical reasons, patients not able to undergo VF induction testing were excluded. Written informed consent was obtained from all subjects prior to participation in the study.

The same study sites participated in the computer simulation to evaluate the possibility of shock reduction. Spontaneous shock episodes from the subjects who underwent implantation of an ICD or CRT-D between March 2001 and March 2008 were used in the simulation.

2.3. End-points

End-points 1–3 were evaluated in the randomized induction study. End-point 4 was analyzed via retrospective computer simulation.

2.3.1. Defibrillation success rates

After randomization, the subjects in both groups received a VF induction. Five minutes later, they were crossed over to the other NID setting and received a second VF induction. The defibrillation success rate was evaluated for each NID setting. The ICD was set to deliver a 25-J shock, 10 J below the maximum shock energy for the

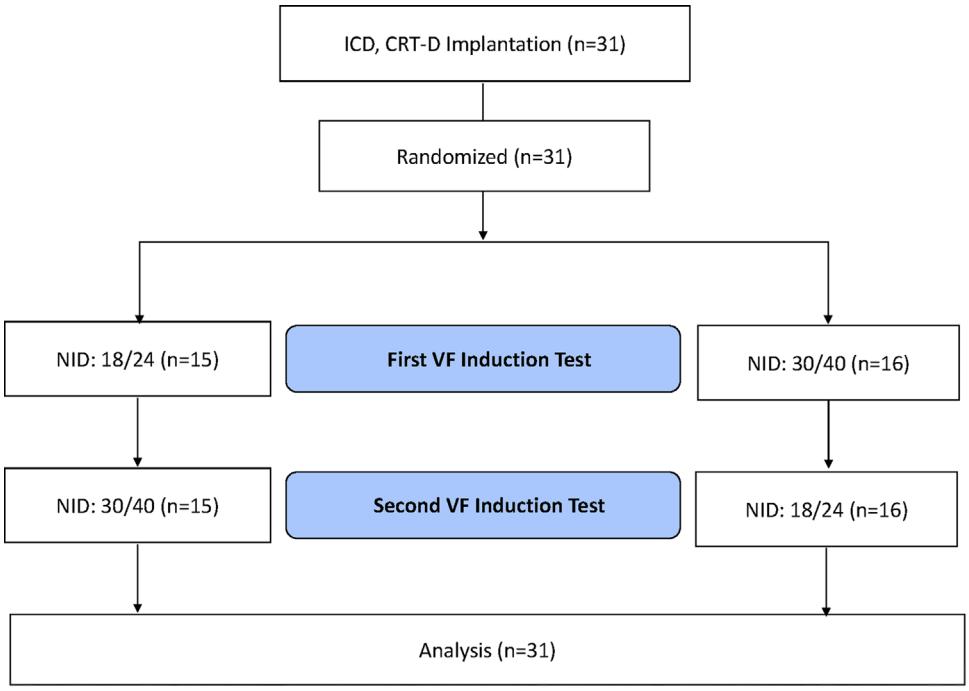

Fig. 1. Study flow diagram for the randomized study. ICD, implantable cardioverter-defibrillator; CRT-D, cardiac resynchronization therapy-defibrillator; NID, number of intervals to detect; VF, ventricular fibrillation.

device. Successful termination of the induced arrhythmia by the 25-J shock implied success.

2.3.2. Time measurement

The times from VF induction to detection, from VF detection to termination, and from VF induction to termination were measured for each NID setting.

2.3.3. Undersensing

The number of undersensed VTAs during detection was counted for each NID setting. The influence of cardiac dysfunction on the number was determined using the following 2 patient groups: patients with left ventricular ejection fraction (LVEF) $<40\%$ and those with LVEF $\geq 40\%$. The sensitivity was set at 1.2 mV for VF induction testing. Undersensing was defined as a failure of the ICD to mark a relevant peak on its electrogram (EGM). The number of unmarked EGM peaks was considered the number of undersensed VTAs.

2.3.4. Shock reduction rate

The inappropriate shock reduction rate was evaluated by modeling NID 24/32 and NID 30/40. ICD EGMs were retrospectively reviewed from subjects previously implanted with an ICD or CRT-D that was programmed to NID 18/24. Inappropriate spontaneous shock episodes with no ATP therapies applied were used for the analysis. The EGM data that included all intervals during these episodes was loaded into a VIP II simulator (Medtronic Inc.) to determine whether the shock could have been avoided if the NID was 24/32 or 30/40. In other words, would the device not have detected and treated the episode had the NID been set to 24/32 or 30/40 instead of 18/24?

This study was performed in compliance with the Declaration of Helsinki and its conduct was approved by the Institutional Review Board or Medical Ethics Committee of each study site (UMIN registration number: UMIN000003442).

2.4. Statistical methods

Continuous variables are reported as the mean $\pm$ standard deviation (SD). The defibrillation success rate was calculated as the percentage of VTA terminated by 25-J shocks. A paired *t*-test was performed for time comparisons between NID 18/24 and NID 30/40. The number of undersensed peaks between low and normal cardiac function was compared using the Wilcoxon rank-sum test. Spearman's rank correlation was used to quantify the variation in the number of undersensed VTAs with time. A value of $p<0.05$ was considered statistically significant. Analysis was performed with SPSS version 19 statistical software (SPSS Inc., Chicago, Illinois).

3. Results

Thirty-one patients were enrolled consecutively, in this randomized study, between January 2010 and March 2012. The mean age was 65.5 $\pm$ 13.7 years. The proportion of patients with primary prevention indication was 25.8% and ischemic cardiomyopathy was 29.0%. All reported patient characteristics are shown in Table 1. Among the consecutive patients, 5 patients were excluded from this study for the following conditions: 2 patients were excluded for old age, 1 patient, for deteriorated general condition due to cancer, and the last 2 patients, for low cardiac function.

The retrospective analysis included 120 patients previously implanted with an ICD or CRT-D. Thirty-two inappropriate shock episodes that occurred in 10 (8.3%) of the 120 patients were analyzed.

3.1. Success rate of ICD shocks

All subjects underwent VF induction testing. Of the 62 induced VTAs, 54 episodes were adjudicated as VF by the investigators and 8 were ventricular tachycardia (VT) with an average cycle length of 287 $\pm$ 83 ms. The success rate of terminating VTA by the first ICD shock was 100% in both the NID 18/24 and NID 30/40 groups, without any related complications.

3.2. Time from VF induction to detection or termination

The time from VF induction to detection was higher in the NID 30/40 group (9.00 $\pm$ 1.31 s) than that in the NID 18/24 group (6.16 $\pm$ 1.29 s; $p<0.001$). The time from VF detection to termination did not differ between the 2 groups ($p=0.62$), whereas the time from VF induction to termination did show a significant increase in the NID 30/40 group (13.48 $\pm$ 1.26 s) as compared to the NID 18/24 group (10.61 $\pm$ 1.33 s, $p<0.001$; Table 2 and Fig. 2).

Table 1
Baseline characteristics of the prospective cohort ($n=31$).

Age (years)	65.5	(13.7)
Male gender	27	(87.1%)
Underlying heart disease		
Ischemic	9	(29.0%)
Dilated cardiomyopathy	7	(22.6%)
Hypertrophic cardiomyopathy	2	(6.5%)
Brugada syndrome	4	(12.9%)
Long QT syndrome	1	(3.2%)
Idiopathic VF	1	(3.2%)
Other	7	(22.6%)
Primary prevention	8	(25.8%)
LVEDD (mm)	55.7	(11.1)
LVESD (mm)	42.2	(14.0)
LVEF (%)	47.1	(16.5)
Medication		
ACE inhibitor	5	(16.1%)
ARB	14	(45.2%)
Beta-blocker	19	(61.3%)
Anti-arrhythmic	13	(41.9%)
Calcium antagonist	6	(19.4%)
Other AAD	5	(16.1%)

AAD, anti-arrhythmic drugs; ARB, angiotensin receptor blocker; ACE, angiotensin converting enzyme; LVEDD, left ventricular end diastolic diameter; LVEF, left ventricular ejection fraction; LVESD, left ventricular end systolic diameter. Data are presented as mean values (standard deviation) or numbers (%).

Table 2
Time from VF induction to detection or termination.

Group	Time (s)	Time difference (s)	*p*-Value
Time to detection from induction (s)			
NID: 18/24	6.16 $\pm$ 1.29	2.84 $\pm$ 1.29	<0.001
NID: 30/40	9.00 $\pm$ 1.31		
Time to termination from detection (s)			
NID: 18/24	4.45 $\pm$ 0.19	0.03 $\pm$ 0.30	0.62
NID: 30/40	4.48 $\pm$ 0.25		
Time to termination from induction (s)			
NID: 18/24	10.61 $\pm$ 1.33	2.87 $\pm$ 1.39	<0.001
NID: 30/40	13.48 $\pm$ 1.26		

NID, number of intervals to detect; VF, ventricular fibrillation. Data are presented as mean $\pm$ standard deviation.

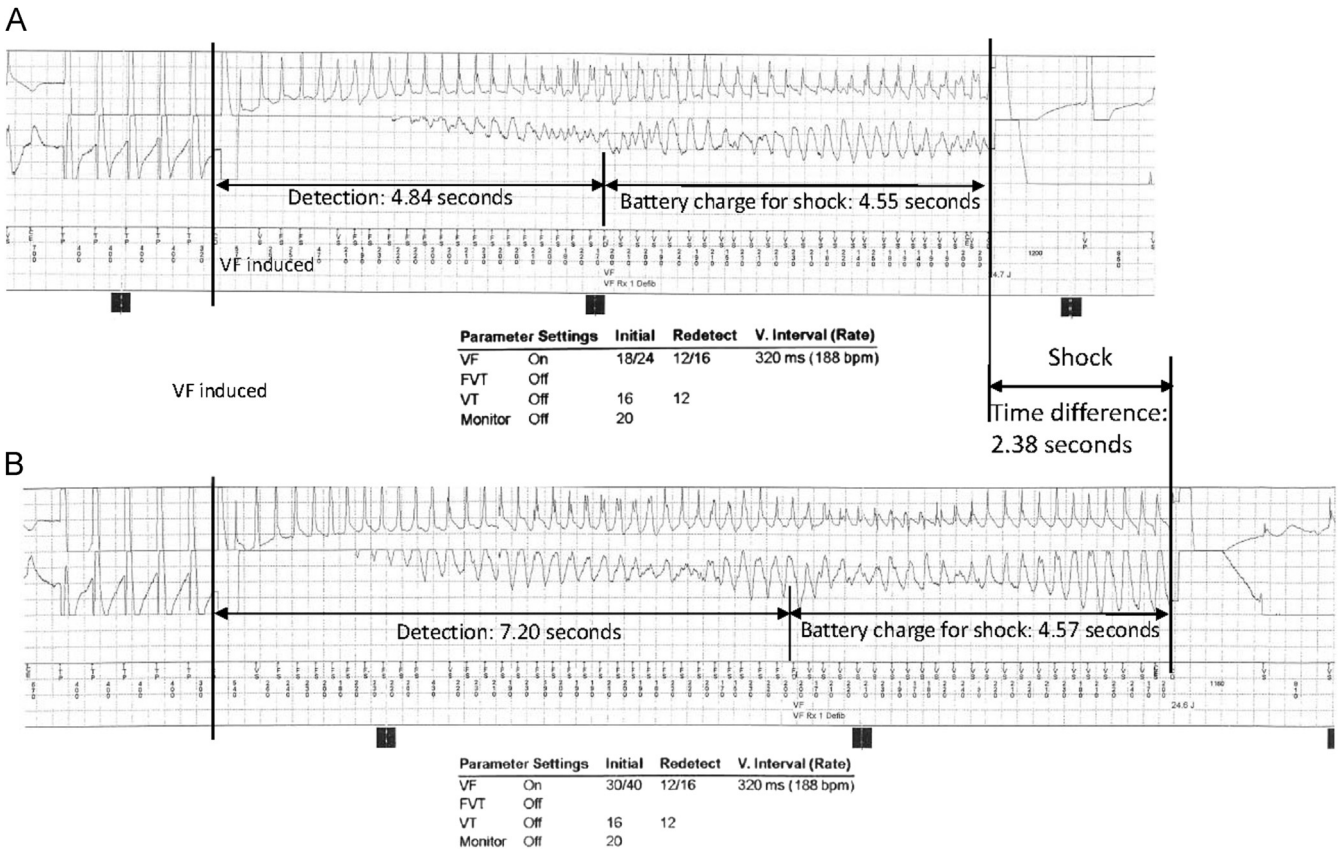

Fig. 2. Two implantable cardioverter defibrillator-stored EGMs from VF induction to termination, with 2 NID settings in a patient (18/24 and 30/40). The panel A EGM was recorded with NID 18/24. The time from VF induction to detection was 4.84 s, and the time from VF detection to termination was 4.55 s; the total time to VF termination was 9.39 s. The panel B EGM was recorded with NID 30/40. The time from VF induction to detection was 7.20 s, and the time from VF detection to termination was 4.57 s; the total time to VF termination was 11.77 s, 2.38 s longer than that with NID 18/24. EGM, electrogram; NID, number of intervals to detect; VF, ventricular fibrillation; VT, ventricular tachycardia; FVT, fast ventricular tachycardia.

3.3. *Undersensing*

There was no difference in the number of undersensed VTAs after VF induction between the groups (NID 18/24; 1.94 ± 2.49 peaks vs. NID 30/40; 2.16 ± 2.54 peaks, $p=0.78$). There was no correlation between the number of undersensed peaks and time after VTA induction (NID 18/24; $r=-0.24$, $p=0.905$, NID 30/40; $r=0.137$, $p=0.385$) (Fig. 3). No relationship was found between the number of undersensed peaks and cardiac dysfunction (Table 3).

3.4. *Shock reduction rate*

The results of the retrospective analysis are shown in Table 4 and Fig. 4. Of the 32 inappropriate shock episodes, 17 and 20 were avoidable when modeling NID 24/32 and 30/40 (53.1% and 62.5%; 95% confidence interval, 34.7–70.9% and 45.7–79.3%, respectively). Regarding NID 30/40, the avoidable shock episodes included 5 of the 5 episodes due to atrial fibrillation (AF, 100%), 1 of the 4 episodes due to supraventricular tachycardia (SVTs, 25.0%), 12 of the 21 episodes due to lead fracture (57.1%), and 2 of the 2 episodes due to P- or T-wave oversensing (100%). With NID 24/30, there were 3 unavoidable inappropriate shocks. All those shocks were due to lead fracture.

4. Discussion

While ICD shock therapy has prevented sudden cardiac death, shock therapy may induce myocardial damage and influence cardiac hemodynamics or life expectancy [1–3,14–17]. It has been suggested that myocardial damage resulting from shock therapy contributes to poor prognosis, whereas the use of ATP minimizes damage and does not affect prognosis. It is therefore important to terminate ventricular arrhythmias with the first ICD shock and minimize the number of inappropriate and unnecessary ICD shocks.

The safety of defibrillation with prolonged detection duration has been a matter of concern owing to the possibility of defibrillation threshold (DFT) elevation and creation of unstable VF waves over time. Windecker et al. noted that VF episodes lasting 10 s or more may have adverse effects on DFTs and negatively affect the effectiveness of ICD therapy [11]. Increasing VF NID prolongs the detection duration and may also cause unstable VF waves, resulting in additional undersensed VTAs. This study demonstrated that NID 30/40 increased the time from VF induction to detection by 2.84 s; however, the defibrillation success rate was 100% by the first ICD shock, and the numbers of undersensed peaks were similar between both NID groups. Further, in patients with cardiac dysfunction, smaller VF waves may lead to more undersensed peaks that could cause prolongation of the time from VF induction to termination. The present study showed no differences in the number of undersensed peaks between patients with cardiac dysfunction and normal cardiac function, even in the NID 30/40 group. These results suggest that VF NID could be increased to 30/40 in a safe manner, with no effects on the sensitivity to VTA or the defibrillation success rate.

Current ICD devices have VT/VF discrimination algorithms to avoid inappropriate ICD shocks (e.g., Sudden Onset, Stability, Morphology Discrimination), although they cannot completely

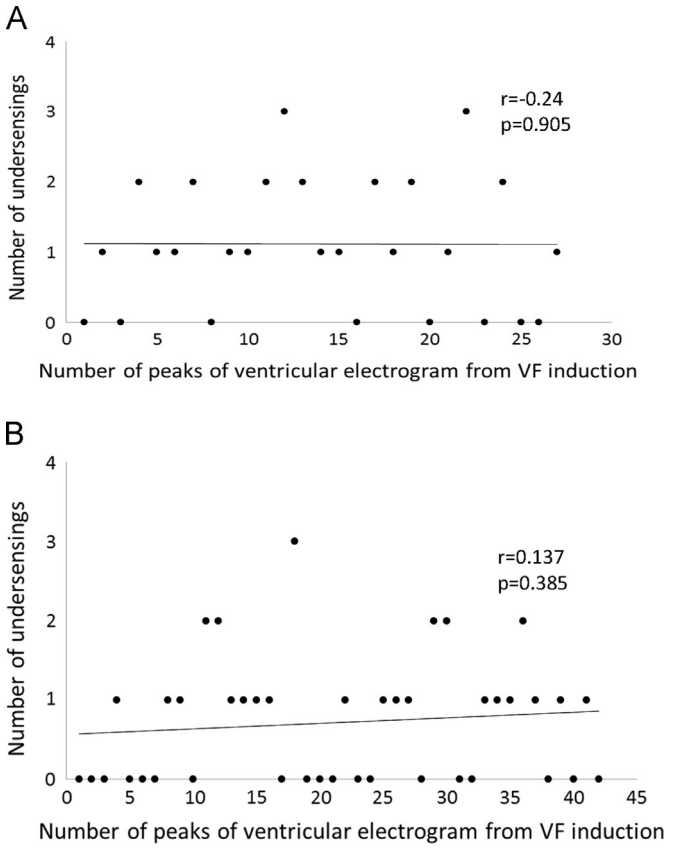

Fig. 3. Variation with time in the number of undersensed ventricular tachyarrhythmia from the first VF induction to detection (panel A, with NID 18/24; panel B, NID 30/40). The horizontal axis shows the number of electrogram peaks and the vertical axis, the number of undersensed peaks in all subjects. No correlation was found between the duration of the episode and the number of undersensed peaks, indicating no variation with time. NID, number of intervals to detect; VF, ventricular fibrillation.

Table 3
The number of undersensed VTAs.

Group	The number of undersensed peaks		*p*-Value
	Mean	Median	
NID: 18/24			
LVEF ≥ 40% (n=11)	1.36 ± 1.50	1	0.48
LVEF < 40% (n=20)	2.25 ± 2.88	1	
NID: 30/40			
LVEF ≥ 40% (n=11)	1.64 ± 2.46	1	0.36
LVEF < 40% (n=20)	2.45 ± 2.61	1.5	

LVEF, left ventricular ejection fraction; NID, number of intervals to detect; VTA, ventricular tachyarrhythmia. Data are presented as mean ± standard deviation.

discriminate VT/VF from relatively regular AF or SVTs with aberrant conduction. In the VF detection zone, the use of the discrimination algorithms is limited. A run of beats in the VF zone is classified according to the number of beats when discrimination algorithms cannot be utilized. Furthermore, ICD rate schemes often misdiagnose AF or oversense and classify episodes as VF, thereby increasing the challenge of avoiding inappropriate ICD shocks in the VF detection zone.

Along with the discrimination algorithms, inappropriate and unnecessary shocks could be avoided by ATP or ICD programming. According to the PainFREE and PainFREE Rx II clinical trials, the ATP success rate in the FVT detection zone (188–250 bpm) was approximately 70% [4,6]. While ATP therapy may terminate FVT and avoid unnecessary shocks, it cannot revert VF, which requires ICD shock therapy. The Primary Prevention Parameters Evaluation (PREPARE) trial reported that in primary prevention patients, increased NID (30/40) and ATP attempts for FVTs decreased the incidence of ICD complications (including appropriate, inappropriate, and unnecessary ICD shocks) without posing safety concerns and improved the life expectancy of ICD recipients [7]. The RELEVANT study showed that prolonged detection duration (NID 30/40) led to a dramatic reduction of ICD interventions without jeopardizing ICD therapy capabilities or increasing morbidity in primary prevention patients [8]. The MADIT-RIT trial also reported that ICD programming for high-rate therapy or delayed therapy in primary prevention patients reduced the occurrence of inappropriate therapy [9]. Furthermore, the ADVANCE III study demonstrated that prolonged detection duration, NID 30/40, could reduce ICD therapy rate including ATP and shocks in both primary and secondary prevention patients safely [10]. Although this study is not exactly comparable to the ADVANCE III study, as ATP therapy was programmed in the ADVANCE III study, the results of the present study are in line with those of the ADVANCE III study.

Among the studies described above, the programming of VF detection interval is different. It still remains unclear how the detection interval should be programmed; therefore, further evaluation of the appropriate detection interval and detection duration is required. In the present study, we aimed to determine whether increased VF NID (from 18/24 to 24/32 or 30/40) reduced the number of inappropriate shocks. In the retrospective analysis of inappropriate shocks, the majority of VF episodes occurred in the pre-programmed R–R interval, while AF and oversensing

Table 4
Inappropriate shock assessment.

Episode no.	Cause of inappropriate shock	Possible to avoid with NID 24/32	Possible to avoid with NID 30/40
1	Oversensing	Yes	Yes
2	Oversensing	Yes	Yes
3	AT	No	No
4	AF	Yes	Yes
5	AF	Yes	Yes
6	AF	Yes	Yes
7	Lead fracture	No	No
8	Lead fracture	Yes	Yes
9	Lead fracture	No	Yes
10	Lead fracture	Yes	Yes
11	Lead fracture	Yes	Yes
12	Lead fracture	No	No
13	Lead fracture	No	No
14	Lead fracture	No	No
15	Lead fracture	Yes	Yes
16	Lead fracture	No	No
17	Lead fracture	No	Yes
18	Lead fracture	No	No
19	Lead fracture	Yes	Yes
20	AF	Yes	Yes
21	AT	No	No
22	ST	No	No
23	AT	Yes	Yes
24	AF	Yes	Yes
25	Lead fracture	Yes	Yes
26	Lead fracture	Yes	Yes
27	Lead fracture	Yes	Yes
28	Lead fracture	No	No
29	Lead fracture	Yes	Yes
30	Lead fracture	No	Yes
31	Lead fracture	No	No
32	Lead fracture	No	No

AF, atrial fibrillation; AT, atrial tachycardia; NID, number of intervals to detect; ST, sinus tachycardia.

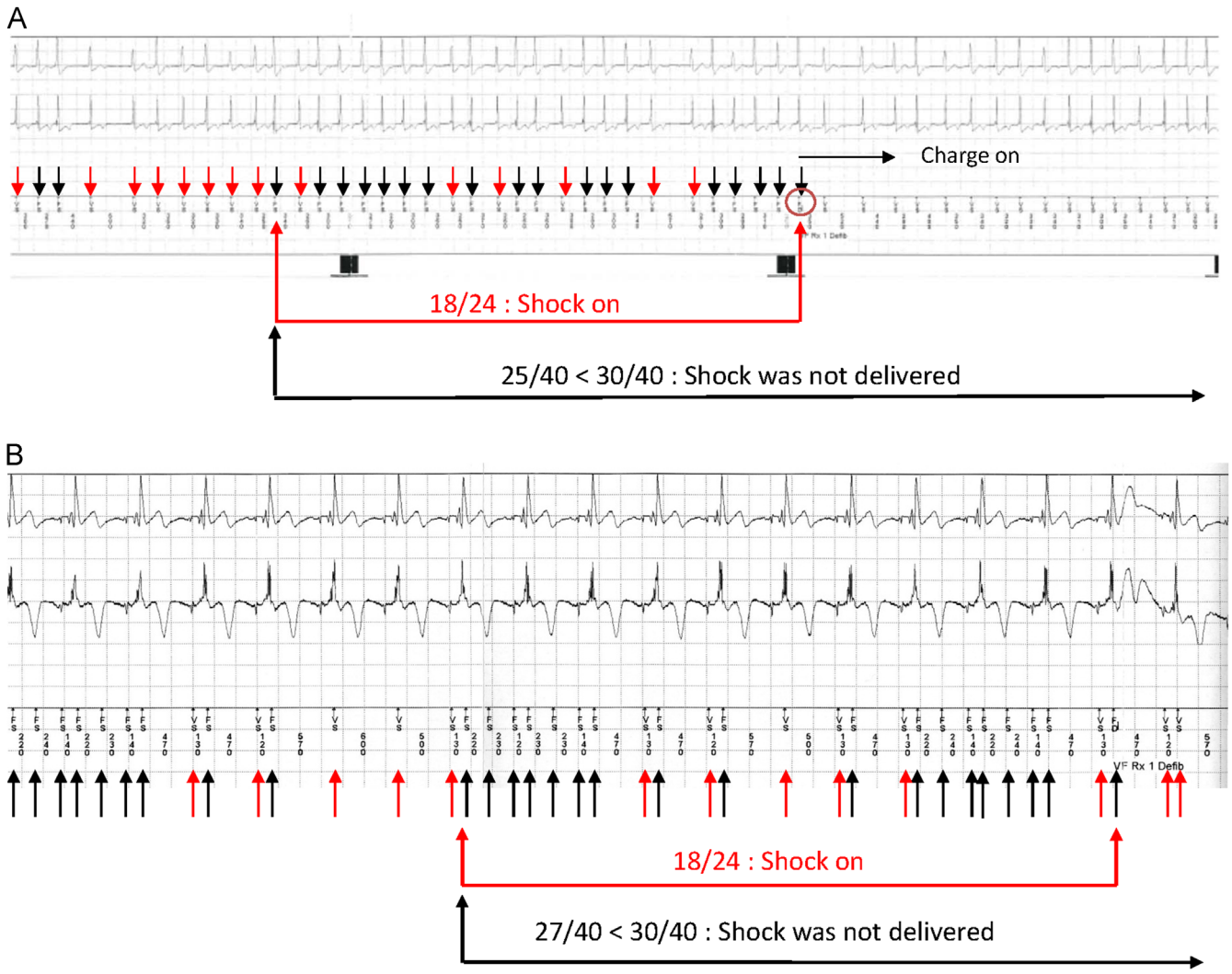

Fig. 4. Inappropriate shocks recorded in implantable cardioverter defibrillator-stored electrograms. (A) An example of atrial fibrillation (black arrows, beats in the VF detection zone; red arrows, those outside the VF detection zone). An inappropriate shock occurred when the number of VF beats reached VF NID 18/24. With VF NID 30/40, the number of VF beats was 25/40, and the shock would be avoidable. (B) An example of P- and T-wave oversensing (black arrows, beats in the VF detection zone; red arrows, beats outside the VF detection zone). An inappropriate shock occurred when the number of VF beats reached VF NID 18/24. With VF NID 30/40, the number of VF beats was 27/40, and the shock was avoidable. NID, number of intervals to detect; VF, ventricular fibrillation.

episodes were more likely to deviate from the VF detection zone. This suggests that increased VF NID is effective in preventing inappropriate shocks due to AF and oversensing. In this study, all 5 inappropriate shock episodes due to AF were avoidable when modeling NID 24/32 and 30/40. For instance, in the 5 episodes with NID 30/40, the maximum number of abnormal beats counted was 20–27, suggesting the necessity of a longer monitoring time sufficient to count approximately 30 beats. Since AF is considered the most common cause of inappropriate shock [1,18], increasing VF NID would be effective in avoiding these shocks. Furthermore, the shock reduction rate was 42.9% or 57.1% in the lead fracture cases with NID 24/32 or 30/40, respectively. Early detection is an important measure against lead fractures. The Lead Integrity Alert, which allows such early warnings and prolongs the detection duration to NID 30/40, has been shown to avoid inappropriate shocks [19–21]. According to the CONNECT trial [22], the time from event onset to clinical decision in response to alerts for AT/AF burden, ventricular rate during AT/AF, and lead impedance out of range could be significantly reduced with a remote monitoring system. In the future, remote monitoring systems will make it possible to more effectively avoid inappropriate shock delivery in addition to the prolonged VF NID approach.

4.1. Limitations

The power of the safety analysis for this study was diminished by the limited sample size (31 subjects). This was attributed to the difficulty in obtaining informed consent owing to the perceived risks associated with increased VF NID and the exclusion of outpatients; this was done to maximize subject safety. Some patients who could not undergo the DFT test because of their clinical condition were excluded from this study. However, since the decision to not undergo a DFT test is not specific to this study, we believe that the patient population of this study reflects a representative population. Further, it is unknown if the characteristics of arrhythmia varied between the first and second VF induction tests, although neither cycle lengths nor wave peaks differed between the 2 NID groups.

The retrospective analysis of inappropriate shocks had a limited sample size resulting in a wide confidence interval for the estimated effect. Device-stored EGM data for each shock episode is deleted when the shock is delivered. Because of this, it is possible that the episodes classified as “inappropriate shock avoided” with modeled NID 30/40 would have actually resulted in a shock in a subsequent detection under real-life conditions.

5. Conclusion

Although increased VF NID (30/40) prolonged the time to shock therapy, ICDs terminated all induced VTA episodes within the safety margin from their maximum shock energy. Inappropriate ICD shocks were considered to be avoidable with VF NID 30/40. These findings support larger studies on this topic, suggesting that VF NID 30/40 can be used in the clinics to reduce the number of inappropriate shocks safely.

Conflict of interest

This work was supported by Medtronic Japan. MN received honoraria from Medtronic Japan, St. Jude Medical Japan and Boston Scientific Japan. YE and TI received honoraria from Medtronic Japan. HS received honoraria from Japan Lifeline. YA, TT, and KK are employees of Medtronic Japan.

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