Trends in implantable cardioverter-defibrillator programming practices and its impact on therapies: Insights from a North American Remote Monitoring Registry 2007–2018 ℮

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BACKGROUND Recent evidence has revealed the utility of prolonged arrhythmia detection duration and increased rate cutoff to reduce implantable cardioverter-defibrillator (ICD) therapies. Data on real-world trends in ICD programming and its impact on outcomes are limited.

OBJECTIVE The purpose of this study was to evaluate trends in ICD programming and its impact on ICD therapy using a large remote monitoring database.

METHODS A retrospective analysis of patients with ICD implanted from 2007 to 2018 was conducted using the de-identified Medtronic CareLink database. Data on ICD programming (number of intervals to detection [NID] and therapy rate cutoff) and delivered ICD therapies were collected.

RESULTS Among 210,810 patients, the proportion programmed to a rate cutoff of ≥188 beats/min increased from 41% to 49% and an NID of ≥30/40 increased from 17% to 67% before May 2013 vs after February 2016. Programming to a rate cutoff of ≥188 beats/min, a ventricular fibrillation (VF) NID of ≥30/40, or a combined rate cutoff

of ≥188 beats/min and VF NID of ≥30/40 were associated with reductions in ICD therapy. The largest reductions in ICD therapy occurred when the combination of rate cutoff ≥ 188 beats/min and VF NID ≥ 30/40 was programmed (antitachycardia pacing: hazard ratio [HR] 0.35; 95% confidence interval [CI] 0.34–0.36; $P < .001$; shocks: HR 0.67; 95% CI 0.65–0.69; $P < .001$; and antitachycardia pacing/shocks: HR 0.43; 95% CI 0.42–0.44; $P < .001$).

CONCLUSION Despite evidence supporting the use of prolonged detection duration and high rate cutoff, implementation of shock reduction programming strategies in real-world clinical practice has been modest. The use of evidence-based ICD programming is associated with reduced ICD shocks over long-term follow-up.

KEYWORDS Antitachycardia pacing; Implantable cardioverter-defibrillator; Number of intervals to detect; Programming; Shock; Ventricular fibrillation

Introduction

Implantable cardioverter-defibrillators (ICDs) reduce mortality in patients at high risk of ventricular arrhythmias.[1–3] Previous ICD programming trials, such as Primary Prevention Parameters Evaluation (PREPARE), Multicenter Automatic Defibrillator Implantation Trial–Reduce Inappropriate Therapy (MADIT-RIT), and Avoid DeliVering TherApies for Non-sustained Arrhythmias in ICD PatiEnts III

(ADVANCE-III), demonstrated that shock reduction strategies not only reduce shock rates but can also reduce hospitalizations and mortality over a follow-up period of up to 14 months.[4–10] Based on these studies, the current clinical practice recommendations suggest programming ICDs to higher rate cutoffs between 185 and 200 beats/min and longer detection times (at least 6–12 seconds or 30 intervals) to reduce unnecessary shocks in primary prevention patients (class I recommendation).[11]

Despite the published evidence and recommendations, a significant proportion of patients are not programmed to these guidelines. A recent analysis[12] demonstrated only a modest increase in shock reduction programming (1.7%–10.1%) before vs after the publication of MADIT-RIT[7] and the consensus statement. Furthermore, 2 years after the publication of the 2015 HRS/EHRA/APHRS/SOLAECE expert consensus statement, only 12% of patients were programmed

to the class I consensus recommendation of both increased rate cutoff for therapies and delayed detection.[11] We sought to evaluate whether the publication of large clinical trials and expert consensus statements was associated with changes in ICD programming and to assess whether shock reduction programming leads to a reduction in ICD therapy over long-term follow-up in real-world practice.

Methods
Study population
All patients from the United States and Canada, implanted with a Medtronic ICD between 2007 and 2018, with a remote CareLink (Medtronic, Minneapolis, MN) transmission were included in the analysis if they met all the following criteria: (1) their first transmission occurred within 180 days of implantation, (2) they had at least 2 transmissions with at least 1 transmission in 2010 or later, (3) their ventricular fibrillation (VF) detection was enabled to exclude patients for whom arrhythmia termination was not part of their goals of care such as patients in hospice (n = 3445 [1.6%]), and (4) they had a minimum of 30 days remote monitoring follow-up. Data were included only from patients who had consented to remote monitoring–derived research as required by their follow-up/implant center, and all data were de-identified before being included or analyzed in the database.

Data collection
Available patient demographic characteristics, date of implantation, clinic size, clinic location, and the programmed parameters from the initial and final transmission remote transmissions from the CareLink remote monitoring database were collected. To assess the effects of the landmark shock reduction trial, ADVANCE-III, and the joint HRS/EHRA/APHRS/SOLAECE expert consensus statement, each patient's initial programmed parameters were compared before May 1, 2013, vs after May 31, 2013 (ADVANCE-III was published on May 8, 2013), and before February 1, 2016, vs after February 29, 2016 (the consensus statement was published on February 2016). *Initial programming* was defined as the programmed parameters from the first remote monitoring transmission within 180 days of ICD implantation, and *final programming* was defined as the programmed parameters from the most recent remote monitoring transmission as of March 8, 2019. The *rate cutoff* defined as the lowest rate for which therapy was programmed and the number of intervals to detect (NID) were collected. Patients were categorized on the basis of rate cutoff <188 beats/min vs ≥188 beats/min and NID <30/40 vs ≥30/40.

Study end points
The occurrence of ICD antitachycardia pacing (ATP) or shock was recorded. Furthermore, the time to first ATP, time to first shock, and time to first therapy (ATP or shock) were determined. Programming was further analyzed on the basis of geographic region and clinic size. In order to provide geographic regions with similar total numbers of patients, patients were categorized into the following regions: Canada and US census regions: Northeast, Midwest, South, and West (Figures 1A and 1B; Online Supplemental Table 1). The effect of clinic size on programming was compared. *Clinic size* was defined as the number of patients in each clinic transmitting remotely through CareLink and analyzed in tertiles. In addition, the effect of nominal shock reduction programming on the initial and final programmed parameters was analyzed.

Statistical analysis
Continuous variables are expressed as mean ± SD. Discrete values are expressed as their value or percentage. The χ^2 test was used to compare proportions. The Kaplan-Meier method was used to generate hazard curves for ICD ATP, shocks, or any therapy. To compare ICD therapy hazard rates between patients grouped according to rate cutoff <188 beats/min vs ≥188 beats/min and NID <30/40 vs ≥30/40, the log-rank test was used. In this analysis, patients were censored if the rate cutoff or NID had been reprogrammed during the interval between the initial transmission and therapy. Cox proportional hazards models were used to estimate hazard ratios (HRs) and 95% confidence intervals (CIs). All statistical analyses were performed using SAS version 9.4 (SAS Institute Inc., Cary, NC).

Results
Overall, 210,810 patients from 4651 clinics with a median follow-up of 2.9 years (interquartile range 1.5–4.9 years) were included in the analysis (mean age 65 ± 14 years; 74% male). Table 1 lists the models of ICDs implanted. The median time between the initial and the most recent transmission was 2.8 years (interquartile range 1.4–4.7 years).

Programming of shock reduction parameters
At the initial transmission, 46% (n = 97,914) and 42% (n = 88,357) of patients were programmed to a rate cutoff of ≥188 beats/min and an NID of ≥30/40, respectively. The proportion of patients programmed to a rate cutoff of ≥188 beats/min increased from 41% (n = 33,140) to 50% (n = 64,238) (P < .001) before May 2013 vs after May 2013 (timing of the ADVANCE-III study publication) and from 45% (n = 62,009) to 49% (n = 34,343) (P < .001) before February 2016 vs after February 2016 (timing of the joint expert consensus statement publication). The proportion of patients programmed to NID ≥ 30/40 before May 2013 vs after May 2013 increased from 17% (n = 13,567) to 58% (n = 74,430) (P < .001). Additionally, the proportion of patients programmed to NID ≥ 30/40 before February 2016 vs after February 2016 increased from 29% (n = 39,812) to 67% (n = 46,704) (P < .001). Therefore, the proportion of patients programmed to NID ≥ 30/40 before May 2013 vs after February 2016 increased from 17% to 67%. The rate cutoff and NID were not reprogrammed between the initial transmission and the last follow-up or time of ICD therapy in 191,791 patients (91%). In the cohort of 154,484 patients
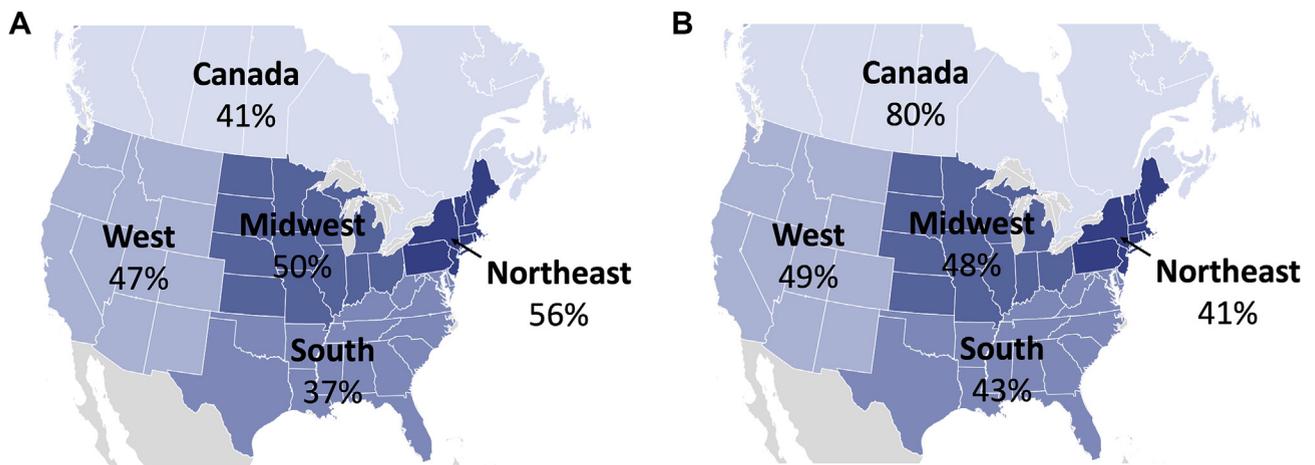
Figure 1   **A:** Proportion of patients with rate cutoff ≥ 188 beats/min programming by region. **B:** Proportion of patients with ventricular fibrillation number of intervals to detect ≥ 30/40 programming by region. Geographic regions are shown with different shades of *blue*.

whose most recent transmission was after February 2016, only 48% (n = 73,588) were programmed to a rate cutoff of ≥188 beats/min, 54% (n = 83,787) to a VF NID of ≥30/40, and 29% (n = 45,298) to both a rate cutoff of ≥188 beats/min and a VF NID of ≥30/40. In this cohort, 45,715 (30%) had a device model with nominal VF NID < 30/40. In this subcohort, only 43% (n = 19,784) were programmed to a rate cutoff of ≥188 beats/min, 33% (n = 15,135) to a VF NID of ≥30/40, and 17% (n = 7765) to both a rate cutoff of ≥188 beats/min and a VF NID of ≥30/40. By contrast, in the subcohort of 108,769 (70%) patients with a device model whose nominal VF NID was 30/40, only 49% (n = 53,804) were programmed to a rate cutoff of ≥188 beats/min, 63% (n = 68,652) to a VF NID of ≥30/40, and 35% (n = 37,533) to both a rate cutoff of ≥188 beats/min and a VF NID of ≥30/40.

Effect of programming on ICD therapy

Overall, 70,449 patients (33%) had ICD therapy during the course of the study. There were significant differences in the rates of device therapy between the programming groups. Compared with patients programmed to a rate cutoff of <188 beats/min, those programmed to ≥188 beats/min had

less ATP (HR 0.480; 95% CI 0.471–0.488; P < .001), shocks (HR 0.749; 95% CI 0.734–0.764; P < .001), and ATP/shocks (HR 0.553; 95% CI 0.544–0.562; P < .001) (Figures 2A and 2B). In addition, patients programmed to a VF NID of ≥30/40 had less ATP (HR 0.648; 95% CI 0.636–0.660; P < .001), shocks (HR 0.838; 95% CI 0.821–0.856; P < .001), and ATP/shocks (HR 0.694; 95% CI 0.682–0.706; P < .001) than did patients programmed to VF NID < 30/40 (Figures 3A and 3B). There was an incremental reduction of combined shock reduction programming (rate cutoff ≥ 188 beats/min and VF NID ≥ 30/40 vs VF NID < 30/40 and rate cutoff < 188 beats/min) in rates of ATP (HR 0.35; 95% CI 0.34–0.36, P < .001), shocks (HR 0.67; 95% CI 0.65–0.69; P < .001), and ATP/shocks (HR 0.43; 95% CI 0.42–0.44; P < .001) (Figures 4A and 4B).

## Differences in programmed parameters by nominal programming, region, and clinic size

Overall, 55% (n = 116,266) of devices remained programmed to nominal VF NID parameters (49% [n = 48,641] if VF NID < 30/40 and 60% [n = 67,625] if VF NID ≥ 30/40). From the initial and most recent transmissions, 58% (n = 57,003) and 53% (n = 52,571) of devices

Table 1   Percentage of devices programmed to VF NID nominal parameters by device model

Model	N	US release date	Canada release date	Nominal programming for model	Initial programming to nominal (%)		Most recent programming to nominal (%)		Initial programming VF NID ≥ 30/40 (%)		Most recent programming VF NID > 30/40 (%)	
Secura	23,378	03/2008	04/2011	18/24	63	58	56	53	19	20	24	26
Virtuoso	36,250	10/2008	06/2006	18/24	67		65		8		16	
Protecta	33,499	03/2011	06/2010	18/24	50		44		30		35	
Evera <2014*	5,499	04/2013	10/2013	18/24	19		18		35		39	
Evera ≥2014*	58,369	N/A	N/A	30/40	52	61	54	62	52	61	54	63
Evera MRI	53,815	09/2015	11/2011	30/40	71		71		71		72	
All	210,810				60		58		42		45	

N/A = not available; NID = number of intervals needed to detect; VF = ventricular fibrillation.
*Evera model devices shipped after November 2013 had 30/40 nominal VF NID programming.
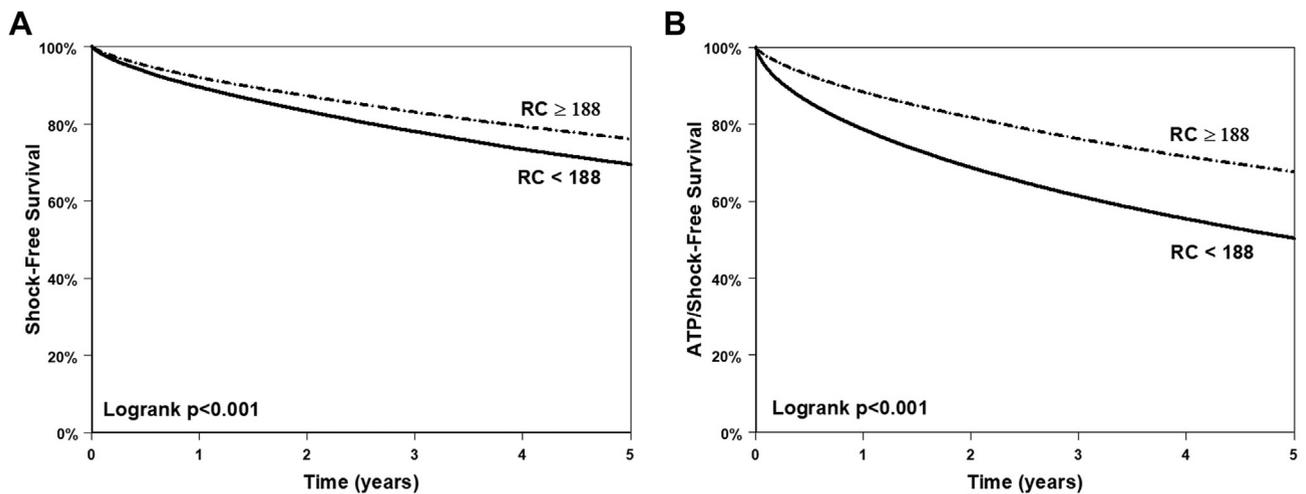
Figure 2 **A:** Shock-free survival by rate cutoff. The proportion of patients with shock-free survival over time is shown for patients programmed to rate cutoff (RC) ≥ 188 beats/min (*dotted line*) vs RC < 188 beats/min (*solid line*). **B:** Antitachycardia pacing (ATP)/shock-free survival by rate cutoff. The proportion of patients with combined ATP and shock-free survival over time is shown for patients programmed to RC ≥ 188 beats/min (*dotted line*) vs RC < 188 beats/min beats/min (*solid line*).

were programmed to nominal VF NID in the ICD models where the nominal VF NID was <30/40 (Table 1). In the ICD models where nominal VF NID was 30/40, 61% (n = 68,587) and 62% (n = 69,834) of the devices were programmed at these nominal settings at the initial and most recent transmissions. There was a substantial variability in the final programmed parameters by region with the rate cutoff of ≥188 beats/min ranging from 37% (n = 30,888/84,030) in the US-South region to 56% (n = 21,156/37,852) in the US-Northeast region ($P <$ .001) (Figure 1A) and the VF NID of ≥30/40 ranging from 41% (n = 15,449/37,852) in the US-Northeast region to 80% (n = 2080/2609) in Canada ($P <$ .001) (Figure 1B). There was no impact of the clinic size on the proportion of ICDs programmed with the evaluated parameters. The proportion of devices programmed to a rate cutoff of ≥188 beats/min

was 46% (n = 1158/2535, 7416/15,982, 89,340/192,293) in each clinic size tertile. The proportion of devices programmed to VF NID ≥ 30/40 was 40% (n = 1022), 42% (n = 6746), and 42% (n = 80,589) in clinics with 1–3, 4–22, and >23 devices per clinic ($P =$ .198).

Discussion
In this large study of >200,000 patients with a Medtronic ICD, we found that (1) there was only a modest effect of randomized controlled trial and expert consensus statement publications on shock reduction programming in clinical practice in the real-world setting, (2) shock reduction programming significantly decreases ICD therapy with combined rate cutoff and increased NID programming having the most profound reduction, (3) the majority of patients
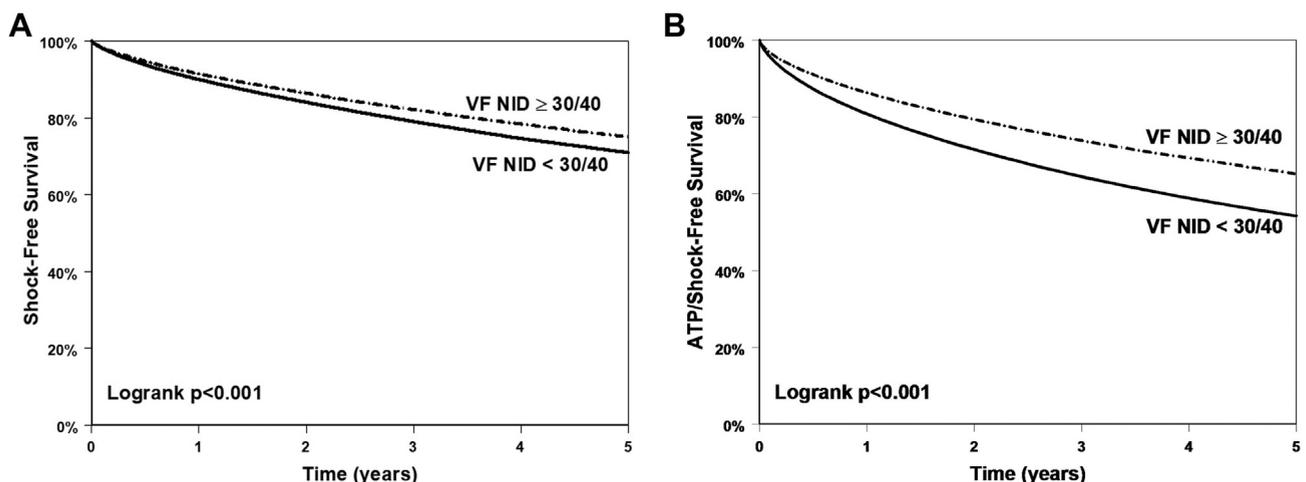
Figure 3 **A:** Shock-free survival by number of intervals to detect (NID). The proportion of patients with shock-free survival over time is shown for patients programmed to ventricular fibrillation (VF) NID ≥ 30/40 vs VF NID < 30/40. **B:** Antitachycardia pacing (ATP)/shock-free survival by NID. The proportion of patients with combined shock/ATP-free survival over time is shown for patients programmed to VF NID ≥ 30/40 vs VF NID < 30/40.
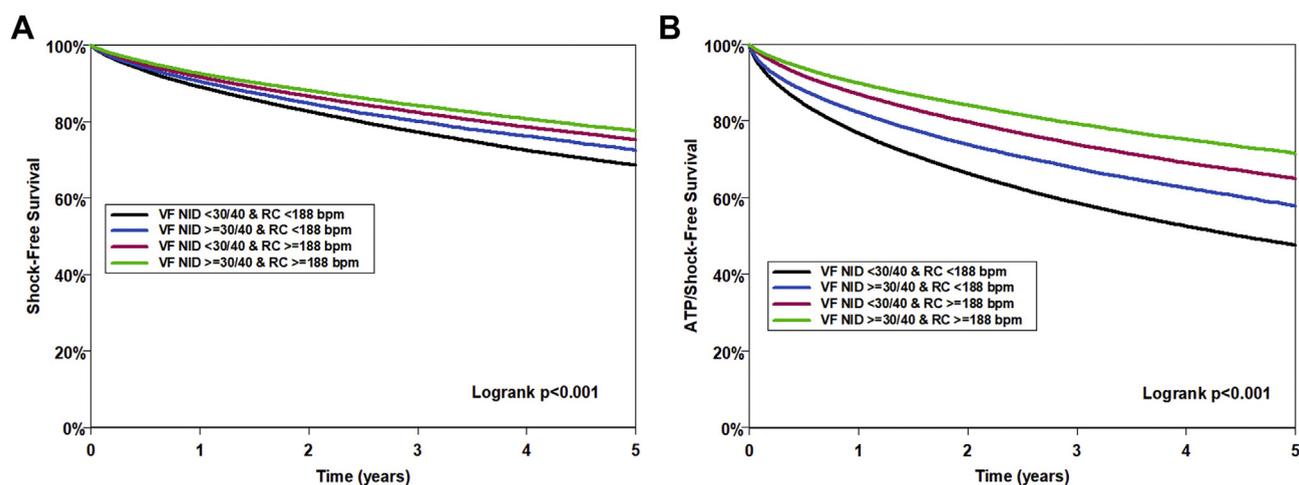
Figure 4   **A:** Freedom from implantable cardioverter-defibrillator (ICD) shock stratified by subgroups according to the number of intervals to detect (NID) and rate cutoff (RC) programming. The proportion of shock-free survival over time is shown for patients programmed to ventricular fibrillation (VF) NID < 30/40 and RC < 188 beats/min (*black line*), VF NID ≥ 30/40 and RC < 188 beats/min (*blue line*), VF NID < 30/40 and RC ≥ 188 beats/min (*pink line*), and VF NID ≥ 30/40 and RC ≥ 188 beats/min (*green line*). **B:** Freedom from combined ICD shock/antitachycardia pacing (ATP) stratified by subgroups according to NID and RC programming. The proportion of combined ATP/shock-free survival over time is shown for patients programmed to VF NID < 30/40 and RC < 188 beats/min (*black line*), VF NID ≥ 30/40 and RC < 188 beats/min (*blue line*), VF NID < 30/40 and RC ≥ 188 beats/min (*pink line*), and VF NID ≥ 30/40 and RC ≥ 188 beats/min (*green line*).

are programmed according to nominal programming, and (4) there is substantial variability in ICD programming by geographic region but not by device clinic size.

In this study, increased intervals to detection and increased treatment rate cutoff were associated with less ICD therapy. Our results are consistent with the findings of landmark shock reduction programming trials such as PREPARE,[10] Role of long dEtection window programming in patients with LEft VentriculAr dysfunction, Non-ischemic eTiology in primary prevention treated with a biventricular ICD (RELEVANT),[6] and ADVANCE-III.[13] These trials included 700, 324, and 1902 patients, respectively, had a mean follow-up of between 12 and 14 months, and examined the use of extended detection in patients programmed to increased rate cutoff. They demonstrated significant reductions in ICD therapy with shock reduction programming (PREPARE: ICD shock: HR 0.48; $P < .01$; RELEVANT: incidence rate ratio: ICD shock: 0.37; $P < .0001$; ATP and ICD shock: 0.12; $P < .0001$; ADVANCE-III, incidence rate ratio: ATP: 0.58; $P < .001$; ICD shock: 0.77; $P = .06$; and ATP/shocks: 0.63; $P < .001$). In our analysis, which included a larger cohort of 210,810 patients and longer follow-up, we found similar reductions in ICD therapies with increased rate cutoff and extended detection intervals. By extending detection intervals, ICD therapies can be reduced by permitting a percentage of ventricular arrhythmia episodes to self-terminate.

In the MADIT-RIT trial, Moss et al compared the rate of ICD therapy in patients programmed with high rate therapy or delayed therapy to conventional therapy. Compared with conventional therapy, there were reductions in the first occurrence of appropriate and inappropriate therapy episodes for both the high rate therapy and the delayed therapy groups. Compared with the conventional therapy group, the high rate therapy group had higher risk reductions than did the

delayed therapy group for inappropriate therapy (HR 0.21; $P < .001$ vs HR 0.24; $P < .001$) and mortality (HR 0.45; $P = .01$ vs HR 0.56; $P = .06$) end points. This is consistent with our findings of further numerical reduction in ICD therapy with high rate therapy compared with delayed detections. We have further built on this finding by showing that the combination of high rate therapy and delayed detection incrementally reduces ICD therapy over each individually.

Varma et al assessed the effect of the publication of MADIT-RIT and the consensus statement in 232,982 patients with Boston Scientific ICDs. In their analysis, the proportion of patients programmed to a rate cutoff of ≥185 beats/min increased from 32.5% to 42.2% in 2012–2013 and from 50.5% to 52.2% in 2015–2016, respectively.[12] This is similar to the increase in programming to an increased rate cutoff we found in our analysis. In the study by Varma et al, the proportion of patients programmed to delayed detection (≥6 seconds) increased from 10.9% to 21.1% in 2012 and 2013, the years immediately before vs after MADIT-RIT, and from 29.6% to 31.4% in 2015 and 2016, the years immediately before vs after the publication of the consensus statement, which is substantially lower than what we found in our analysis.[12] This may be because MADIT-RIT assessed the efficacy of either delayed detection or high rate therapy zone, prompting clinicians to choose either one or the other strategy. In contrast, ADVANCE-III assessed the efficacy of delayed detection in patients who were all programmed to a therapy rate cutoff of 188 beats/min. Therefore, ADVANCE-III trial results may have increased the comfort level of clinicians for combining increased rate cutoff and detect duration programming strategies in our cohort.

Despite evidence that shock reduction programming leads not only to reductions in ICD therapy but also hospitalization and mortality, our study clearly shows that the translation

into clinical practice has been modest. The proportion of devices programmed to a rate cutoff of ≥188 beats/min increased from 41% to 49% and to an NID of ≥30/40 increased from 17% to 67% before the publication of ADVANCE-III vs after the publication of the consensus statement. There may be several factors to explain the higher relative increase in adoption of NID ≥ 30/40 vs rate cutoff ≥ 188 beats/min programming over time. First, at baseline, before May 2013, the proportion of devices programmed to NID ≥ 30/40 was much lower (17%) than those programmed to a rate cutoff of ≥188 beats/min (41%). This would suggest that a significant proportion of clinicians were already comfortable with the use of a rate cutoff of ≥188 beats/min, even before the publication of landmark ICD programming trials and consensus statements. In contrast, before 2013, only a small proportion of patients were programmed to NID ≥ 30/40. This was likely due to concerns about arrhythmia-associated syncope due to delayed ventricular tachycardia (VT)/VF detection. Therefore, the publication of PREPARE, RELEVANT, and ADVANCE-III trials, which demonstrated the benefit and safety of extended detection programming, likely led to increased adoption of this programming strategy. Next, the increase in adoption of NID ≥ 30/40 was likely aided by changes in ICD nominal programming from 18/24 to 30/40 with devices released from 2014 onward, as shown in Table 1. In contrast, altering rate cutoff programming via manufacturer-determined nominal settings is less straightforward given that ICDs can have 1, 2, or 3 active VT treatment zones. For example, while the manufacturer may program the VF detect rate cutoff to ≥188 beats/min, an implanter may also program on a VT treatment zone with a lower nominal cutoff. Therefore, rate cutoff programming is determined not only by treatment zone heart rate cutoffs but also by the number of active treatment zones, which is subject to implanter preference. Interestingly, there was a substantial proportion of patients (29%) whose device models had nominal settings of NID 30/40 who were reprogrammed to NID < 30/40. This may have reflected either lack of implanter familiarity with shock reduction programming literature or implanter concerns about the safety of NID 30/40 programming for specific patients.

We found that the rate of reprogramming of NID and rate cutoffs following initial programming was only 9%. Programming pattern inertia, where clinicians are reluctant to change their programming practice, may be a reason for lack of adoption. The interim publication of clinical trials and consensus statements did not result in a significant proportion of device reprogramming. The lack of reprogramming over time may be due to reluctance on the part of clinicians to alter programming in patients without a change in clinical status or who had not yet had ICD therapy. Our analysis shows progressive divergence of ICD therapy rates over time with high NID and rate cutoff programming, which would suggest that there may be benefit with reprogramming the rate cutoff to 188 beats/min and the NID to 30/40 even in patients with no prior therapy. Regardless, nominal settings

may be the dominant factor determining device programming in clinical practice. With the introduction of models with the VF NID nominal setting of 30/40, the proportion of patients who were initially programmed to NID 30/40 was 61%. Before the introduction of these devices, the proportion of patients programmed to NID 30/40 was 20%. Therefore, this highlights the need for device nominal settings to adapt expeditiously to the latest clinical evidence. This requires collaboration between specialty societies, federal agencies, and device manufacturers.

Finally, our study found significant difference in programming between different geographic regions. For example, we found that only 41% of patients were programmed to an NID of ≥30/40 in the Northeast while 80% of patients in Canada were programmed to an NID of ≥30/40. Geographic variations in programming may be due to various factors including differences in patient populations (eg, primary vs secondary prevention indications) and in implanting physician practice (eg, academic vs nonacademic setting). Of note, Varma et al found significant changes in programming based on the region of device implantation and teaching status of hospital.[12] Specifically, teaching hospitals were associated with increased adoption of therapy reduction programming. The wide region-based discrepancy in ICD programming is striking when considered in the context of the large patient population of our study, and further examination of the factors underlying this observation is warranted.

Limitations

First, because of the large sample size and privacy considerations, our analysis did not permit the inclusion of implanter specialty (electrophysiologist, cardiologist, vascular surgeon, general surgeon, or cardiac surgeon) or patient level factors that may have affected arrhythmia risk or programming preferences such as the indication for ICD (primary vs secondary prevention), ejection fraction, medications, and presence of ischemic or nonischemic cardiomyopathy. Although these factors may have altered programming, one would expect that each region would have comparable patient characteristics (eg, proportion of secondary prevention patients) across a large cohort of patients. Yet, we found a significant discrepancy between the proportion of patients programmed to recommended settings between regions that would suggest that physician preference and not patient-specific arrhythmia risk factors was the likely major determinant of programming practice. Second, given the large number of ICD therapies in our large study cohort, we did not adjudicate appropriate vs inappropriate ICD therapy episodes. Our rates of all-cause ICD therapy were comparable to those reported by the ADVANCE-III, PREPARE, and RELEVANT trials. Third, as we included only Medtronic devices, our findings may limit the generalizability to other vendors. Reassuringly, many of our study findings were consistent with those by Varma et al,[12] which included Boston Scientific devices via the ALTITUDE database. Finally, we did not have access to clinical end point data on mortality, morbidity, and

hospitalizations in our database and were therefore unable to assess the association between the impact of therapy reduction programming on these important outcomes.

Conclusion

We have shown that patients programmed to shock reduction programming reduced rates of all-cause ATP, shocks, and the combined end point of all-cause ATP and shocks. The publication of landmark shock reduction programming trials and the HRS/EHRA/APHRS/SOLAECE joint expert consensus statement had a modest effect on the clinical care, with only 48% of patients programmed to a rate cutoff of ≥ 188 beats/min, 54% programmed to a VF NID of $\geq 30/40$, and 29% programmed to both a VF NID of $\geq 30/40$ and a rate cutoff of ≥ 188 beats/min. Further studies to understand this care gap in order to increase the use of shock reduction programming strategies are necessary.

Acknowledgments

Appendix
Supplementary data

Supplementary data associated with this article can be found in the online version at https://doi.org/10.1016/j.hrthm.2021.10.010.

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