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CLINICAL RESEARCH
Sudden Death and ICDs

Patient-reported outcomes in Danish implantable cardioverter defibrillator patients with a Sprint Fidelis lead advisory notification

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Aims

Few studies have investigated the association between implantable cardioverter defibrillators (ICDs) and lead advisory notifications and patient-reported outcomes (PROs). We examined (i) whether the mode used to inform patients about a device advisory is associated with PROs, and (ii) whether patients with a lead subject to a device advisory report poorer PROs than non-advisory controls.

Methods and results

Patients ($n = 207$) implanted with an ICD at Aarhus University Hospital, Denmark, with a Sprint Fidelis lead subject to an advisory and a non-advisory control group ($n = 510$), completed a set of standardized PRO measures. A Bonferroni correction was applied to all statistical PRO comparisons to adjust for multiple comparisons, with a P -value of 0.0038 (0.05/13 PROs) indicating statistical significance. Device advisory patients did not differ significantly on PROs according to mode of notification (all P -values > 0.0038). They also did not differ significantly from controls on mean scores of depression, anxiety, device acceptance, and health status (all $P > 0.0038$). Differences were only found on ICD concerns ($P < 0.0001$) and on mental health status ($P = 0.003$), with advisory patients reporting fewer ICD concerns and a better mental health status than non-advisory controls.

Conclusions

The mode used to inform ICD patients about the advisory was not associated with PROs, nor was the overall well-being of device advisory patients impaired compared to non-advisory controls. These results indicate that ICD patients are generally able to cope with a device advisory.

Keywords

Anxiety • Device advisory • Health status • Implantable cardioverter defibrillator • Patient-reported outcomes • Sprint Fidelis

Introduction

Implantable cardioverter defibrillator (ICD) therapy is the first-line treatment for the primary and secondary prevention of sudden cardiac death.¹ Despite its medical benefits, ICD therapy is associated with a potential for procedure-related (e.g. infection and bleeding) and device-related (e.g. inappropriate shocks and lead dysfunction) complications.^{2,3} Device-related complications, such as device dysfunction and lead fracture, have increased in the last decade, although it is not a new phenomenon.⁴ However,

guidelines are now in place from the Food and Drug Administration and the Heart Rhythm Society on device performance and also on how device advisory notifications should be communicated to patients.⁵

Device advisories may have an adverse influence on patient-reported outcomes (PROs) such as well-being and quality of life. As voiced in an editorial published in 2008 related to the Sprint Fidelis advisory, there is an urgent need to examine the influence of advisory notifications on patient well-being both with respect to the impact of the advisory itself and with respect to how to

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communicate the risk to patients.⁶ A true estimation of the impact of advisories on patients may serve to counterbalance the associated negative publicity in the press, which has led to patients turning down this potentially life-saving treatment, as reported in the USA.⁷

Few studies have examined the impact of device advisory notifications on patients, as assessed with PROs. In a recent viewpoint,⁸ we identified six studies, with sample sizes ranging from 31 to 86 patients with hardware subject to a Class I or a Class II advisory.^{9–14} The evidence for a psychological impact of device advisory notifications is mixed, as shown in an update of the literature as presented in *Table 1*. Little is also known about the most appropriate way of communicating the risk associated with an advisory to patients and whether different modes may have a differential influence on PROs.⁶

In the current study, we examined (i) whether the mode used to inform patients about the Sprint Fidelis device advisory (i.e. informing patients by letter calling them in for an urgent clinical follow-up visit vs. informing them *ad hoc* during a routine clinical visit) is associated with mean scores on PROs, and (ii) whether patients with a device advisory notification report poorer PROs than non-advisory patients, assessed with both disease-specific and generic measures.

Methods

Patients and study design

Patients ($n = 207$; response rate 87%) implanted with an ICD between 1993 and 2009 at Aarhus University Hospital (Skejby), Denmark, and with a lead (6931 or 6949) subject to the Medtronic Sprint Fidelis ICD lead advisory completed a set of standardized and validated PROs between September and October 2009. The Sprint Fidelis ICD lead advisory was issued due to potential lead fracture that could lead to not only unnecessary (inappropriate) shocks but also failure to deliver life-saving defibrillatory shocks. Lead Integrity Alert™ (LIA; Medtronic, Minneapolis, MN, USA) software was made available for download to the device which would alert patients of potential lead failure. In Denmark, the Sprint Fidelis lead advisory was issued on 15 October 2007. All of our patients were informed about the LIA software and the rationale at the time of downloading it to their device.

Patients were informed about the advisory in one of the following two ways: (i) by letter, in December 2008, calling patients in for an urgent clinical follow-up visit, and (ii) *ad hoc* during a routine clinical visit. Hence, for patients in group (i) the time interval between the device advisory notification and completing the questionnaires was 9 months, whereas for those in group (ii) the interval was variable. Both groups had the LIA software downloaded to their device during the clinical follow-up visit.

A control group of patients ($n = 510$), implanted with an ICD between 1991 and 2006 at our institution but whose hardware was not under advisory, had completed the same questionnaires for a previous study (response rate 84%).^{17,18} For the majority of the control patients (i.e. 95%), the main indication for ICD was secondary prevention, as primary prevention was not generally implemented in Denmark before 2007. Both advisory and control patients had to be ≥ 18 years of age to be eligible to participate. For both groups, if the questionnaire was not returned within 2 weeks, a reminder was sent by post including a duplicate

questionnaire. The study was conducted according to the Declaration of Helsinki.

Measures

Demographic and clinical variables

Information on demographic and clinical variables was obtained from the Danish ICD Register (www.pacemaker.dk) or from purpose-designed questions in the questionnaire.

Patient-reported outcomes

Symptoms of anxiety and depression

We used the 14-item Hospital Anxiety and Depression Scale (HADS) to assess symptoms of anxiety and depression.¹⁹ Items are answered on a 4-point Likert scale from 0 to 3 (score range 0–21), with seven items contributing to the anxiety and depression subscales. A high score on the HADS indicates more symptoms of anxiety and depression. A cut-off score ≥ 8 for both subscales represents probable clinical levels of anxiety and depression.²⁰ The HADS is a valid and reliable instrument that has been used across the world in cardiac and non-cardiac populations,²⁰ and that is not prone to confounding by symptoms of somatic disease.²¹

Device-related concerns

The Implantable Cardioverter Defibrillator Patient Concerns Questionnaire (ICDC) is an eight-item self-report measure tapping into concerns about the ICD giving a shock (e.g. 'I am worried about my ICD firing').^{22,23} Items are rated on a 5-point Likert scale from 0 (not at all) to 4 (very much so), with a higher score indicating a higher level of device-related concerns (score range 0–32). The internal consistency of the eight-item ICDC is good, with Cronbach's $\alpha = 0.91$.²³ Previously, we have shown that high levels of pre-implantation ICD concerns predict mortality in ICD patients.²⁴

Device acceptance

Device acceptance was assessed with the 18-item Florida Patient Acceptance Survey (FPAS).²⁵ Items (e.g. 'When I think about the device, I avoid doing things that I enjoy' and 'I feel less attractive because of my device') are rated on a 5-point Likert scale from 1 (strongly disagree) to 5 (strongly agree). Of all items, 15 contribute to a total score, while the remaining 3 items are filler items. A high score indicates better acceptance. The convergent, divergent, and discriminant validity of the FPAS are good, and the scale has been shown to be internally consistent, as indicated by Cronbach's $\alpha = 0.83$ for the total scale. Previously, we validated the FPAS in Danish ICD patients, with this specific language version indicating good validity and reliability.²⁶

Health status

We used both a disease-specific and generic measure of health status. The Minnesota Living with Heart Failure Questionnaire (MLHFQ) is a disease-specific measure, comprising 21 items.²⁷ Items are answered on a 6-point Likert scale from 0 (no) to 5 (very much). The total score ranges from 0 to 105, with a higher score indicating poor health status. The measure is psychometrically sound, with good internal consistency as measured by Cronbach's $\alpha = 0.91$ – 0.96 for the total scale. The Short Form Health Survey (SF-36) is a generic measure of health status, comprising 36 items that contribute to eight domains:^{28,29} role physical functioning, role emotional functioning, physical functioning, mental health, vitality, social functioning, bodily pain, and general health. Scale scores range from 0 to 100, with a higher score indicating better functioning. The scale has good reliability with Cronbach's $\alpha = 0.65$ – 0.96 for all subscales.²⁸

Table 1 Overview of studies on the impact of device advisories on patient-reported outcomes*

Authors	Origin of study	Advisory	n	Response rate	Study design	Time between advisory and assessment	Endpoint ^a	Impact of device advisory
Birnie et al. (2009) ¹⁴	Canada	Class II advisory (Medtronic)	86 advisory patients; 94 controls	70.5% patients; 70.1% controls	Case-control	>24 months	Device acceptance ²	No significant impact
van den Broek et al. (2006) ⁹	The Netherlands	Class II advisory (Medtronic)	33 advisory patients	90%	Prospective; 14 ± 4 months follow-up	<2 months ^b	Anxiety ¹	Increase in the number of anxious patients from 6.1% pre-compared to 24.2% post-advisory
Cuculi et al. (2006) ¹³	Switzerland	Class I advisory (Guidant)	30 advisory patients; 25 controls	Not reported	Case-control	<1 month	Distress ¹	No significant impact; 3 distress measures were significantly higher in the controls
Gibson et al. (2008) ¹²	USA	Class I advisory: 13/31 (42%) (Guidant)	31 advisory patients; 50 controls	89%	Case-control	<1 to >4 months	Distress ¹ ; QoL ¹	No significant impact
Heatherly et al. (2011) ¹⁵	USA	Class I advisory (Medtronic)	158 advisory patients; 255 controls	Not reported	Case-control	14–22 months	ICD concerns ²	More ICD concerns in recalled group (primarily due to shocks)
Keren et al. (2011) ¹⁶	Canada	Class II advisory (Medtronic)	24 advisory lead fracture; 249 advisory no fracture; 143 controls	92% advisory lead fracture; 74% advisory no fracture; 62% controls	Case-control	13 months	Anxiety ^{1,2} ; depression ¹ ; device acceptance ²	No difference in distress between no fracture and controls; more distress in advisory fracture patients due to inappropriate shocks
Sneed et al. (1994) ¹⁰	USA	Class II advisory (Guidant)	31 advisory patients; 21 caregivers	100%	Prospective, case-control; 1-month follow-up	1–3 months	Distress ² ; uncertainty ² ; confidence in device ²	Patient and caregiver confidence decreased; anxiety increased in patients and confusion in caregivers over time
Undavia et al. (2008) ¹¹	USA	Class I advisory: 43/61 (70%) (not mentioned)	61 advisory patients; 43 controls	90%	Case-control	7.6 ± 1.6 months	Anxiety ¹ ; depression ¹ ; QoL ²	No significant impact

*Adapted from Pedersen et al.⁸

^a'Generic measure' and 'disease-specific measure' are indicated by superscript numbers 1 and 2, respectively.

^bConveyed via personal communication with the author.

Statistical analyses

The three patient groups, that is, device advisory group (i) patients who were informed by letter urging them to come in for a clinical follow-up visit, device advisory group (ii) patients who were informed *ad hoc* during a clinical follow-up visit, and control patients without a device or leads subject to an advisory notification, were compared on baseline characteristics using analysis of variance with a post-hoc Bonferroni correction (if applicable) for continuous variables and the χ^2 test for nominal variables. Student's *t*-test for independent samples was used to compare the two device advisory groups on PROs, and the device advisory groups (irrespective of how information was given about the advisory) with the control group on PROs. Due to multiple comparisons that increase the chance of finding a statistically significant result and to prevent making a Type I error (also known as a false positive), we used a Bonferroni correction for these analyses. Accordingly, given that we had 13 PROs, we divided the standard *P* value of 0.05 by 13, using a *P* value of 0.0038 to indicate statistical significance for the interpretation of these results. However, for all results (both in the text and in the figures), the exact *P* value for each comparison is also reported. All analyses were performed using SPSS 17.1 for Windows (SPSS Inc., Chicago, IL, USA).

Results

Baseline characteristics

Baseline characteristics stratified by advisory groups (i) and (ii) vs. no advisory (control group) are displayed in Table 2. The groups

did not differ systematically on baseline characteristics, except that advisory group (i) patients were more likely to have a cardiac synchronization therapy with defibrillation (CRT-D) device than advisory group (ii) patients and controls, and advisory group (ii) patients were more likely to be prescribed β -blockers than advisory group (i) patients and controls. Time since first ICD implant was longer for controls than for advisory group (i) and (ii) patients.

Patient-reported outcomes in device advisory patients stratified by mode of notification

No statistically significant differences were found on psychological distress (Figure 1A) and health status (Figure 1B) between group (i) patients who were notified about the device advisory by letter calling them in for an urgent clinical follow-up visit and group (ii) patients who were informed *ad hoc* during a routine clinical follow-up visit, with all *P* values >0.0038 which was chosen to indicate statistical significance.

Patient-reported outcomes stratified by device advisory vs. control patients

Given that we found no statistically significant differences on PROs between the two advisory groups stratified by mode of notification, we merged groups (i) and (ii) and compared device advisory patients with a non-advisory control group to examine potential

Table 2 Baseline characteristics stratified by device advisory vs. no advisory^a

Characteristics	Device advisory (i) (n = 74) ^b	Device advisory (ii) (n = 133) ^c	Controls (n = 510)	<i>P</i>
Demographic				
Women	8 (10.8)	20 (15.0)	92 (18.0)	0.26
Age, mean \pm SD (years)	63.2 \pm 13.2	61.6 \pm 14.7	64.0 \pm 13.1	0.18
Partner/married	58 (78.4)	102 (77.1)	393 (77.5)	0.94
Clinical				
CRT-D	22 (30.1)	30 (22.6)	92 (18.0)	0.04
Comorbidity	15 (20.8)	29 (22.3)	116 (23.0)	0.92
Ischaemic heart disease	49 (70.0)	81 (67.5)	327 (70.6)	0.80
Smoking	13 (17.6)	26 (19.8)	119 (23.8)	0.36
Time since first ICD implant (years)	2.0 \pm 1.1	2.2 \pm 1.5	5.3 \pm 3.2	$<0.0001^d$
Medication				
Amiodarone	10 (15.4)	34 (27.0)	123 (24.4)	0.19
β -Blockers	54 (83.1)	116 (92.1)	412 (82.4)	0.03
Diuretics	28 (43.1)	54 (42.9)	236 (46.9)	0.64
Thiazide diuretics	10 (15.4)	12 (9.5)	46 (9.3)	0.30
ACE-inhibitors	52 (80.0)	98 (77.8)	345 (69.8)	0.07
ARBs	13 (20.0)	37 (29.4)	156 (31.1)	0.18
Digoxin	15 (23.1)	23 (18.3)	84 (16.7)	0.43
Psychotropic medication	11 (16.9)	9 (7.2)	67 (14.1)	0.08

^aResults are presented as *n* (%), unless otherwise indicated.

^bDevice advisory (i) patients were notified of the device advisory by letter, in December 2008, calling them in for an urgent clinical follow-up visit.

^cDevice advisory (ii) patients were notified *ad hoc* during a routine clinical visit.

^dGroup differences were significant between controls and device advisory (i) patients and between controls and device advisory (ii) patients (post-hoc Bonferroni $P < 0.0001$), but not between device advisory (i) and device advisory (ii) patients (post-hoc Bonferroni $P = 1.00$).

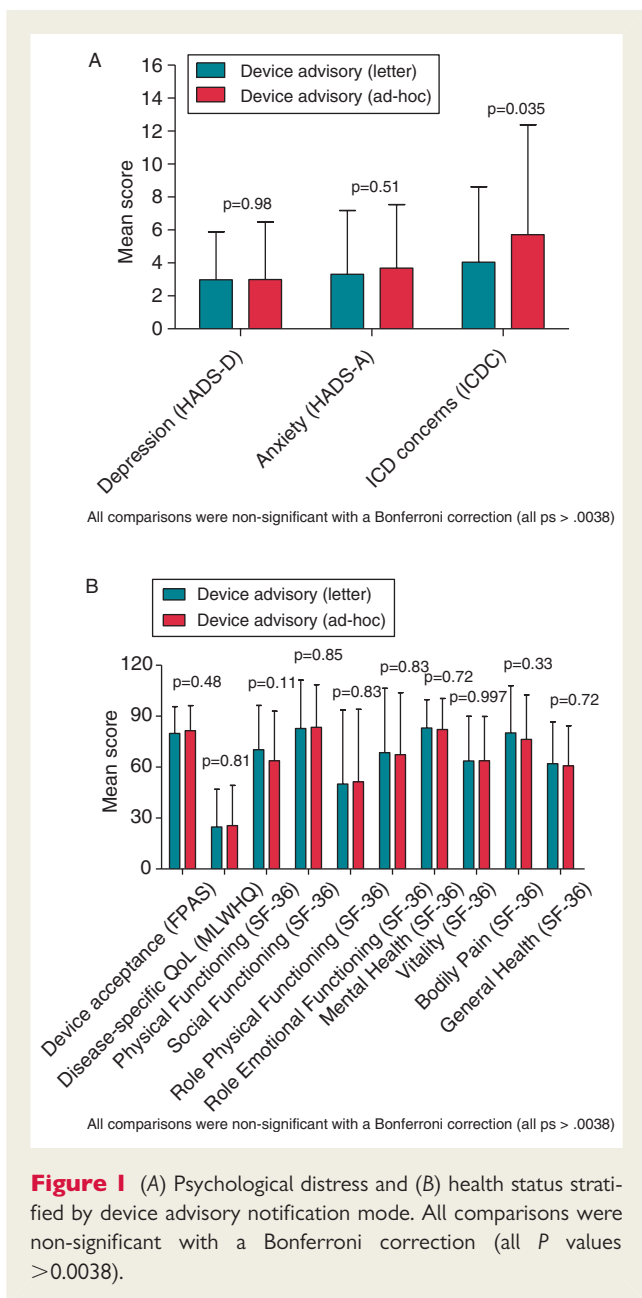


Figure 1 (A) Psychological distress and (B) health status stratified by device advisory notification mode. All comparisons were non-significant with a Bonferroni correction (all P values >0.0038).

differences in PROs. There were no statistically significant differences between advisory and non-advisory patients on symptoms of depression and anxiety, while advisory patients reported less ICD concerns than non-advisory controls (5.12 ± 6.04 vs. 7.67 ± 8.28 ; $P < 0.0001$) (Figure 2A). As for device acceptance and disease-specific and generic health status, there was only one difference between groups, with advisory patients reporting better mental health status than non advisory controls (82.46 ± 17.73 vs. 77.90 ± 19.10 ; $P = 0.003$) (Figure 2B).

Discussion

Device advisories may be unnerving to patients and may reduce patient confidence in their device. For this reason, it is important

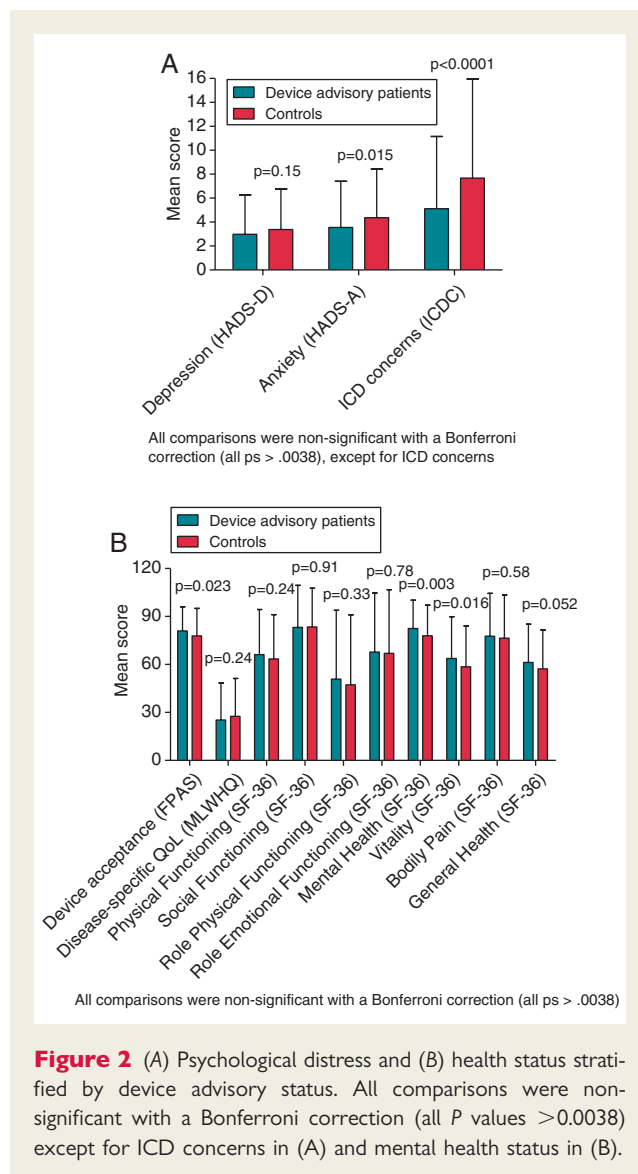


Figure 2 (A) Psychological distress and (B) health status stratified by device advisory status. All comparisons were non-significant with a Bonferroni correction (all P values >0.0038) except for ICD concerns in (A) and mental health status in (B).

to examine the impact of device advisories on patient well-being and device acceptance both with respect to the impact of the advisory itself and with respect to how best to communicate the risk to patients.⁶ In the current study, we examined the association between mode of informing patients about the Sprint Fidelis lead advisory and PROs and the association between having an ICD lead subject to an advisory vs. no advisory and PROs, as assessed with a broad range of PROs, including both disease-specific and generic measures tapping into patient distress, health status, device concerns, and device acceptance.

The mode used to inform ICD patients about the device advisory—that is calling patients in for an urgent clinical follow-up visit vs. informing patients *ad hoc* during a routine clinical visit—was not associated with psychological well-being and health status in our patient cohort, nor was the well-being and health status of device advisory patients impaired compared to patients without an advisory notice. In fact, non-advisory controls reported more ICD concerns and poorer mental health status than advisory patients, which is consistent with the findings of a previous study.¹³

Concurrent with other studies, these results indicate that ICD patients are generally able to cope with a device advisory.^{8,12–14,16} Patients may implicitly accept that with increased complexity of technology to manage heart disease there is a trade-off with respect to the risk of complications and hardware malfunctioning. The downloading of the LIA software, which was applicable to all patients with an advice notification in the current study, might also have helped to reinstate patient confidence in the device.³⁰

It was somewhat surprising that the mode of notification about the device advisory had no influence on patient well-being and health status in our study. A priori, we would have expected that patients receiving a letter calling them in for an urgent clinical follow-up visit would more likely be in a state of panic and therefore experience more distress than patients being informed about the advisory in a more gentle way during a subsequent clinical follow-up visit. It is possible, however, that the mode of debriefing patients about the device advisory may be of less importance than the source of the information (e.g. physician, manufacturer, news media, etc.), which information is provided, and whether patients have the possibility to attend psychological counselling, as reported in some studies.^{11,12} In the current study, the notification about the device advisory was communicated by physicians. Previously, it has been suggested that patients prefer to learn about a device advisory from their physician rather than from the media.³¹ However, the latter study used vignettes and asked patients to rate their concerns with respect to a hypothetical rather than a real device advisory. A more recent study examining the influence of the source of information on patient worry levels showed no overall difference between patients who heard about the advisory from news media and those who heard about the advisory from a physician, industry, or others.³⁰ Given the absence of large-scale well-designed studies, it is too premature to draw any firm conclusions about the influence of mode and source of information about the device advisory on patient well-being.

Currently, the Heart Rhythm Society has provided recommendations to the industry and physicians with respect to monitoring device performance and how to handle device malfunctioning.⁵ Patient recommendations on how to deal with a device advisory notification both at an emotional and at a behavioural level are also available.³² In addition, information on device performance is required to be included in the National Cardiovascular Data Registry (NCDR) ICD Registry in the USA.⁵ All these initiatives are of major importance in monitoring device performance and obtaining a true picture of the incidence of hardware malfunctioning and the concomitant risk to patient health. However, given that neither the recommendations from the Heart Rhythm Society nor those from the NCDR ICD Registry include PROs—that is, asking patients to rate the impact of hardware malfunctioning and device advisories on their well-being and quality of life—the risk that the patient is still ‘left behind’ is prominent, as posited in an editorial to the Sprint Fidelis advisory:⁶ ‘However, in 2008 the important core issues regarding device reliability remain unsolved and longstanding issues regarding patient information and patient well-being are even more acute.’ The inclusion of routine and serial assessments of PROs in national registries such as the NCDR ICD Registry would enable us to track information on how device advisories affect

patient well-being, rather than relying on information from single-center and smaller-scale *ad hoc* studies.⁸

The results of the current study should be interpreted with some caution. First, we used a convenience sample as a non-advisory control group. Secondly, as in previous studies examining the impact of a device advisory notification on patients,^{11,12,14} there was a time interval from the notification to patient completion of the PRO measures. It is possible that the advisory notification may have an impact on patient well-being and quality of life of patients just after the notification, but also that the impact of the advisory dissipates over time, reflecting that patients are able to adapt even short-term. Based on the design of our study, we are not able to deduce whether a short-term effect was present. Thirdly, we did not evaluate patient perception of the risk of having a recalled Sprint Fidelis lead, which could potentially serve as a confounder on PROs. This dimension would be interesting to add to future studies on device advisory notifications, although it may not be patient perception of risk per se that influences PROs but rather whether this knowledge instills fear in and bothers patients. Fourthly, the device advisory patients differed from the non-advisory patients on time since first ICD implant, with controls having had their ICD for a longer period of time. Time since first ICD implant may serve as a potential confounder on the results, although several studies do not support an influence of duration since implantation on PROs.^{17,33} Fifthly, the control cohort was predominantly secondary prevention patients,¹⁷ with the potential that indication might have confounded the results. However, based on the current literature on the impact of indication on PROs, there is no evidence to support this notion, with available studies showing no differences in PROs between primary and secondary prevention patients.³⁴

This study also has several advantages. First, to our knowledge, it is the largest study to date to examine the impact of a device advisory notification on patient well-being, except for the recently published study by Keren *et al.*¹⁶ Secondly, we included a broad spectrum of PROs tapping into patient distress and health status with the use of both disease-specific and generic measures. Disease-specific measures are generally more sensitive to tap symptoms that are relevant to patients and therefore less prone to floor and ceiling effects that may obscure results.³⁵

Conclusion

In conclusion, the mode used to inform ICD patients about the Sprint Fidelis lead advisory was not associated with psychological well-being and health status, as patients informed about the advisory by letter calling them in for an urgent clinical follow-up visit did not differ in psychological distress and health status from patients informed *ad hoc* during a routine clinical visit. We also found no evidence that the well-being and health status of device advisory patients is impaired as compared to patients without an advisory notice. Taken together, these results indicate that ICD patients are generally able to cope with a device advisory. Nevertheless, the arrhythmia community should consider the advantages of including routine and serial assessments of PROs in national registries in order to enhance our knowledge of the impact of device advisories on patient well-being. If this is

implemented as standard practice, with assessments available from the time of implantation, we would not only have a pre-advisory assessment but also be able to track patient well-being following the advisory over time, and hence to draw more firm conclusions about the impact on patients. For the future management and care of ICD patients, such information would be of paramount importance given that ICD lead failures are likely to be here to stay.

Conflicts of interest: S.S.P. has received speaker and consultancy fees from Medtronic, St Jude Medical, Cameron Health, and Sanofi Aventis. H.V. has no conflicts of interest to report. J.C.N. has received speaker and consultancy fees from Medtronic, Biotronik, and St Jude Medical, and institutional research grants from Medtronic, Biotronik, St Jude Medical, and Boston Scientific. P.T.M. has received speaker and consultancy fees from Medtronic, St Jude Medical, and Biotronik. J.B.J. has received speaker's fee from St Jude Medical and Medtronic and is on the advisory board of Medtronic.

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