Europace (2015) **17**, 417–423
doi:10.1093/europace/euu305

Examination of the differential impacts of antitachycardia pacing vs. shock on patient activity in the EMPIRIC study

Samuel F. Sears[1,2]*, Amanda Whited[1,2], Jodi Koehler[3], and Bruce Gunderson[3]

[1]Department of Psychology, East Carolina University, 104 Rawl Building, East 5th Street, Greenville, NC 27858, USA; [2]Department of Cardiovascular Sciences, East Carolina University, Greenville, NC, USA; and [3]Medtronic, Inc., 8200 Coral Sea St NE, Moundsview, MN 55112, USA

Received 9 June 2014; accepted after revision 8 October 2014; online publish-ahead-of-print 19 January 2015

Aims Implantable cardioverter defibrillators (ICDs) have demonstrated mortality advantages over antiarrhythmic drug therapy, but ICD shock has known detrimental effects on quality of life and psychologic functioning. However, it remains unknown how patient activity level is affected by shock, or by antitachycardia pacing (ATP), which was developed to reduce the treatment burden of shocks. Examine the differential impact of ICD shock and ATP on patient activity level as a novel way to capture the relative behavioural repercussions of these ICD therapies.

Methods and results Accelerometer-derived activity data were analysed for a subset of patients (males = 83%; mean age = 62 years) enrolled in the EMPIRIC trial who received shock ($n = 71$) or ATP ($n = 103$). Differences in activity between a week pre-therapy and a week post-therapy were examined to assess the behavioural repercussions of shock vs. ATP when one, few (2–4), or many (5+) therapies were delivered. For patients receiving shock, a significant reduction in activity was observed for few (−26%) and many shocks (−34%) in the first week post-therapy ($P < 0.05$). In weeks 2–4, activity levels recovered towards baseline levels. In contrast, no level of ATP-only therapy significantly reduced patients' activity levels at any time following therapy.

Conclusion This study is the first to evaluate objective, behavioural effects of shock, and whether these effects are comparable with ATP therapy alone. In tandem with existing literature, current results highlight that ICD shocks and ATP have divergent effects on behavioural outcomes, with ATP's effect profile in these domains appearing somewhat favourable.

Keywords Shock • Antitachycardia pacing • Implantable cardioverter-defibrillator • Quality of life • Activity

Introduction

The implantable cardioverter defibrillator (ICD) has demonstrated a mortality advantage in large randomized clinical trials when compared with usual care and to antiarrhythmic drug treatment.[1,2] The experience of shock, whether appropriate or inappropriate, can greatly impact the attitudes of the ICD patient and his or her family, as well as their health behaviours and subsequent wellbeing.[3] Shock is reasonably conceptualized as a noxious stimulus that is perceived as threatening by patients, thereby fostering establishment of behaviour patterns marked by fear and avoidance behaviour.[4] Innovations in programming were triggered by this aversive nature of the life-saving, high-energy shock for patients, and consequent destructive outcomes. As such, antitachycardia pacing (ATP) was developed to reduce the treatment burden of shocks for the full range of stakeholders in device therapy.[5–7]

A sizeable research literature exists examining patient-centric health outcomes to understand the effects of shock. Patient-centric health outcomes often include a battery of self-report measures that encompass clinically relevant factors, ranging from generic and disease/device-specific quality of life, to psychological measures of distress such as anxiety and depression.[8] In summary, this research suggests that approximately 20% of ICD patients experience significant distress.[9] However, despite our growing knowledge of the ways in which shock negatively impacts quality of life and patient distress level, we lack a complementary understanding of the behavioural impact of shock. It is unknown whether the negative impact of shock extends to reductions in patients' daily activity level.

* Corresponding author. Tel: +1 252 328 6118; fax: +1 252 328 6283, *E-mail address*: searss@ecu.edu

What's new?

- This paper expands the literature on the detrimental psychosocial effects of implantable cardioverter defibrillator (ICD) shock by highlighting the behavioural consequences of ICD shock—patient activity level.
- This is the first study to directly compare the behavioural impact of antitachycardia pacing (ATP) in comparison to ICD shock. Whereas ICD shock significantly reduced patient activity level, activity level was not reduced following ATP.
- An unexpected and alarming descriptive finding uncovered during our analyses showed that ICD patients have an extremely low level of baseline activity. Prior to delivery of any ICD therapy, median activity level was merely 22.5 hours per week. Notably, ICD shock decreased that activity level *even further* as indicated above.

Modern ICD technology includes integrated activity sensors that make possible the systematic evaluation of whether ICD shock confers such negative behavioural effects and, further, how the behavioural effects of ATP therapy may differ from shock therapy. Such insight could provide valuable clinical data for use in tailoring and prioritizing feedback to patients to address suboptimal activity levels, or concerning changes in activity levels.

The purpose of this study was to examine the differential effects of ATP vs. ICD shock on patient behaviour as captured by device-measured activity level preceding and following therapy. Specifically, we hypothesized that the administration of shock would result in a significant decrease in patient activity, in contrast to the absence of significant change following ATP. Moreover, we expected that increased frequency of shock would be significantly related to decreased patient activity level in a dose–response manner.

Methods

Sample

All patients with an initial implant of Model 7274 Marquis DR ICD (Medtronic, Inc.) enrolled in the EMPIRIC study[7] between August 2002 and October 2003 who received an ATP or shock therapy were selected. No form of constructed feedback was provided to patients regarding delivered therapies as part of the study protocol. In other words, patients receiving ATP were not notified that they received therapy, and they likely were not independently aware of therapy delivery as ATP is not usually detectable by patients.

Device measurement of daily activity

The activity measurement in the Marquis DR ICD was designed to capture activities of daily living, including walking at a slow pace. A single-axis accelerometer sensor was used to measure the number of minutes a patient was active per day. A minute is considered active if a threshold is reached that incorporates both number and magnitude of the deflections in the accelerometer signal. An 'active' minute corresponds to approximately 70 steps/min as reported in InSync III devices,[10] which is the same activity sensor in all Medtronic ICDs and cardiac resynchronization therapy defibrillator devices. The number of active minutes is stored for the most recent 425 days and was retrieved from the device data that was collected as part of the protocol for the original EMPIRIC study. The same accelerometer was used for the rate response function, and there was a common activity threshold setting (i.e. medium/low) for all patients, except for one patient whose setting was medium/high.

A recent study examined the validity of activity measurement using integrated sensors in Medtronic ICD/CRT devices (including Marquis devices) vs. validated external accelerometers.[11] Significant correlations between measurement methods were evident for both average total daily activity among all patients and daily measurements within each individual. The authors noted some variation in daily activity as measured by the two, proposing that in cases where high precision is necessary, caution may be exercised when solely using data from the ICD sensors clinically.

Analysis windows

Three consecutive windows were defined: pre-therapy, therapy, and post-therapy. A comparison between a 7-day pre-therapy window and a 7-day post-therapy window was used to determine the impact of therapy on patient activity. To achieve an accurate analysis of the effects of therapy on patient activity, we required a minimum of 36 days post-implantation without ICD therapy for inclusion in analyses. This allows 28 days for patient activity to return to baseline following implantation, plus a standardized pre-therapy period of 7 days applicable to all patients. The therapy window consisted of 1–7 days. If patients only experienced one therapy, the window was only 1 day, and the 7-day post-therapy window began immediately following that day. If patients went on to experience one or more additional therapies within the following 6 days, the therapy window was expanded up to 7 days to accommodate and quantify these additional therapeutic events. At the end of the therapy window, the 7-day post-therapy window was applied across all patients. Patients whose 7-day post-therapy windows were interrupted with further therapies were excluded from analyses. Windows were constructed in this way to standardize the data for analysis so that equivalent and standardized time frames were available to capture activity levels both prior to and following therapy. Also, patients with detected ventricular tachycardia/ventricular fibrillation episodes during the post-therapy window were excluded. Detection was required to be ON through the therapy window (could be turned OFF during the post-therapy window).

Data analysis

We determined the change in weekly hours of activity from pre-therapy to post-therapy for shocks and ATP. Patients with an ICD therapy were separated into two groups based on the therapies during the therapy window: shock with or without ATP, and ATP only. As the intensity and salience of shock surpasses that of ATP, the effect of ATP was not analysed separately in the subset of patients receiving shock who also received ATP therapy. Rather, the ATP-only group was analysed against the shock group (with or without ATP) to assess contrasting effects of shock vs. ATP. We calculated the change in activity from cumulative activity 7 days pre-therapy to 7 days post-therapy. The activity change was compared at three therapy levels: one, few (2–4), and many ($\geq$5) therapies. Both the numerical difference and per cent change were calculated. Additional analyses examining the effects of therapy on activity 2, 3, and 4 weeks post-therapy were performed as well.

Statistical analyses

Wilcoxon–Signed Rank was used for the paired pre-therapy vs. post-therapy comparisons, and Kruskal–Wallis was used for comparison across the three therapy levels. Statistical significance was set at $P < 0.05$. SAS version 9.2 (SAS Institute Inc.) was used for all statistical analyses.

Results

Implantable cardioverter defibrillator therapies were delivered to 280 (31%) of 900 patients who were followed over a 1 year period in the EMPIRIC trial. A total of 174 patients were used in the analysis (*Table 1*; *Figure 1*). There were 103 patients who received only ATP, ranging from 1 to 45 ATP sequences during the therapy window. There were 71 patients who received at least one shock, ranging from 1 to 13 shocks during the therapy window.

Activity comparison

The weekly pre-therapy activity was a median 22.5 h (range: 0.05–61.3 h) for all 174 patients. The weekly post-therapy activity was a median 21.3 h (range: 0.02–70.3 h). *Figure 2* shows both pre- and post-therapy activity for each patient compared with unity, or the absence of therapy impact. The maximum change for the shock group was −41 h when the patient received 7 shocks in one day. The maximum change for the ATP group was −17 h when the patient received one ATP sequence.

Activity changed by a median −0.9 (−4%) weekly hours for the 71 patients with at least 1 shock compared with a median change of +0.1 (0.5%) weekly hours for the 103 patients with ATP only (*Table 2*). No significant differences in activity among therapy levels (e.g. one, few, or many) emerged for patients receiving ATP-only (*Figure 3*). In contrast, significant differences among therapy levels were apparent for patients receiving shock. Patients with one shock did not exhibit significantly reduced activity level, but significant activity change did occur for few therapies (−26%, $P = 0.01$; −5.1 h, $P = 0.01$) and many therapies (−34%, $P = 0.01$; −10.2 h, $P = 0.01$). A higher number of ATP sequences did not significantly impact patient activity ($P = 0.88$). However, a higher number of shocks significantly decreased patient activity ($P < 0.001$).

Within the ATP-only group, 6% of patients were hospitalized during at least one of the analysis windows. Within the shock therapy group, 15% of patients were hospitalized during one or more of the analysis windows. Understanding that physical activity levels would likely be reduced during hospitalization due to environment and/or acute health concerns, these patients' data were included in analyses to avoid selection bias in the data. As the primary outcome of interest entailed change in activity level and, therefore, hospitalization at any time could affect the calculation of difference between pre- and post-therapy time points, hospitalization at any point during data collection was noted (see *Table 2*). Analyses were re-performed excluding data from these hospitalized participants. The direction of findings remained the same, but the trend was no longer statistically significant, likely due to very small sample size.

Table 1 Patient demographics

Characteristic	ATP ($N = 103$)	Shock ($N = 71$)
Male gender	85 (83%)	59 (83%)
Mean age (SD)	62 (13)	62 (15)
History of CAD	89 (86%)	60 (85%)
History of MI	72 (70%)	45 (63%)
History of AF/AT/AFL	25 (24%)	22 (31%)
History of HTN	47 (46%)	36 (51%)
Heart failure	62 (60%)	46 (65%)
NYHA I-II	48 (47%)	35 (49%)
NYHA III-IV	14 (14%)	11 (15%)
Mean LVEF (SD)	31 (13)	33 (14)

Note: All $P > 0.05$.
ATP, antitachycardia pacing; CAD, coronary artery disease; MI, myocardial infarction; AF, atrial fibrillation; AT, atrial tachycardia; AFL, atrial flutter; HTN, hypertension; LVEF, left ventricular ejection fraction.

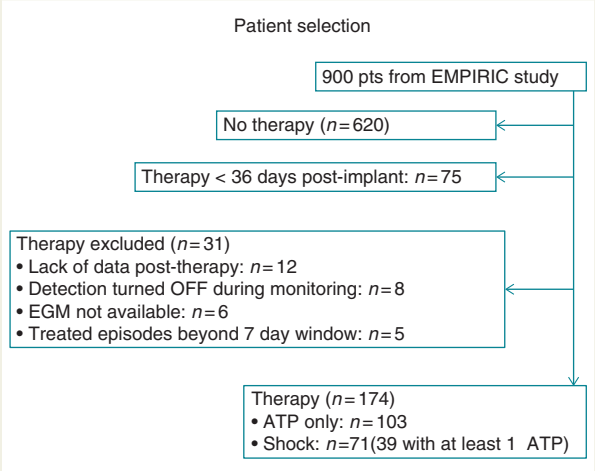

Figure 1 Patient selection. Flowchart showing how the 166 patients used in this analysis were selected from the 900 patients in the EMPIRIC study.

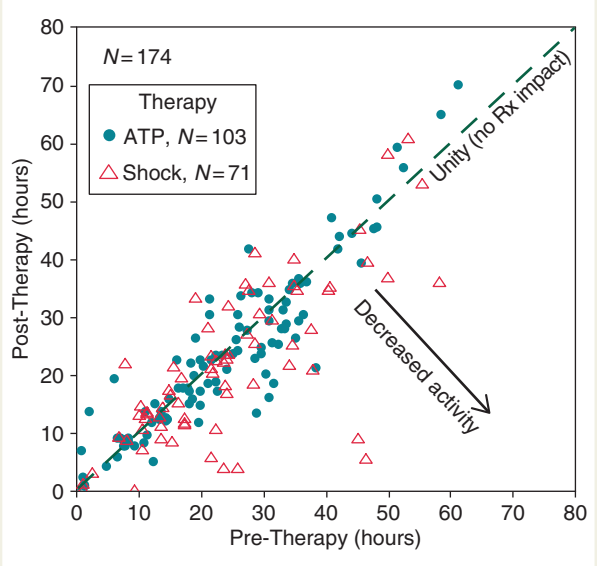

Figure 2 Pre-therapy and post-therapy weekly activity. The circles show the patients who were given only antitachycardia pacing (ATP) therapies, and the squares show the patients who were shocked. Further distance below the unity line indicates an increased negative impact on activity level due to the therapy.

Table 2 Weekly median activity difference

Number of therapies (*N*)	Median difference (post–pre), hours	% Change	Hospitalized (*N*, %)[a]
ATP only			
Any number of ATP therapies (103)	0.1, $P = 0.72$	0.5%, $P = 0.85$	6, 6%
1 therapy (66)	−0.2, $P = 0.61$	−1%, $P = 0.74$	2, 3%
2–4 therapies (27)	0.7, $P = 0.75$	2%, $P = 0.64$	3, 11%
5+ therapies (10)	0.4, $P = 0.77$	2%, $P = 0.92$	1, 10%
P (comparing three therapy groups)[b]	$P = 0.78$	$P = 0.88$	
ICD shock (±ATP)			
Total shock (71)	−0.9, $P = 0.05$	−4%, $P = 0.12$	11, 15%
1 therapy (46)	0.3, $P = 0.35$	2%, $P = 0.20$	3, 7%
2–4 therapies (17)	−5.1, $P = 0.01$	−26%, $P = 0.01$	3, 18%
5+ therapies (8)	−10.2, $P = 0.01$	−34%, $P = 0.01$	5, 63%
P (comparing 3 therapy groups)[c]	$P < 0.001$	$P < 0.001$	

ATP, antitachycardia pacing; ICD, implantable cardioverter defibrillator.
[a]Hospitalizations during any window were included.
[b]After excluding data from patients who were hospitalized, the direction of findings and lack of significance remained the same.
[c]When hospitalized patients were excluded from analyses, the direction of the findings remained the same. However, findings were no longer statistically significant.

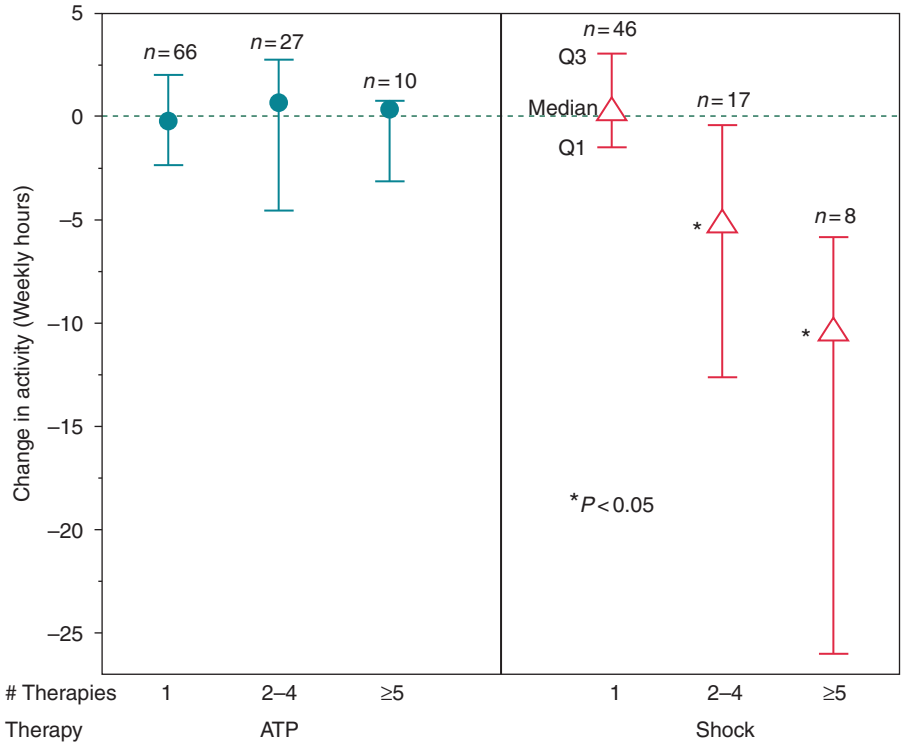

Figure 3 Median activity change from pre-therapy to post-therapy for each therapy and therapy level. The dashed line indicates no change. There was a significant change in activity for the 2–4 ('few' shocks) and ≥5 ('many' shocks) groups.

Activity comparison from weeks 2 to 4

To examine the duration of the effects of therapy type and frequency on activity level, additional comparisons between pre-therapy activity and post-therapy activity level at the 2, 3, and 4 weeks marks were conducted. Results indicated that there were no significant differences in activity among therapy levels (e.g. one, few, or

Table 3 Weekly median activity differences (in hours) for weeks 1– 4 post-therapy

Week (post-therapy)	1	2	3	4
Number of therapies (*N*)		Median activity difference (post−pre, in hours)		
ATP Only				
1 therapy (63)	−0.2, $P = 0.68$	−0.8, $P = 0.83$	0.0, $P = 0.54$	−0.2, $P = 0.84$
2–4 therapies (26)	0.4, $P = 0.82$	0.8, $P = 0.52$	1.7, $P = 0.54$	−0.5, $P = 0.5$
5+ therapies (10)	0.4, $P = 0.77$	−0.7, $P = 0.79$	−0.4, $P = 0.56$	0.5, $P = 0.77$
ICD shock (±ATP)				
1 therapy (43)	0.4, $P = 0.25$	1.1, $P = 0.27$	0.6, $P = 0.50$	0.7, $P = 0.59$
2–4 therapies (16)	−6.0, $P = 0.01$	−2.2, $P = 0.23$	−3.3, $P = 0.30$	−5.1, $P = 0.46$
5+ therapies (7)	−7.5, $P = 0.02$	−5.7, $P = 0.11$	−2.9, $P = 0.16$	−2.3, $P = 0.38$

ATP, antitachycardia pacing; ICD, implantable cardioverter defibrillator.

many) for patients receiving ATP only at any of these intervals (*Table 3*). Similarly, there were no significant differences among therapy levels for shocks at any of these intervals.

Discussion

This study demonstrated that the delivery of ICD shocks was associated with diminished patient activity compared with ATP in the week following therapy. These results provide the first objectively gathered evidence about the effects of ICD shocks on patient behaviour and subsequent lifestyle implications. The current data show that active behaviour, during the first week after shock, appears to be suppressed significantly in the context of ICD shock, whereas suppression of patient activity was absent following delivery of ATP. Patients' median pre-therapy activity level was merely 22.5 h per week, and ICD shock decreased that activity level *even further*. This pattern could indicate a range of concerns as decreases in physical activity is implicated in worsening of cardiac disease and/or comorbid conditions, whereas appropriate physical activity levels facilitate both better exercise tolerance and quality of life (e.g. Refs [12,13]). Supplementary analyses that excluded patients who were hospitalized continued to show a pattern of reduced activity. However, the finding was reduced to statistical non-significance, and possible explanations for this are detailed below. Additional analyses indicated that the effect of reduced activity was diminished after the first week post-therapy. This suggests that there may be a gradual return to the relatively low level of activity for many patients. It is also possible that the differences in activity between levels of ICD shock therapy at weeks 2, 3, and 4 were not impressive enough in magnitude to reach statistical significance given the small number of patients available for this analysis.

The effects of shock were particularly notable as shock increased, especially when the threshold of five shocks was reached or surpassed. These results seamlessly dovetail with the preponderance of previous patient-centered research outcomes, wherein greater than or equal to five shocks has been associated with significant quality of life decrements and psychological distress.[14] When interpreting our data through the lens of that literature, one may speculate that ICD shock increases psychological distress and quality of life, which, in turn, may be responsible for observed decreases in activity. Parsing out whether the effects of ICD shock on patient activity is direct or indirect, and what clinical implications this brings forth, are promising areas for future research. Further, these findings on our behavioural outcome measure align with a recent study of a differential effect of shock, compared with ATP, on a psychological outcome.[15] In a longitudinal study examining whether ICD shock and/or ATP prospectively predicted anxiety at 12 months following device implantation, frequency of ICD shock was associated with subsequent anxiety, whereas frequency of ATP was unrelated to anxiety. In contrast to ICD shock, which is undeniable and likely noxious to patients, patients are not usually aware of receiving ATP in real time. Therefore, patients receiving ATP as a standalone therapy ostensibly receive the benefits of device intervention without the risk for negative behavioural and psychological impact that is likely conferred by ICD shock. In its totality, findings from the current and previous studies indicate that ICD shocks and ATP have divergent effects on behavioural and psychological outcomes, with ATP's effect profile in these domains being favourable.

The effect of ICD shock on activity was evident in our sample within the first 7 days following therapy. Therefore, the current results illustrate that the week immediately post-shock is a critical period to detect problematic repercussions of shock. The substudy of quality of life in SCD-HeFT highlighted that the most significant changes in quality of life following shock were apparent when the measurement of quality of life occurred within 30 days of shock.[16] Specifically, multiple indicators of health and mental health were significantly worse for the group of patients assessed at that time point. It logically follows that measurement of behaviour would show a similar stunting effect after an ICD shock. Further, our findings indicate that an even smaller window of 7 days (vs. 30 days in SCD-HeFT) may be needed to address the behavioural and psychological effects of ICD shock.

Shock therapy saves lives, but the existing research literature indicates that a 'dashboard of health outcomes' spanning patient attitudes and behaviours are increasingly critical to fully examine how ICDs affect patients, especially in ways that may diminish the full clinical potential of these devices. To maximize benefits of ICD therapy, patients must cope both with significant disease and with a significant therapy. The experience of ICD shock has been the primary focus for consideration of the negative consequences of ICD therapy.

Interestingly, a meta-analysis examining ICD shock and generic quality of measures did not show an association, suggesting moderators such as personality variables, preparation for shock, or methodological problems including timing, measurement, and specificity of psychosocial and behavioural outcomes are needed to provide a more complete picture of the impact of ICD shock.[17–20] A focus on physical activity following ICD shock, as in this study, provides a clinical target for education and intervention and sidesteps some of the patient self-report limitations.

The experience of ICD shock remains as an unparalleled experience to cardiac patients, and a broader set of considerations beyond mortality and generic quality of life are needed. Further, we have suggested previously that disease- and device-specific measures such as shock anxiety are needed to identify and intervene on the occurrence of distressed emotions following ICD shock.[21,22] The current findings expand this identified need, supporting the inclusion of post-shock behaviour in patient needs assessments to tailor interventions that mitigate the propensity for blunted activity following ICD shock. We have fortunately overcome what could have been a significant challenge in translating this information into practice—we already possess the integrated technology that provides the necessary information to assess and intervene on patient activity within the context of ICD shock. Activity monitoring is provided in routine interrogations, but the clinical validity and meaning has not been sufficiently studied. This investigation implicates the potential value of activity data.

Although the main focus of this paper was the differential impact of shock vs. ATP on physical activity, our overall descriptive analyses revealed alarmingly low levels of pre-therapy activity in our study sample. Prior to any delivery of device therapy, patients engaged in a median activity level of only 22.5 h per week. To our knowledge, this is the first known objective data that addresses activity levels that are characteristic of patients with ICDs. These data provide novel and concerning insight into how little the typical ICD patient is physically engaged in day-to-day life. Further research on the biomedical and psychosocial implications of this low level of activity could provide an impetus for addressing physical activity levels to mediate negative outcomes associated with such behavioural disengagement.

The current findings are subject to certain limitations. Our sample size was small, particularly when considering the group that received five or more shocks and evidenced the steepest decline in activity level. It also is possible that receiving shocks, especially for those who received at least five shocks, would result in a higher level of hospitalization. Therefore, our findings could be reflective of reduced activity occurring within the context of hospitalization rather than reduced activity due directly to the shock experience *per se*. To that end, when analyses were repeated excluding hospitalized patients, the findings did not reach statistical significance despite maintaining the same pattern of reduced activity. Although this could reflect the effect of hospitalization, it is likely that the extremely small sample size precluded the possibility of achieving statistical significance. The literature shows that shock is associated with psychological distress, including anxiety, shock anxiety, and depression.[3] Such distress may mediate the stunting effect on behaviour that occurred in our sample following ICD shock, but determining to what extent distress drove change in activity level was beyond the scope of this paper. The current findings are limited to a 7 day post-shock window, and the longer-term durability of change in activity level is not known at this time. We also did not control for sex, disease severity, or medications in this study, and it remains a possibility that these factors may have some influence on patients' behavioural responses to ICD shock vs. ATP. Finally, current findings are based on data from patients who were enrolled in the EMPIRIC study between 2002 and 2003. Gathering and analysing data that is more recent and higher in volume through remote monitoring databases will provide additional insight into the differential effects of ICD shock vs. ATP.

Conclusions

This study reinforces existing literature on the detrimental psychosocial effects of ICD shock by expanding clinical targets for consideration to behavioural consequences of ICD shock. It is the first study to directly compare the behavioural impact of ATP in comparison to ICD shock and show that whereas ICD shock significantly reduces activity level, activity level was not reduced following ATP. Our findings provide foundational insight for future investigations that will solidify our understanding of how and why patient behaviour is affected by ICD shock. Additional research will need to further explore the potential advantages of ATP in decreasing unwanted behavioural and/or psychologic consequences of device therapy.

Conflict of interest: Dr Samuel Sears serves as a consultant to Medtronic and has had research grants from Medtronic. These funds from Medtronic are directed to East Carolina University. Dr Sears also has received speaker honorarium from Medtronic, Boston Scientific, St Jude Medical, and Biotronik. Dr Sears is the founder of QOL Apps, Inc. and inventor of ICD Coach. The remaining authors have no conflicts to report.

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EP CASE EXPRESS

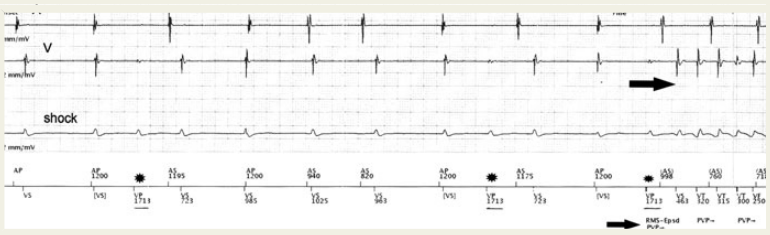
doi:10.1093/europace/euu405

Proarrhythmic effect of 'Reverse Mode Switch' in a patient with dilated cardiomyopathy and drug-induced long QTc interval

Elia De Maria*, Giampiero Patrizi, and Stefano Cappelli

Cardiology Unit, Ramazzini Hospital, Via Molinari 1, Carpi (Modena) 41012, Italy

* Corresponding author. Tel: +39 059659320; fax: +39 059659387. *E-mail address*: e.demaria@inwind.it



A 69-year-old patient with a dual-chamber implantable cardioverter defibrillator (ICD) (Teligen 100, Boston Scientific, Natick, MA, USA) was started with amiodarone for fast ventricular tachycardia (VT) and ventricular fibrillation (VF). After 2 months, a syncopal episode occurred. The electrocardiogram at that time showed a significant QTc prolongation (560 ms). Device interrogation (*Figure 1*) showed initiation of a polymorphic VT degenerating into VF. Pacing programming was: AAI–VVI back-up 50 bpm [Reverse Mode Switch (RMS^{TM})]. Electrogram revealed the mechanism: atrial-based pacing was followed by a ventricular escape beat falling in the blanking period, ventricular sensing [VS]. The device delivered a ventricular back-up pacing (third beat, asterisk), and this happened again at beats 9 and 12. Unfortunately, the last ventricular pacing beat was followed by a premature ventricular contraction, falling in a vulnerable period after a short–long–short (SLS) sequence, and induced VT/VF (black arrows). Amiodarone was stopped; pacing mode was changed to DDD. At 6 months follow-up, no arrhythmic episode was detected and QTc interval returned normal.

In order to minimize ventricular pacing, RMS^{TM} operates in AAI(R) mode with VVI back-up if atrioventricular (AV) conduction is preserved. Recently, it has been reported the case of a patient with congenital long-QT syndrome and a Teligen 100 dual-chamber ICD, in whom VF occurred as a consequence of RMS^{TM} operational features. Here, we have described a similar case with amiodarone-induced QTc prolongation. Managed Ventricular Pacing by Medtronic has already been reported to cause ventricular arrhythmias (including arrhythmic storms and VF) in the setting of AV conduction blocks. Proarrhythmic effect is also possible with RMS^{TM} by Boston Scientific, when changes in ventricular cycle length allow longer pauses and SLS sequences.

The full-length version of this report can be viewed at: http://www.escardio.org/communities/EHRA/publications/ep-case-reports/Documents/proarrhythmic-effect.pdf.