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Recollection of Pain Due to Inappropriate Versus Appropriate Implantable Cardioverter-Defibrillator Shocks

GREGORY M MARCUS, MD, MAS, DERRICK W CHAN, MA, and RITA F REDBERG, MD, MSC

Cardiac Electrophysiology Section (G.M.M.) and Division of Cardiology (D.C., R.F.R.), University of California, San Francisco

Abstract

Background—Although inappropriate shocks are known to be an important consequence of implantable cardioverter-defibrillators (ICDs), the subjective experience of pain intensity perceived by those receiving inappropriate versus appropriate shocks has not previously been examined.

Methods—One hundred ICD patients underwent a standardized interview by an investigator blinded to the clinical history. Patients with a previous ICD shock were asked to describe the intensity of the associated pain on a standard 0–10 scale (10 being the worst pain they had ever experienced). Medical charts were then examined for any history of inappropriate and/or appropriate ICD discharges.

Results—Thirty-five of the 100 patients had a record of at least one ICD shock, and 17 had experienced at least one inappropriate shock. Those with a history of an inappropriate shock described a significantly higher median pain scale (9, interquartile range [IQR] 8–10) compared to those with a history of only appropriate shocks (median 4, IQR 2–8, $p=0.0011$). In multivariable analysis, a history of an inappropriate shock was the only predictor statistically significantly associated with an increase in shock pain: the pain scale for those with inappropriate shocks was higher by 2.8 points on average after multivariable adjustment (95% confidence interval 0.29–5, $p=0.030$). Eighteen patients had considered having their device deactivated, and a history of an inappropriate shock was the only factor independently associated with this consideration.

Conclusions—Compared to those that have received only appropriate shocks, inappropriate ICD shocks are associated with a recollection of greater pain and consideration of device inactivation.

Keywords

Implantable cardioverter-defibrillator; ICD; inappropriate shock; appropriate shock; pain

Introduction

Although implantable cardioverter-defibrillators are known to reduce mortality in patients at high risk for malignant ventricular arrhythmias,^{1–3} the pain associated with ICD discharges may result in a reduced quality of life, anxiety, depression and even post-traumatic stress

Address for correspondence: Gregory M Marcus, 500 Parnassus Ave, MUE 434, San Francisco, CA, 94143-1354, Phone: (415) 476-5706, Fax: (415) 476-3505, marcusg@medicine.ucsf.edu.

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disorder.^{4–8} The degree of pain experienced as a result of an ICD shock has been attributed to patient psychological characteristics,^{9, 10} the amount of energy delivered during a given shock,¹¹ the shock waveform,¹² and the number of shocks.⁴ A painful ICD shock is generally felt to be acceptable if it was given to terminate a life-threatening arrhythmia and unacceptable if it was an inappropriate shock. Despite efforts to avoid them, inappropriate shocks remain common.^{4, 6, 13} To our knowledge, the effect of having an inappropriate versus appropriate shock on the memory of the pain intensity associated with that shock has not previously been evaluated. We sought to test the hypothesis that those with a history of inappropriate ICD shocks recall a greater intensity of pain compared to those who received appropriate ICD shocks.

Methods

We enrolled a convenience sample of 100 ICD patients presenting to the University of California, San Francisco (UCSF) Electrophysiology and Arrhythmia Service Device Clinic from January to April in 2009. Non-English speakers were excluded.

Patients were interviewed by a single investigator (D.C.), using a interview-administered 24-item survey created by the authors of this manuscript regarding knowledge, feelings and attitudes about living with an ICD. The investigator was blinded to the patient's medical record, including any history of shocks. The survey was understandable at a high school reading level and supplemented with verbal explanations from the interviewer when necessary. The interviewer read all questions to the participants and recorded their answers. The interviewer would prompt patients to answer all questions, but "I don't know" after prompting was accepted as a valid response. This manuscript focuses on questions related to shock pain and whether device deactivation was ever considered. All patients reporting an ICD shock were asked, "On a scale of 0–10, how much discomfort does a shock from an ICD cause (0 being no discomfort, 10 being the most discomfort you could possibly imagine)?" Patients who did not recall being shocked were asked, "If you have not had a shock, on a scale of 0–10, how painful do you think a shock from an ICD would cause (0 being no discomfort, 10 being the most discomfort you could possibly imagine)?" Patients that gave a range of numbers were encouraged to narrow down to one answer; if they were unable to give a discrete answer, the range was averaged. Demographic data, past medical history, and history related to device therapy were retrieved from the medical record. In the medical record, an appropriate shock was any ICD shock that occurred in response to a ventricular tachyarrhythmia meeting criteria per the device programming. All other shocks were deemed inappropriate. The distinction between appropriate and inappropriate shock was made by a clinical electrophysiology device nurse, with over-reading by a board certified electrophysiologist. Those with *any* history of inappropriate shock (including those who also had appropriate shocks in the past) were included in the inappropriate shock group.

All patients were also asked the following questions regarding device deactivation, "Have you ever thought about whether you would request at some time to have your device deactivated?"

All participants provided informed, written, and witnessed consent. The study was approved by the UCSF Committee on Human Research.

Statistical Analysis

Normally distributed continuous variables are expressed as means $\pm$ SD and were compared using t-tests; continuous variables that are not normally distributed are expressed as medians and interquartile ranges (IQR) and were compared using the Wilcoxon rank sum test. Categorical variables were compared using the χ^2 test. Continuous variables were compared

to one another using regression analyses, with regression coefficients expressed as point estimates and 95% confidence intervals (CI). Multivariable analyses was performed using logistic regression or linear regression as appropriate. Covariates were selected for inclusion in the model based on a priori plausibility of confounding and associations with both the predictor and outcome of interest with p values < 0.1 . A two-tailed p value < 0.05 was considered statistically significant. Stata version 9.2 (College Station, Texas) was used for statistical analyses.

Results

Thirty-five (35%) of the patients had at least one ICD shock, with a median of 3 (IQR 1–6) shocks each. Twenty-eight had at least one appropriate shock and 17 had at least one inappropriate shock (10 had both). The patient characteristics of those who did and did not experience an ICD shock are shown in Table 1. Those with a secondary prevention device were significantly more likely and those with a history of congestive heart failure were significantly less likely to have received a shock. A greater duration of time with an ICD was associated with the receipt of at least one shock.

Baseline differences between those with at least one inappropriate shock versus those with only an appropriate shock are shown in Table 2. Those who had at least one inappropriate shock reported a median pain of 9 out of 10 (IQR 7–10), while those with a history of only appropriate shocks reported a median pain of 4 (IQR 2–8, $p=0.0011$). The number of shocks was associated with greater pain: on average, each shock for a given individual was associated with a 2 step increase in the 0–10 pain scale (95% confidence interval [CI] 0.79–3.3 increase in pain, $p=0.002$). No other factors measured were associated with the degree of pain reported. After adjusting for the number of shocks and other potential confounding factors, having at least one inappropriate shock was associated with an average 2.8 increase in the pain scale (Figure 1).

Those who had never had a shock anticipated that the pain resulting from a shock would result in a median 7.75 out of 10 pain (IQR 5–9.75). These numbers were lower than what was reported from those with inappropriate shocks, with a trend towards statistical significance ($p=0.073$). The pain reported by those with only an appropriate shock was significantly lower compared to the pain anticipated by those who had never received a shock ($p=0.012$).

Eighteen patients had considered having their device deactivated. The characteristics comparing those who had versus those who had not considered having their device deactivated are shown in Table 3. The only measured factors associated with a greater likelihood of considering device inactivation were number of shocks and a history of inappropriate shocks. In a logistic regression model adjusting for both, the number of shocks was no longer associated with considering deactivating the ICD (odds ratio [OR] 1.02 (95% CI 0.96–1.08, $p=0.58$), but a history of an inappropriate shock remained associated (OR 12.14, 95% CI 1.15–128.10, $p=0.038$).

Discussion

We found that a history of inappropriate ICD shock was independently associated with a recollection of increased pain attributed to the shock compared to those with an appropriate shock. In multivariate models, a history of an inappropriate shock was the only factor statistically significantly associated with a greater amount of pain attributed to the shock and a greater likelihood that an individual had considered having their ICD deactivated.

Although ICDs have proven effective in reducing sudden death and overall mortality in patients at risk,¹⁻³ a decreased quality of life due to device-related concerns remains a problem.⁴⁻⁶ ICD shocks have been associated with depression, anxiety and post-traumatic stress disorder.^{7, 8} Several factors are known to contribute to the intensity of pain experienced with an ICD discharge, including the amount of energy delivered,¹¹ the waveform delivered,¹² the number of shocks,⁴ and the patient's own psychological characteristics.^{9, 10} The majority of these factors are relatively fixed. For example, as the standard of care dictates that an ICD be programmed with a 10 Joule safety margin, most devices will be programmed with several shocks at the maximum output. The waveforms are generally predetermined and only changed to increase efficacy in those rare circumstances wherein initial defibrillation threshold testing is unsuccessful. Finally, the patient's innate personality characteristics are unlikely to change. Despite efforts to avoid them, inappropriate shocks remain common.^{4, 6, 13} A reduction in inappropriate therapies may substantially reduce the risk of decreased quality of life in ICD patients.

Because this study involved an interview that asked the patients to recollect their experience, we can not comment directly on the pain actual felt at the instantaneous moment of the ICD discharge. We suspect that our findings reflect the psychological influence involved when a patient is told their shocks were not necessary to preserve their life and were "inappropriate." While ICD shocks are generally felt to cause severe pain, it is interesting that those with only a history of appropriate shocks described a median pain of only 4 out of 10. In fact, this was statistically significantly lower than the degree of pain from a shock anticipated by the ICD patients who had never experienced a shock. Although the pain we have recorded represents the memory of the pain, this is likely important in determining the patients mood towards the device. As evidence for this, those with a history of an inappropriate shock were more likely to consider having the device deactivated.

Inappropriate ICD shocks have previously been associated with reduced quality of life¹⁴ and increased mortality.¹³ The association between inappropriate shocks and increased mortality has generally been attributed to the underlying arrhythmias thought to be responsible (such as atrial fibrillation), but the exact cause remains unknown.¹³ Ours is the first study to demonstrate that inappropriate shocks also enhance the perceived intensity of the pain associated with ICD shocks.

Several strategies to minimize the risk of inappropriate shocks are available.. All devices now have some means to attempt to distinguish ventricular arrhythmias from supraventricular arrhythmias, but these are generally only relevant in the ventricular tachycardia (not the ventricular fibrillation) zone.¹⁵⁻¹⁹ Drugs might reduce the risk, but toxicities and side effects can also adversely affect quality of life.²⁰⁻²² Finally, wireless monitoring may help reduce the risk of inappropriate shocks by detecting abnormalities or changes (such as changes in lead impedance) before they lead to excessive lead noise and subsequent inappropriate shocks.^{23, 24}

Our study has several limitations. First, the study was restricted to a single practice in a teaching hospital. Patient attitudes and reactions to inappropriate and appropriate shocks may differ in other settings. We did not delineate different episodes of shocks that may have occurred over time, but rather asked for an average rating of ICD shock pain over the entirety of the past. It may be that the shock experience differed substantially even within patients depending on a variety of unmeasured factors over time. We also did not record the time from the last shock until the time of the interview, and it is possible that differences in time from shock to interview differed in the two groups, potentially affecting the results. As this was a retrospective review, we relied on a previous diagnosis of appropriate and/or inappropriate shocks, without a formal review process of the primary data. Although the

device nurse and electrophysiologist making the diagnosis of appropriate versus inappropriate ICD shock were therefore “blinded” to this survey, it is possible that some of the diagnoses were inaccurate. Although we have assumed that the patients’ understanding of the meaning of the shocks received (inappropriate versus appropriate) influenced the memory of the shock, we can not exclude the possibility that there is something intrinsic to the shock indication that was particularly influential. For example, we did not record whether the patient had syncope associated with the shock, a phenomenon that could have occurred more frequently with appropriate shocks and that may have resulted in a loss of recollection of any pain involved. We assessed the recollection of shock pain based on an appropriate versus inappropriate shock determined by the medical record rather than based on the patients’ knowledge regarding a history of an appropriate versus inappropriate shock. We believe this approach erred on the side of accuracy, and that, if anything, this may have *decreased* our power to detect an association. We do not believe this should have resulted in any false positive results. Finally, we did not explore differences in psychiatric/psychological history between groups. Therefore, we can not exclude the possibility that those with inappropriate shocks were more likely to have underlying psychological propensities toward experiencing more severe pain.

Conclusions

We found that a history of at least one inappropriate shock was an independent predictor of greater ICD shock pain. Those with a history of an inappropriate shock were also significantly more likely to consider having their device deactivated. Those with an appropriate shock reported pain intensity significantly lower than what is anticipated by ICD recipients that have never experienced a shock. Strategies to minimize inappropriate shocks are likely of paramount importance in minimizing the reduced quality of life attributed to ICDs.

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Figure 1.

Predictors of ICD shock pain on a 0–10 pain score in the 35 patients with a previous shock after multivariable adjustment. Only a history of inappropriate shock remained statistically significantly associated. Y error bars denote 95% confidence intervals.

Table 1

Baseline characteristics of patients with and without a history of implantable cardioverter-defibrillator shocks

	A history of any ICD Shock (n=35)	No history of an ICD shock (n=65)	P value
Age (mean $\pm$ SD)	60 $\pm$ 15	62 $\pm$ 15	0.57
Male	32 (91%)	51 (78%)	0.10
Female	3 (9%)	14 (22%)	0.10
Race			0.21
White	26 (76%)	44 (77%)	
Black	2 (6%)	0	
Asian	0	3 (4%)	
Other	6 (18%)	11 (19%)	
Hypertension	19 (54%)	40 (62%)	0.48
Coronary Artery Disease	18 (51%)	33 (51%)	0.95
Myocardial Infarction	13 (37%)	27 (42%)	0.67
Congestive Heart Failure	18 (51%)	49 (75%)	0.015
On Hemodialysis	2 (6%)	5 (8%)	0.71
Diabetes	5 (14%)	20 (31%)	0.069
Primary Prevention	20 (57%)	48 (74%)	0.088
Secondary Prevention	11 (31%)	9 (14%)	0.036
Inherited Syndrome*	6 (17%)	9 (14%)	0.66
Duration with ICD (median and IQR days)	1149 (363–1416)	643 (223–1249)	0.042

* Inherited syndrome includes hypertrophic cardiomyopathy (n=8), Brugada syndrome (n=4), long QT syndrome (n=2), arrhythmogenic right ventricular dysplasia (n=1). IQR denotes interquartile range

Table 2

Baseline characteristics of patients with and without a history of implantable cardioverter-defibrillator shocks

	A history of any inappropriate ICD shock (n=17)	A history of only appropriate ICD shock (n=18)	P value
Age (mean $\pm$ SD)	56 $\pm$ 15	64 $\pm$ 13	0.070
Male	17 (100%)	15 (83%)	0.078
Female	0	3 (17%)	0.078
Race			0.26
White	13 (76%)	13 (77%)	
Black	2 (12%)	0	
Asian	2 (12%)	4 (24%)	
Other	1 (1%)	0	
Hypertension	8 (47%)	11 (61%)	0.40
Coronary Artery Disease	8 (47%)	10 (56%)	0.62
Myocardial Infarction	7 (41%)	6 (33%)	0.63
Congestive Heart Failure	8 (47%)	10 (56%)	0.62
On Hemodialysis	2 (12%)	0	0.13
Diabetes	2 (12%)	3 (17%)	0.68
Primary Prevention	9 (53%)	11 (61%)	0.63
Secondary Prevention	6 (35%)	5 (28%)	0.63
Inherited Syndrome *	3 (18%)	3 (17%)	0.94
Duration with ICD (median and IQR days)	1190 (587–1364)	1037 (363–1416)	0.91

* Inherited syndrome includes hypertrophic cardiomyopathy (n=8), Brugada syndrome (n=4), long QT syndrome (n=2), arrhythmogenic right ventricular dysplasia (n=1). IQR denotes interquartile range.

Table 3

Characteristics of patients who did and did not consider having their implantable cardioverter-defibrillator deactivated

	Considered Deactivating Their Device		
	Yes (n=18)	No (n=82)	P value
Age (years, mean $\pm$ SD)	58 $\pm$ 4	62 $\pm$ 2	0.26
Median Number of Days since ICD Implant (interquartile range)	630 (232–1384)	847 (328–1294)	0.72
Male	17 (94%)	66 (81%)	0.15
White	12 (67%)	58 (71%)	0.73
Congestive Heart Failure	12 (67%)	55 (67%)	0.97
End Stage Renal Disease on Hemodialysis	1 (6%)	6 (7%)	0.79
Primary Prevention	11 (61%)	57 (70%)	0.49
Secondary Prevention	3 (17%)	17 (21%)	0.70
Inherited Syndrome	4 (22%)	11 (13%)	0.34
History of Appropriate Shock	6 (33%)	22 (27%)	0.58
History of Inappropriate Shock	6 (33%)	11 (13%)	0.042