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Electrical Storm Has a Significant Effect on Mortality in Those with Structural Heart Disease and ICD Implants

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Abstract

Background: Patients who have an implanted cardiac defibrillator (ICD), which includes cardiac resynchronization therapy devices capable of defibrillation, are at risk for electrical storm (E-Storm), which is defined as many bouts of ventricular arrhythmias occurring quickly. Patients who have pacemakers or other defibrillation-capable devices may also experience e-storms. To far, it is unknown what the precise therapeutic properties of E-Storm are in large populations, particularly for non-ischemic dilated cardiomyopathy (DCM).This research was carried out with the purpose of elucidating the specific clinical elements of E-Storm, such as its prevalence and predictors among patients who were diagnosed with structural heart disease, which included DCM. **Material and Methods:** The Storm Research was a prospective observational study that involved a total of 1570 patients from 48 ICD sites. We carried out an analysis based on the findings of that study. In order to accomplish the goals of this study, we conducted examinations on a total of 1274 patients who had been given a diagnosis of structural heart disease. Ischemic heart disease (IHD) was found in 482 (38%) of those patients, while diabetic cardiomyopathy (DCM) was diagnosed in 342 (27%) of those individuals. **Results:** During a median follow-up period of 28 months, E-Storm presented itself in 84 patients, or 6.6%. (The interquartile range was 23 to 33 months). The incidence of E-Storm did not differ statistically between patients with ischemic heart disease and those with diabetic cardiomyopathy (log-rank p = 0.52). Proportional hazard regression studies revealed that ICD implantation for secondary prevention of sudden cardiac death (p = 0.0001) and QRS width (p = 0.015) were the independent risk variables for E-storm. When survival curves were examined after clinical variables were controlled, a statistically significant difference in mortality was identified between people who had E-Storm and those who did not. The E-Storm was connected to an increased risk of death in patients with structural heart disease, such as DCM.

Keywords: Defibrillation, cardiac resynchronization therapy (CRT-D), lightning storm, Cardioverter defibrillator implant (ICD), venous tachycardia, cardiovascular fibrillation.

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Introduction

In order to prevent sudden cardiac death, defibrillators for the heart, commonly known as implantable cardiac defibrillators (ICDs) and cardiac resynchronization therapy devices that can conduct defibrillation (CRT-Ds), have become a realistic treatment option.[1-5] The development of tachycardia episodes cannot be automatically stopped by an ICD, and certain patients may experience an electrical storm (E-Storm) that necessitates prompt antitachycardia pacing (ATP) or shock delivery.[6-10] This is the case since an ICD is not a device that can work independently. Patients with any form of arrhythmia who do not receive

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shocks from an implanted cardioverter defibrillator (ICD) have a significantly lower chance of surviving than patients who do. It has been proven that this is true.[11-13] Despite the fact that the prevalence, risk factors, and clinical result of patients with E-Storm in those with ischemic heart disease (IHD) were often fully defined, information is currently limited for other underlying cardiac illnesses, such as nonischemic dilated cardiomyopathy (DCM). The Nippon Storm Study was created as a prospective observational study with the aim of gathering clinical data from patients receiving ICD therapy.[14-17] The name of the study is in Japanese. The aim of the study was to investigate the prevalence of E-Storm and clinical features of those who acquire it in Asia, a region with a higher prevalence of DCM than most other Western countries put together.[18-21]

Material and Methods

The storm study has produced a publication that delves into the specifics of the overall study design. In a nutshell, the Indian Heart Rhythm Society and the Indian Society of Electrocardiology were the ones behind the organisation of the Storm Study. Patients in 48 Indian ICD centres were required to register themselves online, and the Indian Heart Rhythm Society collected data from the physicians who were responsible for entering the information on their patients. In accordance with the criteria for the implantation of an ICD, the attending cardiologists at each centre were the ones responsible for determining the indication and the purpose of the implantation.

ICD programing

The accompanying physician's judgement was used to determine the ICD's programming. The businesses Boston Scientific and Medtronic, both of which have offices in Marlborough, Massachusetts, developed the algorithms for discrimination, which included Morphology Discrimination as well as AV Rate Branch, Rhythm ID, PR Logic, and Wavelet (developed by St. Jude Medical, located in St. Paul, Minnesota). The heart rates of the ventricular tachycardia (VT) zone and the ventricular fibrillation (VF) zone were N188 to 200 bpm and at least three trains of ATP, respectively, before the shock. Before allowing changes to either of these zones, we took into account the patient's history. According to the preferences of the many doctors, each E-Storm was treated. If it was thought that myocardial ischemia, cardiac failure, or an electrolyte problem contributed to E-Storm, the aforementioned conditions were rapidly addressed. Beta-blockers, amiodarone, and lidocaine were given as part of an antiarrhythmic medication regimen either sequentially or concurrently, as needed. While enduring the acute phase of EStorm, some patients may need catheter ablation.[22]

Follow-up of it

Chaser is the name we gave to our brand-new tracking system that we developed specifically for the purpose of conducting a detailed follow-up. The most important purpose of the system was to cut down on the amount of follow-up data that was dropped. The information regarding interventions from the ICD, including those that were deemed appropriate and those that were deemed inappropriate, was sent to the office of the Indian Heart Rhythm Society via the website at the most frequent interval of every six months. The number of months that passed in between broadcasts served as the benchmark for calculating this maximum gap. When classifying the ICD therapies, the three categories that were used were ATP, low-energy shocks, and high-energy shocks. An E-Storm was defined as occurring when a patient experienced at least three distinct bouts of VT/VF during a period of twenty-four hours. Each and every E-Storm was judged in a manner that was fully blind to the participants, and the criterion for success was determined by the intracardiacelectrograms that were being recorded at the time of the event.[23]

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Data analysis

The characteristics of the patients were assessed based on the baseline data, which included age, sex, any preexisting heart conditions, the purpose of the indication (main or secondary), and any complications associated to the implantation operation. The occurrence of E-Storm and its determinants were investigated as the primary focus of this study, and the baseline characteristics of the patients were used as the data source. Analyses were conducted on several acute management strategies for EStorm. At last, a comparison of the patients' prognoses was made between those who had E-Storm and those who did not [Figure 1].

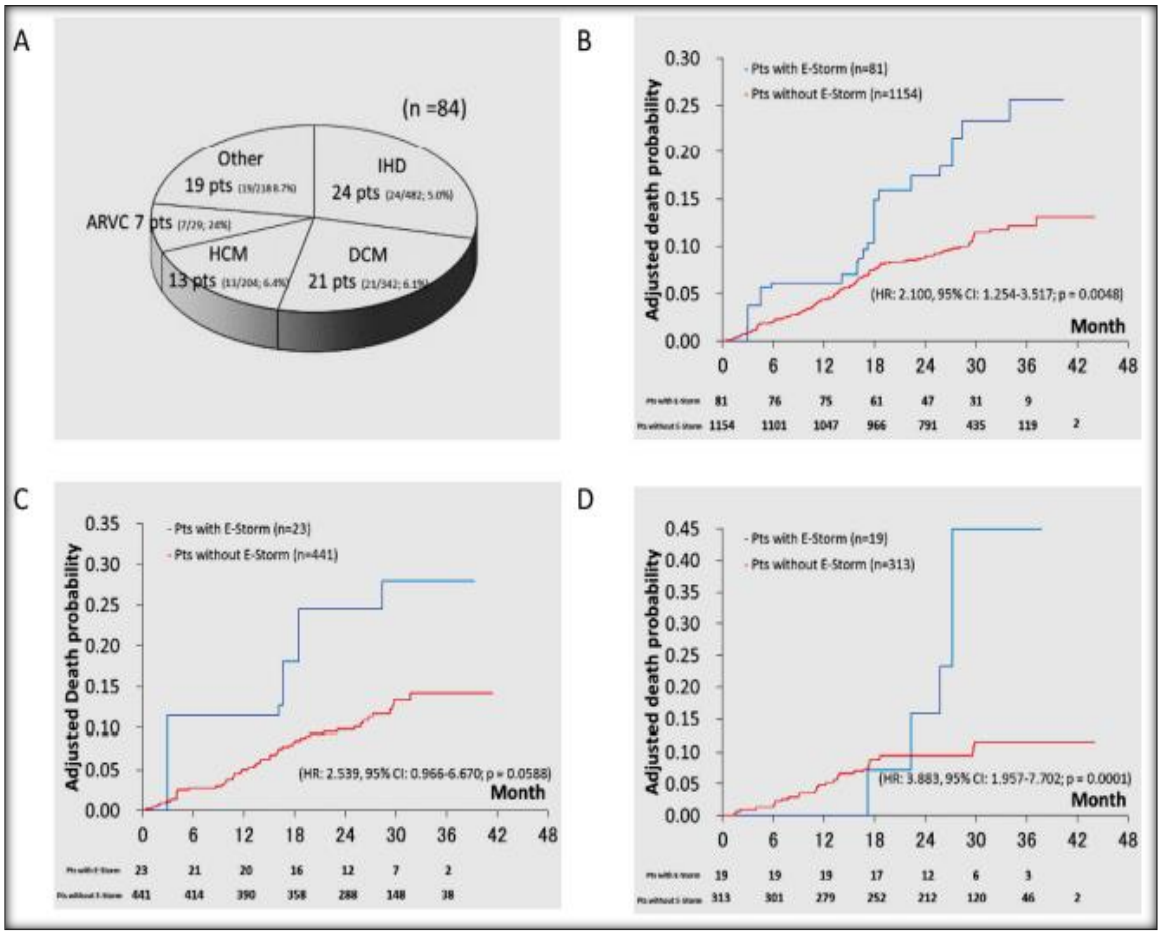

Figure 1: (A, B, C, D) Incidence of electrical storm for each etiological underlying anatomic diagnosis. Kaplan–Meier curves adjusted for baseline characteristics using the inverse probability weighting method and Kaplan–Meier curves adjusted for baseline characteristics using the inverse probability weighting method.

Statistics

The mean and standard deviation represent the continuous baseline values, whereas the number of respondents represents the categorical baseline variables (percent). We utilised the Student's t-test for categorical variables and the 2 test for categorical variables to assess whether there was a difference that might be regarded as statistically significant when comparing any two separate groups. Log rank tests were used for statistical hypothesis testing, and the Kaplan-Meier method was used to create survival curves for time-to-event outcomes. The hazard ratio (HR) and 95% confidence interval (95% CI) were calculated after the impacts of the covariates were examined using proportional hazard models. In order to account for disparities between patients with and without E-Storm, survival curves that had been corrected for factors using the inverse probability weighting method were created. This

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made it possible to compare the following death rates for patients who had and did not have E-Storm. Because E-Storm in patients manifested at various times, we also conducted ground-breaking research at the six-, twelve-, and eighteen-month intervals. The statistical analysis was performed using the SAS software, version 9.4. (SAS Institute Inc., Cary, NC). The p value must be lower than 0.05 for an observation to be deemed statistically significant. [As an example] Each of the participating universities' Institutional Review Boards approved the study's ethics, and the research was conducted in accordance with the guidelines specified in the Helsinki Declaration. After receiving the necessary information and completing a signed consent form, every patient took part in the trial [Table 1].

Table 1: Hazards ratio of storms on clinical variables

Sr. No	Parameters	Univariable Analysis		
		HR	95% Cl	P value
	Clinical Characteristics	1.11	0.666-1.85	0.69
1.	Gender	1.018	0.689- 1.056	0.065
2.	Age	2.195	0.380- 1.235	0.008
3.	Primary prevention	1.07	0.024- 3.022	0.74
4.	ICD CRT-D	0.977	0.921- 1.080	0.93
5.	NYHA II	1.389	0.945- 2.038	0.23
6.	NYHA III	0.336	0.912- 1.038	0.29
7.	NYHA IV	0.948	0.724- 2.038	0.56
8.	Cr mg/dl	1.002	0.989- 1.038	0.98
9.	Hb g/dl	0.989	0.823- 2.021	0.11
10.	LVEF %	0.998	0.999- 1.038	0.21

Results

The study included a total of 1570 patients from 48 different ICD facilities in Japan (Appendix A). 1274 patients with structural heart disease were the subject of our study. There were 342 (27%) patients with diabetic cardiomyopathy and 482 (38%) individuals with ischemic heart disease among the 1274 patients. [Table 1] may be seen here and lists the characteristics of each of the 1274 patients who participated in the trial. The patients were primarily male (76%), with a mean age of 967 at the time of implant surgery of 65.12 years. ICDs were implanted in 638 patients for the primary prevention of sudden cardiac death and 636 patients for the secondary prevention of the same. The number of patients who received ICDs varies depending on the causes for their acquisition. The sum of the two percentages is precisely 50%. ICDs were implanted in 775 patients—61% of all patients—and CRTDs in 499 patients—39% of all patients. Together, these two procedures involved the implantation of ICDs in 775 patients and CRTDs in 499 patients. The average LVEF, also known as ejection fraction from the left ventricle, was found to be 38%. In 1274 individuals, ischemic heart disease and dilated cardiomyopathy were the two most frequent causes of structural heart illnesses (n = 482 and n = 342, respectively).

Incidence of E-Storm

Over the course of a median follow-up of 28 months (range: 23-33 months), 84 patients (6.6%) experienced E-Storm; the annual occurrence rate was 2.8%. 24 patients (5.0%) with ischemic heart disease, 21 (6.1%) with dilated cardiomyopathy, 13 (6.4%) with hypertrophic cardiomyopathy, 7 (24%) with arrhythmogenic right ventricular cardiomyopathy, and 19 (8.7%) with other structural heart diseases like valvular heart disease, cardiac sarcoidosis, or congenital heart disease, among others, experienced E-Storm [Figure 1A]. When it came to the cause of the ICD indication, E-Storm occurred in 4.2% of patients who were receiving

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primary prevention and 9.0% of patients who were receiving secondary prevention. A survival research evaluated the E-Storm-free survival curves of patients with IHD and DCM, and the results revealed no discernible difference between the two groups (log-rank p = 0.52).

Risks for E-Storm

The patients who had EStorm and those who did not have EStorm did not differ significantly in terms of gender, age, the kind of shock device used, the signs and symptoms of heart failure, the left ventricular ejection fraction (LVEF), the baseline heart rate, the prevalence of atrial fibrillation and/or atrial flutter (AF/AFL), QT intervals, or medication. The QRS width was significantly wider in patients with E-Storm than in patients without E-Storm (141 40 vs. 131 35 ms, respectively; p = 0.036), and patients with E-Storm received an ICD for secondary prevention significantly more frequently than patients without E-Storm (68% vs. 49%, respectively; p = 0.007). These two differences both had statistical significance. ICD implantation yielded a hazard ratio (HR) of 2.698 (95% confidence interval [CI], 1.634-4.456; p = 0.0001), and QRS width (per 1 ms) was another risk factor for developing E-storm with an HR, 1.008 (95% CI, 1.001-1.014; p = 0.015): the hazard risk rises by 8% for each 10-ms increment.

Acute management of E-Storm

By lowering or upping the dosage of antiarrhythmic medications in 31 patients, acute management of E-Storm was performed on 59 patients. Antiarrhythmic medication dosages for these patients were raised (administration of intravenous amiodarone in 14, and intravenous nifekalant in 8 patients). During the acute stage of the disease, catheter ablation was performed on a total of 17 E-Storm patients; however, multivariate analysis showed that this procedure was not significantly associated with a lower risk of death in E-Storm patients (hazard ratio [HR], 0.885; 95% confidence interval [CI], 0.470-1.665; p = 0.704).

Discussion

Here are the study's three most important findings: E-Storm occurred in 6.6% of patients with structural heart disease during the course of a median follow-up period of 28 months (annual occurrence rate of 2.8%), and this percentage was similar between patients with IHD and DCM. Second, a multivariate analysis found that the QRS width and secondary avoidance of sudden cardiac death were both significant predictors of E-Storm. This was determined after an examination of the patient. Thirdly, the survival curves after controlling for variables showed a sizable difference in mortality between patients who received E-Storm and those who did not. This study found that the annual incidence risk of E-Storm among patients with structural heart disease was 2.8% (IHD patients for primary prevention 1.2%, IHD patients for secondary prevention 2.7%, DCM patients for primary prevention 2.1%, and DCM patients for secondary prevention 3.8%). It is expected that patients who use their ICDs for primary prevention will have fewer instances of E-Storm than those who only use them for secondary prevention. The Nippon Storm Study is the first research of its kind to conclusively show that secondary prevention ICD patients had a higher likelihood of experiencing an E-Storm than primary prevention patients. The large number of participants in the study made this discovery possible. Previous clinical trials including patients with ICDs for secondary prevention suggested a higher annual incidence of E-Storm (between 7 and 11%) than our findings suggest. The current trend toward programming higher rate cutoffs and longer arrhythmia-detection windows for VT/VF detection in ICDs may result in fewer unnecessary interventions being carried out by ICDs. This may explain why we found such a low rate of EStorm in this study.[24]

Multiple studies have found that lower LVEF, chronic renal failure, advanced age, and a history of VT/VF events are all significant indications of an E-Storm. According to the findings of the current study, E-Storm can be reliably predicted when an ICD is implanted for

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the secondary prevention of sudden cardiac death. This finding is similar to those found in the past. Our results are comprehensive when we account for the fact that patients who have an ICD for secondary prevention of sudden cardiac death are more likely to receive adequate therapy than those who have an ICD for primary prevention of sudden cardiac death. This is due to the fact that patients with a history of arrhythmia are at a higher risk of developing new ventricular arrhythmias following ICD implantation. This is because ICDs are routinely implanted in patients for the secondary prevention of sudden cardiac death. Despite the fact that the LVEF was typically lower in patients who experienced E-Storm, neither the LVEF nor advanced age provided any prognostic value for the chance of ES.[25-27] This was true despite the fact that LVEF tends to be lower. Consistent with the findings reported by Hohnloser and colleagues, this is likely attributable to the patients' preexisting conditions, such as the underlying aetiology of their cardiac illness and an LVEF that was preserved to an admirably high degree (e.g., arrhythmogenic right ventricular cardiomyopathy or hypertrophic cardiomyopathy). A higher risk of E-Storm was shown to be connected with a QRS width of less than 120 ms, as determined by the research of Arya and colleagues. Another study indicated that people with ICDs were more likely to develop VT/VF if their QRS interval was prolonged (ICD). It has been hypothesised that the width of the QRS complex is a marker for the severity of myocardial fibrosis, which can lead to the development of an arrhythmic substrate, most notably depolarization anomalies that may lead to VT/VF.

Limitations

There were several problems with this study. First, there was no randomization because the trial was carried out using a prospective observational design and a multicenter registry, which raised the chance of hidden bias. Our sample accurately reflects the real-world clinical environment of Asian patients with ICD, particularly those with non-ischemic cardiomyopathy. However, caution should be applied when extrapolating our findings to patients in Western nations. This is true even though our conclusions need to be used cautiously. We believe that the current statistics provide novel perspectives on the application of E-Storm in ICD therapy. This is due to the fact that patients with non-ischemic cardiomyopathy have only been studied in a small number of significant E-Storm investigations. Second, relatively low heart rate programming for VT/VF detection in our series may have made it more likely that E-Storm would occur by forcing the ICD to administer treatments that weren't required for the VT/VF to self-terminate. The patient population with the lowest prevalence of clinical VT was used to establish a detection interval, although this programming pattern was most frequently observed in patients receiving secondary prevention. There was a higher detection rate and a longer length interval used in the primary prevention patients as compared to those getting secondary prevention.

Conclusion

In clinical practise, E-Storm is not an extremely uncommon occurrence in people who have DCM or IHD. E-Storm incidents have a strong association with eventual mortality and call for the implementation of appropriate emergency management protocols.

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