

Motor Vehicle Accidents in Patients With an Implantable Cardioverter-Defibrillator

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Objectives. This study was designed to examine driving safety in patients at risk for sudden death after implantation of a cardioverter-defibrillator.

Background. Cardioverter-defibrillators are frequently implanted in patients at high risk for sudden death. Despite concern about the safety of driving in these patients, little is known about their actual motor vehicle accident rates.

Methods. Surveys were sent to all 742 physicians in the United States involved in cardioverter-defibrillator implantation and follow-up. Physicians were questioned about numbers of patients followed up, numbers of fatal and nonfatal accidents, physician recommendations to patients about driving and knowledge of state driving laws.

Results. Surveys were returned by 452 physicians (61%). A total of 30 motor vehicle accidents related to shocks from implantable defibrillators were reported by 25 physicians over a 12-year period from 1980 to 1992. Of these, nine were fatal accidents involving eight patients with a defibrillator and one passenger in a car

driven by a patient. No bystanders were fatally injured. There were 21 nonfatal accidents involving 15 patients, 3 passengers and 3 bystanders. The estimated fatality rate for patients with a defibrillator, 7.5/100,000 patient-years, is significantly lower than that for the general population (18.4/100,000 patient-years, $p < 0.05$). The estimated injury rate, 17.6/100,000 patient-years, is also significantly lower than that for the general public (2,224/100,000 patient-years, $p < 0.05$). Only 10.5% (30 of 286) of all defibrillator discharges during driving resulted in accidents. Regarding physician recommendations, most physicians (58.1%) ask their patients to wait a mean (\pm SD) of 7.3 ± 3.4 months after implantation or a shock before driving again.

Conclusions. The motor vehicle accident rate caused by discharge from an implantable cardioverter-defibrillator is low. Although restricting driving for a short period of time after implantation may be appropriate, excessive restrictions or a total ban on driving appears to be unwarranted.

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Driving recommendations for patients with an implantable cardioverter-defibrillator (ICD) vary widely among cardiologists, with no national consensus at the present time. Despite the emotionally charged discussions that this topic may generate, there are limited data on the risk of driving in patients with ICDs. There have been two surveys of physician practices regarding patients with ICDs (1,2), but these did not include data on specific outcomes in ICD patients who drive.

It is well known that many patients with ICDs drive against physician advice. In a survey of ICD recipients followed up at the University of South Carolina, 70% of patients resumed driving, most by 8 months after implantation (3). Two of the patients reported discharge of their ICDs while driving, but no accident or injury was reported. An analysis of driving hazard, defined as occurrence of ventricular tachycardia or fibrillation, syncope or defibrillator discharge, in patients with ICDs from one university hospital found that it was maximal in the first

7 months after ICD implantation and diminished substantially after that (4). This led to the recommendation to restrict driving in the first 7 months after ICD implantation. However, national data on actual accident rates and fatalities in patients with ICDs could be helpful in formulating policy. We therefore conducted a survey of all physicians involved in ICD implantation and follow-up in the United States to determine their recommendations to patients regarding driving and to collect information on motor vehicle accidents and fatalities in patients with ICDs. The results of the survey form the basis of this report.

Methods

All physicians involved in ICD implantation and follow-up were identified from a computer list provided by Cardiac Pacemakers, Inc. Information requested in the survey included the length of time that the physician had been performing defibrillator implantations, the approximate total number of patients followed up, recommendations made to patients regarding driving, what factors physicians considered in making those recommendations (i.e., type of device, type and stability of presenting arrhythmia), knowledge of state laws about driving in patients with arrhythmias and accidents and fatalities and injuries reported by patients and their families. To main-

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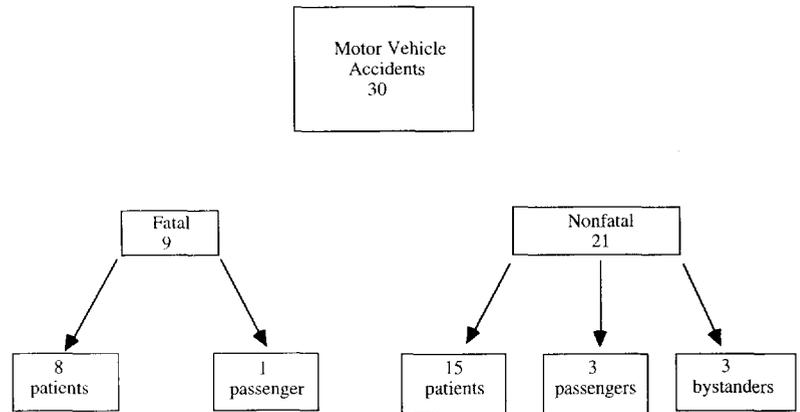


Figure 1. Motor vehicle accidents involving implantable cardioverter-defibrillator recipients. There were a total of 30 fatal and nonfatal injuries reported.

tain confidentiality, the surveys were coded by number. If more than one survey was returned from one institution or practice, the survey of the most senior member of the group as defined by longer duration of time from first implantation and greater number of patients followed up was retained, and the other(s) set aside. Reports of accidents and injuries were checked by one of us for duplication by examining the state of origin of the report. If more than one accident was reported from any one state, the surveys were examined further for the description of the accident and whether two reports came from the same institution, with duplicates set aside. There was one duplicate report each of a fatality and an injury. The frequency of fatal and nonfatal injuries was compared with similar data from the U.S. Bureau of the Census.

Some of the physicians left blanks for some of the questions, so that not all of the percentages presented here add up to 100%.

Statistical analysis. Data for continuous variables are summarized and reported as mean value \pm SD. Percentages and rates estimated from the survey responses are reported with 95% confidence intervals (CI) when appropriate. The chi-square statistic or Fisher exact test was used to compare response percentages between independent groups of respondents. Methods based on the Poisson distribution were used to compare fatality, injury and accident rates among ICD recipients with those among known population rates (5).

Results

Physician experience. A total of 742 surveys were mailed out, of which 452 (61%) were returned. Fifty surveys provided duplicate information for certain centers and were not analyzed further, so that a total of 402 surveys were analyzed for this report. The physicians in the survey, who represented 48 states and the District of Columbia, had been implanting ICDs for a mean of 5.8 ± 2.6 years (range 1 to 12). The mean number of ICD recipients followed up by each physician was estimated by the physicians themselves to be 141 ± 144 (range 1 to 1,000), or $>54,000$ for all respondents of the survey. At the time the survey was sent out (1992), $\sim 32,000$ patients were known to have received ICDs in the United States (personal

communication with U.S. ICD manufacturers). Thus, because 61% of the surveys were returned, the physicians had clearly overestimated the actual number of patients with an ICD and follow-up data.

Accidents among ICD recipients. Despite the large number of ICDs implanted nationwide, very few accidents have been reported among ICD recipients. Fully 93.3% (374 of 401, 95% CI 90.8% to 95.7%) of the physicians were unaware of any accidents among their patients. Twenty-five physicians reported 30 accidents; of the 25, 3 physicians reported 2 accidents each, and 1 reported 3 accidents. Not surprisingly, the most experienced implanters were more likely to be aware of accidents involving patients with devices. For physicians with up to 50 ICD implantations, only 1.4% (2 of 140, 95% CI 0.0% to 3.4%) were aware of accidents, whereas 9.4% of physicians with 51 to 1,000 implants (23 of 244, 95% CI 5.8% to 13.1%) had knowledge of accidents among patients with devices ($p = 0.002$). There were eight patient fatalities, all related to loss of consciousness with the device firing while the patient was driving. There was one fatality of a passenger in a vehicle driven by a patient with an ICD, but no bystanders were fatally injured (Fig. 1).

To determine a driving-related fatality rate for ICD recipients, certain assumptions were necessary because of the overestimation of the numbers of ICD recipients by the responding physicians. At the time of the survey, $\sim 32,000$ patients had received ICDs in the United States. Using 1- to 7-year survival rates for ICD recipients (all-cause mortality; personal communication, Cardiac Pacemakers, Inc., AICD Database; also ref. 6), and extrapolating 8- to 11-year survival rates by assuming a yearly survival rate of 95% after 7 years, the total number of patient-years represented by the 32,000 ICD recipients through 1992 is $\sim 195,900$. If 61% of all ICD recipients are assumed to be represented by the 61% of physicians who responded to the survey, then 119,500 patient-years are represented by the survey results. Nine driving-related fatalities among ICD recipients reported in the survey would thus yield a total fatality rate of 7.5/100,000 patient-years (95% CI 4.1/100,000 to 17.1/100,000). This rate is statistically lower than the 1989 general population driving-related

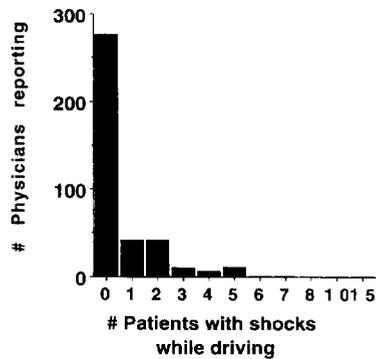


Figure 2. Number of patients whose implantable cardioverter-defibrillator fired while driving, as reported by each physician.

fatality rate of 18.4/100,000 patient-years ($p < 0.05$) (6). If the results of the survey are assumed to represent all 195,900 ICD-recipient patient-years, the driving-related fatality rate for this group would be even lower, 4.6/100,000 patient-years (95% CI 2.1/100,000 to 8.7/100,000), and would also differ significantly from the 1989 general population rate ($p < 0.05$).

Fifteen nonfatal injuries occurred among patients with ICDs; in addition, three passengers and three bystanders were injured (Fig. 1). With 21 injuries among 19,520 patients with an ICD, the driving-related injury rate is 17.6/100,000 patient-years (95% CI 10.9/100,000 to 26.9/100,000). If the 21 reported injuries represented the total number for all 195,900 implant recipient patient-years, the injury rate would be 10.7/100,000 patient-years (95% CI 6.6/100,000 to 16.4/100,000). In either case, these rates are clearly lower than the 1990 national rate of 2,224/100,000 patient-years ($p < 0.05$) (7). However, the proportion of all injuries that were fatal is much higher among ICD recipients than among the general public. The percentage for ICD recipients is 30% (9 of 30, 95% CI 13.6% to 46.4%), whereas that based on national statistics is 0.83% (18.4 of 2,224) ($p < 0.0001$).

Although the fatality and injury rates were low among ICD recipients, a much larger percentage of physicians reported that patients had their devices fire while they were driving without any accident or injury. Fully 30.9% of the physicians who responded (124 of 401, 95% CI 26.4% to 35.4%) reported having patients whose devices had fired while they were driving. Eighty-four of these physicians (67.7%, 95% CI 59.5% to 76.0%) reported one or two instances of ICD shock delivery during driving; the rest reported from 3 to 15 instances (Fig. 2). Because 30 fatal and nonfatal injuries were reported, only 10.5% of ICD discharges (30 of 286 total reported firings, 95% CI 6.9% to 14.0%) resulted in accidents.

Driving recommendations. Driving is permitted by 79% of the physicians responding to the survey; only 20.8% (83 of 400, 95% CI 16.8% to 24.7%) issue a blanket prohibition of driving to their patients. However, the majority of physicians recommend that their patients wait a variable length of time before resuming driving. Most physicians (58.1%, or 233 of 401, 95% CI 53.3% to 62.9%) ask their patients to refrain from driving

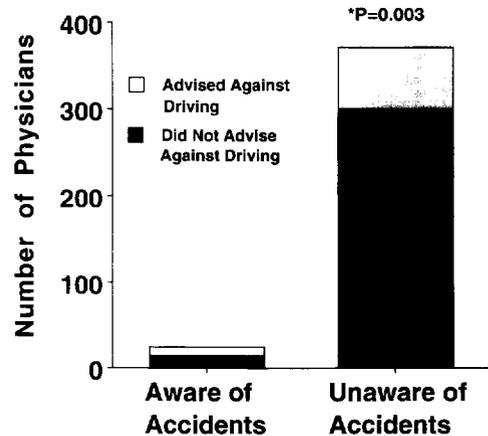


Figure 3. Effect of physician awareness of motor vehicle accidents among implantable cardioverter-defibrillator recipients on driving recommendations.

until a specified length of time has passed without a shock (mean 7.3 ± 3.4 months). The most common shock-free interval mentioned was 6 months, which was the recommendation of 66.1% of the physicians who specified a waiting period (154 of 233, 95% CI 60.0% to 72.2%).

Awareness of ICD-related accidents influenced the policies recommended by physicians to their patients. Of the physicians who were aware of ICD-related driving accidents involving their patients, 44% (11 of 25, 95% CI 24.5% to 63.5%) advised their patients to refrain from driving, whereas only 19.4% of physicians (72 of 372, 95% CI 15.3% to 23.4%) who were unaware of accidents involving their patients advised against driving ($p = 0.003$) (Fig. 3).

Physician awareness of driving laws. Physician awareness of the driving laws in their own states was rather poor. Only 31.2% (125 of 401, 95% CI 26.6% to 35.7%) knew the legal requirements in their own states; the rest reported being unaware of relevant laws. Physician experience with ICDs did not correlate with knowledge of laws about driving (Table 1). Of the 125 physicians who did know their state's laws, 26 (20.8%, 95% CI 13.7% to 27.9%) admitted to advising their patients contrary to those laws.

Influence of type of device and primary event on driving recommendations. The nature of the patient's primary event influenced many physicians' willingness to recommend that their patients drive. Whether the patient's primary event was ventricular tachycardia or ventricular fibrillation was important in decision making for 59.8% of the physicians (237 of 396,

Table 1. Physician Implantation Experience Versus Knowledge of State Law Regarding Driving Restrictions

Aware of State Driving Law (%)	No. of Implantations Performed			
	<50	50-100	100-200	>200
Yes	30	34	32	30
No	70	66	68	70

95% CI 55.0% to 64.7%), but it made no difference for 40.2% (159 of 396, 95% CI 35.3% to 45.0%). Low and high volume implanters were similarly influenced by the patient's primary arrhythmia. If a patient's primary rhythm disturbance was stable ventricular tachycardia, only three physicians (0.7%, or 3 of 402, 95% CI 0.0% to 1.6%) thought that driving should be proscribed. In contrast, 64.2% of physicians (258 of 402, 95% CI 59.5% to 68.9%) would not allow patients to drive with unstable ventricular tachycardia or ventricular fibrillation. Twenty-five percent of physicians (99 of 402, 95% CI 20.4% to 28.8%) would not allow driving for any of these rhythm disturbances. The most conservative physicians were the least likely to be influenced by the type of arrhythmia in advising their patients. Only 20.7% of those who advised against driving completely (17 of 82, 95% CI 12.0% to 29.5%) thought that the presenting arrhythmia made any difference, whereas 75.3% of those who advised a 6-month wait (116 of 154, 95% CI 68.5% to 82.1%) considered the presenting arrhythmia to be important ($p = 0.00001$).

Only a small number of physicians (19.4%, or 78 of 402, 95% CI 15.5% to 23.3%) thought that the newer generations of ICDs with memory and antitachycardia pacing would influence their policies regarding driving. These were most likely to be the low volume implanters (26.2%, or 37 of 141, 95% CI 19.0% to 33.5%); the high volume implanters were less likely to state that newer devices would alter their policies (11.3%, or 39 of 344, 95% CI 8.0% to 14.7%, $p = 0.001$), possibly because they may already have had access to these devices in clinical trials.

Discussion

Physicians are responsible for advising their patients regarding their activities after discharge from the hospital. Driving is a key component of these instructions. To develop a rational policy for driving for ICD recipients, data regarding actual event rates are important. In our survey of 742 physicians involved in ICD implantation and follow-up in the United States, only 30 accidents were reported over a cumulative experience of 12 years. Of these, only nine were fatal, all of which were patient fatalities except for one passenger. In addition, 21 nonfatal injuries occurred. Our survey results probably represent the majority of ICD recipients in the United States and probably most of the accidents. Physicians with experience to report would have been most likely to return the survey. The conclusion to be reached when these data are compared with data from the U.S. Census is that ICD recipients are much less likely than the general public to be involved in accidents resulting in serious injury, and the fatality rate for patients is lower than the national rate. Of course, there is no way to know from the results of the survey just how often and what distances ICD recipients drive, although we know from another study that most patients do resume driving (3).

Larsen et al. (4) analyzed the driving hazard among 501 patients at one university medical center and found that the 1-year event rate (occurrence of ventricular tachycardia or

fibrillation, syncope or defibrillator discharge) was 17%. However, the majority of patients were treated with antiarrhythmic drugs, and only 8% received an ICD. Those investigators found that event rates were highest in the first month after discharge, declined to an intermediate level for months 2 to 7 and then, at the eighth month, dropped to 0% to 1.2%/month. Therefore, they recommended a 7-month period of abstinence from driving. In the interest of keeping our survey simple to maximize the number of returns, we did not collect information as to time after implantation when the accidents occurred, so we cannot make any conclusions as to how many of the accidents would have occurred within this 7-month window.

It should be noted that the calculations of Larsen et al. (4) may actually underestimate the number of shocks among ICD recipients because antiarrhythmic drug treatment, if effective, would be expected to decrease the number of episodes of ventricular tachycardia and fibrillation overall. Long-term experience with the ICD has shown that 54% to 66% of patients receive shocks over follow-up periods ranging from 9 months to several years (6,8,9). The majority of these shocks are for documented or suspected ventricular tachycardia or fibrillation, and the remainder are inappropriate and delivered for problems such as sinus tachycardia, atrial fibrillation, nonsustained ventricular tachycardia and device malfunctions. If 60% of ICD recipients have received shocks, then an absolute minimum of 19,000 shocks have occurred among all patients in the United States. Most patients spend comparatively little time driving, and not surprisingly, the majority of shocks do not occur during driving. Thus, <1% of shocks occurred during driving, and of these, only 10.5% resulted in accidents.

Development of driving policy. In developing a driving policy for ICD recipients, it is important to keep in mind that accidents related to heart disease do not occur solely in patients with ICDs. In one study (10) of 1,348 patients who died of coronary artery disease, 71 (5%) died while driving. Collisions related to sudden death of the driver in the pre-ICD era were estimated to be <6/10,000 motor vehicle accidents (11). If we ignore the risk in patients with a recent myocardial infarction or in those with congestive cardiomyopathy, and we proscribe driving only in patients with implantable devices, we could make ICDs unacceptable therapy to many patients.

At the present time, most physicians do permit ICD recipients to drive at a mean of 7.3 ± 3.4 months after implantation. These results are comparable to those of DiCarlo et al. (2), who surveyed 58 physicians in three states regarding their practices and found that 82% of the physicians recommended a period of abstinence of 6 ± 3 months. Although it was a general consensus among the physicians in our survey that the hemodynamic stability of the presenting arrhythmia is important in decision making about driving, one other study of device patients does not support this approach. In that study (12), regardless of whether a patient's shocks had previously been associated with syncope, there was a 15% incidence of syncope with any newly occurring shocks.

In our survey, physicians were more likely to recommend

abstinence from driving if they were aware of accidents among ICD recipients. In making recommendations to their patients, physicians are most likely concerned not only with patient safety, but with their own potential liability if accidents occur after they have permitted driving. However, it is important to remember that as we all wrestle with the problem of a rational policy for these patients, many patients simply do not listen to the recommendations of their physicians. As mentioned earlier, 70% of patients in one study (3) resumed driving by 8 months after implantation, even though all of them had been advised to abstain from driving permanently.

In view of the data regarding the very low accident rate in patients with ICDs, and the finding that event rates are highest in the first few months, a reasonable policy would be to recommend that patients not drive for at least 1 month and perhaps as long as 6 months after implantation. In addition, as we formulate a policy for patients with ICDs, the problem of inappropriate discharges must be addressed as well. It has been estimated that 27% to 41% of defibrillator discharges are spurious (13). If inappropriate shocks from a defibrillator are determined to have a correctable cause, such as supraventricular tachycardia or device malfunction, then correction of the problem should allow a patient to resume driving immediately if he or she would otherwise be able to drive. Finally, if the consensus is formed among physicians involved in ICD implantation and follow-up that a period of abstinence from driving is necessary, the recommendations are unlikely to be followed by patients unless the state Department of Motor Vehicles is notified.

Study limitations. The results and conclusions presented in this report must be considered within the context of certain limitations. The data collection was retrospective and relied on physician recall. It is unlikely, nor did we expect, that physicians went through their records before responding to us. This may explain the overestimation by responding physicians of the total number of implant recipients. It is impossible to know just how many patients are represented by the 61% of physicians who responded, and so our estimates must be taken as just that. Although underestimation of the number of accidents, injuries or fatalities recalled by physicians may also have occurred, we think that this is much less likely due to the extraordinary nature of these events. We were able to eliminate some degree of overestimation of both total implant recipients and driving-related events by cross-referencing respondents by implantation center and considering only the survey responses of the most senior respondent at a given center as representing the implant recipients at that center. We further cross-referenced accident reports on an individual basis and excluded apparent duplicates. However, the possibility remains that some patients may have been counted more than once.

Another limitation of our study concerns the validity of the estimate of total number of patient-years of ICD experience, which was based on all-cause mortality rates provided by Cardiac Pacemakers, Inc. Such validity ultimately depends on the completeness of mortality reporting to the company during

the 7-year period utilized in our calculation. Early in this period, reporting was passive, and underreporting of ICD patient mortality may have occurred. Underreporting of mortality would result in an overestimation of total ICD-recipient patient-years. Active reporting mechanisms were eventually put into place during this period that would have increased the chances of capturing mortality events in ICD recipients.

A final potential limitation of our survey is that we sent surveys only to physicians who had ever implanted defibrillators from one company. At the time the surveys were sent out, these defibrillators were the only ones approved by the Food and Drug Administration. Although some centers were implanting investigational devices, it is not likely that a center would have been implanting investigational devices but never a commercially released device. Thus, we are confident that the survey was distributed to the vast majority of physicians who were performing implantation at the time.

Conclusions. The motor vehicle accident rate caused by discharge from an ICD is low. Although restricting driving for a short period of time after implantation may be appropriate, excessive restrictions or a total ban on driving may be unwarranted.

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