# Driving Restrictions Advised by Midwestern Cardiologists Implanting Cardioverter Defibrillators: Present Practices, Criteria Utilized, and Compatibility with Existing State Laws

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DiCARLO, L.A. ET AL.: Driving Restrictions Advised by Midwestern Cardiologists Implanting Cardioverter Defibrillators: Present Practices, Criteria Utilized, and Compatibility with Existing State Laws. Although some patients remain at risk of losing physical control or collapsing after implantation of a cardioverter defibrillator for sustained ventricular arrhythmias, little is known about restrictions advised by arrhythmia specialists to patients with implanted devices concerning physical activities such as driving. In this study, all of the 58 cardiologists implanting cardioverter defibrillators in three contiguous midwestern states were surveyed to determine present practices and the compatibility of these practices with existing state law. Of the 51 respondents (88%), 27 cardiologists (53%) advised only those implanted patients who had had arrhythmia-induced presyncope or physical collapse to cease driving. Twenty two of the remaining cardiologists (43%) advised all implanted patients to cease driving, whereas two cardiologists (4%) never advised any implanted patient to restrict driving. Permanent driving abstinence was advised by seven of the responding cardiologists (14%), while temporary driving abstinence for periods of 2-12 months (mean  $6 \pm 3$  months) was recommended by the remaining 42 respondents (82%) who advised against driving. The criteria utilized, driving restrictions advised, and durations advised for driving restrictions were not uniform in any of the 13 surveyed university and nonaffiliated cardiology practices with ≥2 implanting cardiologists. Overall, 38 cardiologists (74%) advised against driving and recommended durations that equaled or exceed their state's minimum legal requirements, although only 27 of the 51 cardiologists (53%) based their practice upon knowledge of their state's driving laws. The results of this survey suggest that the majority of cardiologists who implant cardioverter defibrillators advise their patients against driving postoperatively. However, the criteria and durations utilized in advising driving abstinence are not uniform and do not always conform with existing state laws. (PACE, Vol. 15, August 1992)

antitachycardia devices, cardioverter defibrillator, syncope, ventricular tachycardia, ventricular fibrillation

## Introduction

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Surgically implanted cardioverter defibrillators are utilized presently in the management of patients with recurrent ventricular fibrillation or ventricular tachycardia that cannot be controlled with antiarrhythmic medications or alternative interventional therapy.<sup>1-9</sup> While these implantable devices are therapeutic, they are not prophylactic. Some patients remain at risk of losing physical control or losing consciousness at the time of subsequent device discharges.<sup>10-12</sup> Little is known, however, about postoperative restrictions advised by arrhythmia specialists concerning activities such as driving or the compatability of this advice with existing state laws.

In this study, a regional survey was made of all implanting cardiologists in three contiguous midwestern states to determine their present practices when advising driving restrictions after cardioverter defibrillator implantation, the criteria utilized for advising driving restrictions, and the compatability of present practices with existing state laws.

# **Methods**

## **Physician Population**

All cardiologists implanting cardioverter defibrillators in the contiguous states of Indiana, Michigan, and Ohio were identified from directories available from the North American Society of Pacing and Electrophysiology (NASPE, Newton Upper Falls, MA, USA), and provided by Cardiac Pacemakers, Inc. (St. Paul, MN, USA) who were the sole suppliers of commercially available implantable cardioverter defibrillators in the United States at the time of this survey.

## **Survey Methods**

The survey was conducted by telephone. Attempts were made to contact each implanting cardiologist a minimum of three times during the 4-week survey period. Each implanting cardiologist was informed of the nature of the survey and asked to give his/her verbal consent to participate in the survey before being questioned. Responses to each question were recorded as follows:

- (A) In which state do you practice?
  - (1) Indiana (2) Michigan (3) Ohio
- (B) Do you advise patients to cease driving after implantation of an automatic cardioverter defibrillator?
  - (1) Yes (2) No

- (C) How often do you make such a recommendation?
  - (1) Always (2) Sometimes (3) Never
- (D) If your response to (C) is SOMETIMES, which of the following criteria do you utilize in making your recommendation (you may use more than one)?
- (1) Near-loss or loss of consciousness during spontaneous clinical arrhythmia before device implantation
- (2) Near-loss or loss of consciousness during induced arrhythmia before device implantation
- (3) Near-loss or loss of consciousness during postoperative device testing
- (E) What is the minimum duration of your recommendation against driving?
  - (1) Months (2) Permanent
- (F) Assume that the device you implanted is discharging appropriately for the arrhythmia(s) you intended to treat. Which of the following is the minimum criterion you utilize during out-of-hospital follow-up to subsequently advise a longer period of driving abstinence (please choose only one)?
- (1) A single device discharge without nearloss or loss of consciousness
- (2) Multiple device discharges without near-loss or loss of consciousness
- (3) Near-loss or loss of consciousness at the time of device discharge
- (G) Which of the following would you use to characterize your patients who have had an automatic cardioverter defibrillator implanted (you may use more than one)?
  - (1) Urban (2) Suburban (3) Rural
- (H) Are 25 or more percent of your patients rural?
  - (1) Yes (2) No
- (I) Are there any driving laws concerning arrhythmias and loss of physical control or loss of consciousness in your state which have helped to guide your driving recommendation(s)?
  - (1) Yes (2) No (3) Don't know
- (J) If your answer to (I) is YES, what driving restriction(s) do these laws advise or require?
  - (ANSWER)
- (K) Which of the following characterizes the institution where you implant cardioverter defibrillators (please choose only one)?

- (1) University hospital or medical center
- (2) University-affiliated hospital or medical center
  - (3) Private hospital or medical center

#### **Content of State Laws**

Information concerning the actual existence and content of state driving laws concerning arrhythmias and loss of physical control or loss of consciousness were obtained from the Licensing Bureau, Department of Motor Vehicles, Indianapolis, Indiana; the Department of State, Lansing, Michigan; and the Bureau of Motor Vehicles, Department of Highway Safety, Columbus, Ohio. The information from these three sources was used as a basis for determining the correct responses to survey questions I and J.

## **Data Recording and Analysis**

All responses to all questions were recorded anonymously. The response to all questions were tabulated subsequently, and statistical analysis was performed utilizing paired and unpaired Student's t-tests and tests of p for binomial distribution where appropriate.<sup>13</sup>

## Results

The results of the survey are summarized in Tables I and II.

#### Physicians Surveyed

A total of 58 implanting cardiologists were identified from the sources utilized for the survey. Fifty one of the 58 identified cardiologists (88%) replied to the survey. Twenty-eight respondents (55%) were implanting cardiologists at university or university-affiliated hospitals. The other 23 respondents practiced in nonaffiliated hospitals. The survey included seven university and six nonaffiliated cardiology groups where ≥ two implanting cardiologists practiced together.

Twenty five of the respondents (49%) cared for patients living in almost exclusively urban or suburban locations, while the other 26 implanting cardiologists (51%) had  $\geq$ 25% of their patients living in rural locations.

**Table I.**Physicians Surveyed

	Number	(Percent)
Implanting cardiologists		
Indiana	15	(26)
Michigan	17	(29)
Ohio	26	(45)
Total	58	(100)
Respondents to survey		•
Indiana	14	(93)
Michigan	17	(100)
Ohio	20	(77)
Total	51	(81)
Implanting site		
Academic or university-		
affiliated	28	(55)
Private	23	(45)
Patient population		` ,
Urban or suburban	25	(49)
Rural (≥ 25%)	26	(51)

#### **Criteria for Driving Restrictions**

Twenty-two implanting cardiologists (43%) advised all implanted patients to abstain from driving, whereas two implanting cardiologists (4%) never advised any implanted patient to restrict driving.

The remaining 27 implanting cardiologists (53%) advised driving abstinence only to those implanted patients who had had arrhythmia-induced near-loss or loss of consciousness. Twenty three of these 27 implanting cardiologists (85%) based their recommendation for driving abstinence upon the occurrence of near-loss or loss of consciousness during a spontaneous or induced arrhythmia before device implantation, whereas the other four cardiologists based their recommendation solely upon the occurrence of near-loss or loss of consciousness during postoperative device testing.

#### **Duration**

Permanent driving abstinence was advised by seven of the responding cardiologists (14%), while temporary driving abstinence for periods of 2-12 months (mean  $6\pm3$  months) was recommended

**Table II.**Driving Recommendations

	Number	(Percent)
Recommendation made to:		
No patients	2	(4)
Selected patients	27	(53)
All patients	22	(43)
Driving restriction advised		, ,
(n = 42) for near-loss or		
loss of consciousness		
during		
Spontaneous or induced	39	(94)
arrhythmia before device		
implantation		
Postoperative device	3	(6)
testing		` '
Duration advised for driving		
restriction (n = 42)		
Range (months)	2-12	
Mean ± standard	$6 \pm 3$	
deviation (months)		
Advised duration of		•
restriction (n = $42$ )		
extended if		
Single device discharge	14	(33)
Multiple device discharges	12	(28)
Near-loss or loss of	16	(39)
consciousness at the	. •	(22)
time of device discharge		

by the remaining 42 respondents (82%) who advised against driving.

Criteria for subsequently advising a longer duration of driving restriction were: (1) a single out-of-hospital device discharge (15 physicians, 29%); (2) multiple device discharges (12 physicians, 24%); or (3) hemodynamic collapse at the time of device discharge (17 physicians, 35%) occurring during the initial period of driving abstinence.

#### **Comparison with State Laws**

Overall, 27 of the 51 physicians surveyed (53%) knew the content of their state's laws concerning arrhythmias and temporary loss of physical control or loss of consciousness, and advised their patients concerning driving abstinence based upon that knowledge.

Eleven of the remaining physicians (22%), who incorrectly answered the survey questions concerning such laws, nevertheless advised their patients against driving for durations that equaled or exceeded the minimum legal duration required by their state.

### **Correlation of Results**

The criteria utilized, driving restrictions advised, and durations advised for driving restrictions were not uniform in any of the 13 university and nonaffiliated cardiology practices surveyed.

No significant differences were found between (1) physicians practicing in academic/university-affiliated hospitals versus physicians practicing in nonaffiliated hospitals or (2) physicians with almost exclusively urban/suburban patients versus physicians with ≥25% rural patients, with regard to: (a) making recommendations against driving to all versus selected implanted patients, (b) the criteria utilized for making a recommendation, (c) the duration recommended for driving abstinence, (d) the criteria for extending the duration of driving abstinence, or (e) knowledge of the existence and specific content of laws in the state in which the physicians practiced.

#### Discussion

The modern management of paroxysmal ventricular fibrillation and sustained ventricular tachycardia includes implantation of cardioverter defibrillators in patients whose arrhythmias are not amenable to pharmacological treatment or alternative therapies such as percutaneous or surgical ablation. <sup>1-9</sup> Patient-device interactions are complex, however, and have several limitations.

The reliability of tachycardia detection and termination by presently implanted cardioverter defibrillators is not consistent. Twenty-seven percent to 41% of discharges from presently available commercial cardioverter defibrillators have been reported to occur as a result of misdiagnosis of sinus rhythm, sinus tachycardia, or supraventricular tachycardia as ventricular tachycardia or ventricular fibrillation, or in response to nonsustained supraventricular tachycardia or ventricular tachycardia. Some patients experience transient incapacitation from the cardioverter defibrillator

discharge itself.<sup>2,9</sup> For others, the cardioverter defibrillator discharge may actually result in provocation, rather than termination, of arrhythmias that cause hemodynamic collapse.<sup>15</sup>

Not all patients experience near-loss or frank loss of consciousness due to their ventricular arrhythmias prior to cardioverter defibrillator implantation. However, the ability to maintain consciousness during subsequent, spontaneous arrhythmia recurrences, that cause cardioverter defibrillator discharge varies. 10,11 The ability to maintain consciousness at the time of initial, spontaneous out-of-hospital cardioverter defibrillator discharges does not guarantee consciousness at the time of a subsequent cardioverter defibrillator discharges. 10

The complexity of implantable devices continues to increase. Later generation devices that now incorporate programmed electrical stimulation with automatic cardioversion and defibrillation are being implanted in the United States and abroad. Like implantable devices capable of cardioversion or defibrillation alone, these newer devices have the potential of providing inappropriate therapy as a result of false-positive diagnoses of sustained ventricular arrhythmias. Like commercially available cardioverter defibrillators, they have the potential of provoking rather than terminating arrhythmias capable of causing physical collapse or loss of physical control. 12,16

Postoperative recommendations concerning physical activities such as driving, therefore, might be considered advisable for at least some patients. The results of the present study suggest that the majority of cardiologists who implant automatic cardioverter defibrillators do make recommendations concerning driving after device implantation. However, the criteria utilized for making a recommendation, determining the duration of driving abstinence, and subsequently extending the duration of driving abstinence is not uniform and does not always conform to existing state laws.

The state laws themselves vary significantly. One recent survey of state regulations determined no legal consensus concerning driving restrictions after cardioverter defibrillator implantation.<sup>17</sup> Only one of the three states in the present study had a law that explicitly prohibits driving after impairment or loss of consciousness until the con-

dition(s) causing it has been "corrected, cured, or controlled, or [has] abated for not less than 6 months." The other two states provided for issuance of restricted licenses that limit routes of travel for a minimum of 6 months. None of the three states had laws requiring either the physician or the patient to notify the state's licensing bureau of the patient having such a condition, or of the patient having been advised against driving at the time of the condition's discovery. None of the three states had any laws specifically governing individuals who have had a cardioverter defibrillator implanted for control of cardiac arrhythmias. Uncertainty with regard to this issue is also reflected in the recently published NASPE policy statement, 19 which contains no guidelines or consensus recommendation regarding the operation of automobiles or other machinery after cardioverter defibrillator implantation.

The present study is the first geographic survey that comprehensively characterizes physician practices concerning driving restrictions advised to patients with implanted cardioverter defibrillators. Randomly selected arrhythmia specialists were questioned in another recent study about resumption of driving after implantation of a cardioverter defibrillator in patients who had survived an out-of-hospital cardiac arrest.17 In contrast to the the findings of the present study, fewer respondents to the earlier survey (60%) believed that driving should be restricted, whereas a greater proportion of the respondents to the earlier survey (one third) believed that driving restrictions, when made, should be permanent. Among this earlier study's limitations were its small physician sample size relative to the geographic area represented, its failure to adequately represent any one region or all regions of the United States, its lack of adequate representation of urban or academic medical centers, its consideration only of survivors of out-of-hospital cardiac arrest, and its failure to distinguish between driving restriction as opposed to cessation. The earlier study did not make any assessment of the actual driving restrictions advised by the surveyed physicians, the criteria utilized, or the durations advised when the restriction was temporary, and it did not determine the compatibility of individual physician practices with the laws of the states in which the physicians practiced.

Additional and larger studies will be neces-

sary to determine the scope and prevalence of present physician practices concerning driving or the operation of other machinery after the implantation of antitachycardia devices, as well as the socioeconomic and public health impacts of these practices. Ultimately, the development and implementation of a more uniform and consistent set of guidelines concerning the operation of an automobile or other machinery by patients with implanted antitachycardia devices will require additional clinical investigation, education of physicians concerning existing state laws, and deliberation with lawmakers to modify or to unify existing laws.

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