Addendum to "Personal and Public Safety Issues Related to Arrhythmias that May Affect Consciousness: Implications for Regulation and Physician Recommendations: A Medical/Scientific Statement from the American Heart Association and the North American Society of Pacing and Electrophysiology"

Public Safety Issues in Patients With Implantable Defibrillators

A Scientific Statement From the American Heart Association and the Heart Rhythm Society*

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OVERVIEW In 1996, the American Heart Association developed a scientific statement entitled "Personal and Public Safety Issues Related to Arrhythmias That May Affect Consciousness: Implications for Regulation and Physician Recommendations." Since then, multiple trials have established the role of implantable cardioverter-defibrillators (ICDs) for the primary prevention of sudden cardiac death in patients at risk for life-threatening ventricular arrhythmias.

OBJECTIVE The issue of driving for patients with ICDs implanted for primary prevention was briefly discussed in the original statement, with the recommendation that such patients not be restricted from driving beyond the initial phase of healing. This scientific statement has been developed to extend the original 1996 recommendations and to provide specific recommendations on driving for individuals with ICDs implanted for primary prevention.

SUMMARY OF RECOMMENDATIONS (1) Patients receiving ICDs for primary prevention should be restricted from driving a private automobile for at least 1 week to allow for recovery from implantation of the defibrillator. Thereafter, these driving privileges should not be restricted in the absence of symptoms potentially related to an arrhythmia. (2) Patients who have received an ICD for primary prevention who subsequently receive an appropriate therapy for ventricular tachycardia or ventricular fibrillation, especially with symptoms of cerebral hypoperfusion, should then be considered to be subject to the driving guidelines previously published for patients who received an ICD for secondary prevention. (3) Patients with ICDs for primary prevention must be instructed that impairment of consciousness is a possible future event. (4) These recommendations do not apply to the licensing of commercial drivers.

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Because patients with arrhythmias may experience sudden impairment or loss of consciousness, the American Heart Association developed a scientific statement entitled "Personal and Public Safety Issues Related to Arrhythmias That May Affect Consciousness: Implications for Regulation and Physician Recommendations: A Medical/Scientific Statement From the American Heart Association and the North American Society of Pacing and Electrophysiology."[1] In this publication, recommendations for driving were made with a focus on the treatment of patients who had survived

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Table 1 Overview of clinical trials

Trial	Patients in ICD arm, n	Follow-up, mo	Annual mortality rate, %	Annual SCD mortality rate, %
MADIT I	95	27	7.0	1.4
CABG-Patch	446	32	8.6	NA
MUSTT	161	NA for ICD group alone	4.8	1.8
MADIT II	742	20	1.6	±1.7
DEFINITE	229	29	3.95	0.5
COMPANION	595	16	12.0	NA
SCD-HeFT	829	45.5	5.8	NA
DINAMIT	332	30	7.5	1.5

SCD indicates sudden cardiac death; NA, not available.

a life-threatening arrhythmia that included ventricular tachycardia (VT) or ventricular fibrillation (VF), often referred to as secondary prevention therapy.[2–4]

Since the original publication of that medical/scientific statement, multiple trials have been reported that established the role of implantable cardioverter-defibrillators (ICDs) for the primary prevention of sudden cardiac death in patients at risk for life-threatening ventricular arrhythmias who have never had sustained VT or VF.[5–12] Studies showing the efficacy of the ICD for the primary prevention of sudden arrhythmic death include the Multicenter Automatic Defibrillator Implantation Trials I[5] and II[8] (MADIT I and II), the Multicenter UnSustained Tachycardia Trial (MUSTT),[7] the Defibrillators in Non-Ischemic Cardiomyopathy Treatment Evaluation (DEFINITE) Trial,[9] and the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT).[10] On the basis of the results of these trials, in early 2005, the Centers for Medicare and Medicaid Services expanded the coverage of ICDs for patients with a primary prevention indication for ICD therapy. As a consequence, considerable growth in the prescription of ICDs for such patients has occurred. It may be noted, however, that the term "primary prevention" is somewhat imperfect in that patients with inducible sustained VT in the setting of clinical nonsustained VT were included in the MADIT I and MUSTT primary prevention trials. Similarly, the Canadian Implantable Defibrillator Study (CIDS) secondary prevention trial included patients without documented spontaneous sustained VT or VF but who had inducible VT. Notably, the Centers for Medicare and Medicaid Services covers reimbursement for such patients irrespective of their being classified as having primary or secondary prevention implantation indications.

The recommendations from the 1996 publication regarding public safety issues for patients with ICDs placed for secondary prevention purposes after an episode of sustained VT or VF[1] are still appropriate and do not need to be comprehensively revised; however, these recommendations are not appropriate for patients with primary prevention or "prophylactic" ICDs. In the absence of guidance to the contrary, some physicians and healthcare providers may inappropriately apply the restrictive recommendations published in 1996 for patients with ICDs implanted for secondary prevention to those patients with devices implanted for primary prevention.

The issue of driving for patients with ICDs implanted for primary prevention was briefly discussed in the original statement, with the recommendation that such patients not be restricted from driving beyond the initial phase of healing. Nevertheless, because these patients are at risk for complete or partial loss of consciousness if an arrhythmia occurs, and because questions about activities that are safe for them commonly arise, there is a need to update the recommendations for those patients receiving prophylactic ICDs.

The present scientific statement has been developed to extend the original 1996 recommendations and to provide recommendations regarding individuals with ICDs implanted for primary prevention who may undertake activities, specifically driving, that may put themselves or others at risk if consciousness were to be impaired by a cardiac arrhythmia.

Risk of arrhythmia occurrence in patients with ICDs

To estimate the risk of driving in patients with ICDs, information about the frequency of appropriate shocks and associated symptoms is crucial. Although no published data exist on symptoms at the time of shocks in patients enrolled in trials of ICDs for primary prevention, 4 trials have published information on the rate of ICD discharges.[5,8–10] Of the 8 primary prevention trials, each reported overall mortality data, and rates of sudden cardiac death were reported from 5 trials.[5,7–9,12] Nevertheless, although mortality and sudden cardiac death rates are of some value in estimating the overall risk of the patient population, these characteristics are of limited value for defining the hazards of driving after primary prevention ICD implantation.

Results of primary prevention ICD trials

Table 1 lists those trials that address the benefits of ICD therapy versus control or conventional therapy in patients at risk for life-threatening ventricular arrhythmias who have never had sustained VT or VF. Inclusion criteria for the different trials varied, as would be expected from a series of trials that were initiated between 1990 and 2000. One trial, the Coronary Artery Bypass Graft Patch (CABG-Patch) Trial, was confined to patients undergoing coronary bypass surgery.[6] The Comparison of Medical Therapy, Pacing, and Defibrillation in Heart Failure (COMPANION) Trial was

Table 2 Role of device discharges and therapies

Trial	Discharge rate, % of patients	Comments
CABG-Patch	50% at 1 year; 57% at 2 years	
MADIT I	±60% at 2 years	43.9% of patients received 142 therapies over 27 months (shocks 17.6%)
MADIT II	7.9% of patients per year	13.4% of patients received 701 device therapies (shocks 59% of therapies)
DEFINITE	7.4% of patients per year	41 patients; 91 shocks
SCD-HeFT	7.5% of patients per year	Appropriate shocks: 5.1% of patients per year

primarily designed to address the role of cardiac resynchronization therapy; nevertheless, one arm evaluated ICD plus biventricular pacing therapy.[11] Patients with nonischemic cardiomyopathy were included in 3 of the primary prevention ICD trials.[9–11]

For the purposes of the present statement, the focus of consideration of these trials is on the event rates in patients randomized to receive an ICD. Annualized mortality rates range from 1.6% of patients per year in the MADIT II trial[5] to 12% of patients per year in the COMPANION trial of patients with New York Heart Association class III to IV congestive heart failure.[11] Annualized mortality rates in the other 6 trials ranged from 4% to 8.5% of patients per year. The average annual mortality in the ICD arms of these randomized trials was ≈7% of patients per year, which reflects the patient inclusion criteria of left ventricular dysfunction and/or congestive heart failure. Rates of sudden cardiac or arrhythmic deaths reported in 4 trials are extremely low, ranging from 0.5% to ≈1.7% of patients per year, likely a reflection of the efficacy of the ICD, as shown in Table 1.

ICD discharges

Table 2 summarizes the published data from the randomized trials of primary prevention of sudden cardiac death relative to the rate of ICD shocks during follow-up. These data arguably provide the most important information on the risks of driving in this patient subset.

In 2 trials that used earlier-generation ICDs, device discharge rates were high. In the CABG-Patch Trial, 50% of patients received a discharge during 1 year of follow-up[6]; in MADIT I, 60% of patients received a discharge during 2 years of follow-up.[5] In a small study of 41 patients followed up for 21 months who fulfilled the criteria for entry into the MADIT I trial, 43.9% of patients received 142 appropriate ICD treatments, of which 17.6% were ICD discharges, which corresponds to a rate of only 4.4% per year.[13]

The rates of ICD discharges in more recent trials are quite consistent. In DEFINITE, discharges occurred at a rate of 7.4% of patients per year (41 patients received 91 shocks).[9] A subsequent analysis reported that only 70 (44.9%) of 156 shocks were appropriate.[14] In SCD-HeFT, 259 (31%) of the 829 patients with ICDs received shocks for any reason, with 177 of these shocks being for VF or rapid VT (68% of patients who were shocked, or 21% of patients with ICDs). During 5 years of follow-up, the annual rate of appropriate ICD discharge was 7.5% per year. For rapid sustained VT or VF, the rate of appropriate ICD discharge was 5.1% per year. The number of patients in this group with impairment or loss of consciousness during these episodes was not reported.[10]

There is a paucity of data on symptoms accompanying ICD discharges.[15,16] In a subgroup of patients in the Antiarrhythmics Versus Implantable Defibrillators (AVID) Trial of patients who had been previously resuscitated from near-fatal ventricular tachyarrhythmias, among 295 patients who resumed driving after receiving an ICD, 8% reported receiving a shock while driving.[16] Among the 559 of the 627 patients who completed a questionnaire and had resumed driving, 2% reported loss of consciousness while driving, and 11% reported dizziness or palpitations that necessitated stopping the vehicle.

Temporal aspects of device therapy

In patients who have sustained a myocardial infarction, there is increasing evidence that the benefit of an ICD increases over time after the incident myocardial infarction.[17] In the Defibrillator in Acute Myocardial Infarction Trial (DINAMIT), which enrolled patients within 8 to 40 days of the incident myocardial infarction, there was no mortality benefit from use of an ICD.[12] Nevertheless, the risk of sudden cardiac death/cardiac arrest in patients with a recent myocardial infarction and either left ventricular dysfunction or congestive heart failure is highest in the first 30 days after infarction.[18] In the Valsartan in Acute Myocardial Infarction Trial (VALIANT), the risk of sudden cardiac death/cardiac arrest was 1.4% per month in the first 30 days after a myocardial infarction, 0.5% per month during months 1 to 6 after a myocardial infarction, and 0.27% per month during months 7 to 12 after a myocardial infarction, with a significant decline thereafter to 0.14% per month after 4 years.[18] The lack of ICD benefit early after myocardial infarction contrasts with the increased rate of sudden cardiac death during this period. It has been suggested that ventricular tachyarrhythmias that lead to ICD discharge in the early postinfarction period may be a surrogate marker for other causes of death during this time period,[19] such as congestive heart failure.[20] On the other hand, ventricular tachyarrhythmias that lead to ICD discharge months or years after myocardial infarction may be unassociated with other premorbid conditions, thereby permitting such patients to realize a long-term benefit from ICD therapy.[16,20–23]

From the standpoint of driving privileges, the benefit or lack thereof from an ICD is not relevant; the pivotal factor is the actual rate of events that could lead to loss of control of a motor vehicle, such as VF, VT with hemodynamic

Table 3 Overview of recommendations

Type of driving	Indication	Driving restriction
Private	Primary prevention	Recovery from operation (at least 1 week)
	Secondary prevention[1]	6 months
Commercial (covered by US Department of Transportation guideline[33])	Primary prevention	Cannot be certified to drive
	Secondary prevention	Cannot be certified to drive

instability, syncope, sudden cardiac death, or ICD discharge. Patients randomized in the AVID Trial reported resuming driving early regardless of medical advice to the contrary (80% were driving within 6 months), reported driving frequently (57% reported driving every day), and reported driving significant distances (25% were driving >100 miles/wk).[16] However, these patients, who had survived a near-fatal episode of ventricular arrhythmia, had a very low rate of automobile accidents. Indeed, the frequency of automobile accidents (3.4% of patients per year) was less than that of the general driving population of the United States (7.1% patients per year).[16] Nevertheless, the relatively high event rate soon after the index episode of ventricular tachyarrhythmias led to a suggestion that driving be restricted for all patients for 1 month and for most patients up to 8 months after such an event.[15]

The average person with an ICD drives 8 to 20 miles per day for purely personal reasons.[24] That distance would indicate that the typical private driver with an ICD spends ≈30 minutes per day behind the wheel, which is ≈2% of the day. Coupling these data with those of the SCD-HeFT, DEFINITE, and MADIT II trials of primary prevention, which demonstrated ICD discharge rates of ≈7.5% of patients per year, the likelihood of an ICD discharge while driving may be predicted to be in the range of 0.15% of patients per year. Even if each patient treated by his or her ICD receives >1 shock during any given year, and even if other nonshock ICD therapies, including antitachycardia pacing, were considered to be a possible source of incapacitation, the likelihood of an event while driving is <1%. Variations in cardiac and arrhythmia event rates throughout the day,[25] as well as circadian patterns as a function of day of the week[26] and season,[27] may also affect ICD usage rates.

Nevertheless, the period immediately after ICD implantation represents an unstable state awaiting maturation of the patient–ICD interface. It is during this period of time that many ICD complications occur, including the occurrence of inappropriate shocks. Accordingly, it is appropriate to advise restriction of private automobile driving privileges for the period of recovery from implantation of an ICD for primary prevention. In the absence of data regarding the optimal time for such restriction, a period of at least 1 week is recommended. Thereafter, no private automobile driving restrictions need be applied to patients who are asymptomatic from an arrhythmia standpoint.

A particularly difficult issue for patients and physicians is how to handle a patient with a device implanted for primary prevention who receives therapy, appropriate or inappropriate. Questions that arise include: Should this patient be treated now as a secondary prevention patient and have driving restricted for 6 months?[1] Is the patient treated as a secondary prevention patient only if a shock is delivered versus antitachycardia pacing therapy? Should the patient be treated as a secondary prevention patient only if impaired consciousness occurs with the tachycardia? Unfortunately, no data are available for guidance in this area. However, if we extrapolate from secondary prevention trials, event rates are highest in the weeks and months after a ventricular arrhythmia event and then fall.[15] Furthermore, antitachycardia pacing may accelerate VT.[28,29] Thus, given the uncertainty of their subsequent clinical course, receipt of appropriate therapy for VT or VF, especially with symptoms of cerebral hypoperfusion, warrants transitioning from rules of primary prevention to those of secondary prevention, i.e., restriction from driving, noting that the future clinical course is unpredictable.[1,15] Because the risk to patients and others is significant if there is an important chance for syncope, it appears inappropriate to support driving in such patients.

Finally, these guidelines focus on the arrhythmia potential of patients with ICDs; however, many of these patients have other important illnesses, both cardiac and noncardiac, that may affect driving ability. Indeed, there are often other reasons to restrict these patients from driving, including such unstable medical situations as frequent angina, heart failure, and significant dyspnea with minimal activity. These patients may not have had any tachycardia, yet have an ICD implanted and still have contraindications to driving. Healthcare providers have a responsibility to consider these factors and address them when making recommendations to individual patients.

Ethics, autonomy, regulation, the law, and social responsibility

All human groups must agree to follow certain rules and standards to survive. From the earliest of times, regulations have been created to develop and sustain societies in which citizens can live peacefully and safely. The branch of inquiry known as ethics attempts to critically analyze the ways by which people may live together by agreed-on standards of right and wrong.[30] As citizens of a society, we are expected to act responsibly in relation to ourselves and in relation to others, with the main beneficiary of such regulations being the citizens themselves. Rules, therefore, are enforceable ethical judgments.[30]

A distinguishing quality of any profession is its acceptance of responsibility to society and the public interest, defined as the collective well-being of the people whom the

profession serves. In medicine, ethics deals with issues of medical practice, of medical research, and of public policy as it relates to the health of society.[30] Integrity is a fundamental aspect of any profession, but especially of medicine, and requires that physicians observe the ideals of objectivity and independence. Because any regulation of activity may have a tremendous impact on the individual, particular attention is given to the ethical issues related to regulation of activities of patients with arrhythmias.

In American society, there is a constant conflict between the rights of the individual and the good of society.[30] The individual is given the right to act in whatever manner he or she chooses as long as that act does not impinge on the rights of others. The latter requirement demands that limits be placed on the rights of the individual just as limits are placed on the rights of society to restrict individual action. Ethics tries to address the delicate balance between these 2 conflicting principles.

In American society, individual mobility and access to education, employment, health maintenance, and personal enrichment opportunities are highly dependent on the automobile. Being unable to drive puts limitations on the individual, which results in both emotional stress and loss of economic status. At the same time, the citizens of a society have the right to protect themselves against the harm caused by individuals who are unable to operate a motor vehicle in a safe and prudent manner. In a just and open society, all individuals are treated equally. Therefore, restrictions on the driving ability of patients with arrhythmias must be clearly elaborated and applied uniformly to all.

The physician and other healthcare professionals are bound to uphold the confidentiality of information regarding a patient's medical condition, and such information is shared with others only when consent is given by the patient.[31] If a patient requests that medical information be withheld from his or her employer, the ethical physician will not comply with the patient's request if doing so would pose a risk to others. In such instances, the patient should be asked to release this information. If, however, the patient does not agree, the physician is bound to breach confidentiality. Although breaking the principle of confidentiality may result in legal action by the patient against the physician, the ethical responsibilities of beneficence ("do good and avoid evil") and nonmaleficence ("do no harm") take precedence over the principle of confidentiality in this setting. In such situations, the ethical course is for the physician to release the required information to the proper authorities, such as the state or national departments of transportation, while providing full disclosure to the patient.[32]

Limitations

An important limitation of these guidelines is that no study has, in a randomized fashion, compared outcomes of patients who drive with ICDs and those who drive without ICDs. On the one hand, the general population of drivers without an ICD may be at either greater risk for impaired consciousness because they are unprotected from incapacitation caused by an arrhythmia or at lesser risk because they have neither heart disease nor an arrhythmia propensity. On the other hand, data available from studies of patients treated with an ICD may suffer from bias with respect to driving outcomes, because patients who drove may have been at lower risk than those who did not because of less comorbidity, greater concern for the safety of others, or unknown confounders. Finally, these recommendations do not apply to the licensing of commercial drivers governed by the US Department of Transportation. Commercial licensing is subject to federal law as outlined in the Cardiovascular Advisory Panel Guidelines for the Medical Examination of Commercial Motor Vehicle Drivers, for which the presence of an ICD for any indication, whether for primary or secondary prevention, isexclusionary.[33] We know of no state law that addresses licensing of patients with prophylactic ICDs.

Recommendation summary

Recommendations on driving are given in Table 3 and are summarized as follows:

1. Patients receiving ICDs for primary prevention should be restricted from driving a private automobile for at least 1 week to allow for recovery from implantation of the defibrillator. Thereafter, in the absence of symptoms potentially related to an arrhythmia, these driving privileges should not be restricted.
2. Patients who have received an ICD for primary prevention who subsequently receive an appropriate therapy for VT or VF, especially with symptoms of cerebral hypoperfusion, should then be considered to be subject to the driving guidelines previously published for patients who received an ICD for secondary prevention.[1]
3. Patients with ICDs for primary prevention must be instructed that impairment of consciousness is a possible future event.
4. These recommendations do not apply to the licensing of commercial drivers.

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Table 4 Writing Group Disclosures

Writing Group Member	Employment	Research Grant	Other Research Support	Speakers' Bureau/ Honoraria	Ownership Interest	Consultant/ Advisory Board	Other
Andrew E. Epstein	University of Alabama at Birmingham	Biotronik,* Guidant Corp.,* Medtronic Inc.,* St. Jude Medical*	None	Guidant Corp,* Medtronic Inc,* St. Jude Medical*	None	None	None
Christina A. Baessler	Drexel University	Duska Scientific,† St. Jude Medical,† Medtronic Inc,† Ela Medical,† Guidant Corp,† Sanofi†	None	AHA cardiopulmonary resuscitation instructor	Bristol-Myers Squibb,† Wyeth†	None	None
Anne B. Curtis	University of South Florida	Medtronic Inc,† Guidant Corp,* St. Jude Medical*	None	Medtronic Inc,* Guidant Corp,* St. Jude Medical*	None	Medtronic Inc†	None
N.A. Mark Estes III	Tufts–New England Medical Center	None	None	Guidant Corp,† Medtronic Inc,† St. Jude Medical†	None	None	None
Bernard J. Gersh	Mayo Clinic	None	None	None	None	None	None
Blair Grubb	Medical College of Ohio	None	None	None	None	None	None
L. Brent Mitchell	Calgary Health Region and University of Calgary	Guidant Corp,† Medtronic Inc,† Cardiome†	None	Medtronic Inc,† Guidant Corp,* Cardiome,* Biovail*	Cardiome,† Cryocath*	Medtronic Inc†	None

This table represents the relationships of writing group members that may be perceived as actual or reasonably perceived conflicts of interest as reported on the Disclosure Questionnaire, which all members of the writing group are required to complete and submit. A relationship is considered to be "significant" if (1) the person receives $10 000 or more during any 12-month period or 5% or more of the person's gross income; or (2) the person owns 5% or more of the voting stock or share of the entity or owns $10 000 or more of the fair market value of the entity. A relationship is considered to be "modest" if it is less than "significant" under the preceding definition.

*Modest.

†Significant.

Table 5 Reviewer Disclosures

Reviewer	Employment	Research Grant	Other Research Support	Speakers' Bureau/ Honoraria	Ownership Interest	Consultant/Advisory Board	Other
Sana M. Al-Khatib	Duke University	None	St. Jude, Medtronic, Guidant	None	None	None	None
Hugh Calkins	Johns Hopkins Hospital	None	None	None	None	Pro Rhythm, Guidant, Medtronic	None
John DiMarco	University of Virginia Health System	Guidant, Medtronic, St. Jude	None	Guidant, Medtronic, St. Jude	None	Guidant, Medtronic, St. Jude	None
Kenneth Ellenbogen	Medical College of Virginia	None	None	None	None	None	None
Alan Kadish	Northwestern University	St. Jude, Medtronic, Guidant	None	St. Jude, Medtronic, Guidant	None	St. Jude, Medtronic	None
Patrick O'Gara	Brigham & Women's Hospital	None	None	None	None	None	None
S. Adam Strickberger	Washington Hospital Center	None	St. Jude, Medtronic, Guidant	St. Jude, Guidant, Medtronic	None	None	None
Bruce Wilkoff	Cleveland Clinic	St. Jude, Medtronic, Guidant	None	St. Jude, Medtronic, Guidant	None	St. Jude, Medtronic, Guidant	None

This table represents the relationships of reviewers that may be perceived as actual or reasonably perceived conflicts of interest as reported on the Disclosure Questionnaire, which all reviewers are required to complete and submit.