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Working Group Report

Recommendations for driving of patients with implantable cardioverter defibrillators

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Introduction

Patients with ventricular tachyarrhythmias treated by an implantable cardioverter-defibrillator (ICD) have an ongoing risk of sudden incapacitation that might cause harm to others while driving a car. Thus, if an ICD patient has a medical condition that might cause sudden unexpected unconsciousness that cannot be controlled by medical treatment, it is justified to set up recommendations, guidelines or regulations preventing that ICD patient from driving, since unconsciousness might result in death or injury to the patient and others. The rights of the ICD patient compete with the rights of society to legislate for the level of risk that it considers acceptable for the driving of a car by ICD patients. Any policy must be fair to individuals, recognizing that restrictions may limit personal freedom, job security, and feelings of well-being. Some flexibility must be allowed since the risks associated with arrhythmia recurrence must be placed on a continuum within the context of vocational, personal, and societal needs. The members of the Study Group appreciated these concerns. It must be recognized, however, that the goal of a zero percent risk is unobtainable and that society has already accepted a certain level of risk by allowing other groups of patients such as the young and elderly to resume driving[1–3].

Some European countries have provided guidelines on the assessment of the cardiac patient for fitness to drive[4,5]. For instance, the series *Illness and Vehicular Traffic* published by the German Federal Ministry for Transportation has set forth the following guidelines on the subject of driving for patients with cardiac rhythm disorders: 'Anyone suffering from disorders of cardiac rhythm that might, on occasion, lead to the repeated interruption of oxygen supply to the brain and thus cause disturbances in consciousness or even loss of consciousness, must be considered unsuitable for driving a motor vehicle of any class. ... Once this rhythm disorder has been successfully treated either by drugs or the use of a so-called cardiac pacemaker ... then the driving privilege for (private) vehicles ... may be conditionally reinstated, proving that cardiac function has been normalized for three months and that symptoms resulting from the interruption of the oxygen supply to the brain have not recurred'[6]. While these guidelines are essentially indisputable, it remains unclear how they affect patients with ICDs.

With the exception of Great Britain, no country in Europe has specific regulations governing driving with an ICD[1,7,8]. Licence revocation is recommended in the presence of any arrhythmia that may distract drivers' attention or render them liable to impaired consciousness. Patients who suffer from arrhythmias that can provoke symptoms of weakness, light-headedness, changes in consciousness or awareness, or visual blurring should cease driving until these symptoms are sufficiently controlled. Patients with paroxysmal ventricular tachycardia should be advised not to drive and to notify the Driver and Vehicle Licensing Agency (DVLA). After cardiological investigation and treatment, patients who remain symptom-free with their arrhythmia fully suppressed may be allowed to resume driving subject to annual review. In Great Britain, the regulations state that patients with ICDs should not be permitted to drive and should notify the DVLA[8]. In May 1995, the UK authorities decided to allow certain patients with ICDs to regain their driving licences, subject to official review. To date, 81 licences have been

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restored; four have subsequently revoked after further discharge or related problems. The medical advisory panel has decided to continue with the policy of review in individual cases, and to make a minor revision of the guidelines, i.e. the panel now recommends permanent refusal or revocation unless the following criteria can be met[9]:

(1) The ICD must have been implanted for at least 1 year and shall not have discharged during the past 12 months (except during formal clinical testing).
(2) Any previous discharge must not have been accompanied by incapacity (except during formal clinical testing).
(3) The device must be subject to regular review with interrogation; a period of 1 month off driving must elapse following any revision of the device (generator and/or electrode), or alteration of antiarrhythmic drug therapy.
(4) There must be no other disqualifying condition.
(5) The licence shall be subject to annual review.

The objectives of this document are to provide data to help estimate the risk of death and injury attributable to ICD patients and to provide recommendations regarding ICD patients and fitness to drive. The following issues were taken into account to address the risk that ICD recipients might pose, if they were allowed to drive:

(a) the frequency and the time course of arrhythmia recurrence,
(b) the likelihood that such recurrences are associated with impaired consciousness,
(c) the risk that such an event will cause an accident,
(d) the probability that such an accident will result in death or injury to the patient and other road users, innocent bystanders or passengers.

Of course, the purpose of this paper is not to present practice standards, but to provide standardized recommendations for ICD patients who want to continue driving. The members of the Study Group felt constrained by limitations of the data available on which to make recommendations. These guidelines are, at any time, subject to revision as more precise data become available in the future. It is hoped that the recommendations contained in this document will be used as an aid to judgement by physicians, motor transport administrators and adjudicators in such circumstances and will not be perceived as rigid set of rules and regulations.

Background

European data suggest that approximately 1·5 to 3·4% of road accidents are attributed to sudden driver incapacity, with only a minority being arrhythmia-related[10]. Based on the Canadian experience, only 5% of the fatal road accidents were due to an unexpected medical condition. Fatigue, alcohol, and drugs accounted for a large number of accidents, with medical causes being infrequent[11]. Age is another factor to consider; an increased risk of death among the young and elderly has already been accepted by society for years[1–3]. It is of note that falling asleep, fatigue, and alcohol represent a much greater risk for death and injury at the wheel than sudden incapacitation caused by ventricular tachyarrhythmias[11]. For instance, in Germany 9700 deaths were caused by motor vehicle accidents in 1995. In the United States, approximately 40 000 deaths occur annually due to motor vehicle accidents, and as in Europe and in Canada, it is assumed that medical causes are responsible for only a very small proportion of fatal accidents. Given the inherent difficulty of determining an arrhythmic cause for accidents, currently available data can only be considered a rough estimate. These data do not convincingly show that sudden cardiac death while driving is a major public safety issue, but rather a rare event and that fewer than 2% of sudden driver incapacitations result in death or injury to other road users or innocent bystanders[11–25]. Whether high risk populations, e.g. ICD patients, are responsible for a higher frequency of arrhythmia-related motor vehicle accidents has not yet been proven. In order to establish driving regulations for ICD patients, it seems reasonable that these recommendations should be based on an actuarial approach, such as that pioneered in the field of aviation medicine.

In Europe, the Joint Aviation Authorities (JAA) including 26 countries regulate medical certification for pilots and have developed a comprehensive medical standard, the Joint Aviation Requirements (JAR)[26]. The European approach to medical standards for flying fitness will become uniform and take effect in 1996. European experience indicates that the best commercial airlines achieve more than 2 million (2×10^6) flying hours between fatal accidents, with the majority being caused by human error including design problems[27,28]. The JAA have defined that the maximum acceptable rate of fatal accidents should not exceed one event in 10^6 flying hours and that medical causes of such events should not account for more than 1% of the total[26,29]. Thus, one fatal event due to pilot incapacitation in every 10^8 flying hours will be an acceptable risk on a multicrew aircraft by society. From 1987 to 1992 the fatal accident rate averaged one every 6×10^5 h, while the cardiovascular causes accounted for approximately one every $2{\cdot}5 \times 10^8$ h[26]. For single crew operation, the fatal accident rate is one event in 10^5 flying hours, by extrapolation the objective for medical cause accidents should not exceed one event in 10^7 flying hours. In 1992, the fatal accident rate for private flying was one in every 40–50 000 flying hours, approximately 10 to 20 times worse than the prevailing scheduled airline accident rate[26,29]. It was recommended that medical causes should be responsible for no greater than one in 25 to 50 fatal accidents. As the majority of operations flown by private pilots are single crew, total incapacitation of the pilot in command will almost inevitably lead to an accident. The targets outlined above have been

developed into what has become known as the '1% rule'[30]. This rule may be defined as the predicted annual medical (cardiological) event rate which, if exceeded, should exclude a professional airman from flying a multi-crew aircraft[30]. A 1% risk of event per annum corresponds with one event per 100 years or approximately one event per 10^6 h. Of course, the JAR regulations for pilots are not simply applicable to driving regulations for ICD patients. There are some inherent limitations of the JAR approach that have to be kept in mind: the serious incapacitation rate caused by pilot incapacitation in a single crew operation is likely to equal the fatal accident rate. This assumption may be true in the air, but there are data suggesting that fatal heart attacks on the road are unlikely to cause accidents[21,24]. Therefore, non-fatal events, such as cardiac pain at the wheel, the onset of a benign supraventricular tachycardia, and transient cerebral ischaemia as a result of embolism, may all cause incapacity in a driver and yet leave him alive and asymptomatic a few minutes later[2,31,32].

It has been suggested by the Canadian Cardiovascular Society Consensus Conference[33] that the yearly risk of harm (RH) to other road users posed by a driver with heart disease is assumed to be directly proportional to:

$$RH = TD \times V \times SCI \times Ac,$$

where TD=the time the patient spent behind the wheel or distance driven within a year; V=a constant based upon the type of vehicle driven; SCI=the yearly risk of sudden cardiac death or incapacitation; Ac=the probability that such an event will result in a fatal or injury-producing accident. It may be assumed that the average commercial driver spends 25% of his/her time behind the wheel, whereas the private driver spends only 4% of his/her time driving. Thus, TD=0·25 for a commercial driver and 0·04 for a private car driver. There is evidence that loss of control of a truck or passenger-carrying vehicle does result in more devastating accident than loss of control of a private automobile. The average car driver drives about 16 000 km per year and the average truck driver about 138 000 km per year. Although truck drivers account for just under 2% of the total group (data reflect status in Canada), they account for approximately 5·5% of the total kilometres driven. They are involved in only about 2% of all road accidents, but in approximately 7·2% of fatal accidents. Thus, if V=1·0 for a commercial driver, then V=0·28 for a private driver. Based on existing standards for commercial truck drivers with cardiovascular diseases, an approximate 1% per annum risk of cardiac death is accepted by society[33]. Thus, SCI may be assigned a value of 0·01 for commercial truck drivers. Available data indicate that sudden cardiac incapacitation at the wheel poses a very small risk to public safety. Sudden driver illness causes only 0·9 to 2·1 of every 1000 road accidents with cardiac events occurring between one quarter and two thirds of those road accidents[16,19,24]. Only between 1–5% of sudden cardiac deaths occur while the victim is driving a motor vehicle[15,18,23]. Studies of patients who die suddenly while driving suggest that fewer than 2% of sudden driver incapacitations result in death or injury to other road users or innocent bystanders[11,21,23–25]. Therefore Ac, i.e. the probability that such an event will result in a fatal or injury-producing accident, equals 0·02 for all drivers regardless of what type of motor vehicle they are operating.

Substituting the values in the following equation the risk of harm of a commercial truck driver that results in death or injury to others is approximately 1 in 20 000 (0·00005=1/20 000).

$$RH = TD \times V \times SCI \times Ac,$$
$$RH = 0{\cdot}25 \times 1{\cdot}0 \times 0{\cdot}01 \times 0{\cdot}02 = 0{\cdot}00005$$

This level of risk appears to be generally acceptable to society. If similar calculations are applied to a private driver, then the acceptable yearly risk of sudden death or incapacitation would be in the order of 22%, calculated as follows:

$$RH = TD \times V \times SCI \times Ac,$$
$$SCI = 0{\cdot}00005/(0{\cdot}04 \times 0{\cdot}28 \times 0{\cdot}02) = 0{\cdot}223$$

Thus, the private automobile driver with a 22% risk of sustaining a suddenly incapacitating cardiac event in the year poses no greater harm to other road users or bystanders than a truck driver with a 1% risk.

Sudden cardiac incapacitation in ICD patients

In an attempt to provide driving recommendations for ICD patients with a history of sustained monomorphic ventricular tachycardia or ventricular fibrillation, the sudden cardiac incapacitation rate has to be defined for this specific patient population. The actuarial incidence of ICD shocks varies somewhat from study to study and may be influenced by the study population receiving the ICD. Several studies have shown an incidence of ICD therapy delivery of approximately 50% within the first year of ICD implantation, after which hazard rates calculated for consecutive 12-month intervals decline markedly[34–39]. The initial 6 months are the period of highest risk for appropriate as well as inappropriate shock therapy[34–39]. A powerful predictor of an increased risk of first arrhythmia occurrence is a severely depressed left ventricular ejection fraction, leading to an actuarial incidence of the first ICD therapy at least two to three times greater than that of patients with well preserved left ventricular function[37–39]. The absence of ICD therapy during the first year of ICD implantation has been associated with a lower risk of arrhythmia recurrence, ranging from approximately 10–20% annually[39–42]. In contrast, patients who experience ICD therapy are at increased risk of receiving further

ICD discharges during the subsequent years, with an estimated actuarial incidence in the order of 20–40% in the next 3 years[43–45]. Preliminary data suggest that the occurrence of a first shock did not predict a subsequent period of freedom from a second shock[44]. Furthermore, the second shock free survival curve indicated that the majority of patients who will experience a second shock did so within 6 months or less of the first shock[44]. The results of a recent study supported those findings that subsequent ICD discharges occurred earlier than the first ICD therapy and were not predictable by any clinical variable[45]. Unlike the occurrence of first shock therapies no clinical variable identifies a group at lower risk for subsequent ICD therapies[43–45].

Although actuarial data for the incidence of ICD therapy delivery are available, this does not necessarily equate with the incidence of incapacitation. It is important to stress that most patients with sustained ventricular arrhythmias experience only minimal or no symptoms prior to ICD discharge[38,40,42]. On the other hand, information derived from stored electrocardiograms suggests that in the absence of severe symptoms supraventricular tachycardia accounts for approximately 25% of inappropriate ICD therapies and that approximately 40% of the ICD patients will experience ICD therapy in the absence of severe symptoms for a rhythm other than ventricular in origin[34–42,46]. Inappropriate ICD therapy has been shown to occur predominantly in the first year after ICD implantation, after which hazard rates decline markedly[32–42,46]. The likelihood that treatment of a ventricular tachyarrhythmia in an ICD patient will be associated with disabling symptoms or even syncope has been addressed in a recent study by Kou *et al.* in 180 ICD recipients[47]. The investigators showed that only 16 of 106 patients (15%) who received shock therapy from their ICD had syncope. Unfortunately, no clinical variables including age, sex, history of syncope, left ventricular function, type of underlying heart disease, electrophysiological findings, rate of ventricular tachycardia, antiarrhythmic medications, and type of pulse generator implanted were found to be predictors of syncope[47]. Of the 143 patients who had a history of syncope or aborted sudden death before ICD implantation, 81 patients experienced ICD shocks during a follow-up period of 16 ± 12 months, and 12 patients (15%) had syncope during the shocks. Of the 37 patients who had never lost consciousness during ventricular tachycardia before ICD implantation, 25 experienced ICD shocks during follow-up and four of these patients (16%) had syncope[47]. Furthermore, Kou and co-workers showed[47] that two thirds of the patients who experienced syncope in association with subsequent ICD shocks did not experience syncope during their first shock. Based on their data, they concluded that absence of syncope during the first shock did not predict freedom from syncope during subsequent shocks. Thus, in patients who experience a shock during follow-up, approximately 10–20% have presyncope or syncope in association with ICD therapy delivery[47]. Contrary to the findings from the above mentioned studies, preliminary data from a retrospective analysis demonstrated that ICD patients with a low ejection fraction, inducible fast ventricular tachycardia and/or atrial fibrillation had a high risk of syncope[48]. However, these data are preliminary and retrospective, and more important no information on the programming of the ICDs has been provided. Programming of a certain ICD therapy may have a major impact on the frequency and severity of symptoms during ICD therapy delivery. All these issues have to be adequately addressed in a prospective study design in an attempt to assess the incidence of syncope in ICD recipients. There remains a need for much more data on the incidence of subsequent therapies after the occurrence of a first ICD therapy, and especially to assess the risk of syncope and to evaluate factors that may identify ICD patients at high or low risk. So far, the available data do not convincingly demonstrate that patients who will suffer from syncope can be identified prospectively by any clinical parameter.

With the increasing availability of tiered therapy ICDs capable of delivering antitachycardia pacing, this treatment modality is deemed appropriate for patients with haemodynamically well tolerated monomorphic ventricular tachycardia as well as for patients with frequent attacks of tachycardia episodes[49–51]. Antitachycardia pacing has been proven to be safe and effective for patients with sustained ventricular tachycardia. However, there is a considerable risk of arrhythmia acceleration depending on several parameters including the rate of the tachycardia and the programming of the antitachycardia therapy parameters[50,51]. Furthermore, a potentially longer duration of the tachycardia episode may be caused by applying tiered therapy algorithms. On the other hand, antitachycardia pacing is likely to be associated with less incapacitation than shock therapy because of less discomfort associated with the therapy and more rapid therapy delivery. However, even in the absence of syncope or shock therapy delivery, patients may still suffer from symptoms such as dizziness, graying of vision, and chest discomfort. It is known from a recent study[1] that fast burst pacing over a period of 30 s can be associated with significant cerebral dysfunction and impaired psychomotor performance. Although antitachycardia pacing may prevent shocks in many ICD patients, it also may provoke disabling symptoms and increase the hazards that may occur with driving in selected patients.

The probability that patients will experience recurrence of a ventricular arrhythmia severe enough to impair their ability to operate a motor vehicle in the year following initiation of therapy for the arrhythmia has recently been studied[52]. Larsen *et al.*[52] reported on the arrhythmia recurrence rate in 501 survivors of ventricular tachycardia or fibrillation. Patients were discharged on conventional antiarrhythmic drugs (45%), on amiodarone (23%), no specific antiarrhythmic therapy (24%), or with an implantable cardioverter-defibrillator (8%). Main outcomes included any event that could hamper a patient's ability to operate a motor vehicle. The one-year event rate for all patients was 17%. Analysis of the

monthly hazard rates during the first year after hospital discharge showed that the highest hazard rate was in the first month after hospital discharge (4·22% per month), intermediate in months 2 to 7 (1·81% per month), and lowest in months 8 through 12 (0·63% per month). Since only 8% of the patients in this study were treated with an ICD, these data predominantly refer to patients receiving antiarrhythmic drug treatment. Apart from this limitation, the work from Larsen and co-workers[52] represented ongoing follow-up of a consecutive series of patients, but it was not a formal prospective study. Furthermore, the results may not be generalizable to all survivors of sustained ventricular arrhythmias.

Based on the above mentioned calculations, it can be assumed that approximately 50% of patients with ICDs will receive discharges in the first year after implantation of which 20% will have impaired consciousness (i.e. syncope or presyncope) in association with the arrhythmia event. Thus, the risk of sudden cardiac incapacitation will be 10% in those ICD patients which is significantly less than the 22% risk of a private automobile driver without an ICD, a risk already accepted by society. Several studies in patients without an ICD suggest that fewer than 2% of sudden driver incapacity result in a fatal or injury related accident (*Ac* in the above equation)[15,19,20,25]. These studies are supported by a recent publication which has shown that only 10·5% (30 of 286) of all defibrillator discharges during driving resulted in accidents[53]. In this study by Curtis *et al.*[53], 742 physicians involved with ICD implantation or follow-up in the United States were sent a questionnaire. The physicians were asked about number of patients followed and number of fatal and non-fatal accidents in ICD patients. Of the 61% surveys returned, a total of 30 motor vehicle accidents related to ICD shocks 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 non-fatal accidents involving 15 patients, three passengers and three bystanders. The estimated fatality rate for patients with a defibrillator (7·5 per 100 000 patient-years) is significantly lower than that for the general population (18·4 per 100 000 patient-years). The estimated injury rate for patients with defibrillators (17·6 per 100 000 patient-years) is also significantly lower than that for the general public (2224 per 100 000 patient-years). The major concern of the study by Curtis and colleagues is that the data collection was retrospective and relied on physician recall.

Taking the above mentioned assumptions into consideration, allowing a patient with an ICD to operate a private motor vehicle on the road is associated with an annual risk of harm to other road users or innocent bystanders of approximately 1 in 45 000 (0·0000224) according to the following equation[54]:

$$RH = TD \times V \times SCI \times Ac.$$
$$RH = 0{\cdot}04 \times 0{\cdot}28 \times 0{\cdot}1 \times 0{\cdot}02 = 0{\cdot}0000224$$

Driving after ICD implantation — European experience

Driving restrictions may have a substantial impact on quality of life in ICD patients[55–57]. In a survey of 124 patients in Belgium in 1995, the following parameters were not determinants of driving behaviour after the formal advice according to the existing law not to drive: age, indication for the ICD, underlying heart disease, or shock discharges[58]. It was of note that a significantly higher proportion of female patients refrained from driving (73%) compared to male drivers (36%). In an attempt to develop uniform European driving recommendations for ICD recipients, we conducted a survey on behalf of the Study Group 'ICD and Driving' of the Working Groups on Cardiac Pacing and Arrhythmias of the European Society of Cardiology[59–62]. A specifically designed questionnaire was developed and sent to 47 European National Delegates to ascertain driving behaviour in Europe after ICD implantation. The responses reflected approximately 6000 ICD systems out of 60 000 implantations worldwide. Of the 39 (83%) respondents, 30 (77%) cardiologists advised their patients to cease driving after ICD implantation. The advice to abstain from driving was always given by 22 (56%) cardiologists, but only sometimes by 16 (41%) cardiologists. The criteria utilized in making the recommendation for driving abstinence were based upon syncope in 20 (51%) patients and the history of fast ventricular tachycardia and ventricular fibrillation in nine (23%) patients, whereas only one cardiologist based his recommendation solely upon the occurrence of ventricular fibrillation. Permanent driving abstinence was advised by 13 (33%) of the cardiologists while temporary driving abstinence for periods of 3 to 18 months (mean 9 ± 4 months) was recommended by 25 (64%) cardiologists. The following periods of driving restriction were advised by the cardiologists: 3 months by seven cardiologists, 6 months by 12 cardiologists, 12 months by five cardiologists and 18 months by one cardiologist. Criteria for subsequently advising a longer period of driving abstinence were: pre-syncope by 15 (38%), syncope by 13 (33%) and multiple shocks by two (5%) cardiologists. Overall, 15 (38%) of the cardiologists surveyed knew the content of their national law concerning arrhythmias and temporary loss of physical control or loss of consciousness, whereas five respondents (13%) did not know if any driving laws existed in their country. Despite medical advice not to drive, the majority of patients resumed driving: 16 (41%) cardiologists responded that <10% of their patients resumed driving, seven (18%) cardiologists indicated up to 30%, six (15%) cardiologists stated up to 50%, and four (10%) cardiologists indicated that this group comprises up to 70% of their patients. The vast majority of patients resumed driving against medical advice not to do so 12 months after ICD implantation: three (7%) cardiologists reported resumption of driving after one month, 14 (36%) cardiologists indicated that their patients continued to drive 5 months after ICD implantation, and 11 (28%) cardiologists responded that

their patients resumed driving after 12 months. Two patients experienced ICD discharges while driving, but no motor vehicle accident occurred. One further patient had a motor vehicle collision with a fatal outcome, but this was not caused by loss of consciousness or ICD discharge. The main findings in this European survey are as follows:

(a) fatal accidents or ICD discharges while driving are rare in ICD patients,
(b) about half of the cardiologists always advise their patients to cease driving for a period of 9 ± 4 months,
(c) despite the medical advice not to drive most patients resume driving within 6 months of ICD implantation,
(d) criteria used in advising driving abstinence are not uniform among the cardiologists in Europe.

Similar results were reported by investigators in the United States who determined driving behaviour following ICD implantation[63–65]. A survey conducted in three midwestern states suggested that 74% of the cardiologists who implant ICDs advise their patients against driving. The criteria and durations utilized in advising driving abstinence were not uniform and did not always conform with existing state laws[63]. In a further report on driving safety among patients with ICDs, it was indicated that despite medical advice never to drive again 70% of the patients resumed driving, with the majority doing so by 8 months after ICD implantation[65].

Driving recommendations

Once a patient with documented ventricular tachyarrhythmias has received an ICD, the reliability of the ICD therapy should be assessed not only in the electrophysiology laboratory prior to hospital discharge, but during a defined period of clinical follow-up. This period of follow-up will take into account factors such as clinical arrhythmia presentation and frequency, left ventricular function, use of adjunctive drugs, and the observed response at the time of electrophysiological testing. Recent retrospective data show that routine defibrillation testing procedures may not be necessary[66]. However, these results have to be confirmed by prospective studies before such an approach can be generally recommended. The physician has to follow the patient for a defined period of time after ICD implantation without recurrence of arrhythmia to document adequate arrhythmia suppression. Of course, criteria for adequate suppression of arrhythmias are controversial, differing between arrhythmias and patients, and depending on physician judgement. Each physician must decide for each patient whether the test selected or the time elapsed to judge arrhythmia suppression is reliable in that particular situation. There was discussion with regard to the level of restriction for patients performing personal or commercial driving. A wide variety of potential hazards exist within each of these two categories. For example, the ICD patient who drives to the grocery store twice weekly may pose less risk to others than a private ICD driver who travels 10 km to get to work every day. Despite these differences that must be taken into account in any individual case, the consensus of the members of the Study Group was that restrictions regarding ICD patients should be divided into only two categories: personal and commercial driving. In the Canadian Cardiovascular Consensus Conference the following definitions have been proposed to distinguish a private driver from a commercial driver[33]: a private driver is one who drives less than 36 000 km per year or spends less than 720 h per year behind the wheel, drives a vehicle less than 11 000 kg, and does not earn a living by driving. A commercial driver is any licensed driver who does not fulfil the above definitions for a private driver. Obviously, this definition may apply to Canada and the United States, but may be less adequate for the European countries. Therefore, the members of the Study Group encourage physicians to use personal judgement in deciding whether or not a particular patient's situation warrants including him in the private driving or the commercial driving category.

Taking all the available, but still limited information into account for assessing the fitness of the ICD patient to drive, the following recommendations are grouped into three different categories (Table 1):

Class I: No restriction
Class II: Restriction for a defined time period
- A: without arrhythmia recurrence
- B: until confirmation of absence of disabling symptoms at the time of ICD therapy

Class III: Total restriction.

Class I

Patients grouped into Class I category have no restrictions. The risk of ICD discharge associated with severe haemodynamic compromise seems to be quite small in patients who undergo prophylactic ICD implantation. Those indications may include patients with a strong family history of sudden death, patients with non-sustained ventricular tachycardia and impaired left ventricular function, and other patient groups enrolled in ICD research protocols. If these patients have had no symptoms of haemodynamic compromise, they should not be prevented from private driving, although commercial driving should still be restricted. Therefore, non-commercial driving should be allowed for this patient group without a waiting period as soon as they have recovered from the implantation procedure. Patients with prophylactic ICD implantation who experience ICD shocks during follow-up should be advised not to drive for the subsequent 6 months, especially if the arrhythmia was associated with disabling symptoms.

Class II

Patients classified as Class II patients are restricted for a defined time period without arrhythmia recurrence. For

Table 1 Driving Recommendations for Patients with Implantable Cardioverter Defibrillators (ICDs)

Category	Driving Recommendation	Patient characteristics
Class I	No restriction	Prophylactic ICD implantations (i.e. non-sustained VT, family history)
Class II	Restriction for a defined time period	For all other patients driving non-commercially
A	6-month driving abstinence after ICD implantation	Low risk patients without recurrences of ventricular tachyarrhythmias
B	Extended driving abstinence after ICD therapy until confirmation of absence of disabling symptoms at the time of ICD therapy	Intermediate risk patients with recurrences of haemodynamically well tolerated ventricular tachyarrhythmias
Class III	Total restriction	High risk patients with recurrences of unstable ventricular tachyarrhythmias. Commercial driving

all other ICD patients except for those with prophylactic ICD implantations (Class I) who want to drive non-commercially, a general driving restriction for the first 6 months after implantation is recommended. If no ICD therapy has been delivered within 6 months, patients may fall into a sufficiently low risk group and may resume driving (Class IIA). If an ICD therapy occurs at any time after ICD implantation, either with or without associated syncope or presyncope, patients should be advised not to drive for the subsequent 6 months (Class IIB). This should be a reasonable time period to allow follow-up of the patient and to determine the nature, frequency and severity of arrhythmia recurrences. If arrhythmias still recur during this observation period of 6 months, then the level of consciousness from arrhythmia onset until termination by the ICD should be considered in each patient to decide if he/she is fit to drive. If the arrhythmia is well tolerated by the patient and does not produce an altered state of consciousness, then the patient may be considered fit to drive a car after that period of time. In addition, evidence should be provided that the patient has no impaired consciousness in case of arrhythmia acceleration and back-up shock delivery. However, if the patient develops any disabling symptoms during arrhythmia recurrence, then this patient should be advised not to resume driving. Symptoms are related to the haemodynamic tolerance of the arrhythmia. The tolerability of the arrhythmia is based upon the rate and duration of the tachycardia, the degree of the left ventricular ejection fraction, and the New York Heart Functional Class of the patient. Therefore, patients with New York Heart Functional Class III, severely depressed left ventricular ejection fraction <40%, a fast rate of ventricular tachycardia ≥ 180 beats . min^{-1}, and/or frequent arrhythmia attacks ≥ 3 per 6 months, should be advised not to resume driving unless satisfactory control of the arrhythmia has been achieved. It is probably reasonable to make exceptions to the above recommendations for patients who have not had symptoms of impaired consciousness with their presenting arrhythmia. Thus, in selected individuals, a shorter period of driving restriction may be appropriate depending on the judgement of the responsible physician. A subset of ICD recipients may fall into this group of patients who suffer from multiple episodes of asymptomatic and haemodynamically well tolerated ventricular tachycardia that can be reliably and reproducibly terminated by antitachycardia pacing without arrhythmia acceleration. In such a situation, the above rules against driving may be adjusted on a very selective individual basis.

Class III

Patients classified as Class III patients should have a total restriction of potentially hazardous activities. As it is unlikely that a commercial driver treated with an ICD has an annual risk of incapacitation $\leq 1\%$, it is recommended that all commercial driving be prohibited permanently after ICD implantation.

The present recommendations do not represent practice standards since they are based on limited data. These recommendations will not apply to every patient in every situation, and physicians are encouraged to use judgement in making a recommendation for any given patient. Where numerical values are given in the recommendations, they are intended only as approximations. Clinical judgement should prevail in borderline or questionable cases. There will be patients who require special consideration where the specific recommendations do not apply. The recommendations will require revision as new and more detailed information becomes available. Future revisions should address the long-term safety of ICDs including the incidence and frequency of lead complications[67]. It is important to note the main difference between the European and UK driving recommendations. In the UK, an arrhythmia-free interval of 12 months is required before ICD recipients are allowed to resume driving. The feeling of the members of the Study Group was that a 6 month period of abstinence would be sufficiently long enough to take whatever corrective

action might be appropriate[68]. Patients who remain free of therapy should then be allowed to resume driving.

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Appendix

The Study Group on 'ICD and Driving' was established by the Working Groups on Cardiac Pacing and Arrhythmias in May 1994 under the umbrella of the Joint Committee of both Working Groups of the European Society of Cardiology. All members of the Study Group were invited to submit their ideas. These comments were first discussed at a meeting in Rome on 9 December 1994. As agreed at the meeting in Rome, a specifically designed questionnaire was developed by Werner Jung and Berndt Lüderitz and sent to all members of the Study Group and to all National Delegates of the Working Group on Cardiac Pacing of the European Society of Cardiology. The results of this questionnaire were discussed at a meeting in Istanbul on 4–7 June 1995 and at a further meeting in Amsterdam on 20–24 August 1994. In November 1995, a first draft was written by Werner Jung and Berndt Lüderitz and submitted to the members of the Study Group for their review. The comments of the members of the Study Group were included in a revised version of the document which was circulated in January 1996 to all Nucleus members of the Working Groups on Cardiac Pacing and Arrhythmias for their critical review. After several consultations with the members of the Study Group, an extensive revision of the manuscript including all the suggestions of the members of the Study Group and of the members of the Nuclei of both Working Groups was prepared by Werner Jung, Secretary of the Writing Committee. This final document was again circulated to all members of the Study Group for their approval and to all members of the Nuclei who provided suggestions on the first draft protocol. After written approval was obtained by all members of the Study Group, the manuscript was submitted to the *European Heart Journal* and to the *European Journal of Pacing and Electrophysiology* for external review. The contents of this document represent the opinion of the Study Group and do not necessarily represent the official opinion of the European Society of Cardiology.

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