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CONSENSUS STATEMENT

Consensus statement of the European Heart Rhythm Association: updated recommendations for driving by patients with implantable cardioverter defibrillators

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Patients with an implantable cardioverter defibrillator (ICD) have an ongoing risk of sudden incapacitation that might cause harm to others while driving a car. Driving restrictions vary across different countries in Europe. The most recent recommendations for driving of ICD patients in Europe were published in 1997 and focused mainly on patients implanted for secondary prevention. In recent years there has been a vast increase in the number of patients with an ICD and in the percentage of patients implanted for primary prevention. The EHRA task force on ICD and driving was formed to reassess the risk of driving for ICD patients based on the literature available. The recommendations are summarized in the following table and are further explained in the document.

	Restriction for private driving	Restriction for professional driving
ICD implantation for secondary prevention	Three months	Permanent
ICD implantation for primary prevention	Four weeks	Permanent
After appropriate ICD therapy	Three months	Permanent
After inappropriate ICD therapy	Until measures to prevent inappropriate therapy are taken	Permanent
After replacement of the ICD	One week	Permanent
After replacement of the lead system	Four weeks	Permanent
Patients refusing ICD for primary prevention	No restriction	Permanent
Patients refusing ICD implantation for secondary prevention	Seven months	Permanent

Driving restrictions are perceived as difficult for patients and their families, and have an immediate consequence for their lifestyle. To increase the adherence to the driving restrictions, adequate discharge of education and follow-up of patients and family are pivotal. The task force members hope this document may serve as an instrument for European and national regulatory authorities to formulate uniform driving regulations.

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Introduction

Since the introduction of the implantable cardioverter defibrillators (ICDs) in the early 1980s multiple trials[1–11] have demonstrated the efficacy of ICDs for the prevention of sudden arrhythmic death. This resulted in a significant increase in the number of implanted ICDs. The percentage of patients implanted for primary prevention (treatment of patients at risk for life-threatening arrhythmias who have never had sustained ventricular arrhythmias) is increasing and exceeds in some countries the percentage of patients implanted for secondary prevention (treatment of patients who have survived a life-threatening arrhythmia). In 2007, 79% of the ICDs implanted in the USA were for primary prevention.[12] The registry of the European Heart Rhythm Association[13] showed a significant increase in the number of implanted ICDs from 2003 to 2005. Eucomed reported an increase from 63 000 ICDs implanted in Western Europe in 2006 to 85 500 ICDs in 2008 (Eucomed, personal communication). The Italian ICD registry[14] reported an increase in the percentage of primary indications from 44% in 2005 to 56% in 2007. Of 3294 implantations registered in 2007 in the Spanish Implantable Cardioverter-Defibrillator registry,[15] 50.7% were prophylactic implants.

Since the first implants it has been recognized that patients treated with an ICD have an ongoing risk of sudden incapacitation that might cause harm to others when driving a car.[16–30] It should be emphasized that the risk is mainly a consequence of the underlying condition and not of the presence of the ICD. National and international societies of cardiologists and electrophysiologists have published scientific statements addressing this issue.[31–39] In Europe, the most recent 'Working Group Report: Recommendations for Driving of Patients with Implantable Cardioverter-Defibrillators'[35] was published in 1997. This report focused mainly on patients with secondary prevention and recommended a driving restriction of 6 months after ICD implantation for this patient population. On the basis of this report, legislators in many European countries imposed a driving restriction of 6 months after implantation of an ICD, regardless of the indication.[40–42] In other countries, driving is only prohibited for the first 2 months after implantation.[43] Given the increase in implantations for primary prevention, there was a need to update the recommendations for this patient group. Furthermore, after reviewing the literature on secondary prevention the task force found compelling new data to update the recommendations for secondary prevention as well. The task force would like to stress that the recommendations described in this document have no legal value or legislative intents. However, we hope this document may serve as an instrument for European and national regulatory authorities to formulate uniform driving regulations.

Psychosocial, adherence, and ethical issues of driving restriction on patient and family

Treatment with ICDs has in numerous studies[44–47] been reported to affect the lives of patients and their families. The most common negative effects are anxiety, depression, anger, and fear.[48] Many of the concerns centre on the device itself, while limitations on lifestyle also have been reported to be of importance.[49] However, specific research on psychosocial effects of driving restriction in ICD patients is scarce. One qualitative study conducted in the UK[50] reports that driving restrictions are perceived as difficult for patients and their family and have an immediate consequence for their lifestyle. This entailed feelings of resentment and anger, increased dependence on others, lacking confidence in driving, and imposed family sanctions when driving. Patients and their spouses stated that the imposed driving ban was the hardest part of having the ICD implant. Similar results have been reported in an Australian study[51] on ICD recipients and their families, in which the impact of driving ban was perceived as particularly difficult in relation to independence and societal circumstances. In addition to the psychological and societal impact, the driving ban may also pose a considerable impact on employment and education and thereby economic status. Driving is considered by many as a basic necessity. Following this, driving restrictions may have a substantial impact on ICD recipients' quality of life.

The negative effects of driving restrictions have been of concern when outlining recommendations for driving in ICD recipients. Additional burden on recipients and their families needs to be avoided. At the same time, adherence to advice given by healthcare professionals needs to be maximized. As the driving restrictions can make the life situation of the patient and their families more difficult, this may affect adherence to the recommendations. Several studies[52–60] point in the direction of low adherence among recipients to the driving ban advised by healthcare professionals. In an early report, despite medical advice never to drive again, Finch *et al.*[45] indicated that 70% resumed driving, with the majority doing so by 8 months after ICD implantation. Fifty percent drove daily. A European survey[27] performed amongst 47 European National Delegates found that, despite medical advice not to drive, most patients resume driving within 6 months of ICD implantation. The TOVA (Triggers of Ventricular Arrhythmia) study[60] showed similar results. In ICD recipients driving against medical advice, Craney *et al.*[53] found that there were significant correlations between driving and the importance of driving to maintaining one's lifestyle, driving for necessity, for social reasons, and being the primary driver in the family. The Antiarrhythmics Versus Implantable Defibrillators (AVID) Trial[61] showed that younger, college educated men and those whose index arrhythmia was ventricular tachycardia (VT) were more likely to resume driving early. As there seems to be a gap between recommendations and patient adherence to these recommendations, an adequate discharge education and follow-up of patients and family is pivotal. Hence, driving restrictions poses demands on healthcare professionals in discussing alternative practical solutions. Notably, studies have also identified that advice given to patients about when to resume driving is inaccurate[55] and differ between cardiologists.[27] Improvement in standardized information given to patients is therefore desired.

Experiencing ventricular arrhythmias followed by loss of consciousness while driving may result in death or injury to the patient, other passengers as well as members of the public. Laws

and regulations governing the right of ICD recipients to drive motor vehicles vary across Europe. However, when recommendations that impose limitations on individuals driving privileges need to be considered, this also poses ethical issues. Although a driving ban imposes limitations on the lives of the ICD patient and their family, their safety is also of concern. Similarly, public safety is of utmost importance. The aim of ethics as well as legislation is to ensure that the rights of the individual do not exceed the safety of fellow citizens and at the same time ensure that the rights of society to restrict individual action are limited. However, this poses two conflicting principles; the rights of the individual and the good of the society. The task force has sought to balance these two principles in its recommendations.

Assessing the risk of harm to patients and bystanders

There are no prospective, controlled studies where patients have been randomized to permit driving or studies where patients have been randomized to receive or not to receive physician advice not to drive. Therefore, the Canadian Cardiovascular Society Consensus Conference[31] developed in 1992, a 'Risk of Harm' formula to quantify the level of risk to drivers with ICDs. This formula was used in many other reports including the 'Working Group Report'[35] published in 1997. The updated recommendations described in the current consensus statement are based on new data that became available in the literature. However, it was general consensus of the task force that the Risk of Harm (RH) formula, RH = TD × V × SCI × Ac, remained the major assessment tool.

According to this formula, the yearly RH to other road users posed by a driver with heart disease is directly proportional to:

- proportion of time spent behind the wheel or distance driven in a given time period (TD),
- type of vehicle driven (V),
- yearly risk of sudden cardiac incapacitation (SCI),
- the probability that such an event will result in a fatal or injury-producing accident (Ac).

The Canadian Cardiovascular Society Consensus Conference used following data to calculate the risk: fewer than 2% of reported incidents of driver sudden death or loss of consciousness have resulted in injury or death to other road users or bystanders.[62–65] Therefore, Ac = 0.02 for all drivers. The Ontario Road Safety Annual Report of 1987[66] showed evidence that loss of control of a heavy truck or passenger-carrying vehicle results in a more devastating accident than loss of control of a private automobile. In this report, truckers were involved in only ~2% of all road accidents but in ~7.2% of all fatal accidents. If in the RH formula, $V = 1$ for a commercial driver, then $V = 0.28$ for a private driver. Owing to the lack of published standard or definition of what level of risk was considered acceptable in Canada, the authors proposed following standard: the guidelines of the Canadian Cardiovascular Society and the Canadian Council of Motor Transport Administrators have permitted the driver of a heavy truck to return to that occupation following an acute myocardial infarction provided that he or she is functional class I with a negative exercise stress test at seven metabolic equivalents, has no disqualifying ventricular arrhythmias and is at least 3 months post-infarct. On the basis of available data, however, such a person cannot be assigned a risk <1% of cardiac death in the next year. The risk of sudden death would be lower than this but would be at least partially offset by the risk of other suddenly disabling events such as syncope or stroke. For such a person, SCI is estimated to be equal to 0.01. It was calculated[66] that the average commercial driver spends 25% of his or her time behind the wheel. Thus TD = 0.25. As indicated above, V may be assigned a value of 1 for commercial drivers and Ac = 0.02 for all drivers. Substituting these figures in the RH formula result in following risk:

$$RH = TD \times V \times SCI \times Ac = 0.25 \times 1 \times 0.01 \times 0.02 = 0.00005.$$

Allowing such a driver on the road is associated with an annual risk of death or injury to others of 1 in 20 000 (0.005%). This level of risk appeared to be generally acceptable in Canada. A similar standard was then applied to the driver of a private automobile. The average private driver spends ~4% of his or her time behind the wheel (TD = 0.04).[67] As indicated above, for such a driver, V = 0.28 and Ac = 0.02. The acceptable yearly risk of sudden death or cardiac incapacitation for such a person would be calculated as follows: RH (0.00005) = TD (0.04) × V (0.28) × SCI × Ac (0.02). Therefore SCI = 0.223.

Thus, the private automobile driver with a 22% risk of sustaining an SCI in the next year poses no greater threat to public safety than the heavy truck driver with a 1% risk. Finally, for the commercial driver who drives a light vehicle, such as a taxicab or delivery truck, V = 0.28 and TD = 0.25, placing them at a risk between that of the private driver and the driver of a heavy truck.

Definition of private drivers and professional drivers

The Canadian Cardiovascular Society Consensus Conference[31,32] defined criteria to distinguish a private driver from a commercial driver on the basis of number of kilometres driven per year, hours per year behind the wheel, weight of the vehicle, and whether the vehicle is used to earn a living. Specifically, a private driver was defined as one who drives <36 000 km per year or spends <720 h behind the wheel per year, drives a vehicle weighing <11 000 kg, and does not earn a living by driving. A commercial driver was defined as any licensed driver who does not fulfil the definition of a private driver. In Europe, a Council directive (80/1263/EEC) on 4 December 1980 proposed the establishment of a common European driving licence. A further directive of 29 July 1991 (91/439/EEC) formulated details that have been adopted in most countries of the European Union. Two groups of drivers are defined. Group 1 comprises drivers of ordinary motor cycles, cars, and other small vehicles with or without a trailer. Group 2 includes drivers of vehicles over 3.5 metric tonnes or passenger-carrying vehicles exceeding eight seats excluding the driver. In the Appendix, definitions of the different categories are explained. Drivers of taxi cabs, ambulances, and other vehicles for professional purposes form an intermediate

category. Drivers in Group 2 have to undergo medical examination before a driving licence is issued and should undergo periodic examinations afterwards. Drivers in Group 1 have to undergo medical examination only if they have certain medical disabilities. The European Council Directive delegates the decision on the minimum standards of fitness for driving for the intermediate category to the National legislations of the different countries. For this report on ICD and driving, the task force will use the definitions of the European Council Directive to distinguish between professional driving (Group 2) and private driving (Group 1). The task force strongly believes that drivers in the intermediate category who spend many hours per day at the wheel or carry passengers most of the time should be considered at higher risk. For the purpose of this report, the recommendations for Group 2 apply to this intermediate category. Clinical judgement should prevail in borderline cases, for example for drivers of a small truck, who drive it for a limited time a day to and from a building site or for leisure activities.

Recommendations for private drivers

Risk of driving in patients implanted for secondary prevention

Patients implanted for secondary prevention have already experienced a life-threatening arrhythmia. Factors that determine the risk of harming themselves and others in car accidents are the likelihood that patients will experience a recurrence of their arrhythmia, the likelihood that the arrhythmia while driving will impair consciousness, the probability that such an event will result in a car accident, and the probability that the accident will result in death or injury to other road users.

Risk of recurrence of arrhythmia in patients implanted for secondary prevention

In patients with a history of ventricular tachycardia (VT) or ventricular fibrillation (VF), the 5 years actuarial incidence of appropriate ICD shocks ranges between 55% and 70%.[68–72] The time between ICD implantation and recurrent arrhythmias varies among studies. Tchou *et al.*[73] reported a high incidence of first appropriate shock during the year following implant. Subsequently, the incidence dropped to a relatively steady rate with a rise during the fifth year. In a study of 65 ICD patients, Fogoros *et al.*[74] showed a steadily increase in the cumulative incidence of appropriate shocks. Almost 30% of patients who did not have appropriate shocks during the first 2 years subsequently had appropriate shocks during the second 2 years. The actuarial incidence of appropriate shocks was 28% after 6 months, 33% after 12 months, 50% after 24 months, and 64% after 48 months. Lubinski *et al.*[75] reported data from the Polish registry of 2162 patients implanted for secondary prevention of sudden cardiac death. The probability of ICD intervention for VF or fast VT during 10 years of follow-up was 52.3%. The mean time to first intervention was 344 ± 416 days. Fifty percent of patients had an appropriate ICD intervention during the first 194 days after implantation. The probability of arrhythmic episodes was 1.9% in the first month, 3.3% in the second month, and 3.7% in the third month. In the 3 months thereafter the added probability remained below 2% per month.

Risk of syncope in patients implanted for secondary prevention

Several studies evaluated the risk of having impairment of consciousness associated with an arrhythmia or ICD shock. In a study by Kou *et al.*,[76] ~10% of patients who experienced a shock during follow-up had syncope associated with the shock. In this study, persons who experienced syncope associated with ICD discharge could not be reliably identified prospectively by any clinical criteria, including aetiology of heart disease, severity of ventricular dysfunction, presence or absence of syncope with presenting arrhythmia, or cycle length of VT induced at the time of electrophysiological testing. Freedberg *et al.*[77] followed 125 ICD patients implanted for secondary prevention for 408 ± 321 days. During the first ICD therapy, 14% of the patients had syncope and 18% near syncope. Clinical parameters predicting symptoms of first ICD therapy included presentation with cardiac arrest and inducible VT with cycle length <250 ms. Bansch *et al.*[72] retrospectively analysed data on 421 patients with an ICD followed for 26 ± 18 months. Of these patients, 229 (54.4%) had recurrent VT/VF, and 62 (14.7%) had syncope. Low baseline left ventricular ejection fraction, induction of fast VT (CL <300 ms) during programmed stimulation and chronic atrial fibrillation (AF) were associated with an increased risk of syncope. In a study of 98 patients in France,[78] syncope occurred in 16% of patient who received ICD shocks. Abello *et al.*[79] compared 26 patients with spontaneous syncopal VT with 50 patients with non-syncopal VT prior to ICD implantation. Patients who presented with syncopal VT were more likely to experience syncope at follow-up. The median time to recurrence of syncopal VT was 376 days.

Risk of harm to patients and bystanders

Most studies evaluating the incidence of motor vehicle accidents in patients with an ICD were conducted retrospectively or based on surveys and interviews. Conti *et al.*[80] surveyed 82 patients who were followed 6 years. Fifty-two (63%) patients in this group had defibrillator shocks. Ninety percent of the 52 patients who received an ICD discharge resumed driving and none experienced device discharge while driving during the follow-up time period. In the study of Lerecouvreux *et al.*,[78] none of the patients who received ICD shocks at the wheel had a traffic accident. Curtis *et al.*[81] surveyed 742 US physicians who followed defibrillators patients, 452 physicians responded, and a total of 30 motor vehicle accidents related to shocks from ICDs were reported over a 12 year period. The estimated fatality rate for patients with a defibrillator was 7.5 per 100 000 person years, significantly lower than for the general population (18.4 per 100 000 person years). Of 286 defibrillator discharges documented while driving, 10.5% resulted in an accident. Trappe *et al.*[57] examined the driving behaviour of 291 ICD patients. Fifty patients had never driven. Fifty-nine percent of 241 patients continued driving post-implant and were followed for 38 ± 26 months. No patients died while driving; there were 11 accidents, but only 1 caused by the driver with an ICD and none was related to syncopal symptoms or ICD therapy. Five

percent of all patients received ICD therapy while driving; 74% of these occurred more than 2 years post-implant. No patient had syncope or an accident with this event. Akiyama *et al.*[58] administered questionnaires regarding driving to 909 patients in the AVID study. Of the 758 patients who responded 627 drove in the year prior to their index episode of ventricular arrhythmia. Fifty-seven percent of these drivers resumed driving within 3 months after randomization, 78% within 6 months, and 88% within 12 months. Two percent of patients had a syncopal episode while driving, and 11% had dizziness or palpitations that required stopping the vehicle. Eight percent of the patients with an ICD received a shock while driving. Of the 55 accidents during 1619 patient years after resumption of driving, 11% were preceded by any symptom of possible arrhythmia (0.4% per patient per year). The annual incidence of accidents in the ICD population of 3.4% per patient year was substantially lower than the accident rates in the general driving population in the USA of 7.1% per person year. In this study, there was no relationship between the duration of abstinence from driving after an episode of ventricular tachyarrhythmia and the subsequent risk of a motor vehicle accident.

These studies showed that the risk of symptoms that may lead to incapacity behind the wheel, with or without a defibrillator discharge, in patients with defibrillators implanted for secondary prophylaxis is very low. However, given the methodology, these studies had limitations including the possibility of underreporting. Therefore, most recommendations on driving in patients with ICDs have been based on a prospective study of 501 patients admitted to a hospital after resuscitation from sustained VT or VF by Larsen *et al.*[82] Outcome events, which included syncope, sudden death, ICD discharge, recurrent VF or haemodynamically compromising VT, were analysed. At the end of 1 year of follow-up, 17% of patients had experienced an outcome event. Analysis of the monthly hazard rates during this first year of follow-up indicated that the highest hazard rate was seen in the first month after discharge from the hospital. Hazard rates for months 2 through 7 were moderate, after which they declined substantially. Because only 8% of the entire group was treated with an ICD, these results predominantly reflect the results of antiarrhythmic drug therapy, including Class I drugs in one-third of patients. The authors suggested that survivors of VT or VF should refrain from driving during the first month after hospital discharge. The moderately elevated risk for months 2 through 7 supported restricting driving for most patients until the eighth month after hospital discharge. On the basis of these data most national societies recommended 6 months of restriction of driving for ICD patients in secondary prevention.[31–38]

For a decade, there was no compelling new evidence to question these recommendations. Recently Albert *et al.*[60] reported the results of the TOVA study: a prospective case-crossover study comparing the risk of ICD shock for VT/VF both during and up to 60 min after an episode of driving. Of 1188 ICD patients followed, 73% were implanted for secondary prevention. The majority of patients (80%) reported driving a car at least once a week. Participants reported spending a median of 3.8 h/week or 2.3% of their time driving a car. Over a mean follow-up of 562 days, there were 193 ICD shocks for VT/VF with data on exposure to driving before ICD shock. The absolute risk of ICD shock for VT/VF within 1 h of driving was estimated to be 1 episode per 25 116 person-hours spent driving. The risk occurred primarily during the 30 min period after driving (RR 4.46, 95% CI 2.92–6.82) rather than during the driving episode itself (RR 1.05, 95% CI 0.48–2.30). The authors conclude that the risk for ICD shock for VT/VF was not elevated during driving and the absolute risk was low.

On the basis of the evidence described above, the task force decided to recommend shortening the restriction time for private driving after a life-threatening ventricular arrhythmia. Since patients resuscitated for cardiac arrest very often need extensive time to recover from the event, there was consensus not to reduce the restriction time shorter than 3 months. Patients should have an assessment of their functional class and cognitive functions before resumption of driving.

Recommendations for private driving for patients in secondary prevention:

Type of licence	Indication for ICD implantation	Driving restriction
Private driving	Secondary prevention	Three months

Risk of driving in patients implanted for primary prevention

Patients with ICDs for primary prevention are generally considered at lower risk for sudden incapacitation while driving. This is based on mortality data, rates of sudden cardiac death, and rate of ICD discharges reported from primary prevention trials.[4–11] Annualized mortality rates range from 1.6% of patients per year in the MADIT II trial[7] to 12% of patients per year in the COMPANION trial[10] of patients with New York Heart Association Class III to IV congestive heart failure. Annualized mortality rates in the other six trials ranged from 4% to 8.5% of patients per year. The average annual mortality in the ICD arms of these trials was ~7% of patients per year. Rates of sudden cardiac or arrhythmic deaths ranged from 0.5% to 1.8% of patients per year, which can be considered low. In two trials that used earlier-generation ICDs, device discharge rates were high. In the CABG-Patch trial,[5] 50% of patients received a discharge during 1 year of follow-up; in MADIT I,[4] 60% of patients received a discharge during 2 years of follow-up. In these trials, the percentage of appropriate shocks is unknown since most ICDs were committed and did not have stored electrograms. The rates of ICD discharges in more recent trials were lower. In DEFINITE,[8] discharges occurred at a rate of 7.4% of patients per year. A subsequent analysis reported that only 44.9% of shocks were appropriate. In SCD-HeFT,[9] 259 (31%) of the 829 patients with ICDs received shocks for any reason, with 177 of these shocks being for VF or rapid VT. During 5 years of follow-up, the annual rate of appropriate ICD discharge was 7.5% per year. In an AHA/HRS scientific statement on personal and public safety issues related to arrhythmias that may affect consciousness, Epstein *et al.*[39] calculated the risk of likelihood

of an event while driving in ICD patients implanted for primary prevention. On the basis of data published by Conti *et al.*,[56] the authors assume that the average person with an ICD drives 8–20 miles per day for purely personal reasons, which is ~2% of the day. When coupling these data with results of trials of primary prevention, which demonstrated ICD discharge rates of 7.5% of patients per year, the likelihood of an ICD discharge while driving is in the range of 0.15% of patients per year. The authors conclude that no private automobile driving restrictions need be applied to patients who are asymptomatic from an arrhythmia standpoint. The results of these controlled clinical trials were recently confirmed in routine clinical practice. Alsheikh-Ali *et al.*[83] reported on the incidence and time-dependence of appropriate ICD therapy in 525 patients implanted for primary prevention in a single institute. Appropriate therapy occurred in 115 (22%) patients. The incidence of appropriate therapy was 20% in the first year after implant, 12% in year 2, and 6–11% per year for up to 7 years post-implant. The incidence of syncope was not reported. In a study of 1110 patients implanted for primary prevention in a single centre in the Netherlands (Schalij, personal communication), 211 patients (19%) received appropriate therapy. The incidence of ICD therapy was highest in the first 2 years and declined thereafter. On the basis of these data, the task force concludes that there is no need for driving restrictions in patients implanted for primary prevention after recovery from the procedure.

Recovery from implantable cardioverter-defibrillator implantation

In the period after ICD implantation, the patient needs to recover from the procedure and wound healing needs to take place. Most implanting physicians advise their patients to refrain from vigorous exercise and extensive use of the arm at the side of the implantation for a few weeks after implantation. Complications like lead dislocation, pocket haematoma, and perforation tend to occur in this period. In an Italian[84] multicentre evaluation of 307 patients implanted with an endocardial lead system 30 patients (9.9%) developed early complications within a 30 days interval after ICD implantation, requiring surgical intervention in 3% of patients. In a study of 1000 consecutive patients with a pectoral implantation, Gold *et al.*[85] reported pocket complications in 1.8% of patients and lead complications in 2.1% of patients. Lead dislodgments occurred primarily during the first month following implantation. In a study of 150 consecutive pectoral implantations, Fahy *et al.*[86] reported lead complications in 8% of patients. The median time between lead implant and detection of complications was 37 days. In a recent report Danik *et al.*[87] describe perforation in 8 of 416 patients (1.9%). Patients with perforation developed symptoms of chest pain or shortness of breath within 3 weeks post-implantation. Interrogation the day after implantation did not reveal any abnormalities. Perforation occurred in 23 of 7497 patients (0.31%) in an analysis of by Ebstein *et al.*[88] Nineteen of the perforations occurred within 20 days of implantation. According to the HRS/EHRA Expert Consensus on the Monitoring of Cardiovascular implantable Electronic Devices,[89] patients after ICD implantation should be evaluated within 72 h following implantation and during 2–12 weeks post-implantation. The studies described above show that lead dislodgements, perforations and pocket problems tend to occur later after implantation and will remain unnoticed at the 72 h device check. Therefore, the task force recommends a second system integrity check after 4 weeks before resumption of driving.

Recommendations for private driving for patients in primary prevention:

Type of licence	Indication for ICD implantation	Driving restriction
Private driving	Primary prevention	Four weeks

Risk of driving after implantable cardioverter defibrillator replacement

To replace an ICD, the pocket is opened, the lead is disconnected from the ICD, and a new ICD is connected after assuring the integrity of the lead. The recovery and wound healing following this procedure takes only a few days. Most of the possible complications described following an implantation are related to the lead system.[84-88] Therefore, the task force recommends a driving restriction of 1 week when only the ICD is replaced. In case of replacement of the ICD and the lead system or the lead system alone, a driving restriction of 4 weeks is recommended with a system integrity check before resumption of driving.

Recommendations for private driving after ICD replacement:

Type of licence	Following replacement	Driving restriction
Private driving	Replacement of the ICD	1 week
Private driving	Replacement of lead system	4 weeks

Risk of driving after implantable cardioverter-defibrillator therapy

Risk of driving after appropriate implantable cardioverter-defibrillator therapy

When patients experience ICD therapy for a spontaneous ventricular arrhythmia during follow-up, the risk of driving is determined by the probability of a subsequent arrhythmic event and by the likelihood of symptoms of impaired consciousness. In a study by Freedberg *et al.*[77] of 125 patients implanted with an ICD for secondary prevention, 58 patients (46%) received ICD therapy after 152 $\pm$ 193 days. Only 12 patients (21%) remained free of further ICD therapy. The median freedom from ICD therapy for the second shock was only 22 days, and all second shocks occurred within 1 year after the initial ICD therapy. The mean time to second ICD therapy was 66 $\pm$ 93 days compared with 138 $\pm$ 168 days for first ICD therapy. No correlation was found between time to the first and second ICD therapies. No clinical

predictor for second ICD therapy was found. In this study, symptoms were similar between first and second ICD therapies. Only 2 of 30 patients who were asymptomatic at the time of the first ICD therapy had syncope with the second ICD therapy. The authors conclude that patients presenting with asymptomatic first ICD therapy were at low risk for future syncopal ICD therapy. A similar finding was described by Bansch *et al.*[72] In this study, patients with slow VT and absence of syncope during the first ICD therapy had a low risk of developing future syncope. However, in the study of Kou *et al.*,[76] the absence of syncope during the first ICD therapy did not predict the absence of syncope during subsequent shocks.

In patients implanted for primary prevention, little is published on the risk of recurrent arrhythmias after the first ICD therapy. However, it is known that patients included in the MADIT II trial[90] had an increased risk of death (hazard ratio 3.4) with a high frequency of heart failure after the first appropriate ICD therapy. Sesselberg *et al.*[91] showed that MADIT II patients had a 17.8-fold increased risk of death in the first 3 months after electrical storm, defined as three or more episodes of VT or VF in 24 h. A study of SCD-HeFT patients[92] showed a 5.7-fold increase in mortality, mostly due to progressive heart failure, after an appropriate shock. Following the development of congestive heart failure, patients have again an increased risk for VT or VF (hazard ratio 2.52).[93] These data indicate that patients in primary prevention who receive appropriate ICD therapy are at risk for clinical deterioration and subsequent arrhythmias.

On the basis of the data described above, the task force advises a restriction from driving of 3 months after appropriate ICD therapy, for patients implanted for primary and secondary preventions, especially if the patient experienced symptoms of impaired consciousness. Patients with slow VT and absence of syncope during the first ICD therapy had a low risk of developing future syncope in two studies. However, in other studies, the absence of syncope during the first ICD therapy did not predict the absence of syncope during subsequent shocks. Furthermore, anti-tachycardia pacing may eventually accelerate an episode of well-tolerated VT. Therefore, the task force is reluctant to allow patients to drive immediately after receiving appropriate ICD therapy without symptoms.

Risk of driving after inappropriate implantable cardioverter-defibrillator therapy

Inappropriate ICD shocks (shocks delivered for non-ventricular arrhythmias) occur in 11–32% of patients enrolled in major trials.[94–97] Inappropriate shock is caused by AF, supraventricular arrhythmias, and inappropriate sensing. In the MADIT II population, patients experiencing an inappropriate shock had a mean number of 2.2 $\pm$ 2.5 inappropriate shock episodes. Measures to reduce inappropriate shocks and to prevent recurrence of inappropriate shocks are programming of SVT–VT discrimination algorithms, anti-arrhythmic medication and in case of oversensing reprogramming of the device or electrode replacement in case of lead defects.[98–101] The incidence of syncope or loss of consciousness with inappropriate shocks is unknown. The task force recommends that patients, after receiving inappropriate shocks, are allowed to drive after measures are taken to prevent recurrence of inappropriate shocks.

Recommendations for private driving after ICD therapy:

After ICD therapy	Driving restriction
Appropriate therapy	Three months
Inappropriate therapy	Until measures to prevent subsequent inappropriate therapy are taken

Patients refusing implantable cardioverter-defibrillator implantation

The issue of driving restriction is often discussed at the time the patient is offered an ICD and could be one of the reasons for a patient to refuse the ICD. It should be emphasized that it is not the presence of the device but the underlying heart condition that results in the risk for syncopal arrhythmias. Especially patients in secondary prevention who refuse an ICD are at continuous risk for recurrence of arrhythmias and impairment of consciousness. Recommendation on driving privileges can be deducted from the study of Larsen *et al.*[82] Of 501 patients admitted to a hospital after resuscitation from sustained VT or VF, 17% of patient experienced a syncope or recurrent arrhythmia after 1 year of follow-up. Hazard rates were highest in the first month after discharge from the hospital and intermediate for months 2 through 7. The hazard rates were lowest in months 8 through 12 with a 0.4% potential risk per month. There are no new data on the incidence of sudden incapacitation in patients refusing an ICD after experiencing a ventricular arrhythmia. On the basis of the study by Larson *et al.*,[82] driving privileges for this patient population should be withheld for seven months after the ventricular arrhythmia. For patients in primary prevention, the risk for symptomatic ventricular arrhythmias while driving is described above and is considered low.[39] Therefore, patients refusing an ICD for primary prevention should have no driving restriction for private driving.

Recommendations for private driving for patients refusing ICD:

Patients refusing ICD with indication for:	Driving restriction
Primary prevention	No restriction
Secondary prevention	Seven months

Recommendations for professional drivers

Risk assessment for professional drivers

For private drivers, the risk of incapacitation while driving is considered low based on the studies described above. However, for professional drivers, the impact of the vehicle and the time spend behind the wheel combined with the risk of incapacitation due to occurrence or recurrence of VT/VF results in an unfavourable equation. Using the 'Risk of Harm' formula,[31] a yearly risk of SCI of 1% should be considered the maximum accepted value.

Data described above show a 5-year actuarial incidence of appropriate ICD shocks between 55 and 70% in secondary prevention[68–72] and yearly ICD discharge rates of 7.5% of patients in primary prevention trials.[4–11] Similar data exist for patients with channelopathies such as Brugada syndrome. Sacher *et al.*[102] showed an annual appropriate shock rate of 2.6% in addition to significant risk of inappropriate shocks in a population of 220 Brugada patients. This included 45% asymptomatic patients. Therefore, the task force recommends permanent prohibition of professional driving after ICD implantation for secondary and primary preventions.

Recommendations for professional driving:

Type of licence	Indication for ICD implantation	Driving restriction
Professional driving	Primary prevention	Permanent
Professional driving	Secondary prevention	Permanent

Professional drivers refusing implantable cardioverter-defibrillator implantation

Driving restriction could be one of the reasons for professional drivers to refuse an ICD implantation. As for private drivers, it should be emphasized that not the presence of the device but mainly the underlying heart condition results in the risk for syncopal arrhythmias. For professional drivers who survived a life-threatening ventricular arrhythmia (ICD indication for secondary prevention), the risk of a recurrent arrhythmia in the next year is 17% (Larsen *et al.*[82]). In patients with a primary indication for ICD implantation,[4–11] the yearly mortality rates range from 1.6 to 12%. Rates of sudden cardiac or arrhythmic deaths ranged from 0.5 to 1.8% of patients per year. These data exceed the maximum accepted yearly risk of SCI for professional drivers. Therefore, professional drivers should not be allowed to drive if there is a class I indication for ICD implantation.

Recommendations for professional drivers refusing ICD implantation:

Type of licence	Patients refusing ICD implantation	Driving restriction
Professional driving	Primary prevention	Permanent
Professional driving	Secondary prevention	Permanent

Clinical follow-up and cardiac rehabilitation

Many of the patients implanted with an ICD have, apart from the risk for ventricular arrhythmias, underlying conditions that may impair their ability to drive. Singh *et al.*[93] showed that in patients from the MADIT II population hospitalization for congestive heart failure was associated with an increased risk for VT or VF (hazard ratio 2.52). Interim hospitalization for coronary events was associated with an increased risk for VT, VF, or death (hazard ratio 1.66). These results show that worsening clinical condition and cardiac instability are subsequently associated with a significant increase in the risk for appropriate ICD therapy and death. This emphasizes the need for continued clinical vigilance during the follow-up period after ICD implantation.

Implantable cardioverter-defibrillator patients can safely exercise and should be encouraged to participate in exercise based comprehensive cardiac rehabilitation programmes.[103] Cardiac rehabilitation lowers the incidence of total and exercise-related shocks and psychosocial interventions that utilize cognitive-behavioural protocols will likely prevent or reduce anxiety problems and improve quality of life.[104,105] Attention to the problem of driving restriction during the rehabilitation programs could result in better adherence to the recommendations.

Recommendation summary

(1) Patients receiving ICDs for secondary prevention should be restricted from private driving for 3 months after the index arrhythmia.
(2) Patients receiving ICDs for primary prevention should be restricted from private driving for 4 weeks after the implantation of the device. System integrity check is recommended before resumption of driving.
(3) Patients who have received an ICD for primary or secondary prevention who subsequently receive an appropriate therapy for VT or VF should be restricted from private driving for 3 months after the arrhythmia.
(4) Patients who receive inappropriate therapy should be restricted until measures to prevent subsequent inappropriate therapy are taken.
(5) Patients with ICDs for primary or secondary prevention are not allowed to drive heavy trucks or buses, or transport passengers professionally.
(6) Patients and their family should receive adequate discharge education and standardized information on driving recommendations. Regular clinical follow-up and cardiac rehabilitation are recommended.

Appendix: European Union Council Directive 91/439/EEC of 29 July 1991 on driving licenses

Minimum standards of physical and mental fitness for driving

A power-driven vehicle: definitions

1.1. Group 1
Drivers of vehicles of categories A, B, and B + E and subcategory A1 and B1.
1.2. Group 2
Drivers of vehicles of categories C, C + E, D, D + E and of subcategory C1, C1 + E, D1, and D1 + E.
1.3. National legislation may provide for the provisions set out in this Annex for Group 2 drivers to apply to drivers of Category B

vehicles using their driving license for professional purposes (taxis, ambulances, etc.).

Category A
Motorcycles with or without side-car.

Category B
Motor vehicles with a maximum authorized mass not exceeding 3500 kg and having not more than eight seats in addition to the driver's seat; motor vehicles in this category may be combined with a trailer having a maximum authorized mass which does not exceed 750 kg combinations of a tractor vehicle in Category B and a trailer, where the maximum authorized mass of the combination does not exceed 3500 kg and the maximum authorized mass of the trailer does not exceed the unladed mass of the tractor vehicles.

Category B + E
Combination of vehicles consisting of a tractor vehicle in Category B and a trailer, where the combination does not come within Category B.

Category C
Motor vehicles other than those in Category D and whose maximum authorized mass is over 3500 kg; motor vehicles in this category may be combined with a trailer having a maximum authorized mass which does not exceed 750 kg.

Category C + E
Combinations of vehicles where the tractor vehicle is in Category C and its trailer has a maximum authorized mass of over 750 kg.

Category D
Motor vehicles used for the carriage of persons and having more than eight seats in addition to the driver's seat; motor vehicles in this category may be combined with a trailer having a maximum authorized mass which does not exceed 750 kg.

Category D + E
Combinations of vehicles where the tractor vehicle is in Category D and its trailer has a maximum authorized mass of over 750 kg.

Medical examinations

Group 1
Applicants shall be required to undergo a medical examination if it becomes apparent, when the necessary formalities are being completed or during the test which they have to undergo prior to obtaining a driving licence, that they have one or more of the medical disabilities mentioned in this Annex.

Group 2
Applicants shall undergo medical examination before a driving licence is first issued to them and thereafter drivers shall undergo such periodic examinations as may be prescribed by national legislation.

The standards set by Member States for the issue or any subsequent renewal of driving licences may be stricter than those set out in this Appendix.

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