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Chapter 8

Driving Restrictions after Implantable Cardioverter Defibrillator Implantation: an Evidence Based Approach

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Eur Heart J 2011;32:2678-2687

ABSTRACT

Aims

Little evidence is available regarding restrictions from driving following implantable cardioverter defibrillator (ICD) implantation or following first appropriate or inappropriate shock. The purpose of the current analysis was to provide evidence for driving restrictions based on real-world incidences of shocks (appropriate and inappropriate).

Methods and results

A total of 2786 primary and secondary prevention ICD patients were included. The occurrence of shocks was noted during a median follow-up of 996 days (IQR, 428–1833 days). With the risk of harm formula, using the incidence of sudden cardiac incapacitation (SCI), the annual risk of harm to others posed by a driver with an ICD was calculated. Based on Canadian data, annual risk of harm to others of 5 in 100 000 (0.005%) was used as a cut-off value. In both primary and secondary prevention ICD patients with private driving habits, no restrictions to drive directly following implantation or an inappropriate shock are warranted. However, following an appropriate shock, these patients are at increased risk to cause harm to others road users and therefore should be restricted to drive for a period of 2 and 4 months, respectively. In addition, all ICD patients with professional driving habits have a substantial elevated risk to cause harm to other road users during the complete follow-up after both implantation and shock and should therefore be restricted to drive permanently.

Conclusion

The current analysis provides a clinically applicable tool for guideline committees to establish evidence-based driving restrictions.

INTRODUCTION

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. Although numerous recommendations exist, thus far evidence is scarce to justify them. As a result, a large variation exists between different countries concerning the legislation of driving restriction after both primary prevention and secondary prevention ICD implantation.[1-3] Since driving restrictions are often being perceived as difficult for patients and their families, clear evidence on the necessity of these restrictions is vital. Furthermore, these restrictions should take into account the indication for ICD implantation (primary or secondary prevention). In the end, however, it must be recognized that the goal of a zero percent risk is unobtainable and that society has to accept a certain level of risk by allowing patients at risk to resume driving.[4-6]

With the constant increase in ICD implants worldwide, clear guidelines regarding driving restrictions in both primary and secondary ICD patients are warranted. In this analysis we determined the risk for ICD therapy following ICD implantation or following previous device therapy (appropriate and inappropriate shock) in relation with driving restriction for private and professional drivers in a large number of primary and secondary ICD patients.

METHODS

Patients

The study population consisted of patients from the South-western part of the Netherlands (comprising 1.500.000 people) who received an ICD for primary prevention or secondary prevention in the Leiden University Medical Centre, the Netherlands. Since 1996, all implant procedures were registered in the departmental Cardiology Information System (EPD-Vision®, Leiden University Medical Centre). Characteristics at baseline, data of the implant procedure, and all follow-up visits were recorded prospectively. The data collected for the current registry ranged from January 1996 up to September 2009.

Eligibility for ICD implantation in this population was based on international guidelines for primary and secondary prevention. Due to evolving guidelines, indications will have changed over time.[7, 8]

Device implantation and programming

All defibrillator system implantations were performed transvenously, without thoracotomy. Testing of sensing and pacing thresholds and defibrillation threshold testing was performed during the implant procedure. Implanted systems were manufactured by Biotronik (Berlin, Germany), Boston Scientific [Natick, MA, USA, formerly CPI, Guidant (St Paul, MN, USA)], Medtronic (Minneapolis, MN, USA), and St Jude Medical/Ventritex (St Paul, MN, USA).

Defibrillators were programmed as follows: a ventricular arrhythmia monitor zone was programmed in all patients (150-188 bpm). No therapy was programmed in this zone until arrhythmias were detected during follow-up. Ventricular arrhythmias faster than 188 bpm were initially attempted to be terminated with two bursts of antitachycardia pacing (ATP) and, after continuation of the arrhythmia, device shocks were the indicated therapy.

Ventricular arrhythmias faster than 210 bpm were directly attempted to be terminated by device shocks. Furthermore, atrial arrhythmia detection was set to >170 bpm with supraventricular arrhythmia–discriminators enabled. Settings were adapted, only when clinically indicated (e.g. hemodynamic well-tolerated ventricular tachycardia (VT) at high rate; VT in the monitor zone).

According to Dutch legislation, updated in June 2004, private driving was prohibited for the first 2 months after implantation for both primary prevention and secondary prevention ICD patients. Furthermore, private drivers are restricted from driving for a period of 2 months following an appropriate shock and professional drivers are permanently restricted from driving following ICD implantation.[9]

Patient follow-up

Patient check-up was scheduled every 3-6 months, which included device interrogation. In case of unplanned hospitalization or symptomatic episodes of arrhythmia, additional device interrogations were performed. During device interrogation, episodes were assessed for appropriate and inappropriate ICD therapy (ATP or shocks) and verified by an electrophysiologist. Shocks were classified as appropriate when they occurred in response to VT or ventricular fibrillation (VF) and as inappropriate when triggered by sinus tachycardia or supraventricular tachycardia (SVT), T-wave oversensing, or electrode dysfunction. After delivery of an appropriate shock, efforts were made by a trained electrophysiologist to reduce the recurrence rate of arrhythmic events. When clinically indicated, ICD settings and/or antiarrhythmic medication were adjusted.

Since periodical follow-up was performed every 3-6 months, patients without data for the most recent 6 months prior to the end of the study were considered as lost to follow-up. However, these patients were included in the analysis as far as data was acquired.

End-points

The first shock (appropriate or inappropriate) was considered the primary end-point. For the second shock analysis, only those patients who received a first shock were considered at risk for a second shock and only subsequent shocks occurring more than 24 hours after first shock were considered second shocks. Noteworthy, ATP therapy was discarded from the analysis since the number of patients experiencing syncope – and therefore incapacitation – during ATP therapy is low. [10, 11]

Risk assessment

Currently, prospective controlled studies in which ICD patients have been randomized to permit driving are not available. In 1992, a 'risk of harm' formula was developed to quantify the level of risk to drivers with ICDs by the Canadian Cardiovascular Society Consensus Conference.[12, 13] This formula, with the following equation: RH = TD × V × SCI × Ac, calculates the yearly risk of harm (RH) to other road users posed by a driver with heart disease and is directly proportional to:

- proportion of time spent on driving 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).

Based on the literature, it is known that on average a private driver spends ~4% (TD = 0.04) and a professional driver spends ~25% (TD = 0.25) of his time driving.[14, 15] In addition, it was shown that more injurious accidents were caused by heavy truck or passenger-carrying vehicles when compared to private automobiles. In the Ontario Road Safety Annual Report, truckers were involved in ~2% of all road accidents but in ~7.2% of all lethal accidents. Based on this data, V = 1 for a professional driver and V = 0.28 for a private driver in the risk of harm formula.[14, 15] Furthermore, less than 2% of reported incidents of driver sudden death or loss of consciousness has resulted in injury or death to other road users or bystanders (Ac = 0.02).[16-18] In this analysis, the yearly risk of sudden cardiac incapacitation was based on the cumulative incidence of ICD shocks (appropriate or inappropriate) which were calculated for different follow-up periods as described previously. However, the actual influence of an ICD shock on the capacity to drive is unknown. According to the literature, 31% of the patients experience syncope or near syncope during an appropriate shock.[19] Since this proportion of patients receiving an appropriate shock will then be incapacitated to drive, it was assumed that the SCI is equal to the cumulative incidence of appropriate ICD shocks times 0.31. So far, no reports exist which describe the proportion of patients experiencing syncope or near syncope during an inappropriate shock. Based on the causes of inappropriate shocks (atrial fibrillation, sinus tachycardia, T-wave oversensing and lead failure) it is less likely that inappropriate shocks coincide with more hemodynamic consequences then appropriate shocks do. With the assumption that 31% of the patients with appropriate shocks experience syncope, it was supposed that at most the same proportion of patients receiving an inappropriate shock will experience syncope. Therefore, similar to appropriate shocks, the SCI is equal to the cumulative incidence of inappropriate ICD shocks times 0.31.

Considering the fact that driving restrictions for ICD patients are implemented as a protection for both ICD patients, as well as other road users, the risk of harm formula is an easy tool to calculate the potential harm brought to other road users on a yearly basis when ICD patients are not restricted to drive.

Unfortunately, data regarding an acceptable level of risk for private and professional drivers with an ICD in society are scarce. However, in Canada an annual risk of death or injury to others of 5 in 100 000 (0.005%) appeared to be in general acceptable.[3] Therefore, this generally accepted level of risk will be used as a cut-off value in the current study.

Private and professional drivers

Criteria to distinguish a private driver from a professional driver were defined on the basis of the Canadian Cardiovascular Society Consensus Conference.[12, 13] According to these criteria, a private driver was defined as follows: 1) driving < 36 000 km per year; 2) spending < 720 h per year driving; 3) driving a vehicle weighting < 11 000 kg, and 4) does not earn a living by driving. Any licensed driver who does not fulfil one of these criteria was considered to be a professional driver.

Statistical analysis

Continuous data are expressed as mean with standard deviation (SD) or median and first and third quartile when appropriate; dichotomous data are presented as numbers and percentages. Cumulative incidences for first and second appropriate shock were determined by the Kaplan-Meier method to take different follow-up times per patient into account. Cumulative incidences were determined for several periods of time after implantation and presented with a 95% confidence interval (CI) as the estimate plus or minus 1.96 times the standard error.

Standard errors were derived from the binomial distribution, and the confidence interval constructed with the normal approximation. The risk of harm formula was used to calculate the yearly risk of harm to other road users posed by an ICD treated driver. With this formula, various outcomes were calculated on basis of distinct ICD indication (i.e. primary and secondary prevention), type of driver (i.e. private and professional driver) and type of vehicle driven (i.e. heavy truck and passenger-carrying vehicle or a private automobile). All statistical analyses were performed with SPSS software (version 18.0, SPSS Inc., Chicago, Illinois).

RESULTS

Patients

Since 1996, data of 2786 consecutive patients receiving an ICD for primary (n=1718, 62%) or secondary (n=1068, 38%) prevention were prospectively collected. One hundred and ninety eight of these patients (n=126 (64%) primary prevention; n=72 (36%) secondary prevention) received an ICD for diagnosed congenital heart disease or monogenetic heart disease. A total of 196 (7.0%) patients were lost to follow-up, however included in the analysis as far as data was acquired. Median follow-up time was 996 days (interquartile range, 428–1833 days). The majority of patients (79% men, mean age 61 years (SD 13 years) had ischemic heart disease. Baseline patient characteristics are summarized in Table 1.

Device therapy in primary prevention patients

In the group of primary prevention patients, median follow-up was 784 days (interquartile range, 363–1495 days). During this follow-up, a total of 190 (10%) patients received an appropriate shock. Median time to first appropriate shock was 417 days (interquartile range, 134 to 960 days). From those 190 patients who received a first appropriate shock, 65 patients (34%) received a second appropriate shock. Median time between first and second appropriate shock was 66 days (interquartile range, 29-379 days). Cumulative incidences for first and second appropriate shock are displayed in Figure 1.

Inappropriate shocks occurred in 175 (10%) patients with a median time of 320 days (interquartile range, 124 to 711days). From the 175 patients with a first inappropriate shock, 47 patients (27%) received a second inappropriate shock. Median time between first and second inappropriate shock was 224 days (interquartile range, 77 to 580 days). Cumulative incidences for first and second inappropriate shock are displayed in Figure 2.

Table 1. Baseline patient characteristics.

	Total (n = 2786)	Primary prevention (n = 1718)	Secondary prevention (n = 1068)
Clinical characteristics			
Age (years)	61±13	62±13	61±14
Male (%)	2192 (79)	1336 (78)	856 (80)
Left ventricular ejection fraction (%)	33±15	31±14	39±16
QRS, mean (SD), ms	125±34	129±35	119±32
Renal clearance, mean (SD), ml/min	81±37	81±36	82±39
Ischemic heart disease (%)	1800 (65)	1077 (63)	723 (68)
History of atrial fibrillation/flutter (%)	683 (25)	447 (26)	236 (22)
Medication			
ACE inhibitors/AT II antagonist (%)	2107 (76)	1407 (82)	700 (66)
Aspirin (%)	1107 (40)	649 (38)	458 (43)
Beta-blocker (%)	1513 (54)	1074 (63)	439 (41)
Diuretics (%)	1738 (62)	1221 (71)	517 (48)
Statins (%)	1610 (58)	1075 (63)	535 (50)
Antiarrhythmic medication *			
Amiodarone (%)	497 (18)	221 (13)	276 (26)
Sotalol (%)	386 (14)	184 (11)	202 (19)

*ACE = angiotensin-converting enzyme; AT = angiotensin; SD = standard deviation. * Patients could be taking >1 antiarrhythmic drug.*

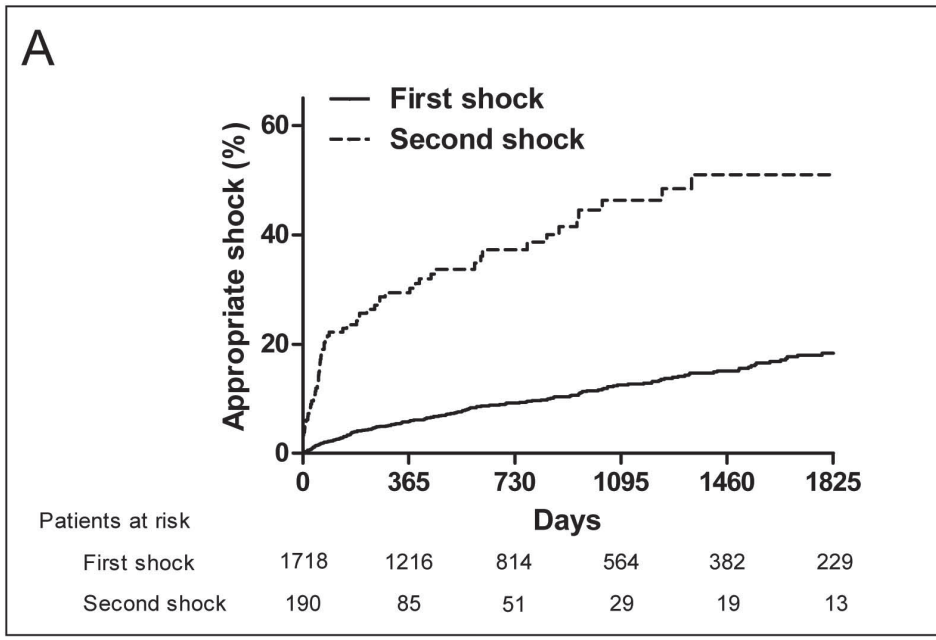
Device therapy in secondary prevention patients

In the group of secondary prevention patients, median follow-up time was 1442 days (interquartile range, 618–2469 days). During this follow-up, a total of 342 (32%) patients received an appropriate shock. Median time to first appropriate shock was 509 days (interquartile range, 141 to 1137 days). From those 342 patients with a first appropriate shock, 166 (49%) patients received a second appropriate shock. Median time between the first and second appropriate shock was 400 days (interquartile range, 107-1072 days). Cumulative incidences for first and second appropriate shock are displayed in Figure 1.

Inappropriate shocks occurred in 177 (17%) patients with a median time of 639 days (interquartile range, 190 to 1676 days). From the 177 patients with a first inappropriate shock, 60 patients (34%) received a second inappropriate shock. Median time between first and second inappropriate shock was 243 (interquartile range, 47 to 435 days). Cumulative incidences for first and second inappropriate shock are displayed in Figure 2.

Risk assessment in primary prevention ICD patients

In the risk of harm formula (RH = TD × V × Ac × SCI), the annual risk of harm per specific time point is calculated with the prespecified variables TD, V, and Ac and with the SCI. SCI equals the cumulative incidence of ICD shocks multiplied by the proportion of



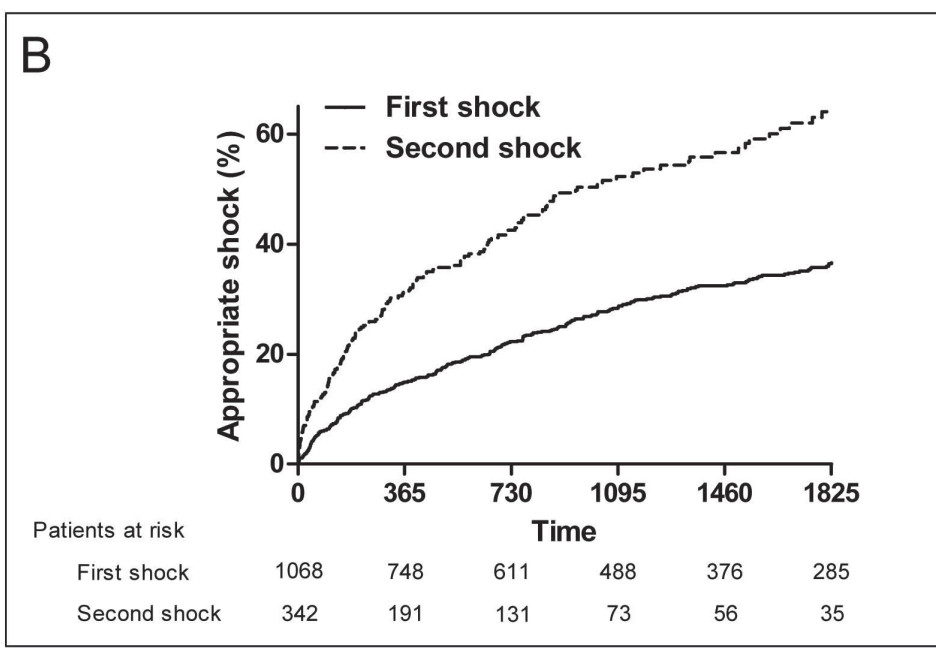
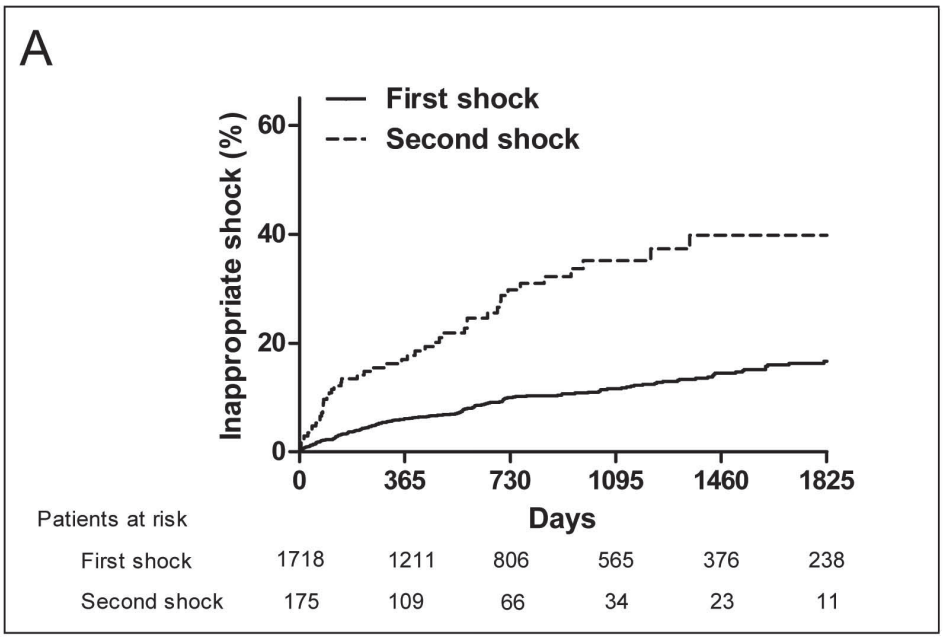


Figure 1. Kaplan-Meier curve for first and second appropriate shock in primary (panel A) and secondary (panel B) prevention ICD patients. Only patients who received a first appropriate shock were included in the analysis for the second appropriate shock. The time to the occurrence of a second appropriate shock was counted (in days) from the first appropriate shock.



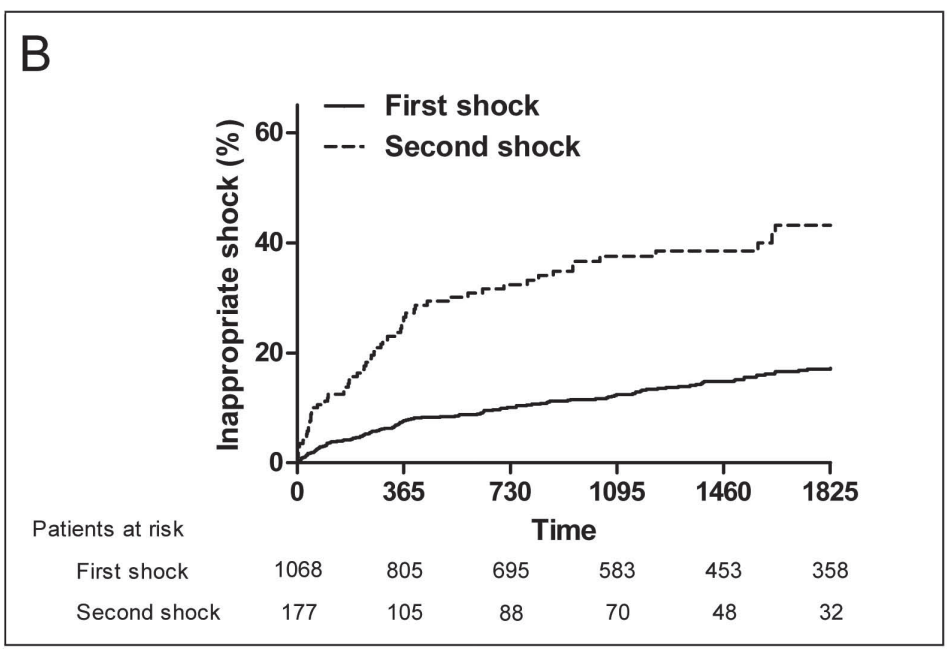


Figure 2. Kaplan-Meier curve for first and second inappropriate shock in primary (panel A) and secondary (panel B) prevention ICD patients. Only patients who received a first inappropriate shock were included in the analysis for the second inappropriate shock. The time to the occurrence of a second inappropriate shock was counted (in days) from the first inappropriate shock.

patients experiencing syncope (31%). For instance, for primary prevention ICD patients the cumulative incidence for an appropriate shock at one month following implantation is 0.9%. Since the formula uses yearly incidences, the monthly incidence is converted to a yearly incidence of 10.8% (0.9% × 12) and hereafter multiplied by the proportion of patients experiencing syncope or near syncope during an ICD (i.e. 31%) shock. Therefore, SCI in this example equals 0.03 (0.009 × 12 × 0.31). Accordingly, the risk of harm to other road users per 100 000 ICD patients for primary prevention ICD patients with private driving habits one month after implantation is calculated as follows: 0.04 × 0.28 × 0.02 × 0.009 × 12 × 0.31 = 0.75. After one year, the cumulative incidence for appropriate shocks in these patients is 6.0% following implantation. Consequently, the risk of harm to other road users for these patients declines to 0.43 (RH = 0.04 × 0.28 × 0.02 × 0.062 × 0.31) per 100 000 ICD patients per year (Figure 1 and Figure 3). Directly after implantation, the risk of harm to other road users in primary and secondary prevention ICD patients with private driving habits remains below the acceptable cut-off value of 5 per 100 000 ICD patients. Also after experiencing a first inappropriate shock the risk of harm to other road users remains below the accepted cut-off value (Figure 4).

Following an appropriate shock, the annual risk of harm declines from 8.0 (RH = 0.04 × 0.28 × 0.02 × 0.096 × 12 × 0.31) after one month to 2.1 (RH = 0.04 × 0.28 × 0.02 × 0.302 × 0.31) per 100 000 ICD patients after one year (Figure 1 and Figure 3). In Figure 3 it is shown that the risk of harm declines below the accepted cut-off value after 4 months following an appropriate shock in primary prevention ICD patients with private driving habits. However, following an inappropriate shock, the risk of harm in these patients is again directly below the accepted cut-off value (Figure 4).

Due to the heavy type of vehicle driven and the hours spent driving, the annual risk of harm following both implantation and appropriate shock was found to be 22.3 times higher in primary prevention ICD patients with professional driving habits as compared to private drivers. Consequently, the risk of harm to other road users following implantation or shock remains above the acceptable cut-off value during the complete follow-up.

Risk assessment in secondary prevention ICD patients

In secondary prevention ICD patients with private driving habits the annual risk of harm based on an appropriate shock was found to be 1.8 (RH=0.04*0.28*0.02*0.022*12*0.31) per 100 000 ICD patients 1 month following implantation (Figure 1 and Figure 2). Similar to primary prevention ICD patients with private driving habits, the risk of harm to other road users of these patients remained below the cut-off value of 5 per 100 000 ICD patients during follow-up. Also if the risk of harm to other road users after implantation was based on the cumulative incidence of inappropriate shocks, outcomes were directly following implantation below the accepted cut-off value (Figure 4).

However, after an appropriate shock, the risk of harm to other road users declined from 6.9 (RH=0.04*0.28*0.02*0.083*12*0.31) to 2.2 (RH=0.04*0.28*0.02*0.315*0.31) casualties on an annual basis per 100 000 ICD patients 1 month and 12 months following appropriate shock respectively. This risk following appropriate shock declined below the accepted cut-off value after 2 months in the group of secondary prevention ICD patients with private

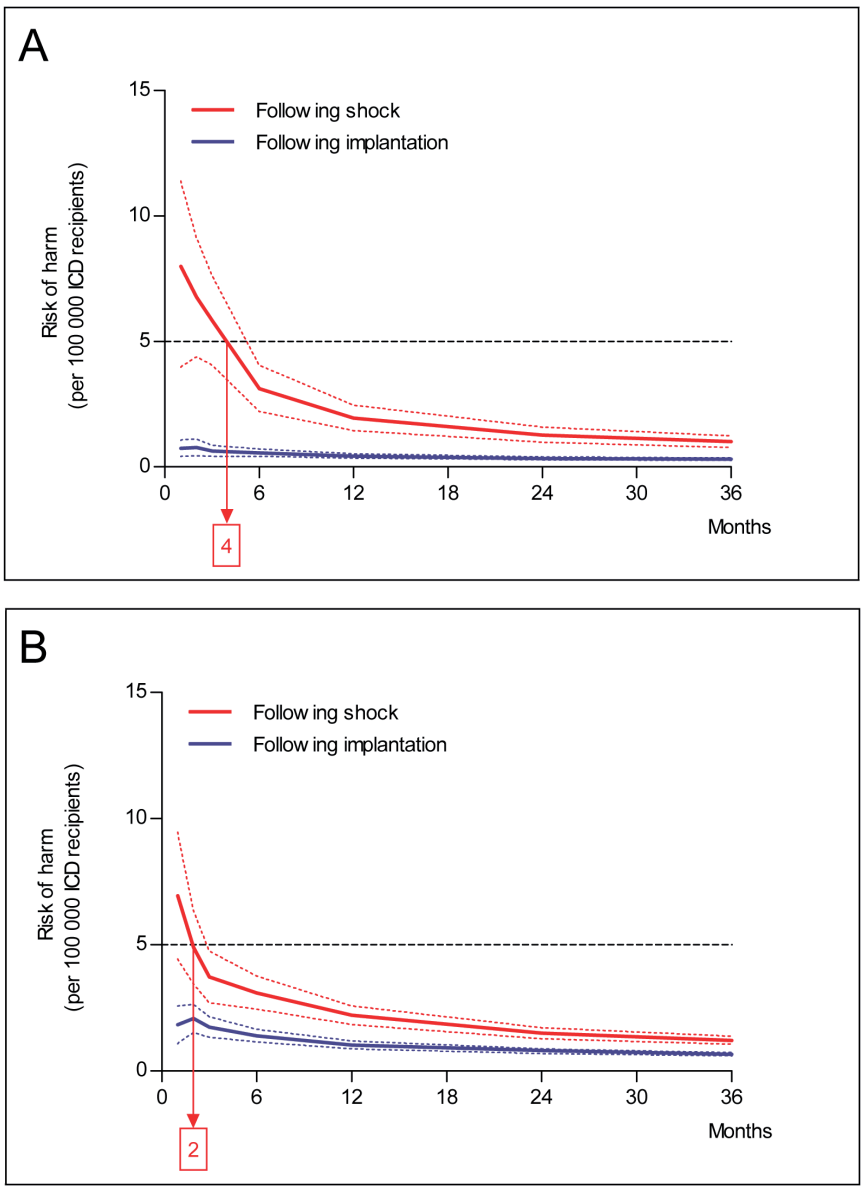


Figure 3. The annual Risk of Harm to other road users (Y-axis) in primary (panel A) and secondary (panel B) prevention ICD patients based on the cumulative incidence of appropriate shocks is illustrated. Risk of harm (solid lines) is calculated in the months (X-axis) following implantation or appropriate shock. The horizontal dotted line represents the cut-off value for the accepted level of risk of harm (5 per 100 000). Blue and red dotted lines represent the range of the risk of harm, based on the confidence interval of the cumulative incidence for appropriate shocks. In primary prevention ICD patients (panel A), driving is acceptable directly following implantation (blue line) and should be restricted for 4 months following appropriate shock (red line). In secondary prevention ICD patients (panel B), driving is acceptable directly following implantation (blue line) and should be restricted for 2 months following appropriate shock (red line).

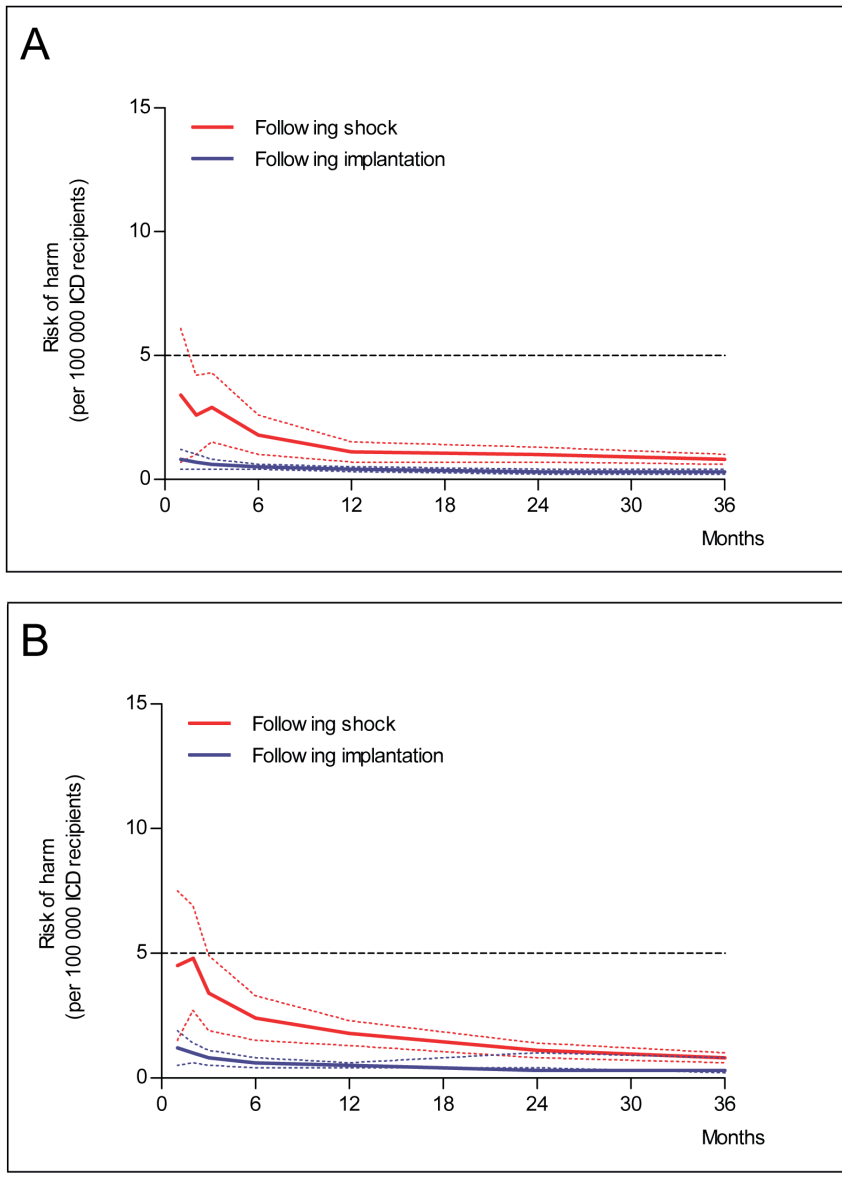


Figure 4. The annual Risk of Harm to other road users (Y-axis) in primary (panel A) and secondary (panel B) prevention ICD patients based on the cumulative incidence of inappropriate shocks is illustrated. Risk of harm (solid lines) is calculated in the months (X-axis) following implantation or inappropriate shock. The horizontal dotted line represents the cut-off value for the accepted level of risk of harm (5 per 100 000). Blue and red dotted lines represent the range of the risk of harm, based on the confidence interval of the cumulative incidence for inappropriate shocks. In primary prevention ICD patients (panel A), driving is acceptable directly following implantation (blue line) as well as directly following inappropriate shock (red line). Similar results were found in secondary prevention ICD patients (panel B), were driving is again acceptable directly following implantation (blue line) as well as directly following inappropriate shock (red line).

driving habits (Figure 1 and Figure 2). Following an inappropriate shock, the risk of harm in these patients is again directly below the accepted cut-off value (Figure 4).

Professional driving in secondary prevention ICD patients was above the cut-off value following both implantation and shock during the complete follow-up.

DISCUSSION

In this evidence based assessment of driving restrictions using the risk of harm formula, the findings can be summarized as follows: 1) following device implantation, primary and secondary prevention ICD patients with private driving habits have an acceptable risk of harm and therefore can be directly permitted to drive; 2) after an inappropriate shock, the level of risk remains below the accepted cut-off value and therefore no restrictions should be applied in all ICD patients with private driving habits; 3) in the case of an appropriate shock, primary and secondary preventions ICD patients with private driving habits should be restricted to drive for 4 and 2 months respectively; 4) ICD patients with professional driving habits do not reach an acceptable level of risk during follow-up and therefore should be permanently restricted to drive.

Risk of driving in primary prevention ICD patients

With increasing rates of primary prevention ICD implantations worldwide, clear guidelines regarding driving restrictions are essential. Although the risk for sudden incapacitation while driving is considered lower in this group of ICD patients than in secondary prevention ICD patients, no distinction is made in driving restrictions following ICD treatment. These differences in event rates are based on mortality data, rates of sudden cardiac death, and rate of ICD discharges reported from primary prevention trials.[20-27] With the lack of randomized controlled trials concerning ICD patients and the risk of driving, recommendations of the European Society of Cardiology (ESC) and American Heart Association (AHA) on driving restrictions in the group of primary prevention ICD patients are based on data from these trials.[1, 3]

The current study shows a cumulative incidence of 6.0% appropriate shocks after 1 year. Furthermore, ICD discharges were highest in the first period following implantation and showed a slight decline in the years thereafter (Figure 1). These data are not comparable with the MADIT I trial which described a shock rate of 30.0% on an annual basis during two years follow-up or with the MADIT II trial which described a shock rate of 11.7% on an annual basis during three years follow-up. However the appropriateness of the defibrillator discharges could not be assessed reliably in the MADIT I trial.[26, 28] Furthermore, with regard to the MADIT II trial, devices were unable to deliver ATP therapy which could lead to a higher shock rate. In the SCD-HeFT trial, the annual rate of appropriate ICD discharge during 5 years of follow-up was 7.5% per year.[20] In the DEFINITE trial, a shock rate of 7.4% occurred on an annual basis, however only 44.9% of discharges were appropriate.[25] Data of the SCD-HeFT and DEFINITE trials are comparable with data from the current study.

In the current analysis 10% of the primary prevention ICD patients received an inappropriate shock which is more or less comparable with the 11.5% of the MADIT II trial.[29]

Currently, ESC and AHA recommend primary prevention ICD patients with private driving habits not to drive for 1 month and 1 week respectively. It should be noted that this is not because of an increased risk of SCI, but to improve recovery from implantation of the defibrillator.[1-3] The current study demonstrates that the risk of harm for private drivers remains well below the acceptable cut-off level after implantation and therefore is in agreement with these recommendations (Figures 3 and 4). In addition, for professional drivers the outcomes of the risk of harm formula in the current analysis are unfavourable during the entire period of ICD implantation. As a result, based on the outcomes of this study, these drivers should be permanently restricted from driving which is in line with the current recommendations of the ESC and AHA.[1-3]

Risk of driving in secondary prevention ICD patients

Secondary prevention ICD patients have already experienced a life-threatening arrhythmia (e.g. VT or VF). The probability that patients will experience a recurrent arrhythmia is therefore an important factor determining the risk of harm, both with respect to themselves as well as others in car accidents. With regard to inappropriate shocks, only 17% of the secondary prevention ICD patients in the current analysis received such a shock. This proportion is more or less comparable with the 15% found in secondary prevention ICD patients included in the PainFREE Rx II trial.[30] However, the 5 year cumulative incidence of appropriate shock ranged between 55% and 70% in various trials, compared with a 36% cumulative incidence of appropriate shock in the current analysis.[19, 31-34] This difference is at least in part explained by the ATP therapy which was less frequently applied in the older secondary prevention studies which could prevent degeneration of VT in VF resulting in a lower cumulative incidence of appropriate shock therapy in the present study. Almost similar to Lubinski et al., the probability of arrhythmic episodes resulting in appropriate shocks in the current analysis was 2.2% in the first month, 2.9% in the second month, and remained below 2% per month in the months thereafter.[35] However, it was assumed that the risk for road accidents is just a fraction of the monthly probability of appropriate shocks, as described previously. Therefore, in patients with defibrillators implanted for secondary prevention, the risk of symptoms that may lead to incapacity while driving is low. Consequently in the current analysis, the risk of harm to other road users, based on both the cumulative incidence of appropriate and inappropriate shocks, remains below the acceptable risk. Therefore, no driving restrictions for secondary prevention ICD patients with private driving habits following implantation should be implemented. However, this outcome is in contrast with the current guidelines for secondary ICD patients with private driving habits, where the ESC and AHA recommend a 3 and 6 months driving restriction respectively.[1-3]

With respect to professional drivers, outcomes of the risk of harm formula are unfavourable during the entire period. Therefore, similar to primary prevention patients, secondary ICD patients should be restricted from professional driving.

Risk of driving following appropriate or inappropriate shock

A particularly difficult issue for patients and physicians is the consideration of driving restrictions in an ICD patient who has received an appropriate ICD shock. Following appropriate ICD therapy, guidelines of the ESC and AHA prescribe a 3 and 6 month

period of driving restriction in ICD patients respectively.[1, 3, 36] When patients experience an appropriate shock 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. However, symptoms of impaired consciousness during the first appropriate ICD therapy are not unambiguously predictive for future syncope during subsequent shocks.[31, 37] In a study of 125 ICD patients by Freedberg et al., the median freedom from ICD therapy for the second shock was only 22 days, with a one year cumulative incidence of a second appropriate shock being 79%.[19] These were all secondary prevention ICD patients and the cumulative incidence for a second appropriate shock shows large dissimilarity when compared with the one year cumulative incidence of 32% observed in the secondary prevention group in the present study. However, since these are all older devices without the option of ATP, shock rates in the study by Freedberg et al. are probably comparable with cumulative incidence of all ICD therapy in the current analysis.

Finally, substituting these cumulative incidences for appropriate shock in the risk of harm formula results in a significant increase in the risk of harm to other road users when ICD patients are allowed to drive in the period following this shock. This risk of harm to others is above the cut-off value of 5 per 100 000 on an annual basis for a period of 4 months and 2 months following appropriate shock in primary and secondary ICD patients respectively (Figure 3). These outcomes are more or less in line with the guidelines of the ESC and AHA.[1-3]

Since, to our knowledge, the incidence of syncope following an inappropriate shock is unknown, calculating the corresponding risk of harm is problematic. Therefore, it was assumed that the incidence of syncope or near syncope during an inappropriate shock is equal to the incidence of syncope or near syncope during an appropriate shock. Even with this apparent defensive approach in which the potential risk of harm could be overestimated, the actual risk of harm following an inappropriate shock remained below the acceptable cut-off value for both primary and secondary ICD patients. Therefore, in line with the current guidelines of the ESC and AHA, no driving restrictions following an inappropriate shock should be applied in these patients. [1-3] However, it is needless to say that all efforts should be made to prevent subsequent inappropriate shock before those patients should be permitted to drive again.

Private and professional drivers

It is however important to recognize the difference between the Canadian and European classification of private and commercial drivers. In Canada a private driver is defined as one who drives less than 36000 km per year or spends less than 720 h driving per year, drives a vehicle weighing < 11 000 kg, and does not earn a living by driving. A commercial driver is defined as any licensed driver who does not fulfill the definition of a private driver. In Europe, two groups of drivers are defined: Group 1 comprises drivers of motor cycles, cars, and other small vehicles with or without a trailer. Group 2 includes drivers of vehicles over 3.5 metric tons or passenger-carrying vehicles exceeding eight seats excluding.[3]

As the risk of harm estimations are based on the Canadian data it may be necessary to reevaluate the strict European rules. For example a private driver with a motor-home exceeding the 3.5 metric ton limit automatically is a group 2 driver and restricted from driving after ICD implant which seems to be an unnecessary restriction.

Clinical implications

Recently, EHRA and AHA provided consensus documents on driving restriction for ICD patients. Since no data from routine clinical practice was available at that time, restrictions were based on data from randomized clinical trials, which to a certain extent differ from routine clinical practice. This study is the first to provide accurate data on the incidences of appropriate and inappropriate shocks during follow-up in routine clinical practice and based on this, established driving restrictions. However, it is of course up to the guideline committees and national regulatory authorities to determine final driving restrictions for ICD patients. It should be emphasized that for the current study, an acceptable risk of harm of 5 per 100 000 ICD patients was used based on Canadian consensus. Increasing or decreasing this cut-off value may hold significant consequences for the recommendations. Moreover, in the current formula, Ac was considered 2% (i.e. 2% of reported incidents of driver sudden death or loss of consciousness has resulted in injury or death to other road users or bystanders). This data is derived from the Ontario Road Safety Annual Report since exact data usable for the formula are scarce. It should be noted that differences in these data will exist between different countries or areas affected by population density, driving habits, and type of vehicle driven. This could affect the risk of harm to other road users. However, if available, data from other countries can be implemented in the formula.[2] Finally, guidelines committees and national regulatory authorities must taken into account the serious impact of driving restrictions on patient's life and the fact that ICD patients will ignore (too rigorous) driving restrictions.[38-40]

Limitations

This was a prospective observational study assessing the incidence of SCI in ICD patients. Since patients received ICDs in a single center over a long period of time, evolving guidelines could have created a heterogeneous population. Moreover, median follow-up time was 2.1 years in primary prevention and 4.0 years in secondary prevention ICD patients which resulted in relatively broad confidence intervals of the cumulative incidences at long-term follow-up. In addition, ATP was discarded from the analysis since, according to the literature, minority of patients receiving ATP experience syncope.[10, 11] As a result, calculated risk of harm to others might be underestimated. Moreover, ICD programming was not homogeneous since ICD settings were adapted when clinically indicated. Finally, only the first and second shock (appropriate or inappropriate) of the ICD patients were taken into account. Although patients sometime received more than two shocks, the number of patients receiving three or more shocks was small and had limited follow-up making assessment of the SCI unreliable.

CONCLUSION

The current study provides reports on the cumulative incidences of SCI in ICD patients following ICD implantation and following first appropriate or inappropriate shock. The risk of harm to others was assessed using this SCI multiplied by the estimated risk of syncope, which resulted in specific outcomes for the risk of harm to other road users per different scenario (Figure 5). This study may serve as a basis and founding of driving recommendations which can be used by national regulatory authorities.

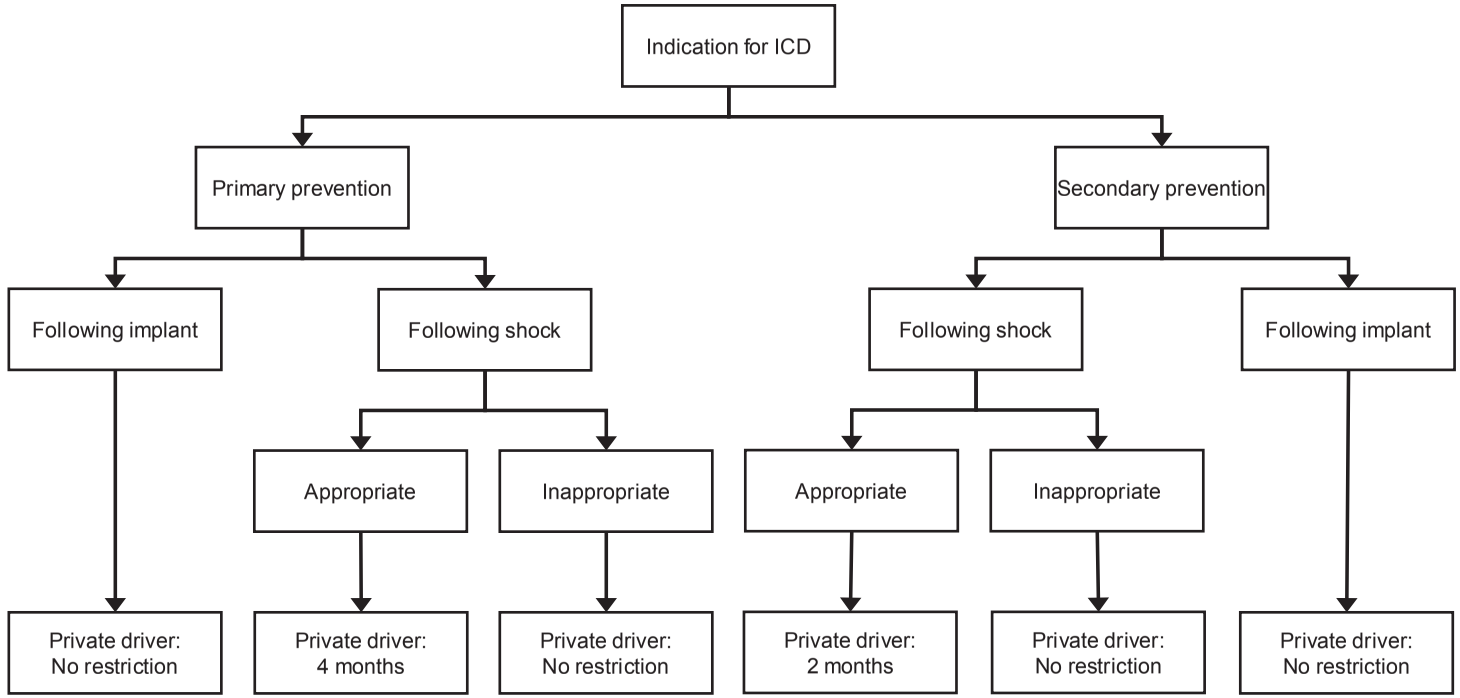


Figure 5. Flowchart demonstrating the recommended driving restrictions for ICD patients with private driving habits.

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