Driving restriction in patients with cardiac implantable electronic devices: an overview of worldwide regulations

Driving restriction in patients with cardiac implantable electronic devices: an overview of worldwide regulations

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Running title: Driving restrictions in patients with cardiac implantable electronic devices

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Abstract

Introduction: It is common belief that driving with an implantable cardioverter defibrillator (ICD)/pacemaker (PM) might be associated with sudden cardiac incapacitation, road traffic accidents and chance to harm to self and others. On the other hand, the ability to drive is highly valuable in the modern era, representing a cornerstone of daily living and employment. National regulations try to balance the right to drive of ICD/PM patients and the risk they pose to public safety, but rules for granting them a driving licence are considerably different

worldwide. For the same subset of patients driving restrictions may vary between 1 week and 1 year depending on the local law.
Areas covered: In this article we systematically review driving restrictions in ICD/PM patients in 16 countries all over the world, highlighting their differences and analyzing data from the literature that underlie their formulation.
Expert opinion: Current regulations are mainly based on historical data that do not take into account improvements in ICD/PM technologies and driving environment, which have made driving with an ICD/PM is substantially safe. Newer studies and updated regulatory documents are warranted to set the best driving restrictions and reach homogeneity worldwide.

Keywords: driving licence, PM, pacemaker, ICD, implantable cardioverter defibrillator, CRT, cardiac implantable electronic device, sudden cardiac death

Article highlights

- Driving with a PM/ICD can be associated with sudden cardiac incapacitation, road traffic accidents and chance to harm to self an others. On the other hand, the ability to drive is a cornerstone of daily living and employment.
- Driving with a PM/ICD should be substantially safe for private drivers; on the contrary it is not for professional drivers.
- Considerable heterogeneity exists among driving restriction periods in PM/ICD patients worldwide.
- Adequately powered, well-designed, *ad hoc* trials are needed to properly assess the risk that ICD/PM patients pose to personal and public safety while driving and to draw up more homogeneous regulations all over the world.

1. Introduction

Implantable cardioverter defibrillators (ICD) and pacemakers (PM) are electronic devices indicated for the treatment of tachy and bradyarrhythmias. Despite their well-recognized life-saving role (1-11), patients treated with these devices are at higher risk of sudden cardiac incapacitation (SCI) due to either delivery of device therapy or events related to the underlying heart disease (12-16). Sudden cardiac incapacitation is a fearful event, particularly while driving, since it can result in car accidents and harm to self and bystanders. On the other hand, the ability to drive is highly valuable in the modern era, representing a cornerstone of daily living and employment. Furthermore, driving restrictions imposed after ICD/PM implant have immediate detrimental effects on patients' quality of life and economic status (17-21). As a consequence, compliance to the driving ban is low and the majority of patients resume driving despite physician's unfavorable opinion (15, 16, 22-31). Two studies specifically examined the factors correlated with the early resumption of driving. One study found that the

importance of driving to maintain one's lifestyle, driving for necessity or social reasons, and being the primary driver in the family were predictors of low adherence to driving restrictions (23). The other study pointed out that younger, college educated men and those whose index arrhythmia was ventricular tachycardia were more prone to drive before the end of the restriction (30). These data highlights the negative effects of driving bans on patient's wellbeing and self-esteem. Therefore, physicians should provide an appropriate discharge education and schedule adequate follow-up visits to maximize patients' adherence to the driving restrictions, mitigating patients' and families' discomfort.

National regulatory agencies and cardiovascular societies published several documents trying to balance the right to drive of ICD/PM patients and the risk they pose to public safety. The duration of driving bans varies between countries and within the countries themselves, and is also influenced by the physicians' discretional evaluation (Table 1 and table 2). This heterogeneity sometimes leads to confusion and complaints by patients and uncertainty in decision making for physicians.

The aim of this article is to review driving restrictions in ICD/PM patients in different countries all over the world, highlighting their differences and analyzing data from the literature that brought to their formulation. Laws ruling the issuance of a driving licence in the broad scenario of "heart disease" patients (general cardiopathic population) vary between countries and are outside the object of this review.

2. Definition of driving licence categories

There are two main driving licence categories: private drivers (group 1) and professional (commercial) drivers (group 2). The definition of these two groups varies between countries on the basis of several parameters such as: number of kilometers driven per year, hours per year behind the wheel, weight of the vehicle and whether the vehicle is used to earn a living (Table 3). Drivers of Taxi Cabs, ambulances and other vehicles for professional purposes form an intermediate category, which usually falls in group 2, but can be locally determined.

3. Sudden cardiac incapacitation (SCI) during driving and assessment of the risk of harm (RH) to patients and bystanders

Arrhythmias and ICD therapies during driving may lead to syncope and sudden cardiac incapacitation (SCI), which in turn represents a risk to self and others.

Data regarding the risk of driving in people with heart disease (with or without ICD) are essentially retrospective observational. Since 1992, the "Risk of Harm" (RH) formula (32) (33) is considered the major risk assessment tool to quantify the yearly risk posed by a driver with heart disease to self and other road users. The RH formula is based on the Ontario Road Safety Annual Report (34) and can be calculated as follows:

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

1) TD is the time spent driving, which is 0.04 (1 hour per day) for private drivers and 0.25 (6 hours per day) for professional drivers. 2) V is a vehicle-specific constant. V = 0.28 for family cars and V = 1 for heavy trucks (involved in fewer road traffic accidents but with a higher rate of fatality) (34). 3) SCI is the yearly risk of sudden cardiac incapacitation (which can vary according with the underlying heart disease). Historically, the Canadian Cardiovascular Society and the Canadian Council of Motor Transport Administrators permitted to heavy-truck drivers who experienced an acute myocardial infarction, are in functional class I, have a negative exercise stress test at 7 metabolic equivalents, have no documented ventricular arrhythmias and are at least 3 months post infarct to return to their occupation, and to people with the above reported characteristics was assigned a SCI value of 0.01. 4) Ac is the probability that an episode of SCI will result in a fatal or injury-producing accident and is estimated to be 0.02 for all drivers.

Based on these assumptions, an annual RH of 0.005% (1:20,000) was proposed as the cut-off value for issuing a driving licence. Of note, the V constant plays a major role in predicting the risk of harm. Notably, according to the RH formula, a private car driver with 22% yearly risk of SCI poses no greater risk than a heavy truck driver with 1% risk.

4. ICD therapies while driving

In ICD patients, shock rate while driving is low and, in general, the number of shocks causing car accidents is lower than the total number of shocks delivered.

Curtis et al. (24) analyzed the 452 responses of a survey sent to 742 U.S. physicians following-up patients with ICDs for secondary prevention. A total of 268 ICD shocks while driving were reported over a 12-years period. Thirty out of 268 (10.5%) ICD discharges resulted in a car accident and 9/30 (30%) accidents were fatal for 8 patients with a defibrillator and 1 passenger. Of note, in this study the estimated fatality rate for patients with defibrillator was significantly lower than that observed in the general population

(7.5/100,000 patient-year for ICD drivers *vs.* 18.4/100,000 patient-years for the general population, $p < 0.05$). Trappe et al. (27) reported that 8/241 (5%) ICD patients received a shock while driving over a follow-up period of 38±26 months and no ICD discharge resulted in a car accident. The AVID trial (16), comparing the survival benefit between antiarrhythmic drug therapy and ICD in secondary prevention patients, showed similar results: 8% of patients with an ICD received a shock while driving, but no one was associated with a car accident. The TOVA study (29) showed that the risk of ICD shock for VT/VF was higher in the 30 minutes period after driving (RR 4.46, 95% CI 2.92 – 6.82) than during driving (RR 1.05, 95% CI 0.48 – 2.3). The authors concluded that the risk of ICD shock for VT/VF was not elevated during driving and the absolute risk was low. Finally, in 2013 Mylotte et al. (35) reported a 1.5% annual risk of shock while driving among 275 patients implanted for primary and secondary prevention. Eight patients (3.3%) received a shock during driving and 5/8 shocks resulted in a road traffic accident.

No trial specifically addressed the issue of ICD therapies during driving in patients implanted for primary prevention, but data extrapolated from the major primary prevention ICD trials suggest that the frequency of ICD shocks and the rate of syncopal events are low. In fact, coupling the ICD discharge rate derived from the SCD-HeFT (9), DEFINITE (8) and MADIT-II (7) trials (~7,5% of patients per year) with the average miles per day driven by ICD drivers (8 to 20 miles per day, which is ~2% of the day) (26), the likelihood of an event resulting in SCI while driving is < 1% (36). Therefore it can be hypothesized that the rate of ICD shocks while driving is lower than in secondary prevention patients.

Modern ICDs are programmed to deliver bursts of antitachycardia pacing (ATP), which are effective in terminating fast VT and are associated with a low risk of syncope (37, 38). Kim et al. (39)reported that in a predominantly primary prevention population, the likelihood of receiving a shock at 6 months when the first ventricular arrhythmia was terminated by a shock was 30%. By contrast, when the first ventricular arrhythmia was terminated by ATP the risk of shock was 9.9%, 3 times lower. Consequently, ATP can further reduce the number of SCI and accidents during driving and, therefore, the duration of the driving restrictions might be less restrictive when applied to drivers receiving ATP (39).

Taken together, these data suggest that the risk of harm of ICD patients during driving is not greater than that in the general driving population (16).

5. PROFESSIONAL DRIVERS

The risk of harm to patients and bystanders is considerably high if SCI occurs while a professional driver is driving. Using the "Risk of Harm" formula (32), given the huge impact on the equation brought by the type of vehicle driven and the substantial amount of time spent behind the wheel, a yearly risk of SCI below 1% should be considered as the maximum accepted value to grant a professional driving licence. However, since both primary (4-11) and secondary (40-44) prevention trials as well as studies on inherited cardiomyopathies (45, 46) and channelopathies (47, 48) showed an incidence of appropriate ICD shocks well above that cut-off value, all the national regulations and guidelines analyzed in this paper agree on the permanent prohibition of professional driving after ICD implantation for primary and secondary preventions.

In most of the countries, after PM insertion, professional drivers have a longer driving ban than private drivers, but they can return to their occupation.

Driving restrictions in ICD/PM patients according with different national regulations for both professional and private drivers are reported in table 1 and table 2.

6. PRIVATE DRIVERS

6.1 Driving restrictions in ICD patients implanted for secondary prevention

Patients who have had an ICD implanted for secondary prevention have already experienced a life-threatening arrhythmic event.

To determine the risk of harm to patients and bystanders, and consequently the proper driving restriction period after an ICD implant, it is necessary to estimate the risk of arrhythmia recurrence and the likelihood that the arrhythmia will result in sudden incapacitation while driving. According with previous studies, the 5 years actuarial incidence of appropriate ICD shocks ranges between 55-70% (40-43, 49). The risk of syncope associated with ICD shocks in secondary prevention patients have been evaluated by several studies and ranges from 2% to 16% with an average of 11.2% (50). Predictors of symptoms associated with ICD therapies were: presentation with cardiac arrest (40), induction of a fast VT (cycle length < 300 ms) during electrophysiologic study (40, 43), low baseline left ventricular ejection fraction (43), chronic atrial fibrillation (43) and syncopal VT (51) prior to ICD implantation. These clinical features may help identifying high-risk patients. Indeed, in the UK Driver and Vehicle Licensing Agency (DVLA) guidelines, the temporary driving ban for patient implanted because of VT/VF with incapacity is up to six months, while it decreases to 1 month in patients implanted for sustained VT without incapacity based on 3 findings: 1) left ventricular ejection fraction > 35%; 2) no fast VT is induced at electrophysiologic study; 3)

any induced VT could be pace-terminated by the ICD twice, without acceleration, during the post implantation study.

Another aspect considered when deciding the duration of the driving ban comes from a study by Larsen et al. (44), showing that the hazard rate of syncope, sudden death, ICD discharge, recurrent VF or hemodynamically unstable VT was highest in the first month after hospital discharge, moderate between months 2 and 7, substantially declining thereafter. Based on this data, a driving restriction of 6 months after an ICD implant was recommended by many national societies and countries, including American Heart Association, Canada, Japan, Australia, UK DVLA and Austria.

Newer evidences came from the TOVA study (29) in 2007. In this prospective case-crossover study, Albert et al. showed that the risk of ICD shock for VT/VF within 1 hour of driving was not elevated (1 episode per 25,116 person-hours spent driving), while the risk was higher in the 30 min period after driving (RR 4.46, 95% CI 2.92 – 6.82) than during the driving episode itself (RR 1.05, 95% CI 0.48 – 2.3). On this basis, the European Heart Rhythm Association (EHRA) 2009 guidelines (52) proposed a shorter restriction time of 3 months after ICD implant for secondary prevention for private driving, and many European countries (such as Denmark, France, Germany, Norway and Sweden) apply these standards (in the Netherlands the restriction is 2 months). Interesting data favoring an even shorter driving restriction period come from Thjissen et al. (53). In a cohort of 2,786 ICD patients (36% implanted for secondary prevention) the annual RH was below the cut-off value of 0.005%, suggesting that no specific restrictions to drive directly following ICD implant are warranted.

6.2 Driving restrictions in ICD patients implanted for primary prevention

ICDs as primary prevention are offered to patients at high risk of malignant ventricular arrhythmias that may lead to sudden cardiac death.

Patients with ICDs for primary prevention are considered at lower risk for sudden incapacitation than secondary prevention patients. The average annualized mortality rate reported in primary prevention trials in the ICD arm is nearly 7% of patients per year (range 1.6% - 12% of patients per year) (4-11). The average ICD discharge rate in recent trials was ~ 7.5% per year (7-9) and the mean incidence rate of syncope associated with ICD shock was ~ 1.6%,(50) much lower than that in secondary prevention patients (11.2%). Finally, Epstein et al. (36) showed that the likelihood of an ICD shock during driving is ~ 0.15% of patient per year and concluded that no private car driving restrictions need to be applied to patients who are asymptomatic from an arrhythmia standpoint.

According with these evidences, many countries recommend 1-4 weeks post-implant driving restriction (table 1 and table 2). These restrictions are not mainly due to the risk of ICD discharge; they are imposed to allow the patient to recover from surgery, the wound to heal and to cover the time period during which perforations, lead dislodgement and other complications are more likely to occur.

7. Driving restrictions after ICD therapies

Besides a distinction in driving restrictions between patients implanted for primary or secondary prevention, a driving ban is also applied after ICD therapies. In fact, ICD therapies (including both shocks and ATPs) represent a possible cause of SCI and car accidents. The occurrence of symptoms during the first appropriate ICD shock is considered predictive of subsequent impairment of consciousness by some authors (40, 43), an opinion which is not shared by others (54). Indeed, recent trials have reported a lower incidence of shock delivery and of clinical events by an improved programming aiming to avoid unnecessary therapy delivery(55-58). Though this aspect is pivotal to estimate the true occurrence of clinically relevant arrhythmias, it is not considered in the appraisal of the RH and of individual patients.

Thijssen et al. (53) suggested that a 4 or 2 months driving restriction should be applied to primary and secondary ICD patients, respectively, after the occurrence of an appropriate shock. Of note, a historical syncope rate of 31% associated with ICD shocks was used in this study. A shorter duration of driving restriction (1 month) after an ICD shock is suggested by a recent study (59), which analyzed the RH in 14,230 ICD recipients in which the estimated prevalence of loss of consciousness associated with ICD shocks was 14%.

Based on these data, most countries consider most prudent to apply the same driving restrictions to primary and secondary ICD patients whether the first appropriate shock was symptomatic or not (table 1 and table 2).

Regarding inappropriate ICD shocks, the prevalence reported in major trials (60-63) ranges between 11% and 32%, although this is largely outdated in newer studies applying up-to-date programming and arrhythmia discriminators, showing a two-years inappropriate shock rate of 3%(64, 65). Inappropriate ICD therapies may have a proarrhythmic effect (66, 67), but the associated incidence of syncope is little unknown yet. The only study that investigated the magnitude of sudden cardiac incapacitation risk after inappropriate ICD therapies was conducted by Watanabe et al. (68). The authors reported that inappropriate ICD therapies were responsible for syncope in only 0.7% of patients. They also calculated an annual RH to others after the first therapy, which was 0.11 in 100,000 and 0.12 in 100,000 in primary and

secondary prevention patients respectively; a RH value which was far below the acceptable risk threshold described previously (32). The article by Watanabe et al. (68) contributed to the deregulation of driving restrictions after inappropriate ICD therapies not associated with syncope. However, significant regulatory differences between countries still remain, reflecting the lack of robust data (table 1 and table 2). For example, in Germany, France, Netherlands, Norway, Spain, Denmark and Sweden, no specific driving restriction period is set after an inappropriate ICD therapy, as long as the underlying cause has been removed. In Japan, private drivers do not have to cease from driving after an asymptomatic inappropriate ICD therapy, but they should stop for 3 months if they lost consciousness at that time. In UK, patients have to abstain from driving for 1 month after the cause of the inappropriate therapy has been corrected. In US, the driving restriction is up to 6 months.

8. Driving restrictions in patients refusing ICD implantation

This issue is not specifically addressed in the literature and by most of the national regulations. Since the study by Larsen et al. (44) on ICD patients implanted for secondary prevention showed that the hazard rate of syncope, sudden death, ICD discharge, recurrent VF or hemodynamically unstable VT declines starting from the first month post implant, reaching low levels at 8 months, the EU guidelines(52) suggest a seven months driving restriction in private drivers with a secondary prevention indication, refusing ICD. No driving restriction is set for private drivers refusing ICD with indication for primary prevention. Commercial drivers are not allowed to drive instead (table 1 and table 2).

9. Driving restriction after PM insertion, generator changes and leads revisions

Driving with a PM is substantially safe. The incidence of syncope in paced patients is low (69) and PM dysfunction is not a major cause of syncope (70). The driving ban following PM implantation, generator changes or leads revisions is imposed to let the patients recover from surgery, the wound to heal and to unmask peri-procedural complications, such as lead dislodgements, perforations and pocket problems. Since syncope at presentation could be a predictor of recurrence post-implant (69), in some countries (such as Denmark, Germany and Norway) a longer driving restriction period is suggested for patients with a history of syncope compared with asymptomatic patients (table 1 and table 2).

10. Conclusions

The evaluation of fitness to drive in patients with ICD/PM is considerably different worldwide and there is a large variability in national regulations and guidelines. This heterogeneity reflects the ethical and legal complexity of balancing the individual right to drive and the perception of safety from the society standpoint. While professional drivers are not allowed to drive after ICD implant, private drivers have restrictions ranging from 1 week to 12 months.

Current regulations are mainly based on historical data, which do not consider improvements in vehicles and driving environment that made driving safer (for instance, automatic emergency braking and lane keep). Recent developments in ICD technologies, programming and algorithms, and the impact of ATP on arrhythmias termination are not considered as well. A 2002 US patent (US 6,480,744 B2) by Dr. Božidar Ferek-Petrić enabling communication between the ICD and the car computer, such as the onset of an arrhythmia potentially causing cardiac incapacitation would automatically trigger braking and stopping the vehicle, was never adopted by any car manufacturer, owing to the complexity of the regulatory in this field. This highlights the need of patients-centered rather than of regulatory-compliant policies. Newer studies are warranted to address these issues, making the publication of updated and more homogeneous regulatory documents possible.

Finally, the issue of patients refusing the device or those in whom the device is not recommended based on current guidelines (but have a non-negligible sudden-death occurrence) should be more extensively addressed, since the risk of harm while driving is mainly a consequence of the underlying heart disease and not of the presence of a device itself(71, 72).

11. Expert opinion

Driving restrictions in patients with implantable electronic devices are an extremely intriguing and current issue. On one hand, cardiac implantable electronic devices (CIEDs) therapies while driving may result in sudden cardiac incapacitation and thus lead to serious road traffic accident. On the other hand, the right to drive is of paramount importance and driving bans affect patients both mentally and financially (17-21). Moreover, the duration of these bans are considerably different worldwide, within countries themselves and may vary even according with the physicians' discretional evaluation. This wide heterogeneity sometimes leads to confusion and complaints by the patients and to poor adherence to driving bans (15, 22, 23, 30, 73).

A reason that may explain this variability in accessing the fitness to drive in CIED patients may be found in the ethical and legal complexity of balancing the individual right to drive and the good for the society. Another reason is the lack of randomized controlled trials that specifically address this issue. Therefore, current regulations are mainly based on historical data that do not take into account improvements in CIED technologies (with a special mention to antitachycardia pacing (37, 38), which proved effective in terminating fast VT and is associated with a low risk of syncope) and driving environment, which in turn made driving with a CIED safer than previously thought. In particular, no trial specifically addressed the issue of ICD therapies during driving in patients implanted for primary prevention and data are extrapolated from the major primary prevention ICD trials which were made between years 2002 and 2005 and suggested that the frequency of ICD shocks (~7,5% of patients per year) and the rate of syncopal events are substantially low (7-9). A larger amount of data is available for ICD implanted for secondary prevention and evidences move towards a reassuring safety profile of ICD patients at the wheel. In 1994 Larsen et al. (44) showed that the hazard rate of syncope, sudden death, ICD discharge, recurrent VF or hemodynamically unstable VT was highest in the first month after hospital discharge and significantly lower after month 7. This study laid the basis for a driving ban of 6 months (after an ICD implant for secondary prevention), which was applied by many countries. On the contrary, such a pattern of therapy delivery was never observed in the more recent MADIT-II trial that addressed a more contemporary population. In 2007 Albert et al. (29) showed that the risk of ICD shock for VT/VF within 1 hour of driving was not elevated (1 episode per 25,116 person-hours spent driving), while the risk was higher in the 30 min period after driving (RR 4.46, 95% CI 2.92 – 6.82) than during the driving episode itself (RR 1.05, 95% CI 0.48 – 2.3). On this basis, many countries set a shorter driving ban of 3 months. Finally, in 2011 Thijssen et al. (53) found that in a cohort of 2,786 ICD patients (36% implanted for secondary prevention) the annual risk of harm was below the cut-off value of 0.005%, suggesting that no specific restrictions to drive directly following ICD implant are warranted.

However, newer and more specific studies are needed to update regulatory documents, to set better driving restrictions and reach homogeneity worldwide, bearing in mind that the risk of sudden cardiac incapacitation while driving is mainly a consequence of the underlying heart disease and not the presence of a CIED itself which, on the contrary, represents the therapy**.**

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Country	EU		Austria		Belgium		Denmark	
Document type	Consensus document		Consensus document		Administrative document		Consensus document	
Driving licence group	Private	Commercial	Private	Commercial	Private	Commercial	Private	Commercial
ICD								
Secondary prevention	3 months	NA	6 months *	NA	12 months	NA	1 week and 3 months after last VF/VT	NA
Primary prevention	4 weeks	NA	4 weeks in asymptomatic patients if LVEF > 35%; no rapid VT induced during EPS (RR < 250 ms); induced VT can be terminated twice by the ICD without acceleration during post-implantation examination	NA	12 months	NA	2 weeks (1week if home monitoring established)	NA
Generator change	1 week		4 weeks		NR		1 week	
Lead revision	4 weeks		4 weeks				2 weeks (1week if home monitoring established)	
Primary indication, patient refusing device	NR	NA					NR	NA
Secondary indication, patient refusing device	7 months	NA					3 months	NA
Appropriate therapy	3 months		6 months				3 months (No restrictions for ATP)	
Inappropriate therapy	Until measures to prevent subsequent inappropriate therapy are taken						Until measures to prevent subsequent inappropriate therapy are taken	
PACEMAKER								
Insertion	NR Wound healing and PM functioning has to be confirmed	2 weeks and wound healing and PM functioning has to be confirmed	1 week	1 week	4 weeks	12 weeks	1 week	1 week (2 weeks if history of syncope)
Generator change	NR Wound healing and PM functioning has to be confirmed	2 weeks and wound healing and PM functioning has to be confirmed	1 week	1 week	NR	2 weeks		
Lead revision					4 weeks	12 weeks		

Country	France		Germany		Italy		Netherlands	
Document type	Administrative document		Administrative document		Administrative document		Administrative document	
Driving licence group	Private	Commercial	Private	Commercial	Private	Commercial	Private	Commercial
ICD								
Secondary prevention	3 months	NA	3 months	NA	Tailored ban	NA	2 months	NA
Primary prevention	2 weeks	NA	1 - 2 weeks	NA	Tailored ban	NA	2 weeks	NA
Generator change	NR: according with specialized opinion		1 week		Tailored ban			
Lead revision	NR: according with specialized opinion		1 - 2 weeks					
Primary indication, patient refusing device		NA						
Secondary indication, patient refusing device		NA						
Appropriate therapy	3 months		3 months		Tailored ban		2 months	
Inappropriate therapy	Until measures to prevent subsequent inappropriate therapy are taken		Until measures to prevent subsequent inappropriate therapy are taken		Tailored ban		Until measures to prevent subsequent inappropriate therapy are taken	
PACEMAKER								
Insertion	NR According with specialized opinion	2 weeks According with specialized opinion	NR Wound healing and PM functioning has to be confirmed	1 week (4 weeks if history of syncope or PM dependent patient)	NR	Tailored ban	NR	
Generator change			NR Wound healing and PM functioning has to be confirmed	1 week (4 weeks if history of syncope or PM dependent patient)	NR	Tailored ban	2 weeks	
Lead revision			NR Wound healing and PM functioning has to be confirmed	4 weeks				

Country	Norway		Spain		Sweden		UK	
Document type	Administrative document		Administrative document		Administrative document		Administrative document	
Driving licence group	Private	Commercial	Private	Commercial	Private	Commercial	Private	Commercial
ICD								
Secondary prevention	3 months	NA	3 months	NA	3 months	NA	6 months**	NA
Primary prevention	1 week	NA	2 weeks	NA	2 weeks	NA	4 weeks	NA
Generator change	1 week pain free				2 weeks (Primary prevention)		1 week	
Lead revision	1 week						4 weeks	
Primary indication, patient refusing device								
Secondary indication, patient refusing device	Health requirements apply as with specific cardiac condition	NA						
Appropriate therapy	3 months		3 months		3 months		6 months (if no incapacity). If incapacity: stop for two years. Six months if steps to control arrhythmia are taken (antiarrhythmics/ ablation) and no recurrence. Includes ATP	
Inappropriate therapy	Until measures to prevent subsequent inappropriate therapy are taken		Until measures to prevent subsequent inappropriate therapy are taken		Until measures to prevent subsequent inappropriate therapy are taken		1 month after underlying cause has been removed	
PACEMAKER								
Insertion	1 week	1 week (4 weeks if history of syncope)	2 weeks	4 weeks	NR	2 weeks	1 week	6 weeks
Generator change					NR	2 weeks	1 week	6 weeks
Lead revision								

Table 1: Driving restrictions after implantation of cardiac implantable electronic devices in Europe and in 11 European countries.

* Other conditions: 1) the device has not delivered any treatment (shock and/or ATP for symptomatic tachycardia) within the last 6 months (except for formal clinical testing). 2) No ICD therapy over the past 2 years since implantation of the device has been accompanied by syncope, presyncope or abnormality (either caused by the device or the arrhythmia), except: the underlying cause has been identified and controlled. 3) A break of 1 month after each change of antiarrhythmic drug treatment should be followed. ** Driving may resume 1 month after implantation provided all of the following are met: 1) presentation was a "non-disqualifying" cardiac event (i.e. haemodynamically stable sustained ventricular tachycardia without incapacity), 2) left ventricular ejection fraction is greater than 35%, 3) any ventricular tachycardia (VT) induced on electrophysiological study (EPS) has RR interval greater than 250 milliseconds, 4) during the post implantation EPS, any induced VT could be pace-terminated by the ICD twice, without acceleration. If any of the above not met, must not drive for 6 months following implantation; ATP = antitachycardia pacing; CA = cardiac arrest; EPS = electrophysiological study; ICD = implantable cardioverter defibrillator; LVEF = left ventricular ejection fraction; NA = not allowed; NR = no restriction; PM = pacemaker; SVT = sustained ventricular tachycardia; VF = ventricular fibrillation; VT = ventricular tachycardia.

References (52, 74-87).

Country	Europe		US		Canada		Australia		Japan	
Document type	Consensus document		Consensus document		Administrative document		Consensus document		Consensus document	
Driving licence group	Private	Commercial	Private	Commercial	Private	Commercial	Private	Commercial	Private	Commercial
ICD										
Secondary prevention	3 months	NA	6 months	NA	1 week post implant and 3 months after last SVT episode without impaired consciousness or 6 months if syncopal VT/VF.	NA	6 month after CA or 2 weeks after implant (whichever the longest)	NA	6 months	NA
Primary prevention	4 weeks	NA	1 week	NA	4 weeks	NA (but may drive if risk of events < 1%/year)	2 weeks	NA	1 week	NA
Generator change	1 week						2 weeks		1 week	
Lead revision	4 weeks								1 week	
Primary indication, patient refusing device	NR	NA								
Secondary indication, patient refusing device	7 months	NA								
Appropriate therapy	3 months		6 months		6 months (if loss of consciousness or disabling symptoms. ATP included)		4 weeks (if symptoms of hemodynamic compromise		3 months	
Inappropriate therapy	Until measures to prevent subsequent inappropriate therapy are taken		6 months						NR (3 months if syncope)	
PACEMAKER										
Insertion	NR Wound healing and PM functioning has to be confirmed	2 weeks and wound healing and PM functioning has to be confirmed	NR (1 week if pacemaker dependent)	NR (4 weeks if pacemaker dependent)	1 week	4 weeks	2 weeks	4 weeks	1 week	NA until PM integrity is ascertained
Generator change	NR Wound healing and PM functioning has to be confirmed	2 weeks and wound healing and PM functioning has to be confirmed								
Lead revision										

Table 2: Driving restrictions after implantation of cardiac implantable electronic devices in 5 countries around the world.

References (36, 50, 88-90)

	Private	Commercial
EU	Ordinary motor cycles, cars and other small vehicles with or without a trailer	Vehicles over 3.5 metric tons or passenger-carrying vehicles exceeding eight seats excluding the driver
Austria	Similar to EU	Similar to EU
Belgium	Similar to EU	Similar to EU
Denmark	Similar to EU	Similar to EU
France	Similar to EU	Similar to EU
Germany	Similar to EU	Similar to EU
Italy	Similar to EU	Similar to EU
Netherlands	Similar to EU	Similar to EU
Norway	Similar to EU	Similar to EU
Spain	Similar to EU	Similar to EU
Sweden	Similar to EU	Similar to EU
UK	Similar to EU	Similar to EU
US	Drivers who do not meet commercial drivers' definition	Vehicles weighing >26,001 pounds; truck with double/triple trailers or carrying hazardous materials; passenger vehicles designed to carry >16 passengers including the driver
Canada	Driver who drives < 36,000 km/year or spends < 720 h/year behind the wheel and drives a vehicle < 11 tons and does not earn a living from driving	Drivers who do not meet private drivers' definition
Australia	Cars < 4.5 tons and seating up to 12 adults including the driver or light rigid vehicle between 4.5 and 8 tons (or 9 tons if having a trailer)	Any vehicle > 8 tons (or 9 tons with a trailer), carrying public passengers for hire or reward, carrying dangerous goods or working as a driver instructor
Japan	Driver of ordinary motor cycles, cars and other small vehicles with or without a trailer and does not earn a living from driving	Drivers who drive for a commercial operation (including taxi, bus, private ambulance)

Table 3: Driving licence categories in 16 countries.

References (33, 50, 75-79, 81-86, 89-94)