



Review

Driving restrictions in patients with implantable cardioverter defibrillators and pacemakers

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ABSTRACT

Implantable cardioverter-defibrillators (ICDs) improve the survival in patients at risk of sudden cardiac death. However, these patients have an ongoing risk of sudden incapacitation that may cause harm to individuals and others when driving. Considerable disagreement exists about whether and when these patients should be allowed to resume driving after ICD therapies. This information is critical for the management decisions to avoid future potentially lethal incidents and unnecessary restrictions for ICD patients. The cardiac implantable device committee of the Japanese Heart Rhythm Society reassessed the risk of driving for ICD patients based on the literature and domestic data. We reviewed the driving restrictions of ICD patients in various regions and here present updated Japanese driving restrictions.

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Contents

1. Introduction	594
2. Syncope while driving a motor vehicle	595
3. Driving-related arrhythmias and ICD discharges while driving.	595
4. Risk assessment of patients and bystanders	595
5. Definition of private drivers and commercial (professional) drivers.	596
6. Risk of harm and driving restrictions for private drivers (secondary prevention patients)	596
7. Risk of harm and driving restrictions for private drivers (primary prevention patients).	596
8. Risk of harm and driving restrictions for commercial drivers (both primary and secondary prevention patients)	597
9. Driving restrictions after inappropriate ICD therapies.	597
10. Replacement of ICD and lead system	599
11. Pacemakers	599
12. Adherence to driving restrictions after ICD therapies	599
13. Automobile accidents in the elderly	599
14. Conclusions	600
Conflict of interest.	600
Acknowledgment	600
References	600

1. Introduction

Implantable cardioverter-defibrillators (ICDs) improve survival in patients who have been resuscitated from ventricular fibrillation (VF) or ventricular tachycardia (VT) (i.e., secondary prevention of sudden cardiac death) as well as primary prevention of sudden

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cardiac death. An increasing number of patients are implanted with ICDs in Europe (EU) and the United States (US) [1] and [2]. The Japan Arrhythmia Device Industry Association (JADIA) reported that 5789 and 5969 ICDs and cardiac resynchronization therapy with defibrillators (CRT-Ds) were implanted in 2014 and 2015, respectively [3]. From 2006 to 2016, approximately 60,000 patients have been implanted with ICDs or CRT-Ds [3].

Most ICD patients may be healthy enough to drive a motor vehicle. However, patients with ICDs are known to experience complete or partial loss of consciousness. The privilege of driving is cherished, but driving restrictions are necessary when it poses a threat to others. According to literature, the rate of syncope or loss of consciousness associated with ICD therapy varies widely [4–9] and [10]. Many countries have regulations for driving restrictions in ICD patients, but large varieties exist between countries [11–15] and [16]. These large varieties are due to the lack of information about the rate of syncope while driving, which results in serious harm or death in ICD patients.

The cardiac implantable device committee of the Japanese Heart Rhythm Society reassessed the risk of driving in ICD patients based on the literature and domestic data. We reviewed the driving restrictions of ICD patients in various regions and present a revised regulation of the Japanese driving restrictions. This information is critical for the management decisions to avoid future potentially lethal incidents and unnecessary restrictions for ICD patients.

2. Syncope while driving a motor vehicle

Syncope is a common clinical problem, with an incidence rate of 6.2 per 1000 person-years in the Framingham study [17], and is often recurrent [18]. Syncope while driving has evident personal and public implications, but data on the causes and outcome of syncope while driving are scarce. Previous observational studies reported that the most frequently identified causes are neurally mediated syncope, followed by tachycardic or bradycardic arrhythmias, and orthostatic hypotension [19] and [20]. Among the arrhythmias in these patients, supraventricular tachycardia and VT are more frequently observed than bradycardia [19] and [20]. Notably, the recurrence rate of syncope while driving is only 0.7% at 6 months and 1.1% at 12 months. Furthermore, most of these patients with syncope while driving have had an underlying diagnosis of not arrhythmia but neurally mediated syncope. These data suggest that patients with syncope while driving can resume driving with a relatively low risk of harm to drivers and bystanders [21] and [22].

3. Driving-related arrhythmias and ICD discharges while driving

Driving brings mental and physical stress. It causes an increased heart rate, blood pressure, and peripheral resistance through elevated sympathetic activity [23]. An early study showed that significant ST depression and T wave changes develop while driving in patients with ischemic heart disease [24]. This study also showed that even healthy subjects have significant ST–T changes while driving. Such elevated sympathetic activity while driving is expected to lead to an increased propensity for arrhythmias. However, only a few studies have examined driving-related arrhythmias.

An early study by Trappe et al. [6] showed that 8 out of 241 ICD patients (5%) had ICD shocks while driving but they were not associated with syncopal symptoms. Only one accident was caused by the driver, but it was not related to syncopal symptoms

or an ICD therapy. The Antiarrhythmics Versus Implantable Defibrillators (AVID) trial, which compared the survival benefit between antiarrhythmic drug therapy and ICDs in patients who had been resuscitated from VT or VF, showed that 8% of 295 patients had ICD shocks while driving but they were not related to accidents [8] and [25].

The triggers of ventricular arrhythmia study [26] compared the risk of the occurrence of VT/VF during and up to 60 min after driving with that during other activities among 1188 ICD patients. Of the 193 total ICD shock episodes for VT or VF, 44 occurred within 1 h of driving a car among 23 patients. Of the 44 ICD shocks that occurred within 1 h of driving, 7 (16%) occurred during driving, 30 (68%) occurred 30 min immediately after beginning driving, and 7 (16%) occurred during the last 30-min period. An ICD shock for VT or VF was twice as likely to occur within 1 h of driving a car as compared with that during other activities or rest. However, none of the shocks for VT or VF that occurred while driving resulted in lightheadedness or syncope, and only 1 resulted in an automobile accident. Patients who received ICDs for primary prevention were shown to be less likely to abstain from driving compared with secondary prevention.

According to an early survey in 452 physicians in the US, 30 motor vehicle accidents related to shocks from ICDs occurred over a 12-year period from 1980 to 1992 [27]. Eight patients died due to loss of consciousness with the device firing while the patient was driving, and one passenger died in a vehicle driven by a patient with an ICD. This survey found that 10.5% (30 of 286 total reported shocks) of ICD shocks during driving resulted in accidents. The authors estimated the fatality rate for patients with an ICD of 7.5/100,000 patient-years, which was significantly lower than that for the general population (18.4/100,000 patient-years, $p < 0.05$).

Few studies have specifically examined the incidence of ICD discharges while driving in patients receiving ICDs for primary prevention. However, the low frequency of ICD shocks and very low rate of syncopal episodes reported in the recent primary prevention ICD trials [9,28–30] and [31] suggest that the incidence rate of ICD shocks while driving may be lower than that in secondary prevention patients. Furthermore, strategic arrhythmic programs, including higher detection rates, longer detection intervals, antitachycardia pacing, and optimized supraventricular tachycardia discriminators, reduce ICD shocks without increasing arrhythmic syncope among ICD patients for primary prevention [9,28–30] and [31]. Taken together, this evidence suggests that ICD patients should not translate into a significant rate of personal or public injury.

4. Risk assessment of patients and bystanders

The effect of an ICD shock delivery on the level of consciousness and ability to drive is an obvious concern. Data regarding the risks associated with driving in ICD patients are primarily retrospective, with no prospective, randomized trials dividing patients into driving with or without restrictions. The “risk of harm (RH)” analysis provided useful information for future consideration of driving to improve the public safety for both the patients and general public.

The Canadian Cardiovascular Society Consensus Conference postulated an RH formula [32] to quantify the level of risk to drivers and bystanders according to the Ontario Road Safety Annual Report [33]. This formula has been used in many other reports to provide the policy for driving restrictions [14,22,34,35] and [36]. The risk of harm formula is shown below:

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

which calculates the yearly RH to other road users posed by a driver with heart disease.

- (1) **TD** equals the proportion of time the patient spends driving during the year, which is 0.04 (4%, 1 h/day) for the private driver and 0.25 (25%, 6 h/day) for the commercial driver [33].
- (2) **V** is a vehicle-specific constant based on the type of vehicle driven. In the RH formula, it is defined that $V=1$ for a commercial heavy truck and $V=0.28$ for a standard-size passenger car.
- (3) **SCI** is the annual probability of sudden cardiac incapacitation, which is estimated to be 0.01 (1%/year) by the Canadian Cardiovascular Society and the Canadian Council of Motor Transport Administrators.
- (4) **Ac** is the probability of injury or an accident after the SCI and is estimated to be 0.02 for all drivers. Substituting these values in the RH formula results in the following risk:

$$RH = TD \times V \times SCI \times Ac = 0.25 \times 1 \times 0.01 \times 0.02 = 0.005.$$

The Canadian Cardiovascular Society and the Canadian Council of Motor Transport Administrators proposed an annual RH to others of 5 in 100,000 (0.005%) as a cut-off value.

The RH while driving after the first ICD shock for private drivers is estimated as follows. For example, the cumulative incidence of second shock at 6 months is 10% (0.1); the incidence at 6 months is multiplied by 2 to obtain an annual risk ($0.1 \times 12/6 = 0.2$) because the RH formula uses the annual risk for SCI. The risk for SCI is then estimated by multiplying the annual risk for receiving a second ICD shock (0.2) by the probability of syncope associated with a shock (i.e., 0.3), ($0.2 \times 0.3 = 0.06$). Then, the $RH = 0.04 \times 0.28 \times 0.06 \times 0.02 = 1.3/100,000$, which is below the acceptable level of 5/100,000. However, for the commercial truck driver, the $RH = TD (0.25) \times V (1) \times SCI (0.06) \times Ac (0.02) = 30/100,000$, which exceeds the acceptable level. Therefore, commercial drivers are not certified for commercial driving if they have received ICDs.

5. Definition of private drivers and commercial (professional) drivers

In Japan, class 1 driver's license (private drivers) is defined as any licensed driver of ordinary motorcycle, automobiles, and other vehicles with or without a trailer, and does not earn a living by driving. A commercial driver (class 2 driver's license) is defined as one who drives for a business (commercial operation) including a taxi, bus, or private ambulance. Those who received ICDs can drive an ordinary automobile weighing < 5000 kg, but cannot drive motorcycles or passenger-carrying vehicles. There are no restrictions in the time spent behind the wheel or distance driven in a given time period. In Canada, a private driver is defined as one who drives < 36,000 km/year or spends < 720 h/year behind the wheel, 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 [37] and [38]. In EU, Group 1 (private drivers) is comprised of drivers of ordinary motorcycles, cars, and other small vehicles with or without a trailer. Group 2 (professional drivers) includes drivers of vehicles over 3.5 metric tons or passenger-carrying vehicles exceeding eight seats excluding the driver [14] and [16]. In the US, a commercial driver is defined as one who drives any single vehicle with a weight of 26,001 pounds or more, truck with double or triple trailers, or truck with a tank, or a truck carrying hazardous materials. It also includes a passenger vehicle designed to transport 16 or more passengers (including the driver) [39] and

[40]. There are subclasses of private and commercial drivers in each state.

6. Risk of harm and driving restrictions for private drivers (secondary prevention patients)

As presented in the previous section, the factors that affect the RH are the recurrence rate of ICD shock, and the probability of a loss of consciousness associated with an ICD shock while driving. Given the limited data on the probability of ICD shocks while driving associated with syncopal symptoms, we used the syncope rate associated with ICD shocks instead (not limited to a shock while driving). According to the literature that included mainly secondary prevention patients, the mean incidence rate of syncope associated with appropriate ICD shocks was 11.2% (Fig. 1).

Thijssen et al. [35] calculated the annual RH to others posed by a driver with an ICD using 2786 patients (primary prevention 62%). When a syncope rate of 32% associated with an ICD shock was used, the RH fell below the accepted threshold (0.005%) at 2 months after an initial shock in the primary prevention group and at 4 months after an initial shock in the secondary prevention group. Recently, Merchant et al. [36] reported an RH using large data extracted from remote monitoring systems. They examined the 73,503 ICD recipients who were followed by a remote monitoring system and analyzed 14,230 (19.4%) patients who experienced at least 1 ICD shock. When a frequency of syncope of 32% associated with an ICD shock was used [7] and [35], the RH fell below the accepted threshold (0.005%) at 4–6 months after the initial shock. However, the use of a contemporary estimate for syncope associated with an ICD shock of 14% [36] showed that the RH fell below the threshold at 1 month after the initial shock. We calculated the RH while driving in the Japanese ICD survey 2 using a likelihood of syncope of 9.5% (Fig. 2). We found that the RH fell below the accepted threshold (0.005%) at 3 months after an initial shock. Based on the evidence and these calculations, current restrictions on driving advise patients with an ICD implanted for secondary prevention to avoid operating a motor vehicle for 3 months for Japan and EU [14] and 6 months after the last ICD shock in the US [11,12] and [13] and UK [16] (Table 1). In the UK, refraining from driving for 1 month after the initial implantation is recommended in secondary prevention patients who have sustained VT with incapacity. In addition, avoidance of driving for at least 6 months after an initial implantation is recommended in Japan, the US [13], and the UK [16], and 3 months in EU [14] (Table 1).

7. Risk of harm and driving restrictions for private drivers (primary prevention patients)

Patients with ICDs for primary prevention are considered at lower risk for sudden incapacitation while driving compared with the secondary prevention population. We summarized the syncope rate and patient characteristics in recent reports aimed to assess strategic programming in mainly primary prevention patients (Fig. 3). The mean incidence rate of syncope was calculated to be 1.6%, which was approximately one-tenth of that in the secondary prevention patients. Patients who have received an ICD for primary prevention who subsequently receive an appropriate therapy for VT or VF should be considered to be subject to the driving guidelines like secondary prevention. In addition, avoidance of driving for at least 7 days after the initial implantation to allow for healing has been recommended in Japan and the US [13], and 1 month for the UK [16] and EU [14] (Table 1).

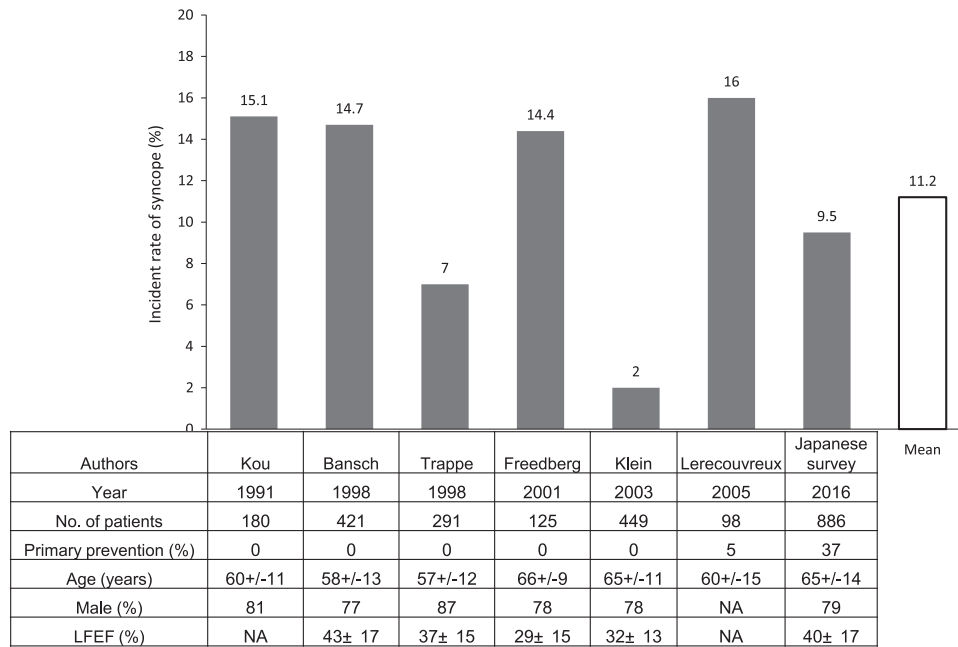


Fig. 1. Incidence rate of syncope associated with appropriate ICD therapies in secondary prevention patients. Literature reported incidence rates of syncope associated with appropriate ICD shock deliveries are presented in a chronological order. These earlier studies primarily included more secondary prevention patients. The mean value of the seven studies (Kou [4], Bansch [5], Trappe [6], Freedberg [7], Klein [8], Lerecouvreux [56], and the Japanese survey for appropriate ICD therapies (Japanese ICD survey 2)) was 11.2%. In the Japanese ICD survey 2, the appropriate ICD therapy event data between 1997 and 2014 from 58 Japanese institutions were analyzed retrospectively (unpublished data). In brief, 1415 appropriate ICD therapies (ATP, cardioversion, and defibrillation for VT/VF) occurring in 886 patients (age 65 ± 14 years, secondary prevention 63%) were analyzed. For the second therapy analysis, only a subsequent inappropriate therapy occurring > 24 h after the first inappropriate shock was considered a second therapy. A total of 532 (60%) experienced a second appropriate therapy during a follow-up period of 3.6 years. ICD: implantable cardioverter-defibrillator, ATP: antitachycardia pacing, VT: ventricular tachycardia, VF: ventricular fibrillation.

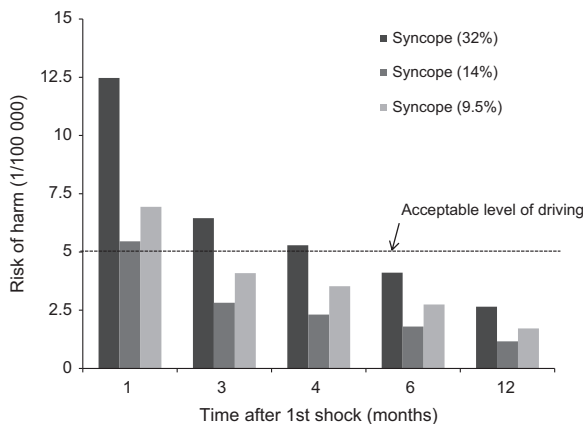


Fig. 2. Annual risk of harm from appropriate ICD therapies in a Japanese survey. The annual risk of harm in ICD patients based on the cumulative incidence of appropriate ICD therapies is illustrated. In the Japanese survey for appropriate ICD therapies (Japanese ICD survey 2), the annual RH to others was lower than 5 in 100,000 at 3 months after the first shock. The syncope rates of 32% and 14% were reproduced from Merchant et al. [36].

8. Risk of harm and driving restrictions for commercial drivers (both primary and secondary prevention patients)

For commercial drivers, incapacitation while driving places the driver and bystanders at that time in serious jeopardy. In view of the RH, the risk of commercial drivers exceeds an accepted threshold (0.005%). Therefore, all four driving restrictions presented in this review recommend permanent prohibition of commercial driving after an ICD implantation for secondary and primary prevention (Table 1).

9. Driving restrictions after inappropriate ICD therapies

The driving restrictions after inappropriate ICD therapies differ among countries. This difference is probably due to the not well known incidence of syncope or loss of consciousness with inappropriate shocks. The ICD can provoke or worsen arrhythmias (i.e., proarrhythmia) that may result in syncope [41] and [42]. We analyzed inappropriate ICD therapy event data from 50 Japanese institutions (Japanese ICD survey 1, unpublished data). A total of 772 inappropriate ICD therapies occurring in 417 patients (age 61 ± 15 years, primary prevention 65%) were examined. Patients experiencing an inappropriate therapy had a mean number of 1.8 ± 1.5 therapy episodes during the mean follow-up period of 5.2 years. Only 3 patients (0.7%) experienced syncope associated with inappropriate therapies. The RH formula revealed that the annual RH to others was 0.16 in 100,000 immediately after an onset of inappropriate therapy, which was far below the acceptable level of 5 in 100,000.

Previous Japanese driving restrictions for ICD patients advised no driving for 12 months after receiving either an appropriate or inappropriate therapy [15]. However, based on the data described above, the current driving restrictions advise that private drivers do not have to refrain from driving after receiving an inappropriate ICD therapy if it was not associated with a loss of consciousness (Table 1). However, if drivers lost consciousness at the time of the inappropriate therapy, they should abstain from driving for 3 months. In the US, a private driver has to cease from driving for 6 months after receiving an inappropriate therapy and no difference exists in the restriction between appropriate and inappropriate therapies [43]. In the UK, a patient has to refrain from driving for 1 month after the cause of the inappropriate therapy has been corrected [16]. In EU, no period of time is set but the

Table 1
Driving restrictions in patients with ICD and pacemaker in four regions.

	License type	Japan	UK	USA	EU
Pacemaker implant	Class 1	Cease driving for 1 week	Cease driving for 1 week	Cease driving for 1 week	Cease driving for 1 week
	Class 2	Disqualified until pacemaker integrity is ascertained.	Cease driving for 6 weeks	Cease driving for 4 weeks	Disqualified if persistent symptoms.
ICD implant for VT/VF with incapacity (secondary prevention)	Class 1	Cease for 6 months after first implant	Cease for 6 months after first implant	Cease for 6 months after first implant	Cease for 3 months
	Class 2	Permanently bars	Permanently bars	Permanently bars	Permanently bars
ICD implant for sustained VT without incapacity (secondary prevention)	Class 1	Cease for 6 months after first implant	Cease for 1 month after first implant provided all of the following are met: (a) LVEF > 35% (b) No fast VT on EPS (c) Any induced VT could be pace-terminated by the ICD twice, without acceleration, during the post-implantation study.	Cease for 6 months after implant	Cease for 3 months after implant
	Class 2	Permanently bars	Permanently bars	Permanently bars	Permanently bars
Prophylactic ICD implantation (primary prevention)	Class 1	Cease for 1 week	Cease for 1 month	Cease for 1 week	Cease for 4 weeks
	Class 2	Permanently bars	Permanently bars.	Permanently bars	Permanently bars.
ICD and lead system replacement	Class 1	Cease for 1 week after replacement of the lead system or replacement of the ICD.	Cease for 1 month after a revision of the leads or antiarrhythmic drug change.	No specific guidance	Cease for 4 weeks after replacement of the ICD and lead system or the lead system alone. Cease for 1 week after replacement of ICD.
Delivery of ICD therapy	Class 1	Cease for 3 months after appropriate therapy Inappropriate therapy: no restrictions for asymptomatic episodes. Cease for 3 months in case of syncope.	Appropriate shock+symptomatic ATP: Cease for 6 months with corrective measures to prevent recurrence provided no further symptomatic therapy Inappropriate therapy: cease for 1 month after the cause of the inappropriate therapy was corrected.	Cease for 6 months after appropriate therapy Inappropriate therapy: no distinction made from appropriate therapy.	Cease for 3 months after appropriate therapy Inappropriate therapy: cease until cause of inappropriate therapy was corrected.

Adapted from References [11–16], and [34].

ICD: implantable cardioverter-defibrillator, ATP: antitachycardia pacing, VT: ventricular tachycardia, VF: ventricular fibrillation, LVEF: left ventricular ejection fraction, EPS: electrophysiologic test.

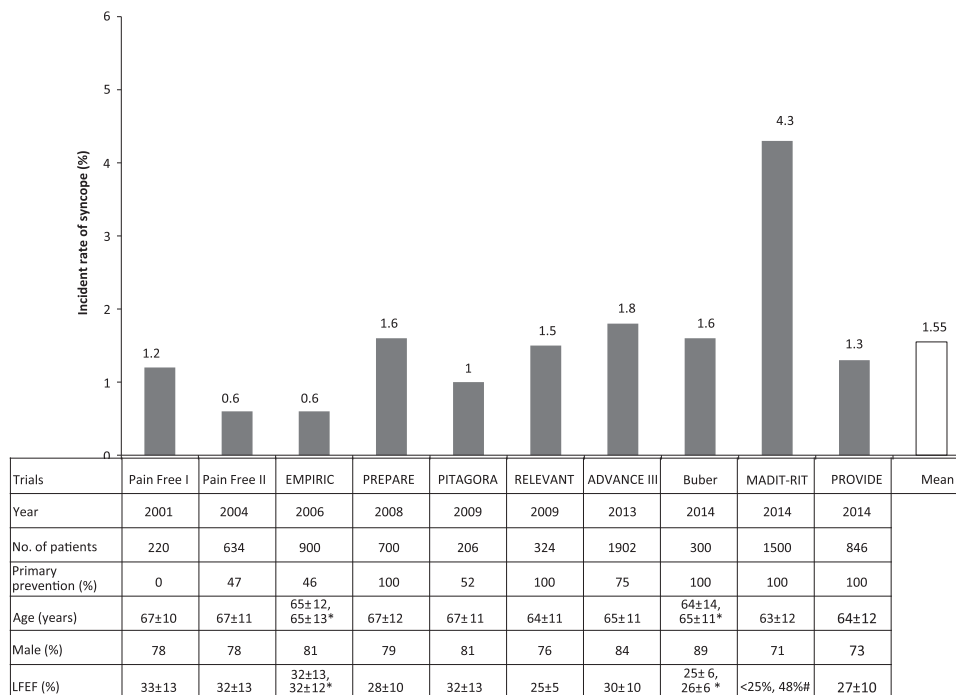


Fig. 3. Incidence rate of syncope associated with appropriate ICD therapies in primary prevention patients. Literature has reported the incidence rate of syncope associated with appropriate ICD shock deliveries sorted in a chronological order. These studies aimed to examine the effect of strategic programming mainly for primary prevention patients. The mean value of the ten studies (Pain Free I [57], Pain Free II [58], Comparison of Empiric to Physician-Tailored Programming of ICDs (EMPIRIC) [59], Primary Prevention Parameters Evaluation (PREPARE) [28], PITAGORA [60], Role of Long Detection Window Programming in Patients With Left Ventricular Dysfunction, Non-ischemic Etiology in Primary Prevention Treated with a Biventricular ICD (RELEVANT) [29], Avoid Delivering Therapies for Nonsustained Arrhythmias in ICD Patients III (ADVANCE III) [61], Buber [9], Multicenter Automatic Defibrillator Implantation Trial—Reduce Inappropriate Therapy (MADIT-RIT) [30], and Programming Implantable Cardioverter-Defibrillators in Patients with Primary Prevention Indication to Prolong Time to First Shock (PROVIDE) [31]) was 1.6%.

patient is not allowed to drive until the cause of the inappropriate therapy is corrected (Table 1) [14].

10. Replacement of ICD and lead system

In Japan, a driving restriction of 1 week is recommended when an ICD or lead system is replaced and the system integrity should be ascertained before resumption of driving (Table 1). The task force of EU recommends a driving restriction for 1 week when only the ICD is replaced. The UK recommends a driving restriction for 1 month after a revision of the leads or antiarrhythmic drug change [14] and [16]. The US does not have a specific guidance for driving restriction after replacement of ICD and lead system.

11. Pacemakers

In Japan, 1 week before resumption of driving following a pacemaker implantation (including cardiac resynchronization therapy pacemaker) or generator replacement is recommended to allow healing for private drivers [44,45], which is similar to those in the US [45] and EU [18]. Commercial drivers should be disqualified until the pacemaker integrity was ascertained [44] (Table 1).

12. Adherence to driving restrictions after ICD therapies

Driving a motor vehicle plays an important role in emotional and economic health, and a driving ban impacts one's QOL [46]. ICD recipients perceive a loss of independence and changed self-image when they have restrictions of driving [47]. Several studies

reported a low adherence rate among ICD recipients to the driving ban despite advice by physicians or healthcare providers [25,48–50] and [51]. The AVID Trial [50] showed that the majority of patients (58%) resumed driving an automobile within 6 months of their index arrhythmia. They found that being younger than 65 years of age, college educated men, and those whose index arrhythmia was VT were more likely to resume driving early. Carney et al. [49] examined the factors that influence the resumption of driving despite a driving ban instruction by their physician. In this study, 74% of the 97 patients reported driving an average of 60 min/week. They found that factors related to driving resumption were an importance of driving to maintaining one's lifestyle, driving for necessity for social reasons, and being the primary driver in the family. Therefore, well-informed discharge education and scheduled follow-up of patients are essential to maintain higher adherence to the driving restrictions. In Japan, a legal regulation exists for driving for ICD recipients. The recipients must submit a medical certificate, which includes the ICD therapy status, to the National Public Safety Commission every 6 months to drive an automobile. They will be punished if an accident occurs while driving despite an order for a driving ban by their physician.

13. Automobile accidents in the elderly

Most of the ICD patients were elderly. In the Japanese ICD Survey 2 data, approximately 70% of patients were aged 60 and older (Fig. 4). In 2015, there were approximately 24 million licensed drivers aged 60 and older in Japan, which comprised 29.4% of all licensed drivers [52]. Traffic accidents have decreased over the past 10 years (0.60 times in 2004), but accidents due to elderly drivers have been high (1.07 times the same) because of the increase in the number of elderly driver licenses [53]. Since

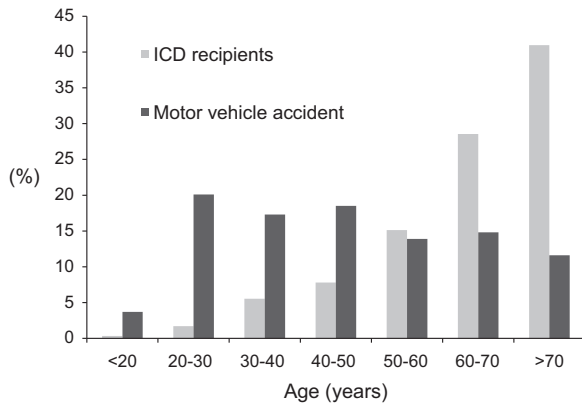


Fig. 4. Age distribution of the ICD recipients and motor vehicle accidents in Japan. The age of the ICD recipients in our ICD survey 2 and motor vehicle accidents in Japan in 2014 are shown. The number of ICD recipients increases in proportion to an advancing age, but the rate of motor vehicle accidents has relatively decreased in the population of more than 70 years old.

the system of voluntary return of a driver's license began in 1998, voluntarily returning persons have been rapidly increasing, exceeding 100,000 in 2012 and exceeding 200,000 in 2014. It doubled in only two years. One of the reasons for the increased voluntary repayment is “preferential treatment of voluntary repayers.” For example, free delivery to homes by some grocery shops, discounts at restaurants for eating and drinking, and preferential treatment by public transportation systems, such as buses and taxis, are also available. Furthermore, since 2017, if drivers over 75 years of age have a traffic accident, they will have to consult a doctor afterwards. If it is diagnosed as cognitive impairment, it will be subject to cancellation or suspension of one's driver's license.

Most of the seniors are characterized by physical changes that may affect serious accidents. These involve a slower reaction time, depth perception change, vision and hearing problems, decreased ability to focus, and medical problems [54]. Compared with accidents caused by young people, accidents due to safety uncertainty for elderly people are particularly high. In Japan, renewal of driver's license of a person over 70 years of age requires attendance of an “Elderly Personnel Course” before the renewal procedure. In brief, this lesson includes a lecture on traffic law or traffic accident statistics, driving aptitude test, and actual vehicle driving, among others. The National Center for Geriatrics and Gerontology in Japan and an automobile school jointly developed a lecture curriculum to improve the safety of driving in elderly people. When tested in the elderly with a decline in cognitive function, the ability for safe driving, including one's attention and judgment, greatly improved, and the effect was sustained even after one year [55].

14. Conclusions

The safety of driving in patients with cardiac arrhythmias is a common concern. All guidelines or statements of the four areas we examined suggest that most ICD patients can resume driving after appropriate or inappropriate shocks with a relatively low risk of harm to themselves and others. It should be emphasized that the risk while driving is mainly a consequence of the underlying heart disease (acute coronary syndrome or heart failure, etc.) and not the presence of an ICD. Driving restrictions are necessary to protect the society from harm, but the lifestyle or QOL of ICD patients should be maintained as well. Therefore, adequate education of driving restrictions for ICD patients and their families is indispensable to comply with driving recommendations. Innovations,

such as self-driving technologies, may be a promising approach to mitigate driving restrictions for the ICD recipients.

Conflict of interest

Dr. Watanabe received a lecture fee from Daiichi-Sankyo and Boehringer Ingelheim Japan.

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