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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.

Contents

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 cardiac death. An increasing number of patients are implanted

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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 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.

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