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#### Review

## Driving restrictions for patients with reflex syncope

### Masataka Sumiyoshi\*

Department of Cardiology, Juntendo University Nerima Hospital, 3-1-10 Takanodai, Nerima-ku, Tokyo 177-9521, Japan

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#### ABSTRACT

Reflex syncope is the most common form of syncope that occurs while driving. The 2014 revision of Japanese Road Traffic Laws placed stricter driving restrictions, along with some associated legal penalties, on individuals with recurrent syncope. "Recurrent syncope" is defined as the occurrence of more than two episodes of syncope over a period of 5 years. No restrictions are recommended for private drivers unless they experience syncope without a reliable prodrome while driving or sitting. For commercial drivers, a driving restriction is recommended unless the efficacy of treatment can be confirmed. The "risk of harm" (RH) to other road users appears to be particularly high when commercial driving is involved. The RH formula is calculated using the time of driving, the type of vehicle driven, the risk of sudden cardiac incapacitation, and the probability of a fatal or injury-producing accident. Reducing the driving time or driving a lighter vehicle can reduce the RH. Physicians should talk to their patients about driving and advise their high-risk patients to refrain from driving.

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### 1. Introduction

Reflex syncope is the most common cause of syncope while driving. Syncope while driving has dangerous implications for personal and public safety; thus, considering the restriction of driving privileges is necessary to protect both the individuals with syncope and the public. However, since most patients do not want to give up driving, restricting driving privileges leads to strained

physician-patient relationships. This must be balanced with public safety [1]. In Japan, motor vehicle driving by patients with recurrent syncope is restricted by the Guidelines for the Diagnosis and Management of Syncope; Japanese Circulation Society (JCS) published online in 2012 [2]. The 2014 revision of the Japanese Road Traffic Law placed stricter restrictions on driving for individuals with loss of consciousness, along with some legal penalties. The Working Group of the Japanese Heart Rhythm Society recently issued a statement regarding driving restrictions for individuals with recurrent syncope; this was to provide a practical application of the JCS 2012 guideline [3]. In this review, I address the current

<sup>\*</sup> Fax: +81 3 5923 3217. E-mail address: sumi@juntendo.ac.jp

evidence concerning syncope while driving, specifically reflex syncope, and the current recommendations for driving fitness in individuals with reflex syncope.

#### 2. Syncope while driving: Crash, injury, and mortality rates

Table 1 provides a summary of the published studies on syncope while driving, which has been reported to occur in 2.9-9.8% of syncopal patients [4-6]. The reported syncope-while-driving crash rate was 0.96-4.4% with a crash-related injury rate of 0.96-3.4% and a crash-related death rate of 0–0.3% [4–7]. Although most of the studies shown in Table 1 involved a very limited number of patients, Soraija et al. [5] studied 3877 consecutive patients who underwent evaluation for syncope at the Mayo Clinic (Rochester, MN, U.S.). Of these 3877 patients, 381 patients (9.8%) had experienced syncope while driving, with a crash-related injury occurring in 109 patients (2.8%) but no crash-related deaths. Soraija et al. also demonstrated that the long-term (>8 years) survival in patients who experienced syncope while driving was comparable to that of an age- and sex-matched cohort from the Minnesota population (p=0.15) [5]. In their study, syncope while driving was commonly caused by reflex syncope (37.3%) and cardiac arrhythmia (11.8%) [5]. A 2016 Danish nationwide cohort study further showed that 1791 of 41,039 patients (4.4%) with syncope had a motor vehicle crash through a median follow-up of 2 years, of which 3.4% (n=1398) led to injury and 0.3% (n=6) led to death [7]. The author of this study concluded that prior hospitalization for syncope was associated with an increased risk of motor vehicle crashes throughout the follow-up period: the 5-year crash risk following syncope was 8.2% compared with 5.1% in the Danish general population [7].

# 3. Reflex syncope while driving: Crash, injury, and mortality rates

Studies of individuals who experienced reflex syncope (or neutrally mediated syncope or vasovagal syncope) while driving are also summarized in Table 1. In patients with reflex syncope,

the occurrence rate of syncope while driving has been reported to be 0.48%-9.4%, whereas that of crash-related injury is reported to be 0%-3.7% [8–11]. There has been only one crash-related death due to reflex syncope [8–11]. Tan et al. [11] assessed the prospective risk of syncope during driving in 418 patients who had multiple episodes of vasovagal syncope. Only two patients experienced syncope while driving without fatality or injury during the follow-up of 0.77 years per person, with a likelihood of 0.62% per person-year. Tan et al. concluded that the estimated risk of serious harm or death was < 0.0035% per person-year in highly symptomatic vasovagal syncope patients, less than the risk of serious harm or death in the general population of the U.S., United Kingdom, and Canada [11].

#### 4. Recurrence of syncope while driving

The recurrence rate of syncopal episodes in individuals with a history of syncope while driving was reported as 3.4-26% [4,5,9,10], but the recurrence rate of syncope while driving was much lower at 1.0-4.3% (Table 1) [4,5,9,10]. Soraija et al. [5] reported that 14.1% of the 381 patients who experienced syncope while driving had another syncopal episode within 1 year of follow-up even though the annual recurrence of syncope while driving was 1.1%. Conflicting results concerning the estimated risk of driving a motor vehicle among individuals with syncope were reported in 2016. The author of the above-cited Danish nationwide cohort study [7] concluded that prior hospitalization for syncope was associated with an increased risk of motor vehicle crashes throughout the follow-up period, but as Chen-Scarabelli and Scarabelli [12] have pointed out, the patients in the Danish study were older (median age: 66 years) with a high incidence of cardiovascular disease (34.8%) [7]. Therefore, although the causes of syncope were not reported in the Danish study, this group of patients possibly had syncope due to causes other than reflex syncope [12]. In contrast, in Tan et al.'s recent study of highly symptomatic patients with vasovagal syncope, the subjects were younger (mean age:  $38 \pm 17$  years) and had a low incidence (0.48%) of syncope while driving and a low estimated risk of serious harm or death ( < 0.0035% per person-year) [11].

**Table 1** Studies of syncope while driving.

Author	Sheldon	Bhatia	Li	Maas	Soraija	MacMahon	Nume	Tan
Reported year	1995	1999	2000	2003	2009	2012	2016	2016
Area		Milwaukee	Nebraska		Minnesota		Denmark	
Objective	NMS	NMS	NMS	syncope	syncope	syncope	syncope	vasovagal syncope
No. of patients	209	155	245	104	3877	64	41039	418
Age of patients	$42 \pm 19 \text{ yrs}$	$49 \pm 19 \text{ yrs}$		48 ± 16 yrs		72 yrs (median)	66 yrs (median)	$38 \pm 17 \text{ yrs}$
Synope while driving	5 (2.3%) 0.33%/driver-year	2 (1.3%)	23 (9.4%)	3 (2.9%)	381 (9.8%)	2 (3.1%)		2 (0.48%) 0.62%/person-year
Presence of prodrome	3		61%		87%			71 · · · · · · · · · · · · · · · · · · ·
Crash	4 (1.9%) 0.26%/driver-year	1 (0.65%)		1 (0.96%)		1 (1.6%)	1791 (4.4%)	0
Crash-related injury	2 (0.96%) 0.13%/driver-year	1 (0.65%)	9 (3.7%)	1 (0.96%)	109 (2.8%)	1 (1.6%)	1398 (3.4%)	0
Crash-related death	0	0	1	0	0	0	6 (0.3%)	0
Cessation of driving		6 (3.9%)	4 (17%)	2 (1.9%)				
Recurrence of syncope		5/149 (3.4%)	6 (26%)	19 (18%)	72 (19%)			
Recurrence of syncope while driving		0	1 (4.3%)	1 (1%)	10 (2.6%)			
					1.1%/year			
Follow-up period		22 mo (median)	4.3 yrs (mean)	1 yr	3.9 yrs (mean)			
Reference no.	8	9	10	4	5	6	7	11

NMS: neurally mediated syncope.

#### 5. Risk of harm

The Canadian Cardiovascular Society (CCS) provided a formula to calculate the "risk of harm" (RH) while driving (Table 2) [13]. The RH to other road users posed by a driver with heart disease is assumed to be directly proportional to the following: (1) the time spent behind the wheel or distance driven in a given time period (the proportion of time of driving: TD): 0.04 or 16,000 km/year for the average private car driver, and 0.25 or 138,000 km/year for the average commercial driver; (2) type of vehicle driven (V): 1.0 for a commercial heavy truck and 0.28 for a standard-size passenger car; and (3) the risk of sudden cardiac incapacitation (SCI): 0.01. The SCI value was calculated as follows: when a heavy truck driver wants to return to his/her occupation as a driver in Canada following an acute myocardial infarction without any complications after 3 months post-infarction, on the basis of available data, such a person cannot be assigned a risk of cardiac death in the next year lower than 1%. The risk of sudden death would be lower than this but would be at least partially offset by the risk of other suddenly disabling events such as syncope or stroke. For such a person, the SCI is estimated to be equal to 0.01 in the RH formula; and (4) the probability that such an event will result in a fatal or injuryproducing accident (Ac): 0.02.

This statement is expressed by the formula:  $RH=TD\times V\times SCI\times Ac$ . Based on the above calculations, an acceptable RH was considered to be 0.00005 (0.005%) (Table 2). Of note, this equation includes the time spent driving and the special risk of a trucking accident given the size of the vehicle.

#### 5.1. Definition of private and commercial drivers

There is no practical definition to distinguish between private and commercial driving except for the CCS Consensus Conference report [13]. The CCS Consensus defined criteria to distinguish a private driver from a commercial driver on the basis of the number of kilometers driven per year, the number of hours per year behind the wheel, the weight of the vehicle, and whether the vehicle is used to earn a living [13]. A private driver is defined as one who drives fewer than 36,000 km/year or spends fewer than 720 hours/year behind the wheel, drives a vehicle less than 11,000 kg, and does not earn a living by driving. A commercial driver is defined as any licensed driver who does not fulfil the definition of a private driver.

#### 5.2. Risk of harm for private driving

Using the data reported by Soraija and colleagues [5], which demonstrated that the actuarial recurrence of syncope over the first 12 months was 14.1%, the RH for average private driving is equal to  $0.04 \times 0.28 \times 0.141 \times 0.02 = 0.00003$  (0.003%). This value is considered to be an acceptable risk because it is less than 0.00005 (Table 3).

Table 2
"Risk of Harm" formula.

#### Risk of Harm (RH)= $TD \times V \times SCI \times Ac$

**TD** (the annual proportion of time of driving): time spent behind the wheel or distance driven in a given time period;

0.04~(16,000~km/year) for the average private driver, 0.25~(138,000~km/year) for the average commercial (professional) driver

**V** (**type of vehicle driven**): V=1.0 for a commercial heavy truck and V=0.28 for a standard-size passenger car

SCI (the annual probability of sudden cardiac incapacitation): SCI = 0.01; refer to the text

Ac (the probability of injury or accident after SCI): Ac=0.02 for all drivers Allowing such a driver on the road is associated with an annual risk of death or injury to others of approximately 1/20,000 (0.00005).

RH=0.25 (TD)  $\times$  1 (V)  $\times$  0.01 (SCI)  $\times$  0.02 (Ac)=0.00005 (0.005%) This level of risk appears to be generally acceptable.

Table 3

"Risk of Harm" formula for individuals with syncope while driving.

# Risk of Harm (RH)=TD (private or commercial) $\times$ V (0.28: standard-size or 1.0: heavy truck) $\times$ SCI (annual recurrence rate of syncope) $\times$ Ac (0.02)

The generally acceptable level of RH is 0.005% per year (the standard value). The annual recurrence rate of syncope was 14.1% according to the Mayo Clinic study.

1. Private driving: average TD is 0.04

 $RH = 0.04 \times 0.28 \times 0.141 \times 0.02 \text{ (Ac)} = 0.00003 \text{ (0.003\%)}$ 

2. Commercial driving

1) Canadian standard: average TD=0.25 Standard-size car: RH=0.25  $\times$  0.28  $\times$  0.141  $\times$  0.02=0.0002 (0.02%) Heavy truck: RH=0.25  $\times$  1  $\times$  0.141  $\times$  0.02=0.00071 (0.071%) 2) CCS definition: minimum TD=0.082 (TD was calculated as 720 h per yr) Standard-size car: RH=0.082  $\times$  0.28  $\times$  0.141  $\times$  0.02=0.000065(0.0065%) Heavy truck: RH=0.082  $\times$  1  $\times$  0.141  $\times$  0.02=0.00023 (0.023%)

In the RH formula, when the average daily driving time exceeds approx.  $90 \, \text{min}$  (standard-size car) or approx.  $30 \, \text{min}$  (heavy truck),

the RH exceeds the accepted value of 0.005%.

CCS: Canadian Cardiovascular Society.

a from reference [5].

#### 5.3. Risk of harm for commercial driving

The RH for average commercial driving is calculated in the following manner:  $0.25 \times 0.28 \times 0.141 \times 0.02 = 0.0002$  (0.02%) for standardsize vehicle driving and  $0.25 \times 1.0 \times 0.141 \times 0.02 = 0.00071$  (0.071%) for heavy truck driving (Table 3). These values are four and 14.2 times higher than the acceptable RH of 0.00005 and 0.005%, respectively. The RH for commercial driving is thus considered to be socially unacceptable. However, according to the above-mentioned definition of the CCS Consensus [13], a commercial driver is defined as a driver who spends at least 720 hours per year or more behind the wheel. As calculated with this definition, the minimum proportion of TD is 0.082 (calculated as 720 hours per year). As a result, the RH is reduced to 0.000065 (0.0065%) for standard-size driving and 0.00023 (0.023%) for heavy truck driving (Table 3). The RH values could be thus reduced to 1.3 and 4.6 times greater than the acceptable RH of 0.00005, respectively. Reductions of driving time or driving a lighter vehicle could reduce the RH. However, as Curtis and Epstein [14] commented from a public safety perspective, the restrictions for commercial driving must be much more stringent than for private driving, often involving permanent prohibition of operating a commercial vehicle.

#### 6. Driving restrictions for patients with reflex syncope

Table 4 shows the driving recommendations for patients with reflex syncope described in the JCS 2012 Guideline [2]. In patients with a single or a *mild* syncopal episode, there is no restriction for private driving. For commercial driving, there is no restriction unless driving with a high-risk activity (such as driving on a highway at high speed). "*Mild* syncope" is defined as no syncope occurring without a reliable prodrome while driving or sitting.

Patients with *recurrent* or *severe* syncopal episodes are recommended to restrict their private driving until their symptoms are controlled. For commercial driving, driving restrictions are recommended unless effective treatment has been established. In this situation, "*recurrent* syncope" is defined as the occurrence of more than two episodes of syncope over the period of 5 years. "*Severe* syncope" is characterized as syncope occurring during driving or in the sitting position without a reliable prodrome.

Patients with unexplained syncope are advised to have no restriction for private driving unless presence of severe structural heart disease, absence of a prodrome, or syncope occurring during driving. There is no restriction for commercial driving after diagnosis and appropriate therapy is established.

**Table 4** Japanese restrictions on driving for patients with reflex syncope.

	Private Driving	Commercial (Professional) Driving
Single/mild episode Recurrent/severe episode	No restriction After symptoms are controlled	No restriction unless driving with a high-risk activity Permanent restriction unless effective treatment has been established
Unexplained syncope	No restriction unless presence of severe structural heart disease, absence of prodrome, or occurrence during driving	After diagnosis and appropriate therapy is established

#### 7. Recommendations to prevent syncope while driving

The etiology and recurrence rate of syncope do not differ based on whether or not the index episode occurred while driving [5]. Therefore, the clinical approach to syncope evaluation, and the recommendations for driving, should not differ with regard to the time or activity related to the presentation of the syncopal episode [14]. Several mechanisms or factors may trigger reflex syncope while driving: the passively seated position without muscle tension (enhances venous pooling in the legs), preexisting dehydration or intravascular depletion, the warm environment of a car (leads to cutaneous vasodilatation), and strong emotional stimulation while driving [1,14–16].

The treatment for preventing reflex syncope while driving is the avoidance of triggering events, and reassurance. Patient education may be important for minimizing the risk of both recurrent syncope and harm to the individual and others. Most individuals who suffered from syncope while driving had some warning in the form of prodromal symptoms before the syncope [5]. Greater awareness of these symptoms could help drivers control their driving and avoid terrible traffic accidents.

Generally, encouraging frequent breaks while driving, maintaining an optimal environment in the vehicle, and taking appropriate salts and fluids are recommended for most syncope patients [1,14–16]. The benefits of pharmacological treatment such as betablockers, alpha-antagonists, and mineral corticoids have not been confirmed in long-term placebo-controlled trials, but these agents have shown some benefit in shorter-duration trials [16]. Non-pharmacological treatments such as counter-pressure maneuvers (including leg crossing, hand gripping, and arm tensing) could increase blood pressure significantly enough to delay or avoid loss of consciousness [16], although it may be difficult to perform such a maneuver during driving. However, these recommendations are speculative and based on common sense, and there is insufficient evidence to support them at present [1].

Among syncope patients, compliance with driving restrictions is reported to be poor, with most patients resuming driving irrespective of any recommendations [4]. Redelmeier et al. [17] recently reported that a physician's warning to syncope patients who are potentially unfit to drive may reduce the subsequent trauma from road crashes, but they also noted that such a warning may exacerbate mood disorders and compromise the doctor-patient relationship.

#### 8. Conclusions

The driving restrictions in Japan for individuals with recurrent syncope became stricter, and were accompanied by certain legal penalties in 2014. For private driving, no restriction is recommended unless the syncope occurred without a reliable prodrome while driving or sitting. For commercial driving, restriction of driving is recommended unless the efficacy of treatment can be confirmed. Reducing driving time, or driving a lighter vehicle, can reduce the risk of harm presented by drivers with syncope.

#### **Conflict of interest**

The author declares no conflicts of interest related to this study.

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