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Prospective Assessment of the Risk of Vasovagal Syncope During Driving

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ABSTRACT

OBJECTIVES This study sought to estimate the likelihood of a motor vehicle accident causing serious risk or harm in patients with frequent vasovagal syncope, and compare this with international accident data.

BACKGROUND Recurrent vasovagal syncope poses a risk because of fainting while driving, but prospective, benchmarked estimates of this risk have not been reported.

METHODS Data were from the POST (Prevention of Syncope Trial)-1 and -2, which were multicenter randomized studies of patients with ≥3 lifetime vasovagal syncope spells. POST-1 patients (reported in 2005) received metoprolol or placebo for ≤1 year between 1998 and 2004; POST 2 patients received fludrocortisone or placebo for ≤1 year between 2006 and 2011. Accident data were recovered from Internet reports from the United States, United Kingdom, and Canada.

RESULTS A total of 418 patients (age 38 ± 17 years) had a median of 10 lifetime faints and a median of 3 faints in the previous year. Total follow-up time was 323 years, or 0.77 years per person. A total of 174 subjects fainted, having a total of 615 faints. Two patients fainted while driving, without fatality or injury, with a likelihood of 0.62% per person-year. The risk of serious harm or death was <0.0035% per person-year, and 0.0018% per faint. In the general U.S., U.K., and Canadian driving populations, the risk of serious harm or death was 0.067% per driver-year, and the risk of death was 0.009%.

CONCLUSIONS The estimated risk of serious harm or death was <0.0035% per person-year in highly symptomatic patients, less than the risk of serious harm or death in the general population. (A Randomized Clinical Trial of Fludrocortisone for Vasovagal Syncope: The Second Prevention of Syncope Trial [POST II]; NCT00118482) (J Am Coll Cardiol EP 2016;2:203–8) © 2016 by the American College of Cardiology Foundation.

Vasovagal syncope is common, and commonly recurrent (1,2). The predilection to syncope lasts many years to decades, and this raises concerns about the risk of syncope while driving (3). A sudden incapacitation while driving might cause a motor vehicle accident, significant property damage, serious injury, or death. All countries have regulations regarding the ability to drive of citizens with a predilection to syncope, and even among the United Kingdom, American states, and Canadian provinces, there is a wide range of reporting requirements and regulations about driving (4–7). This wide range reflects the lack of information about the likelihood that patients with vasovagal syncope will faint while driving, thereby causing serious injuries or death.

Several reports have attempted to estimate the likelihood of vasovagal syncope while driving, and of the faint causing an accident (3,8–11). However, the reports generally were either retrospective, and therefore open to selective referral and reporting, or included patients with a range of etiologies, and therefore not specific to vasovagal syncope. Although the true likelihood of an accident causing serious harm or death has not been reported, it can be estimated

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ABBREVIATIONS AND ACRONYMS

AC = accident consequences

CCS = Canadian Cardiovascular Society

RH = risk of serious harm

SCI = sudden cardiac incapacitation

TD = time driving

V = type of vehicle

with the Risk of Harm formula of the Canadian Cardiovascular Society (CCS) (12). The benchmark risk of harm from this formula has not been tested against contemporary societal tolerance of harm.

The purpose of this study was to use prospectively collected data to assess the risk of syncope and driving in a high-risk population of patients with vasovagal syncope. From these data we estimated the likelihood of syncope while driving, and derived the risk of a serious motor vehicle accident. We then compared these with historical benchmarking and contemporary motor vehicle accident data from the United States, United Kingdom, and Canada.

METHODS

STUDY SUBJECTS. The subjects were participants in the POST (Prevention of Syncope Trial)-1 (13) and -2 (14). Both trials were randomized, placebo-controlled, double-blind trials. POST-1 and POST-2 assessed the effects of beta-blockers and fludrocortisone, respectively, comparing with placebo in preventing vasovagal syncope. All involved institutional ethics committees approved both studies. POST-1 was reported in 2005, and POST-2 is registered with www.controlled-trials.com (ISRCTN51802652) and www.clinical-trials.gov (NCT00118482). Neither trial demonstrated significant benefit compared with placebo, although trends to benefit were noted. Patients were eligible for POST-1 if they had a positive response to standard tilt test protocols and ≥3 lifetime syncopal spells, and were eligible for POST-2 if they had vasovagal syncope according to the Calgary Syncope Score (15) and ≥3 lifetime syncopal spells. Advice on driving restrictions was left to local physicians, and compliance was not monitored. Driving guidelines and regulations differ among jurisdictions, adherence to driving guidelines by physicians is likely to be incomplete (16,17), and compliance by patients is unknown (5).

DATA EXTRACTION. Both POST-1 and POST-2 followed patients for up to a year. We reviewed all case report forms for syncope as an outcome. Outcomes adjudication committees reviewed all outcomes for syncopal spells. These forms contain checklists and narrative fields, all of which were reviewed for syncope while in or on a moving, wheeled vehicle. The likelihood of vasovagal syncope while operating a moving motor vehicle was computed on a per patient-year and per-faint basis. Outcome forms were also reviewed for motor vehicle accidents and for bodily injury and fatalities.

PUBLISHED REPORTS. To identify previous reports of the risk of fainting and driving we searched PubMed using these terms: driving AND syncope, drive AND faint, motor vehicle accident AND syncope, motor vehicle accident AND faint. We included papers that reported the total observation period of the population studied, the number of faints while driving, and that specified the population consisted of patients with vasovagal syncope.

STATISTICAL ANALYSIS. Continuous data were summarized as mean ± SD or median (interquartile range), and categorical data as counts (percentage). The rate of events (fainting while driving per year) was computed based on occurrence of events over total follow-up time (years per person). Time-dependent events were displayed using Kaplan-Meier survival analysis.

ESTIMATION OF RISK OF HARM. The CCS Consensus Guidelines on Fitness to Drive introduced the Risk of Harm formula (12), which quantifies the risk of serious harm or death (RH) as: TD × SCI × V × AC. Here, TD (time driving) is the fractional time spent driving, SCI (sudden cardiac incapacitation) is the time-dependent likelihood of syncope, V is the type of vehicle, and AC (accident consequences) is the probability that a syncope spell during driving results in a fatal or injury-producing accident. The CCS determined V = 0.28 for private drivers and AC = 0.02 per spell. Based on existing societal norms in 1993, the acceptable RH was determined to be 0.005% per person-year.

The product of SCI and TD (probability of fainting per unit time × TD) is determined empirically from POST-1 and -2 as the percentage of subjects fainted while driving normalized to 1 year. From this the theoretical Risk of Harm can be calculated as: (faints while driving per driving-year) × (0.02 × 0.28).

ESTIMATION OF CURRENT SOCIETAL TOLERANCE. The original estimate of societal tolerance for RH was based on the likelihood that a commercial truck driver would have an accident following myocardial infarction, and estimates of the likelihood that an accident would result in serious injury or death. To obtain current implied societal tolerances for accidents causing injury or death, we searched the Internet for data on motor vehicle accident rates and serious injury in the United Kingdom, United States, and Canada.

RESULTS

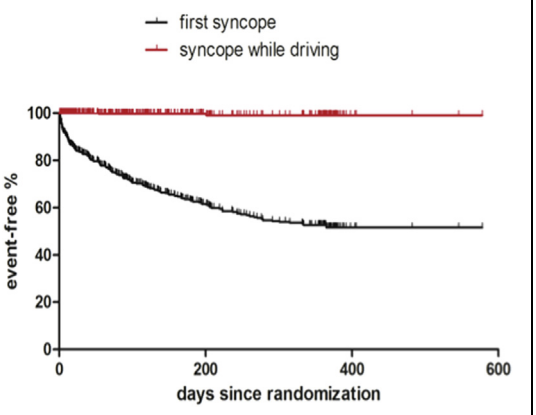
SUBJECT POPULATION. A total of 418 patients with vasovagal syncope were enrolled and followed for up to 1 year. The mean age at study enrollment was

38 ± 17 years, and the mean onset age of vasovagal syncope was 22 ± 16 years. The subjects had a median of 10 lifetime faints and a median of 3 faints in the previous year (Table 1). The total observation time was 323 years or 0.772 years per person. Fully 174 subjects developed vasovagal syncope in follow-up, with a total of 615 syncopal spells. The actuarial probabilities of remaining free of syncope, and free of syncope while driving, are displayed in Figure 1.

SYNCOPE WHILE DRIVING IN POST SUBJECTS. Five patients had syncope while on or in a moving wheeled vehicle. Three were excluded: 2 were passengers in cars, and 1 was on a bicycle. Two (0.48%) patients (1 each from POST-1 and POST-2) fainted while driving, with times to first faint of 54 and 307 days. No patients drove commercial vehicles. Thus 0.48% subjects fainted while driving, and the probability of syncope while driving (the empirically derived TD × SCI) was 0.62% per person-year (Table 2). Multiplying this by (V × AC), the estimated RH was 0.0035% per person-year, less than the CCS benchmark of 0.005%. Similarly the estimated RH per faint was 0.0018%. One patient had prodromal symptoms while driving before fainting, and safely drove to the roadside before fainting. A second subject had no prodromal symptoms and had a minor accident with no injury to anyone involved.

REPORTS OF SYNCOPE WHILE DRIVING. The systematic search detected 444 publications. A review of titles eliminated 432 based on duplication and lack of relevance. A full review of the text narrowed the sample to 3 reports (8,10,18). Table 3 summarizes the likelihood of syncope while driving from these reports and our current data. In total, 9 subjects fainted while driving during a total observation period of 2,945 years, with a likelihood of 0.31% faints while driving per driving-year. From this we estimate a risk of an accident causing injury or death of ≤0.0017% per driving year, less than the CCS benchmark of 0.005%.

FIGURE 1 Survival Free of Syncope and of Syncope While Driving in Subjects in the POST-1 and -2



POST = Prevention of Syncope Trial.

SOCIETAL TOLERANCE. Table 4 summarizes all motor vehicle accidents and casualties in Canada, the United Kingdom, and the United States. These data are from reporting years that range from 2009 to 2012, depending on availability. Not all data were available, some resulting in gaps and requiring estimation. Taken together, they suggest the mean likelihood of a motor vehicle accident is 1.1% per driver-year. In 2012 in Canada, the likelihood of a motor vehicle accident causing any injury, serious injury, and death was 0.51%, 0.044%, and 0.009% per driver-year. In the United States in 2009 (more recent data are not available), the likelihood of a motor vehicle accident causing any injury and death was 0.63% and 0.013% per driver-year. In 2013 in the United Kingdom, the risk of accidents causing any injury, or serious injury and death, was 0.52%, 0.078%, and 0.0044%. Taken together, we estimate the risks of death, and

TABLE 1 Baseline Characteristics of the Study Population

Number of subjects, n	418
Mean age when enrolled	38 ± 17
Mean onset age	22 ± 16
Mean history duration, yrs	18 ± 15
Mean syncope in history	94 ± 583
Median syncope in history	10 (5-30)
Mean syncope in prior year	15 ± 56
Median syncope in prior year	3 (2-8)
Total follow-up time, days	117,841
Total follow-up time, yrs	323
Total follow-up time, yrs per person	0.772
Subjects fainting in study	174
Total faints in study	615

Values are n, mean ± SD, or median (interquartile ranges).

TABLE 2 Estimated Risk of Harm Caused by Syncope While Driving in the POST-1 and -2 Subjects

Item	Count or Frequency
Subjects fainted while driving, n	2
Subjects fainted while driving per year	2.59
Percent subjects fainted while driving	0.48%
Percent subjects fainted while driving per year	0.62%
Estimated risk of serious harm or death	0.0035%

The risk of harm according to the CCS Guidelines is (probability of fainting while driving per year) × 0.02 × 0.28.

CCS = Canadian Cardiovascular Society; POST = Prevention of Syncope Trial.

TABLE 3 Reported Frequencies of Fainting While Driving

First Author (Ref. #), Year	Data Collection	Syncope While Driving	Patients	Driving Years	Syncope Per Driver-Year, %
Sheldon and Koshman (18), 1995	Retrospective	5	217	1,534	0.33
Bhati et al. (8), 1999	Retrospective	2	155	646	0.31
Folino et al. (10), 2012	Prospective	0	90	442	0
Tan et al., 2015	Prospective	2	418	323	0.62
Totals		9	880	2,945	0.31

serious injury or death to be 0.061% and 0.009%. These likelihoods far exceed our estimate of the maximum likelihood of a syncopal spell causing an accident resulting in either death, or serious injury or death of ≤0.0017% per driver-year.

DISCUSSION

The principle findings are that both the rate of syncope during driving, and the estimated risk of death, are several fold lower than the tolerated risk in the CCS Risk of Harm formula (12). They are also lower than current collision and death rates among all private drivers in Canada, the United States, and the United Kingdom. The rates are similar in 4 reports of different populations. These findings might guide policy makers and physicians when speaking with individual patients.

RISK OF HARM FORMULA. The data reported and compiled here are a pragmatic test of the CCS Risk of Harm formula and the Fitness to Drive Guidelines (12). The guidelines are intended to reduce the likelihood of an accident resulting in serious injury or death to <0.005% per driver-year. To do this, the risk of syncope during driving must be less than 1% per year, and our pooled estimate of syncope during driving (Table 3) was 0.31% per driver-year. This provides an estimate of serious injury or death of ≤0.0017% per driver-year. In the POST populations, there were no accidents resulting in any injury, and the RH can only be estimated from the formula as <0.0035%.

PUBLIC POLICY IMPLICATIONS. Here we focused on a large population of patients with vasovagal syncope, having a mean age of 38 years and a wide age range. Guidelines refer specifically to these patients as a large subset of all syncope patients (12). The CCS Fitness to Drive Guideline (12) was developed to keep the RH caused by SCI to <1/20,000 per driver-year. This benchmark was based on the risk that a commercial truck driver incurred following a myocardial infarction. We used a different approach based on real-world data in 3 western countries. We assumed that society at large accepted the current likelihoods of having an accident, and of it causing serious injury or death, in the absence of measures to reduce it drastically beyond the current levels. The mean risk of having a motor vehicle accident in the United States, United Kingdom, and Canada is 1.1% per driver-year; the CCS Guidelines target 1%; and the risk caused by syncope is 0.31% per driver-year. The estimated mean risk of having a motor vehicle accident associated with serious injury or death within the United States, United Kingdom, and Canada is 0.067% per driver-year; the CCS Guidelines target 0.005%; and the risk caused by syncope is estimated to be <0.0017% per driver-year. Despite the variations in definitions and local driving practices, the rates of driving accidents in the community are consistently several-fold higher than might be attributed to syncope, and the documented death rate in motor vehicle accidents is about 60-fold higher than the modeled fatality rate caused by syncope.

PRACTICE SUGGESTIONS. Ironically, the small number of events in all 4 studies precludes firm recommendations. There were only 9 faints while driving in 880 subjects observed for 2,945 subject-years. Most of the subjects in the POST studies were Canadian, and advice about driving was informed by the CCS Guidelines about syncope and driving private vehicles. For private driving, it recommends no restriction for a single episode of typical vasovagal syncope, and a 1-month waiting period for patients with more than 1 faint in 12 months. These were based on semiquantitative estimates of the likelihood that recurrent faints might presage a period of higher-frequency fainting, and did not specify the time between the last faint and clinic visit. Patients with long prodromal times, very infrequent faints, or no

TABLE 4 Estimated Risk of Harm Caused by Syncope While Driving Compared With the Frequency of MVAs and Injuries in Alberta, Canada, the United Kingdom, and the United States

Location, Year (Ref. #)	MVAs, %	Injuries, %	Serious Injury, %	Death, %	Serious Injury and Death, %
Canada, 2012 (19,20)	0.56 (est)	0.51	0.044	0.009	0.053
United States, 2009 (21)	2.29	0.63	NR	0.013	>0.013
United Kingdom, 2013 (22,23)	0.49	0.52	0.078	0.0044	0.082
Country averages	1.11 ± 1.02	0.55 ± 0.07	0.061 (exc U.S.)	0.009 ± 0.004	0.067 (exc U.S.)
CCS Guidelines (12)	<1	N/A	<0.005	<0.005	<0.005
Syncope	0.31	N/A	≤0.0017 (est)	≤0.0017 (est)	≤0.0017 (est)

The rates are expressed as likelihood of event per 100 driver-years, denoted as %.
est = estimated; exc = excluding; MVA = motor vehicle accident; NR = not reported; other abbreviation as in Table 2.

faints while sitting, or who faint in unique or avoidable circumstances are restricted less, whereas those who faint while sitting and without a prodrome are urged to adhere scrupulously to the guidelines. This is a difficult part of practice, and although accidents are uncommon, they do occur. All physicians should know and adhere to local guidelines and legislation.

STUDY LIMITATIONS. Although this analysis was based on POST-1 and POST-2, they were not designed to evaluate the risk of syncope during driving. Patients were followed for only 1 year, although this seems a reasonable horizon for driving advice. We do not have the data on how many patients in both trials did have a private vehicle driving license, and this potentially would underestimate the risk of harm. However, only 5 of 418 subjects were less than 18 years old, and almost all adults have private driving licenses. Furthermore, there were few patients >70 years old in the studies, and therefore our findings cannot be extrapolated to these older patients. We also do not know the advice offered by physicians and whether it adhered with guidelines. It may be that physician adherence to restrictive guidelines was very low (16,17).

We are also unable to determine the compliance of patients after receiving advice about driving restrictions, and how many refrained from driving. Indeed, patient compliance with restrictive guidelines may be low (5). If high-risk patients in particular stopped driving, this could lower the overall estimate of risk. However, the 4 estimates are similar, and they reflect real-world outcomes based on patient populations, local policies and laws, physician advice, and patient adherence. Self-selection by some patients is to be expected, and is included in the overall estimates.

We relied on patient self-reporting of syncope and accidents. However, this was done in a research setting, and privacy was ensured as part of participation in the study. As well, self-reporting was used in all similar studies that are reported in **Table 3**. Similarly, we have no systematic data on the restrictions that might have been imposed on the subjects. Again, this is a common feature of the similar studies in **Table 3**. Finally, the United States, Canada, and the United Kingdom have slightly different reporting requirements and definitions of the severity of accidents. This does not impact on our estimates of syncope and accidents, but is a limitation in assessing the societal context.

In Alberta, which contributed 170 of 418 subjects, patients who faint are very rarely prohibited from driving for more than a week. The patients were a highly selected group because they were attending mostly referral centers. The follow-up duration is short, and a longer follow-up period potentially might capture more faints during driving. Finally, the definitions of injury, serious injury, and death caused by accident are not consistently stipulated, and the requirements for reporting an accident are not reported. This makes interjurisdictional comparisons difficult, although the consistently similar data provide reassurance about their validity.

Balancing these limitations were the multijurisdictional nature of the study and the highly symptomatic nature of group, with a median 3 faints in the year before study enrollment and 615 faints in follow-up. As well, the data were collected prospectively, rather than through chart review. It evaluated a highly clinically relevant issue with prospectively collected and time-stamped data. The patient cohort is the largest of any reported, and the follow-up duration captures a reasonable horizon of clinical decision making. Finally, the analysis includes external data that speak to societal expectations.

CONCLUSIONS

The estimated RH caused by vasovagal syncope was 0.0035% per person-year in this highly symptomatic group, comfortably within the CCS Fitness to Drive guideline (12). Neither of the patients who fainted during driving was injured. Thus, patients with frequent vasovagal syncope are safe to drive with minimal restrictions.

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PERSPECTIVES

COMPETENCY IN MEDICAL KNOWLEDGE: The likelihood of a motor vehicle accident in patients with moderately frequent vasovagal syncope is very low, and well within societal tolerance based on general motor vehicle accident rates.

TRANSLATIONAL OUTLOOK: Despite this low risk, physicians must know and adhere to the legal guidelines of their particular political jurisdictions. Much larger and prospectively designed studies are required to provide more precise estimates of risk for policy makers.

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