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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