Predicting and Reducing Driving Mishaps Among Drivers With Type 1 Diabetes

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OBJECTIVE

Two aims of this study were to develop and validate A) a metric to identify drivers with type 1 diabetes at high risk of future driving mishaps and B) an online intervention to reduce mishaps among high-risk drivers.

RESEARCH DESIGN AND METHODS

To achieve aim A, in study 1, 371 drivers with type 1 diabetes from three U.S. regions completed a series of established questionnaires about diabetes and driving. They recorded their driving mishaps over the next 12 months. Questionnaire items that uniquely discriminated drivers who did and did not have subsequent driving mishaps were assembled into the Risk Assessment of Diabetic Drivers (RADD) scale. In study 2, 1,737 drivers with type 1 diabetes from all 50 states completed the RADD online. Among these, 118 low-risk (LR) and 372 high-risk (HR) drivers qualified for and consented to participate in a 2-month treatment period followed by 12 monthly recordings of driving mishaps. To address aim B, HR participants were randomized to receive either routine care (RC) or the online intervention "DiabetesDriving.com" (DD.com). Half of the DD.com participants received a motivational interview (MI) at the beginning and end of the treatment period to boost participation and efficacy. All of the LR participants were assigned to RC. In both studies, the primary outcome variable was driving mishaps.

RESULTS

Related to aim A, in study 1, the RADD demonstrated 61% sensitivity and 75% specificity. Participants in the upper third of the RADD distribution (HR), compared with those in the lower third (LR), reported 3.03 vs. 0.87 mishaps/driver/ year, respectively ($P < 0.001$). In study 2, HR and LR participants receiving RC reported 4.3 and 1.6 mishaps/driver/year, respectively ($P < 0.001$). Related to aim B, in study 2, MIs did not enhance participation or efficacy, so the DD.com and DD.com + MI groups were combined. DD.com participants reported fewer hypoglycemia-related driving mishaps than HR participants receiving RC ($P = 0.01$), but more than LR participants receiving RC, reducing the difference between the HR and LR participants receiving RC by 63%. HR drivers differed from LR drivers at baseline across a variety of hypoglycemia and driving parameters.

CONCLUSIONS

The RADD identified higher-risk drivers, and identification seemed relatively stable across time, samples, and procedures. This 11-item questionnaire could inform patients at higher risk, and their clinicians, that they should take preventive steps to reduce driving mishaps, which was accomplished in aim B using DD.com.

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Vehicular collisions are the eighth leading cause of death worldwide, accounting for 1.24 million deaths in 2010. They are projected to be the fifth leading cause of death by 2030 (1). In the U.S., 35,092 fatalities and an estimated 2.44 million nonfatal injuries occurred in 2015, costing the U.S. economy more than $99 billion (2). Compared with spouses without diabetes, drivers with type 1 diabetes have greater risk of vehicular collisions (2), possibly because of the acute disruptive effects on cognitive-motor abilities during periods of extreme blood glucose (BG) (3,4) and chronic complications such as retinopathy and neuropathy that can interfere with safe motor vehicle operation (5). However, not all drivers with type 1 diabetes are at an elevated risk of driving mishaps. Research demonstrates that compared with those without driving mishaps, drivers with two or more mishaps in the previous 12 months had greater insulin sensitivity, released less epinephrine during hypoglycemia, had fewer hypoglycemia-specific symptoms (6,7), performed worse on neuropsychological tests during hypoglycemia (8), and drove more poorly in a driving simulator during hypoglycemia (but not euglycemia) (6,7). When examining drivers who documented driving mishaps prospectively over 12 months, mishaps were not related to age, sex, duration of disease, HbA$_{1c}$, or awareness of self-reported hypoglycemia. Instead, future mishaps corresponded to the use of insulin pumps, a history of collisions, severe hypoglycemia, and hypoglycemia-related driving mishaps (9).

In recognition of this increased rate of mishaps among drivers with type 1 diabetes, the American Diabetes Association (ADA) released a position statement on diabetes and driving (10), which recommends that clinicians should screen for elevated risk and intervene to reduce it. However, no specific screening tool or intervention is available. To address this gap, we developed and tested a brief questionnaire that would allow a clinician to screen drivers with type 1 diabetes for a high risk of driving mishaps (aim A). Further, we developed an Internet intervention (DD.com) intended to assist high-risk individuals to better anticipate, prevent, detect, and treat hypoglycemia while driving in order to avoid future driving mishaps (aim B).

AIM A: DEVELOPMENT AND VALIDATION OF THE RISK ASSESSMENT OF DRIVERS WITH TYPE 1 DIABETES

Overview
A screening questionnaire was created in two phases: development (study 1) and validation (study 2). In study 1, driving-relevant psychometrically sound questionnaires were administered to drivers with type 1 diabetes, who were then followed monthly for a year to document the occurrence of driving mishaps. Post hoc analyses selected 11 items that predicted drivers who would subsequently experience driving mishaps. These items were then used to create the Risk Assessment of Diabetic Drivers (RADD) (professional.diabetes.org/radd). Study 2 measured the validity of the RADD by comparing screening categorizations to rates of mishaps over a prospective 12-month observation period.

STUDY 1: RADD DEVELOPMENT
Hypotheses
It was hypothesized that more driving mishaps would be reported by individuals who 1) have a reduced concern for hypoglycemia (Hypoglycemic Fear Survey [HFS] [11]), 2) mismanage hypoglycemia (Risk Assessment of Severe Hypoglycemia [RASH] [12]), 3) have significant concerns about hyperglycemia (Hyperglycemia Avoidance Scale [HAS] [13]), 4) have a history of driving mishaps, 5) drive extensively, 6) report impaired awareness of hypoglycemia (14), and 7) have retinopathy and/or neuropathy.

Methods
Participants
The study sample and methods have been presented in detail elsewhere (9). Participants were 536 active drivers with type 1 diabetes recruited from Boston, MA (Joslin Diabetes Center), central Virginia (University of Virginia), and Minneapolis, MN (International Diabetes Center), as part of a year-long study of driving performance. Participants were recruited through newspaper, radio, and diabetes media ads, and were eligible if they 1) had type 1 diabetes for at least 12 months, 2) performed self-measurement of BG at least two times daily, 3) had a valid driver's license, and 4) drove at least 5,000 miles/year. After excluding individuals with incomplete data, the remaining sample consisted of 371 drivers with the following characteristics: mean age, 42.5 ± 12.5

years; 48% male; mean diabetes duration, 24.5 ± 12.9 years; and an estimated HbA$_{1c}$ of 7.8 ± 0.8% (62 mmol/mol ± 8.7) (15). The median range of miles driven was 12,000–14,000 miles/year.

Procedure
Participants completed the HFS (11), RASH (12), and HAS (13); a hypoglycemia awareness scale (14); a questionnaire assessing demographics, driving history, and diagnoses of retinopathy, neuropathy, or cardiovascular disease; and both visual acuity and peripheral vision screening using the Department of Motor Vehicle's Titmus 2n Vision Screener. Subsequently, participants were followed monthly with e-mail messages asking them to report the number of driving mishaps they had in that month—the primary outcome variable. The driving mishaps selected for inclusion in these monthly diaries were based on focus groups and our past research (9), and represented dangerous driving situations that either involved a collision or could have resulted in a collision. Driving mishaps were defined as collisions, moving vehicle violations, episodes of severe hypoglycemia while driving, loss of vehicle control, automatic driving (finding themselves at a destination with no awareness of the drive), and instances of impaired driving in which someone else took over driving (9).

To maximize precision of the measurements, item response modeling techniques (16,17) estimated latent trait scores for subscales or individual items of the scales administered. These scores became indicators in a logistic regression model (18,19) predicting low risk (LR; no or one mishap) versus high risk (HR; more than one mishap) for driving mishaps. The best-fitting model was established, retaining the significant predictors. This model was then compared, using the Vuong closeness test (20), with an identical model (same predictors) in which the item response modeling technique scores were replaced by summed raw scores. Findings indicated no significant difference between the two models ($P > 0.05$). Therefore, we used the simpler model using the summed raw score for all further classification analyses (see Table 1 for RADD items and scoring). Finally, a receiver operating characteristic curve based on the summed raw scores model was constructed and examined to establish a cut point for classification into the HR group.

Results

Over the 12-month follow-up period, participants reported an average of 1.77 ± 3.26 driving mishaps/driver/year, with 8.4% reporting six or more driving mishaps. The logistic regression model revealed that annual driving distance, peripheral neuropathy, number of past hypoglycemia-related driving mishaps, and the RASH subscale measuring the degree to which the individual is bothered by hypoglycemia in general, were all statistically significant independent predictors of risk for future driving mishaps ($P < 0.05$). Table 1 presents the questions used in this model, the response options, and the scoring procedures used to predict the probability of being at higher risk for future driving mishaps.

The logistic regression equation used to calculate the RADD risk was:

$$P(HighRisk) = \frac{1}{1 + e^{3.84 - 0.74*Neuropathy - 0.08*PreviousMishaps - 0.58*AnnualMilesGroup - 0.24*RASH}}$$

A receiver operating characteristic curve (Supplementary Fig. 1) was constructed by computing the sensitivity and specificity at probability cut points ranging from 0.01 to 0.99. The area under the curve, a global measure of model performance, was estimated to be 0.73, indicating that the model performed better than chance at classifying participants into the two risk categories. Further examination suggested an optimal cut point at a risk index score of 0.339, corresponding to 61% sensitivity (correct classification as HR) and 75% specificity (correct classification as LR). Overall, the model classified 37.5% of participants as HR. These participants averaged 3.03 ± 4.39 driving mishaps during the 12-month follow-up

period. Conversely, the participants included in the lowest 37.5%, who had risk scores below 0.248, reported significantly fewer driving mishaps (mean 0.87 ± 1.92; $P = 0.002$) (Fig. 1).

STUDY 2: RADD VALIDATION

Hypotheses

It was hypothesized that 1) the distribution of RADD scores between studies 1 and 2 would be similar, and 2) using the same cutoff criteria established in study 1, the RADD would identify a subgroup of drivers with type 1 diabetes who had a higher rate of driving mishaps over the subsequent 12 months.

Methods

Participants

Participants were recruited through diabetes websites (e.g., MyGlu.org, dLife.com, Dex4.com), professional organizations (American Association of Diabetes Educators), and by direct referral from clinicians. A total of 1,739 drivers from all 50 states consented to complete an online screening questionnaire in order to determine whether they were eligible for the intervention study. The screening questionnaire included the RADD.

The study 2 sample comprised 1,404 drivers; this sample was compared with the distribution of RADD scores from study 1. Of the 1,739 screened participants, 335 were excluded because they did not have type 1 diabetes ($n = 45$), had diabetes for <1 year ($n = 26$), did not perform self-monitoring of BG at least twice a day ($n = 37$), did not have a driver's license ($n = 1$), did not drive more than 5,000 miles/year ($n = 225$), or applied after the study had closed ($n = 29$). Twenty-eight participants met more than one exclusion criterion. The mean age of this sample was 40.2 ± 13.6 years; 245 participants were between the ages of 18 and 25 years, and 32 were older than 65 years. Men comprised 48% of the sample. The median reported range of miles driven annually was 12,000–14,000.

Of these 1,404 individuals, 493 qualified for the prospective intervention arm of study 2 and signed an online

Table 1—RADD items, response options, and scoring for study 1

| Questions	Response options	Scoring
In the past 2 years, because of low BG (hypoglycemia), how many times did you:		
1. Have an automobile accident?		
2. Receive a moving vehicle violation?		Simple sum of the endorsed numbers of mishaps
3. Did someone else take control of your car?	0–9, ≥10	
4. Did you experience *severe* hypoglycemia, where it was impossible to treat yourself because of low BG?		
5. How many miles do you drive per year?	<1,000 1,000–3,000 3,000–5,000 5,000–7,000 7,000–9,000 9,000–11,000 11,000–13,000 13,000–15,000 15,000–17,000 ≥17,000	0 if <7,000 1 if 7,000–14,999 2 if >14,999
6. Have you ever been told by a doctor that diabetes has affected your toes or feet?	Yes No Not sure	1 if yes
In the past 6 months, how often:		
7. Did you have low BG (<70 mg/dL)?		
8. Did low BG come on suddenly and unexpectedly?		
9. Were you awakened by symptoms of low BG, such as sweating, trembling, pounding heart, or body temperature changes?	Never (0) Rarely (1) Sometimes (2) Almost always (3) Always (4)	Simple sum of all item responses
10. Was it a hassle trying to hide dizziness or other symptoms of low BG?		
11. Were you embarrassed by the effects of low BG?		
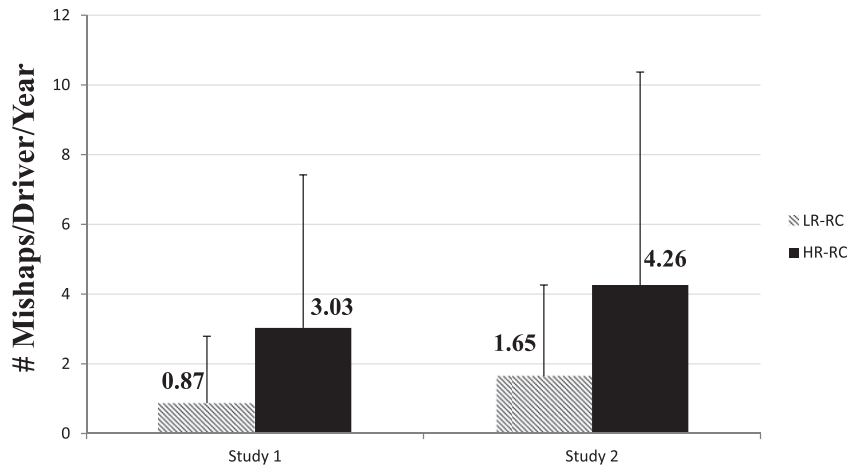
Figure 1—Frequency of driving mishaps for LR and HR drivers as it relates to aim A in studies 1 and 2.

consent form to participate. Drivers were excluded if, in addition to the above-mentioned criteria, they had an intermediate risk score (0.248–0.339) or lacked routine access to the Internet ($n = 324$), qualified for the LR group after it was already full ($n = 339$), decided not to participate in the study intervention ($n = 186$), or were included but randomized to the wrong group because of a clerical error that was later corrected ($n = 79$). Seventeen participants met more than one exclusion criterion.

Procedure
Between March 2012 and June 2013, 1,739 interested individuals signed the online consent form and completed an online screening questionnaire that included the RADD. The screening RADD used in study 2 differed slightly from that used in study 1 in two ways: *1*) there were slight wording differences (e.g., "How many miles do you drive per year?" vs. "On average, how many miles do you drive in a typical year?"), and *2*) the time frame for assessing driving mishaps differed. It was changed from "In the past 2 years" to "In the past 12 months," assuming a shorter time frame would result in more accurate recall.

A total of 493 candidates completed the screening, qualified for the intervention study, and signed the online consent form to participate. Of these, 240 participants were assigned to the routine care (RC) group. They received no Internet intervention, and thus formed the sample for prospectively validating the RADD categorizations. Among these RC participants, 122 were

classified as HR (RADD score ≥0.339), and 118 were classified as LR (RADD score ≤0.248). As in study 1, these participants recorded their driving mishaps monthly for the next 12 months. Participants were compensated $10 for each month of driving mishap data they provided.

Results
The distribution of RADD scores from the Internet-based study 2 had a slightly lower mean (0.30 vs. 0.34; $P < 0.01$), median (0.97 vs. 0.99; $P < 0.01$), and maximum (2.50 vs. 2.99; $P < 0.01$) than in the face-to-face study 1. These differences in scores were not related to sex or age. Using the criterion established for HR driving in study 1 (RADD score ≥0.339), the percentage of participants assigned to the HR category in study 2 was 35.3%, compared with 37.5% in study 1.

To examine driving mishaps in study 2, negative binomial regression (a model of count data that controls for overdispersion in participant responses [21]) was used to compare the number of self-reported driving mishaps that occurred prospectively over 12 months for the HR and LR groups. The post hoc Tukey test assessed whether significant differences existed between groups. The model fit the data ($\chi^2 = 239.42$; df = 231; $P = 0.338$), with group placement as a significant predictor of total mishaps (likelihood ratio = 21.58; $P < 0.001$). As was hypothesized and observed in study 1, participants in the LR group reported significantly fewer average mishaps (1.65) than those in the HR group (4.26; $z = 4.82$; $P < 0.001$) (Fig. 1).

The model was then adjusted to control for age (higher risk being ≤25 years of age), sex (higher risk being male), insulin delivery (higher risk using insulin pump delivery), and hypoglycemia awareness (higher risk with reduced awareness on the measure developed by Clarke et al. [14]). The controlled model also fit well ($\chi^2 = 239.58$; df = 227; $P = 0.271$), with group placement as a statistically significant predictor of total mishaps (likelihood ratio = 26.12; $P < 0.001$). Supporting hypothesis 2, the mishap rate of the HR group was 2.83 times higher than that of the LR group when all other variables were held constant ($z = 5.41$; $P < 0.001$).

In terms of covariates, only age and hypoglycemia awareness statistically contributed to the model. Younger drivers (<25 years old; $z = 3.186$; $P = 0.001$) and participants with impaired awareness ($z = 2.378$; $P = 0.017$) reported significantly more mishaps than older and hypoglycemia-aware drivers when accounting for all other variables in the model.

AIM A DISCUSSION
In response to the ADA position statement, a brief psychometric questionnaire was developed from questionnaire items in study 1 to empirically identify drivers with type 1 diabetes who are at elevated risk of being involved in future driving mishaps. Consistent with laboratory studies (6,7) and a multinational survey (2), the RADD identifies a subset of individuals at elevated risk of driving mishaps. The weights of the logistic regression equation indicate the relative contribution of the factors, which are (in order of importance) peripheral neuropathy (0.74), driving exposure (miles driven; 0.58), problems with hypoglycemia in general (RASH; 0.24), and a history of hypoglycemia-related driving mishaps (0.08). Factors in study 1 that did not account for the unique variance of future driving mishaps in this equation were fear of hypoglycemia, concerns with hyperglycemia, other diabetic complications (e.g., retinopathy, cardiovascular disease), impaired hypoglycemia awareness, duration of disease, vision, sex, and age. Age and impaired hypoglycemia awareness were significant covariates only in study 2. This does not mean that such factors as fear of hypoglycemia do not relate to driving mishaps for an individual driver,

only that in combination with the other variables they do not add to the predictive model.

A strength of this 11-item scale is its brevity. In study 2 we attempted to augment the RADD by replacing the single neuropathy item with a neuropathy questionnaire (Neuropathy-Specific Quality of Life scale [22]). This did not improve the sensitivity or specificity of the scale, so the simpler version of the RADD was retained.

The RADD is a psychometrically sound instrument. Using two different samples and methods of administration, the distributions of RADD scores were similar. In both samples, the RADD identified approximately a third of the drivers with type 1 diabetes as being at elevated risk of future driving mishaps. The slightly higher mean, median, and maximum RADD scores in study 1 may be attributed to the longer period of recent driving mishaps considered (2 years vs. 1 year). More importantly, using the cutoff criteria from study 1 on a different sample, obtained using a different method of administration, again showed that those identified as being at HR for future driving mishaps did, in fact, report significantly more mishaps in the subsequent 12 months. This resulted even when traditional risk factors of driving mishaps, such as age and impaired hypoglycemia awareness, were controlled. Further external validation comes from the mishap item, "Did you require assistance from someone else while driving due to your extreme BG?" In study 2, participants in the HR group reported that their passengers intervened 111 times because they perceived that the driver was impaired. This only occurred 27 times in the LR group.

A limitation to the routine use of the RADD in a paper-and-pencil format is its complicated scoring formula. However, this barrier can be eliminated by making the RADD available online, where automatic scoring and confidential feedback can be provided to users at any time and location. The ADA will soon make the RADD freely and publicly available on their website. Another limitation is that the RADD was not tested with adolescents, so the above results cannot be extrapolated to this already HR population. This limitation is significant because driving safety is a major concern of parents of novice drivers trying to negotiate driving challenges and their

diabetes (23). Further, it may be that the RADD could be made more comprehensive by incorporating the disruptive effects of extreme hyperglycemia (e.g., >250 mg/dL or 13.9 mmol/L), which has been associated with cognitive symptoms (24), cognitive impairments (23,25,26), and driving mishaps (9,27).

The RADD had a false-negative rate of 24%, classifying people as LR drivers when they reported more than one driving mishap during the subsequent 12 months. This illustrates that any driver has a risk of being involved in a collision or receiving a citation, and any driver with type 1 diabetes has the additional risk of experiencing disruptive extreme BG that can result in a mishap while driving. While ideally all drivers with type 1 diabetes should measure their BG before driving, they should at least be counseled that whenever they take more insulin, eat fewer carbohydrates, or engage in more physical activity than usual, they should measure their BG before driving. If their glucose is between 70 and 90 mg/dL (3.9 and 5 mmol/L), they should eat carbohydrates as a preventive measure. If their BG is <70 mg/dL (3.9 mmol/L), they should eat carbohydrates immediately and not start driving until their glucose is above 90 mg/dL (5 mmol/L) and their cognitive and motor functioning has normalized (6). Because driving has a metabolic demand (28,29), drivers should be further counseled to measure their glucose periodically during long drives.

As with any risk profile (such as the ADA's Type 2 Diabetes Risk Test [30,31]), an elevated RADD score does not definitively mean that the driver will have driving mishaps in the next 12 months. In fact, study 2 found a 36% false-positive rate among HR participants receiving RC. However, a RADD score classified as HR does mean that the potential for a diabetes-related mishap should be considered and that it would be prudent to diminish the risk. This could involve educating patients and assisting them in taking steps that will allow them to better anticipate and prevent hypoglycemia while driving. Efforts to reduce risk should also involve better detection and treatment of mild hypoglycemia (70–55 mg/dL or 3.9– 2.8 mmol/L [32]) while driving in order

to halt progression toward disruptive hypoglycemia. Aim B was to implement an intervention program motivated by these pedagogical principles, focusing on the HR drivers defined by aim A.

AIM B, STUDY 2: VALIDATE AN INTERVENTION TO ASSIST HR INDIVIDUALS IN REDUCING THE OCCURRENCE OF FUTURE DRIVING MISHAPS

It was hypothesized that the Internet intervention DiabetesDriving.com (DD .com), designed to aid drivers in better anticipating and preventing, detecting, and treating hypoglycemia while driving, would 1) lead to fewer future driving mishaps among HR drivers; 2) reduce the occurrence of driving mishaps among HR individuals to the level observed in the LR group, effectively "normalizing" risk of future driving mishaps; and 3) achieve greater adherence and efficacy when combined with motivational interviewing (MI; reported elsewhere [33]). Secondary aims were to determine whether DD.com had an effect on driving parameters related to the risk of mishaps.

Methods
Overview
A total of 118 LR and 375 HR drivers qualified for aim B (see STUDY 2: RADD VALIDATION). Using the randomization function in Microsoft Excel, HR participants were randomly assigned to one of three conditions: RC (n = 122; the same participants as in the RADD validation study), DD.com (n = 124), and DD.com + MI (n = 129). These participants were compared with the LR participants receiving RC in study 2, as they relate to aim A. Figure 2 depicts the study design. Participants completed baseline questionnaires online at study day 0. After completing questionnaires, DD.com participants received immediate access to the intervention, whereas DD.com + MI participants received access after an MI session by telephone. Both DD.com groups had 70 days to complete the intervention, whereas participants in the RC group continued with RC. At the end of the 70-day period, all study participants completed posttreatment assessment questionnaires. All participants then completed 12 monthly driving diaries online, where they recorded their driving mishaps and the attributed
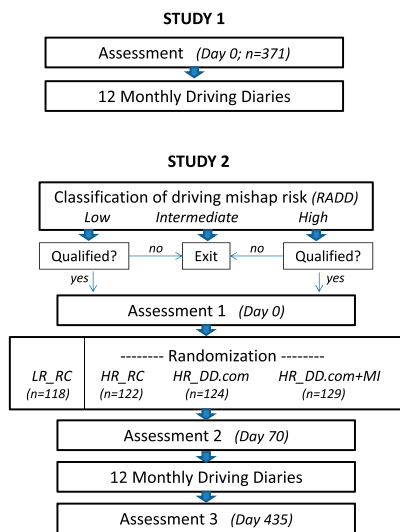
Figure 2—Flow charts of studies 1 and 2.

source (hypoglycemia, hyperglycemia, or other reasons). After 12 months of recording driving mishaps, participants completed a final set of assessment questionnaires (study day 435). Participants were paid $50 and $100 for completing assessments at days 70 and 435, respectively, and $10 for each monthly driving diary completed.

Assessment Questionnaires
Assessment questionnaires were administered three times: on days 0, 70, and 435. Assessments took approximately 45 min to complete and consisted of a demographic questionnaire and questionnaires assessing both attitudes and behaviors related to hypoglycemia and to driving (Table 2).

After assessment, DD.com participants also rated the usefulness of different elements of the intervention in achieving their goal of reducing driving risk (Supplementary Table 2).

DiabetesDriving.com
DD.com consisted of five units, and the content of each unit is summarized in

Table 3. An initial "how to use" unit (unit 0) became available 7 days after completing the day 0 assessment, and during this time the study coordinator mailed participants a "tool kit" (described below) for unit 1. Units 1 and 2 became available immediately after completing the previous unit. Units 3–5 required that participants complete three homework assignments within a 7-day window before gaining access to the next unit. Each unit began with a review of the participant's homework from the preceding unit.

The tool kit in unit 1 was a clear plastic case containing *1*) a predriving checklist (similar to a pilot's preflight checklist) that focused on considering whether BG is or may become low during the drive; *2*) glucose sources, both fast-acting (dextrose tablets) and long-acting (cheese crackers); *3*) a keychain with a stoplight logo to remind drivers of BG benchmarks (the green light indicated they could drive right away [BG >90 mg/dL or 5 mmol/L], yellow indicated caution because BG could go low during a drive and require prophylactic carbohydrates [BG between 70 and 90 mg/dL, or 3.9 and 5 mmol/L], and red indicated they should stop immediately, eat fast-acting carbohydrates, and delay driving until BG recovered [BG <70 mg/dL or 3.9 mmol/L]); *4*) stoplight logo stickers to place on the dashboard or near their car keys; and *5*) a BG meter to encourage self-monitoring of BG before and during long drives. Participants were encouraged to keep the tool kit in the car in a consistent location that was easily accessible to the driver and easily replenished when needed.

At the end of units 2–5, participants reviewed the unit's content and selected three homework activities to do daily over the next week. Homework aimed to help them become safer

drivers by applying what they had just learned. Each day, they received an e-mail message instructing them to log on to the website in order to record completed homework assignments and rate their success at achieving their homework goals.

If 3 days elapsed without response to an assigned element of DD.com (e.g., assessments, homework activities, starting a unit, or completing a monthly driving diary), participants received an e-mail message inviting them to log on to the website to reengage in DD.com. If they did not respond to the prompt within 3 days, another was sent. If there was no response in the allotted time period, these prompts continued at progressively longer intervals in order to give participants an opportunity to reengage.

Motivational Interviewing
The goal of the MI sessions was to increase participants' motivation to complete DD.com and its assignments, thus maximizing the positive effects of DD.com on their driving habits. Interviews were conducted via telephone, were semistructured, and were partially scripted to enhance fidelity to MI techniques and to maximize consistency across counselors. A description of the MI component, its fidelity, and its effect on DD.com was previously published (33).

Results
Completion Rates
Of those assigned to DD.com or DD.com + MI, 96.5% completed unit 0, 92.5% completed unit 1, 87.5% completed unit 2, 68.6% completed unit 3, 52.3% completed unit 4, and 42.2% completed the entire program in the 70-day treatment period. However, an additional 28% completed DD.com during the 12-month follow-up, resulting in an overall completion rate of 70%.

Driving Mishaps
Participants from the LR and HR groups receiving RC, the DD.com group, and the DD.com + MI group completed 98%, 94%, 77%, and 78% of all monthly driving diaries, respectively. This was the primary outcome variable.

Because of the nature of the data (counts) and to correct for overdispersion among participant responses, negative binomial regression was used to analyze monthly driving diary outcomes

Acronym	Scale	Construct assessed
HFS	Hypoglycemia Fear Survey, worry subscale	General concerns about experiencing hypoglycemia
RASH	Risk Assessment of Severe Hypoglycemia	Behaviors that increase the risk of severe hypoglycemia
HAS	Hyperglycemia Avoidance Scale	Worries about high BG
NSQL	Neuropathy-Specific Quality of Life	Symptoms associated with neuropathy of the lower extremities
CARDS	Cox Assessment of Risky Driving Scale	General risky driving behaviors

Table 2—Psychometrics used in study 2 assessments (days 0, 70, and 435)

Table 3—Description of the units in the DD.com manual

Unit	Time to complete (minutes)	Focus	Content	Homework
0	10	How to navigate the website	Described how to use and proceed through the website	No
1	10	Tool kit	Provided a general overview of DD.com and introduced participants to the tool kit, designed to support anticipation, prevention, detection, and treatment of hypoglycemia while driving	No
2	25	General driving safety	Discussed general driving safety, e.g., the need for properly inflated tires, not driving while fatigued, and the potential effects of chronic complications of diabetes, such as lower limb neuropathy and retinopathy	No
3	40	Anticipating/preventing hypoglycemia	Reviewed insulin kinetics, the effect of recent carbohydrate ingestion, and the effect of moderate to vigorous physical activity on future BG	Yes
4	40	Detecting/treating hypoglycemia	Identified personally relevant, driving-specific, autonomic and neuroglycopenic symptoms (e.g., difficulty reading road signs or remembering the route) and the immediate and effective treatment needed to prevent mild hypoglycemia from progressing to more severe hypoglycemia	Yes
5	40	Long-term maintenance	Reviewed past homework and unit content, and developed a plan to sustain safe driving habits	Yes

using R statistical software version 3.1.2 (19). No significant differences were found between the DD.com and DD.com + MI groups on any outcome variables (number of units completed, daily progress notes completed, completion rate of DD.com, or number of driving mishaps [33]). Therefore, treatment outcomes are presented with these participants collapsed into a single intervention group, DD.com^{All}.

Looking first at the total number of mishaps in the 12-month follow-up period, the negative binomial model fit the data (χ^2 = 441.19; df = 424; P = 0.272), with group placement functioning as a significant predictor of yearly mishaps (likelihood ratio = 23.08; df = 2; $P <$ 0.001). The DD.com^{All} group reported fewer mishaps than the HR group receiving RC (z = 2.86; P = 0.01) but reported 1.58 times more mishaps than the LR group receiving RC (z = 2.59; P = 0.026). Specifically, DD.com reduced the difference in mishaps between the HR and LR groups receiving RC by 63% (Fig. 3, vertical bars).

Attribution of Driving Mishaps
This analysis examined the number of mishaps that participants attributed to hypoglycemia, hyperglycemia, or other factors. Figure 3 illustrates that the LR and HR groups receiving RC, the DD.com group, and the DD.com + MI group reported 0.75, 2.95, 1.65, and 1.53 hypoglycemia-related driving mishaps/

year/driver, respectively. The negative binomial model fit the data for total reported hypoglycemic driving mishaps (χ^2 = 364.43; df = 424; P = 0.983), with group placement as a significant predictor (likelihood ratio = 27.02; df = 2; $P <$ 0.001). The DD.com^{All} group reported fewer mishaps attributed to hypoglycemia than the HR group receiving RC (z = 2.86; P = 0.012) but more than the LR group receiving RC (z = 3.16; P = 0.004).

For driving mishaps attributed to hyperglycemia, the negative binomial model fit the data (χ^2 = 147.33; df = 424; P = 1.00). However, group

placement was not a significant predictor. Post hoc tests found no significant differences between groups in the number of hyperglycemic driving mishaps (see Fig. 3).

Psychological and Behavioral Assessments
It was hypothesized that specific diabetes-related attitudes and behaviors would differ between HR and LR groups at baseline, and would improve after DD.com. These included the management of hypoglycemia (RASH), fear of hypoglycemia (HFS), concerns about hyperglycemia (HAS), and general risky driving behaviors (Cox Assessment of Risky Driving Scale [CARDS]). It was
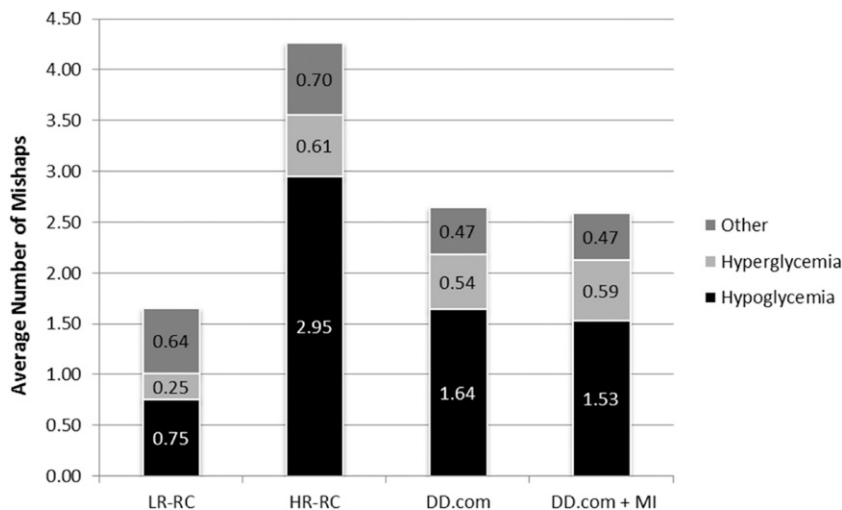

Figure 3—The average number of driving mishaps/year/driver based on cause: hypoglycemia, hyperglycemia, or other.

hypothesized that neuropathy-related quality of life, serving as a control variable, would remain the same or worsen as a result of the progressive nature of diabetes.

Supplementary Table 1 displays the mean group scores on these surveys for participants who completed all three assessments. Significant differences were found between the DD.com[All] and the RC groups at each assessment, as determined by post hoc Tukey honestly significant difference between-group tests. In addition, the table presents Bonferonni-corrected α values for significant within-group changes from day 0 assessment to day 70 and 435 assessments. In some analyses, scores were root-transformed to correct for excessive skew and/or kurtosis (see Supplementary Table 1).

The study hypotheses were generally supported. At baseline, no differences were found among the HR participants assigned to DD.com[All] or RC. By contrast, HR drivers reported more problems with hypoglycemia and driving than LR drivers on all measures at baseline. After assessment, neuropathy and quality of life did not improve, whereas scores on the HFS and the RASH improved for both HR groups (DD.com[All] and RC). However, improvements in these measures did not normalize the DD.com[All] group to the level of the LR group receiving RC, as seen in Supplementary Table 1. The mean score of the DD.com groups was significantly higher than that of the LR group receiving RC. No deterioration was seen in any of the psychobehavioral measures from day 70 to day 435 for the DD.com[All] group.

DD.com User Experience
After assessment, participants answered 14 questions concerning their experiences with DD.com. These were rated on a Likert scale, from 0 (not at all) to 4 (very). Mean item ratings from participants who did or did not complete DD.com on time appear in Supplementary Table 2.

DD.com completers rated all positive items higher than noncompleters (e.g., "How useful was the tool kit?": 3.53 vs. 2.80, respectively [$P < 0.004$]; "How easy was the web program to use?": 3.37 vs. 3.03, respectively [$P = 0.03$]). By contrast, noncompleters rated the two negative items higher than completers ("I didn't have time in my schedule": 0.67 vs. 1.46, respectively [$P = 0.001$]; "DD.com took too long to do": 0.51 vs. 1.03, respectively [$P = 0.001$]).

Discussion
The Internet program, DD.com, which focuses on the anticipation, prevention, detection, and treatment of hypoglycemia while driving, was effective at reducing hypoglycemia-related driving mishaps among HR drivers with type 1 diabetes. Beyond its efficacy, an advantage of this intervention is the online format, which made it immediately available to participants (regardless of their geographic location) in the privacy and convenience of their own homes, and did not require any clinic visits.

The improvement in hypoglycemia-related driving mishaps cannot be attributed to changes in general attitudes and self-reported behaviors involving driving and hypoglycemia, as these improved equally in participants in the DD.com[All] group and the HR group receiving RC. It is also important to note that DD.com only affected hypoglycemia-related driving mishaps, not hyperglycemia- or non-diabetes-related mishaps. Together, these data suggest that DD.com had the specific effect intended: reducing the occurrence of hypoglycemia-related driving mishaps. The results also suggest that the HR group receiving RC derived some psychological and behavioral benefits from participating in this study, perhaps by completing questionnaires that raised their level of awareness regarding their own driving risk.

Like the Diabetes Control and Complications Trial (DCCT), which relied on participant self-report of severe hypoglycemia (34), this randomized clinical trial relied on self-report of driving mishaps and causal attributions. Concern about participant response bias is lessened by the fact that HR participants receiving RC reported a higher incidence of driving mishaps than LR participants receiving RC, and that all groups reported a similar number of hyperglycemia- and non-diabetes-related driving mishaps. It may be that individuals who devoted the time and effort to complete this program had a differential bias in not reporting driving mishaps. This seems unlikely, however, given that the number of driving mishaps in the two DD.com groups was similar, whereas the number of mishaps reported in the two RC groups differed.

Other methodological limitations exist, which should be noted. 1) This design did not allow us to determine whether a simpler, shorter intervention could have been as effective as this five-unit program. It may be that just giving HR drivers the tool kit and simple instructions concerning how to anticipate, prevent, detect, and treat hypoglycemia would have yielded similar results. 2) Because we did not test DD.com with LR or intermediate-risk drivers, we cannot determine the effect of the intervention on those samples of drivers. 3) Because DD.com[All] participants attributed 25% of their driving mishaps to hyperglycemia, this intervention could possibly be enhanced by also focusing on anticipating, preventing, detecting, and treating driving-related hyperglycemia. 4) Given that the participant sample was recruited via the Internet, results from this selective sample may not generalize to all drivers with type 1 diabetes. 5) An additional limitation is that only 70% of the participants eventually completed the intervention, regardless of whether they received MIs. This is unlikely to be a consequence of the online study format, since both RC groups had a higher rate of monthly diary completion (96%) than either of the intervention groups. Noteworthy is that the highest dropout rate coincided with the completion of unit 3, in which there was the highest demand for "homework" activities (i.e., extensive reporting of driving diary activities). Nonetheless, in this large-scale, national, randomized trial with a 12-month follow-up, DD.com significantly reduced the risk of future driving mishaps among HR drivers with type 1 diabetes. This demonstrates that driving risk can be reduced in those drivers who are more vulnerable to hypoglycemia-related driving mishaps.

GENERAL CONCLUSIONS
This series of studies demonstrates that some drivers with type 1 diabetes are at greater risk of driving mishaps. These HR drivers can be identified using the RADD, a brief, psychometrically sound questionnaire that the ADA will soon host on their website. Finally, the incidence of future driving mishaps among HR drivers can be reduced via

the DD.com Internet intervention, which helps drivers with type 1 diabetes to better anticipate, prevent, detect, and treat hypoglycemia while driving.

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