IMPAIRED DRIVING PERFORMANCE IN PATIENTS WITH PRIMARY INSOMNIA

Impaired Driving Performance Associated with Effect of Time Duration in Patients with Primary Insomnia

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Study Objectives: To evaluate driving performance and psychomotor vigilance in patients with primary insomnia.
Design: After 1 night of polysomnography, participants performed a 1-h simulated monotonous driving task and a psychomotor vigilance task (PVT). Self-ratings of sleepiness, mood, and driving performance were completed.
Setting: This study was conducted at the CHU of Caen Sleep Unit and the University of Caen.
Participants: Twenty-one primary insomnia patients and 16 good sleepers.
Interventions: Not applicable.
Measurements and Results: Results revealed a larger standard deviation of lateral position (P = 0.023) and more lane crossings (P = 0.03) in insomnia patients than in good sleepers. Analyses of effect of time on task performance showed that the impairment in patients occurred after 20 min of driving, which was not the case for good sleepers. No difference between groups was found for the PVT, neither for the mean reaction time (RT) (P = 0.43) nor the number of lapses (P = 0.21) and the mean slowest 10% 1/RT (P = 0.81). Patients rated their sleepiness level higher (P = 0.06) and their alertness level lower (P = 0.007) than did good sleepers (P = 0.007). The self-evaluation of the driving performance was not different between groups (P = 0.15).
Conclusions: These findings revealed that primary insomnia is associated with a performance decrement during a simulated monotonous driving task. We also showed that patients are able to drive safely only for a short time. It appears advisable for clinicians to warn patients about their impaired driving performance that could lead to an increased risk of driving accidents.
Keywords: daytime impairment, duration of task, monotonous driving, primary insomnia, vigilance
Citation: Perrier J, Bertran F, Marie S, Couque C, Bulla J, Denise P, Bocca ML. Impaired driving performance associated with effect of time duration in patients with primary insomnia. *SLEEP* 2014;37(9):1565-1573.

INTRODUCTION

One of the most prevalent sleep disorders is insomnia, which affects from 5% to 30% of the general population.[1–3] The wide range of prevalence values is mainly linked to the definition used to assess insomnia, which differs across studies. The current work focuses on primary insomnia. According to the Diagnostic Statistical Manual of Mental Disorders, 4th Edition (DSM-IV) definition, primary insomnia is a complaint of nonrestorative and/or insufficient sleep with various symptoms, such as difficulties in initiating and maintaining sleep and early morning awakenings associated with complaints of daytime consequences without comorbidity. Using this definition, the prevalence of primary insomnia was found to occur in 3–5% of the general population.[2]

Insomnia is a public health problem, with annual direct and indirect costs estimated at $1,253 greater than for patients without insomnia in the United States[9]; these costs were estimated at $5,010 per year in the province of Quebec, Canada.[10] These costs are the result of reduced productivity, higher work absenteeism, and nonmotor vehicle accidents in patients with insomnia in comparison with good sleepers.[11–13] Another consequence of insomnia is the increased risk of road accidents. Sleep disorders comprise one of the many factors suspected of increasing the risk of road accidents.[14] Insomnia was associated with a 2.5- to 3-fold higher risk of serious road accidents in comparison with good sleepers, according to a French survey.[15] However, no experimental studies have been performed to evaluate the effects of insomnia on driving performance. Staner et al.[16] showed that patients with insomnia treated with hypnotics had impaired driving performance in comparison with placebo-treated patients with insomnia. This study did not include a control group of good sleepers. Consequently, because the use of hypnotics is associated with impaired driving performance[17–19] and increased risk of driving accidents,[20–22] whether insomnia without hypnotic treatment leads to impaired driving performance in comparison with good sleepers has not been established. The primary objective of the current study was therefore to evaluate the effects of untreated insomnia on driving performance.

Driving a car requires the possession of sufficient cognitive, visual, and motor skills, and involves managing attention in order to perform various driving- and nondriving-related tasks.[23] Epidemiological and experimental studies have focused on some factors leading to road accidents or driving impairments. Sleepiness and fatigue are often cited.[24] For example, it has been demonstrated that sleepiness is responsible for almost 15–20% of road accidents.[25–30] Because patients with primary insomnia have not been found to be sleepy in most studies,[31] Smolensky et al.[14] hypothesized that the increase in car crashes may be caused by other factors, such as daytime fatigue and

A commentary on this article appears in this issue on page 1411.

Submitted for publication August, 2013
Submitted in final revised form March, 2014
Accepted for publication March, 2014
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cognitive impairment, which are consistently reported. The secondary objective of this study was to assess the effects of untreated insomnia on a cognitive function, i.e., vigilance. For this, we used the classic test used in sleep deprivation and driving studies, the Psychomotor Vigilance Test (PVT), which is based on a simple visual reaction time.[32–36] Assessment of subjective feelings, i.e., change of mood, alert feelings, and subjective driving performance evaluation, were assessed using the Karolinska Sleepiness Scale (KSS),[37] a Visual Analog Mood Scale (VAMS),[38] and a driving scale.[39]

METHODS

Participants

Participants were recruited via announcements posted in public transportation centers, medical centers, and newspapers. Following a telephone interview, participants from both groups were carefully interviewed by a sleep clinician to ascertain: (1) sleeping difficulties and diagnosis of DSM-IV insomnia for the insomnia patients group; and (2) good physical condition: the absence of sleep, alertness, neurological, cardiovascular, respiratory, hepatic, renal, or metabolic disorders, and absence of poor hygiene or habitual abnormal sleep patterns (e.g., night or shift work) for the good sleepers group.

Participants included in the insomnia group had to meet the following inclusion criteria according to DSM-IV primary insomnia criteria: (1) presence of a subjective complaint of insomnia, defined as difficulty initiating (sleep onset latency (SOL), > 30 min) and/or maintaining sleep (time awake after sleep onset > 30 min); (2) early awakening (< 6.5 h of sleep or waking up earlier than the desired wake time); (1) and (2) had to occur at least 3 nights per week; (3) insomnia for at least 6 mo; (4) insomnia or its perceived consequences causing marked distress or significant impairment of occupational or social function (problems of concentration); and (5) presence of a subjective complaint of at least one negative daytime consequence attributed to insomnia (e.g., fatigue, mood disturbances).

The exclusion criteria were: (1) current medical or neurological disorder that could compromise sleep; (2) serious psychopathology that could induce insomnia; (3) consumption of psychotropic or other medications known to alter or induce sleep; (4) poor hygiene or habitual abnormal sleep patterns (e.g., night or shift work); and (5) other sleep disorders (assessed by polysomnography [PSG]) such as sleep apnea (apnea-hypopnea index > 10), or periodic limb movements during sleep (myoclonic index with arousal > 10). All participants with insomnia and good sleepers were excluded if they: (1) had current or past dependence on alcohol, opiates, benzodiazepines, or any illicit drugs; (2) smoked more than five cigarettes per day; (3) drank more than 28 units of alcohol per week; or (4) consumed more than 150 mg of caffeine per day. All participants had normal or corrected to normal vision (visual acuity greater than or equal to 7/10). They had all driven regularly for at least 2 y and drove at least 5,000 km/y.

Twenty-one participants suffering from chronic primary insomnia (9 men and 12 women; mean age = 48 ± 16; age range = 24–77 y) and 16 good sleepers (6 men and 10 women; mean age = 48 ± 14; age range = 23–64 y) were included in this study. It was granted ethical approval by the Caen Northwest III ethics committee and by the Health Ministry (number DGS 2005/0388). Each participant provided written consent in accordance with the requirements of the committee.

Experimental Procedure

To avoid motion sickness, participants were familiarized with the simulator 1 w before the experimental day. None of the participants suffered from motion sickness. The day before the tests (driving, self-assessments, and PVT), the participants arrived at the sleep unit at 20:30 for a PSG recording. Lights out was initiated at 22:30 and participants were awakened at 07:00 the following morning by the experimenter.

After a standardized breakfast, participants were brought to the laboratory to perform the tests. At 08:30, blood and urine samples were collected for routine laboratory drug screening for alcohol, opiates, cocaine, cannabis, amphetamines, and barbiturates.

At 09:00 (i.e, 2 h after waking up), participants were brought to the simulator room to complete a 1-h simulated driving test. After a short break, they completed self-assessment scales at approximately 10:15 (i.e., 3 h and 15 min after waking up) relating to their subjective sleepiness (KSS), their subjective mood (VASM), and their subjective driving performance. They underwent PVT at 10:30 (i.e., 3.5 h after waking up). The PSG and daily schedules were standardized across all subjects and both groups (insomnia patients and good sleepers).

Sleep Recordings

Sleep was recorded using an ambulatory PSG monitor (Medatec Dream). A standard montage of PSG was used, including eight electroencephalographic (EEG) channels (F3, F4, C3, C4, O1, O2, T3, T4, referenced on A1 and A2), two electro-oculogram (EOG) channels, and one submental electromyogram channel. The setup was complemented by recordings from the left and right anterior tibialis muscle, recordings of nasal/oral airflow, thoracic and abdominal effort, body position, and oximetry. All PSG were scored according to the standard criteria[40] by experienced sleep specialists (CC, FB).

Objective measures of sleep included SOL (min), wake after sleep onset (WASO, min), total sleep time (TST, min), sleep efficiency (SE, %), total time (min), latencies (min), and percentage of stages 1, 2, 3-4, and rapid eye movement (REM).

Simulated Driving Test

The driving experiment was carried out on the SIM2 INRETS fixed-base driving simulator equipped with an ARCHISIM object database.[41] This simulator is composed of a steering cab connected to a personal computer for managing signal acquisition, sound restitution, and image display (Figure 1). The images, generated at a frequency of approximately 30 Hz, were projected by a video projector onto a screen (H: 60°; V: 49°) located 1.90 m from the driver's eyes. The center of the screen was located at the driver's eye level (1.38 m). The acquisition frequency for the different signals (position, speed, acceleration, etc.) was 30 Hz.

The monotonous driving test consisted of 1 h of driving in a driving simulator in monotonous conditions (no traffic, repetitive landscape). Participants were instructed to drive as straight as possible within the right traffic lane while maintaining a

constant speed of 110 km/h. The primary parameter was the amount of weaving of the car, measured by the standard deviation of lateral position (SDLP, m), which is an index of safe driving or of road-tracking error. The SDLP was calculated using the lateral position data, and we first excluded all lateral position data that were outside the right traffic lane. Then, we calculated the mean lateral position and the standard deviation of this mean lateral position according to the mathematical definition of a standard deviation described in the study by Verster and Roth.[42] The standard deviation of speed (SDS, km/h), the mean lateral position (mLP, m), mean speed (mS, km/h), and the number of lane crossings (LC) were also analyzed.

We previously used the INRETS-FAROS simulator to evaluate monotonous driving performance after medication intake and showed that the simulator was sensitive enough to reveal driving impairments in monotonous conditions after drug intake.[19]

Vigilance Evaluation

The PVT is a 10-min computerized task that assesses sustained attention and simple reaction time and requires continuous attention to detect randomly occurring stimuli.[43,44] The PVT requires acknowledgment of a visual stimulus (a white circle presented at the center of the screen) by pressing the response button. The response time was displayed on the screen after a subject's response. If the participant responded later than 500 ms or failed to respond within 1.5 sec, a "lapse" was recorded. Each stimulus was separated by a randomly determined interstimulus interval ranging from 3 to 10 sec. The number of lapses (n), the mean reaction time (RT) (ms) and the mean slowest 10% 1/RT (ms) were quantified. A lapse was defined as a response slower than 500 ms, in accordance with Drummond et al.[45] The variable "slowest 10% 1/RT" was calculated according to the methodology described in Basner and Dinges.[47] For calculating mean 1/RT and then the slowest 10% 1/RT, each RT (ms) was divided by 1,000 and then reciprocally transformed. The transformed values were then averaged.

Subjective Evaluations

After the monotonous driving task, all participants rated their sleepiness with the KSS,[37] their subjective feelings regarding change of mood with VAMS,[38] and their "subjective driving quality," using a continuous scale for self-rating their driving quality.[39]

The KSS is a nine-point verbally-anchored scale with the following stages: (1) very alert; (3) alert; (5) neither alert nor sleepy; (7) sleepy; and (9) very sleepy, fighting sleep. Other points represent intermediate stages between the two neighboring points without definitions. This scale is often used to evaluate the acute sleepiness level.[46]

The driving scale consisted of a 100-mm vertical visual analog scale with three levels: (1) "I drove exceptionally poorly" at 0 mm; (2) "I drove normally" at 50 mm; and (3) "I drove exceptionally well" at 100 mm. Responses were given on a visual analog scale of 100 mm with an "x" marked at the appropriate level. If the response was near ± 50 mm, the participants estimated that they drove normally and safely.

The VAMS comprised nine 100-mm lines anchored by antonyms (alert/drowsy, attentive/dreamy, muzzy/clear-headed, mentally slow/quick-witted, lethargic/energetic, well coordinated/clumsy, strong/feeble, interested/bored, proficient/incompetent). Participants were asked to place a mark on the horizontal line equivalent to the strength of a particular feeling at the given time before and after the driving task.

Figure 1—Example of the visual interface of the simulator used for the experiment.

Statistical Analysis

Statistical analyses were carried out using R 2.15.0 software (www.r-project.org). The driving and VAMS data that were analyzed are of longitudinal structure with both random and fixed effects. To capture these effects, we selected linear mixed effects models as the methodological approach. To capture serial within-subject correlation, we investigated different correlation structures. Using the Bayesian information criterion (BIC), the time series typical AR(1) error structure was selected. Moreover, heteroscedasticity of the residuals was taken into account by the model structure. To evaluate whether a variable had a significant effect, we followed the approach of Pinheiro and Bates[47] and compared models with and without the respective variable by means of a likelihood ratio test (LRT). The statistical result of this model comparison is represented as the likelihood ratio L.r. value and the associated P value (e.g., L.r. = XX; P = XX). When the LRT indicated a significant effect of a variable, the coefficients of the model were further examined and represented as the *t* and P values associated with each variable tested (e.g., $t_{(35)}$ = XX; P = XX). For analyses with several variables of interest, these were included stepwise into the model: starting with the variable subject to the strongest effect, and successively adding those with weaker effect.

For driving data, the choice of comparing the first 20 to the last 30 min via a dummy variable was taken after visual inspection of the data, which suggested that the two groups progressed differently over time. As the main effect manifests itself via a constant increase in the variable considered during the last 30 min, the modeling approach via a dummy variable seemed natural from a statistical point of view. Therefore, we added a dummy variable for the last 30 min of driving in interaction with the group membership.

Table 1—Baseline characteristics of participants

Questionnaires	INS (n = 21) Mean (SD)	GS (n = 16) Mean (SD)	Statistical test used [a]	P values	Effect sizes [b,c]	
					Cohen's d	Cliff's delta
ISI	16.00 (4.96)	2.55 (1.64)	*t*	< 0.0001	3.94	1.00
PSQI	10 (2.72)	4 (2.07)	*t*	< 0.0001	2.54	0.95
Horne and Ostberg	57.81 (9.13)	60.33 (8.7)	*t*	0.42	0.28	-0.14
Epworth	6.9 (4.55)	6.2 (3.88)	*t*	0.65	0.16	0.12
Driving license (date of obtention)	1980 (15)	1983 (13)	W	0.63	0.19	-0.10
Number of accidents	0.7 (0.92)	0.92 (0.95)	W	0.51	0.15	-0.10
Age	48.71 (16.18)	48.31 (14.21)	W	0.94	0.026	-0.012
Sex	9M/10F	6M/10F	χ^2	0.73	0.041[c]	

Between-group analyses: [a] The *t*-test/Welch test were used if the normality hypothesis was not rejected by the Shapiro-Wilk test. For non-Gaussian samples, preference was given to the Wilcoxon-Mann-Whitney test. For the categorical sex variable, Fisher's exact test investigates the equality hypothesis of the population probabilities, and the Φ coefficient measures the effect size. [b] Effect sizes were calculated for all comparisons. We report Cohen's d and Cliff's delta, where Cohen's d should be preferred for Gaussian and Cliff's delta for non-Gaussian samples. [c] We used the Φ coefficient for measuring the effect size of the categorical sex variable. P < 0.05 was considered significant between groups. GS, good sleepers; INS, insomnia patients; ISI, Insomnia Severity Index; PSQI, Pittsburg Sleep Quality Index; SD, standard deviation.

For comparisons of two (unpaired) groups, the *t*-test and Welch test were used if the normality hypothesis could not be rejected by the Shapiro-Wilk test. For non-Gaussian samples, preference was given to the Wilcoxon-Mann-Whitney test.

Finally, the relationship of the main parameter of driving (SDLP) with the main sleep variables (TST, SE) was evaluated with tests for correlation, and 2 × 2 frequency tables were analyzed by Fisher's exact test.

For all statistical methods applied, we report the respective effect sizes. That is, for comparison of two groups we provide Cohen's d[48] and Cliff's delta.[49] Cliff's delta is more appropriate for samples violating the normality assumption, whereas Cohen's d should be considered in the Gaussian case. The effect size calculated for 2 × 2 frequency tables is the phi coefficient,[50] and for mixed effects models we used partial and conditional R^2, introduced by Nakagawa and Schielzeth.[51] The level of statistical significance was set at P < 0.05.

RESULTS

After PSG screening, five of 42 participants were excluded because of other sleep disorders (e.g., sleep apnea or periodic limb movement), three of whom were in the insomnia group and two in the good sleepers group. Twenty-one patients with insomnia and 16 good sleepers were included in the final analyses (Table 1).

Sleep Recordings

Participants with insomnia had significantly lower SE (P = 0.048) and a longer duration of awakenings after sleep onset (P = 0.021) compared to good sleepers. Patients with insomnia and good sleepers did not differ in the other sleep parameters (Table 2).

Monotonous Driving Test

Results are presented in Tables 3A and 3B, and Table S1 in the supplemental material provides details on the mixed effects model used for the main driving parameters.

Analysis of the primary parameter, the SDLP variable, showed a significant group effect (L.r. = 5.34; P = 0.021). The model coefficient indicated that participants with insomnia had a significantly greater SDLP than good sleepers ($t_{(35)}$ = 2.38; P = 0.023). The resulting division of the test into two periods (the first 20 min and last 30 min) using the dummy variable is supported by the LRT (L.r. = 7.55; P = 0.023). Investigation of the model coefficients revealed a significant difference between the two periods for the insomnia group ($t_{(146)}$ = 2.70; P = 0.008). However, no significant difference between the two periods could be detected in the good sleepers group ($t_{(146)}$ = -0.53; P = 0.60). These results indicate that the insomnia group is subject to a significant increase in the SDLP after 20 min of driving.

Similarly, analyses of data on the number of lane crossings showed a significant effect of both the group variable (L.r. = 4.82; P = 0.0282) and the aforementioned dummy variable effect (L.r. = 13.89; P = 0.001). The model coefficient indicated a significant difference between patients with insomnia and good sleepers ($t_{(35)}$ = 2.2; P = 0.030). Moreover, participants with insomnia showed a significant increase in the number of lane crossings ($t_{(146)}$ = 3.03; P = 0.003) during the last 30 min, whereas a smaller but significant decrease in the number of lane crossings occurred in the good sleepers group ($t_{(146)}$ = -0.26; P = 0.025) (Table 3 and Figure 2).

No significant group effect was found for the SDS (P = 0.617), the lateral position (P = 0.061), or the mS (P = 0.646). These three parameters were used as controls to ensure that participants respected the driving instructions (Table 3B).

Self-Assessment Scales

Results are presented in Tables 4A and 4B, and Table S1 in the supplemental material provides details on the mixed effects model used for the VAMS.

Patients with insomnia evaluated their own driving performance as accurately as good sleepers (P = 0.15). Results of the sleepiness scale revealed a non-significant trend in group effect; insomnia patients felt less awake than good sleepers (P = 0.060) (Table 4A). For the VAMS data analyses with a mixed model, group and time of testing revealed significant effects of group

Table 2—Sleep characteristics of participants

Sleep parameters	INS (n = 21) Mean (SD)	GS (n = 16) Mean (SD)	Statistical test used [a]	P values	Effect sizes [b]	
					Cohen's d	Cliff's delta
TSP (min)	462.52 (29.53)	448.46 (53.72)	W	0.72	0.35	0.077
TST (min)	376 (49.96)	395.85 (55.28)	*t*	0.29	0.40	-0.22
SE (%)	74.38 (10.19)	81.38 (7.67)	*t*	0.030	0.75	-0.43
REM Latency (min)	175.85 (93.56)	133.92 (31.24)	W	0.32	0.54	0.21
Wake time (min)	86.14 (50.24)	51 (32.88)	W	0.045	0.79	0.42
Number of WASO	28.52 (14.81)	20.22 (8.09)	W	0.085	0.65	0.36
Stage 1 (% TST)	13.13 (5.23)	12.06 (4.37)	*t*	0.53	0.22	0.12
Stage 2 (% TST)	40.89 (9.43)	45.92 (8.69)	*t*	0.12	0.55	-0.29
SWS (% TST)	28.89 (8.61)	25.05 (5.77)	*t*	0.13	0.50	0.26
REM (% TST)	15.56 (5.43)	16.96 (3.58)	*t*	0.37	0.29	-0.17

Between-group analyses: [a] The *t*-test/Welch test were used if the normality hypothesis was not rejected by the Shapiro-Wilk test. For non-Gaussian samples, preference was given to the Wilcoxon-Mann-Whitney test. [b] Effect sizes were calculated for all comparisons. We report Cohen's d and Cliff's delta, where Cohen's d should be preferred for Gaussian and Cliff's delta for non-Gaussian samples. P < 0.05 was considered significant between groups. GS, good sleepers; INS, insomnia patients; REM, rapid eye movement; SD, standard deviation; SE, sleep efficiency; SWS, slow wave sleep; TSP, total sleep period; TST, total sleep time, WASO, wake after sleep onset.

Table 3—Monotonous driving task results

A. Main driving parameters	INS (n = 21) Mean (SD)	GS (n = 16) Mean (SD)	Group effect	Dummy variable × INS	Dummy variable × GS	Marginal R^2, conditional R^2
SDLP (m) (first 20 min)	0.41 (0.09)	0.36 (0.09)	0.023	0.008	0.60	0.12
SDLP (m) (last 30 min)	0.43 (0.12)	0.36 (0.08)				0.83
Lane crossings (first 20 min)	0.29 (0.60)	0.47 (0.92)	0.03	0.003	0.025	0.09
Lane crossings (last 30 min)	1.02 (1.52)	0.13 (0.33)				0.12

B. Secondary driving parameters	INS (n = 21) Mean (SD)	GS (n = 16) Mean (SD)	Statistical test used [a]	P values	Effect sizes [b]	
					Cohen's d	Cliff's delta
SDS (km/h)	2.81 (2.63)	2.27 (1.94)	W	0.62	0.23	0.10
Lateral position (m)	7.37 (0.21)	7.5 (0.21)	*t*	0.061	0.64	-0.39
Mean speed (km/h)	111.44 (3.39)	111.12 (1.32)	W	0.65	0.12	0.092

(A) Main driving parameters. A linear mixed effects model with two fixed effects, the group variable and a binary dummy variable corresponding to the last 30 min of driving, was estimated. The model was fitted stepwise by including the group effect, the dummy variable, and their interaction. Marginal and conditional R^2 quantify the effect size and model fit in terms of proportion of explained variance by random and fixed effects, respectively. Note that the structure of the lane crossing data (zero-inflated count data) results in comparably low values. **(B)** Secondary driving parameters. [a] The *t*-test/Welch test were used if the normality hypothesis was not rejected by the Shapiro-Wilk test. For non-Gaussian samples, preference was given to the Wilcoxon-Mann-Whitney test. [b] Effect sizes were calculated for all comparisons. We report Cohen's d and Cliff's delta, where Cohen's d should be preferred for Gaussian and Cliff's delta for non-Gaussian samples. P < 0.05 was considered significant between groups. GS, good sleepers; INS, insomnia patients; SD, standard deviation; SDLP, standard deviation of lateral position; SDS, standard deviation of speed.

(L.r. = 7.64; P = 0.006) and session (L.r. = 4.03; P = 0.045). The coefficients of the model showed that the patients with insomnia had a lower alertness score than the good sleepers ($t_{(36)}$ = 2.87; P = 0.007); participants with insomnia felt less alert than good sleepers. Moreover, the model coefficients revealed a significantly higher alertness score for the session before driving than for the session after driving; the participants felt less alert after driving than before driving ($t_{(35)}$ = 2.10; P = 0.043) (Table 4B).

Psychomotor Vigilance Test

Analyses of the PVT data showed no group effect for all variables analyzed (Table 5).

Correlation Between Driving and Sleep Data

Coefficients of correlation revealed a significant negative effect of TST (P = 0.011) and SE (P = 0.009) for predicting the weaving of the car (SDLP), but no significant effect for the duration of WASO. When TST or SE decreases, SDLP increases, thus driving performance decreases (Table 6).

DISCUSSION

This study was primarily aimed at evaluating the driving performance of untreated patients with primary insomnia in comparison with good sleepers. Our results revealed that patients with primary insomnia had impaired simulated

monotonous driving performance compared to good sleepers, as shown by the increase in SDLP and the number of road exits.

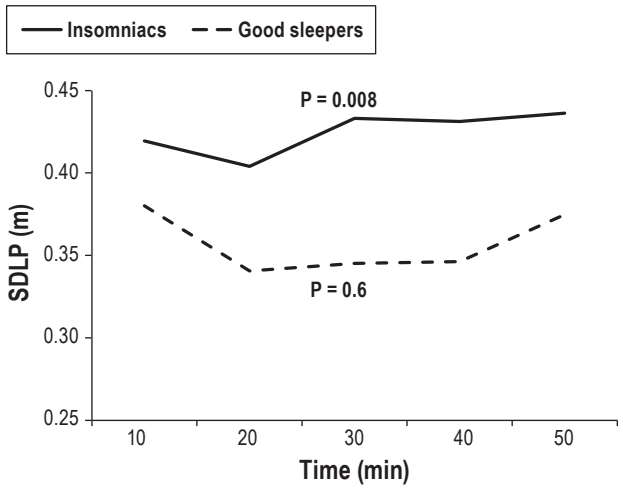

Figure 2—Standard deviation of lateral position (SDLP) throughout the driving task. Significant effects of the dummy variable are indicated on the graph. The dummy variable represents the comparison between the period of the first 20 min and the period of the last 30 minutes of driving for each group. P < 0.05 was considered significant between periods.

These findings indicate that patients with primary insomnia experienced more difficulty in maintaining the trajectory of the simulated vehicle than did good sleepers. In terms of traffic safety, each driving lane crossing could lead to a loss of trajectory control and thus to a potential accident. The impaired simulated driving performance in the insomnia group appeared to be in agreement with an epidemiological study showing that patients with insomnia had approximately three times more risk of having traffic crashes than controls.[15] However, in this epidemiological study,[15] no specific analysis was performed between treated and untreated patients with insomnia. The current study is the first to reveal that simulated monotonous driving performance is impaired in patients with primary insomnia. Moreover, the current findings also revealed that impairments occurred during the last 30 min, both for the SDLP and the number of lane crossing parameters, which indicates that patients with insomnia were no longer able to perform as well as good sleepers after 20 min of simulated driving.

Although the values of SDLP in the current study are higher than those usually found in on-the-road driving studies,[52] they are in agreement with values reported in several studies using simulators.[53,54] The difference in SDLP values can be explained by several methodological characteristics inherent to the simulators such as the field of vision, the force feedback of the steering wheel, or the type of road (straight line or curves). In addition,

Table 4—Results of the self-assessment scales

A. Self-assessment scales	INS (n = 21) Mean (SD)	GS (n = 16) Mean (SD)	Statistical test used [a]	P values	Effect sizes [b] Cohen's d	Effect sizes [b] Cliff's delta
KSS (Sleepiness)	4.81 (2.05)	3.47 (1.93)	*t*	0.060	0.49	-0.24
Driving performance	-0.44 (2.52)	0.82 (2.74)	W	0.15	0.76	0.36

B. VAMS	INS (n = 21) Mean (SD)	GS (n = 16) Mean (SD)	Group effect	Session effect	Marginal R^2, conditional R^2
Before Driving	2.79 (1.70)	1.90 (1.28)	0.007	0.043	0.54
After Driving	3.79 (2.13)	2.12 (0.97)			0.14

(A) Self-assessment scales. [a] The *t*-test/Welch test were used if the normality hypothesis was not rejected by the Shapiro-Wilk test. For non-Gaussian samples, preference was given to the Wilcoxon-Mann-Whitney test. [b] Effect sizes were calculated for all comparisons. We report Cohen's d and Cliff's delta, where Cohen's d should be preferred for Gaussian and Cliff's delta for non-Gaussian samples. P < 0.05 was considered significant between groups. **(B)** For the Visual Analog Mood Scale (VAMS), a linear mixed effects model with group and session variables as fixed effects was used, as before fitted stepwise. No interaction of the session and group variables was found. Marginal and conditional R^2 quantify the effect size and model fit in terms of proportion of explained variance by random and fixed effects, respectively. P < 0.05 was considered significant between groups. GS, good sleepers; INS, insomnia patients; SD, standard deviation; KSS, Karolinska Sleepiness Scale; VAMS, Visual Analog Mood Scale.

Table 5—Results for the Psychomotor Vigilance Test

PVT parameters	INS (n = 21) Mean (SD)	GS (n = 16) Mean (SD)	Statistical test used [a]	P values	Effect sizes [b] Cohen's d	Effect sizes [b] Cliff's delta
Mean RT (min)	267.98 (39.57)	259.68 (22.60)	*t*	0.43	0.25	0.20
Mean Slowest 10% 1/ RT (min)	536.10 (257.05)	433.44 (151.05)	W	0.81	0.47	0.25
Number of lapses	3.62 (5.27)	1.31 (1.40)	W	0.21	0.17	0.051

[a] The *t*-test/Welch test were used if the normality hypothesis was not rejected by the Shapiro-Wilk test. For non-Gaussian samples, preference was given to the Wilcoxon-Mann-Whitney test. [b] Effect sizes were calculated for all comparisons. We report Cohen's d and Cliff's delta, where Cohen's d should be preferred for Gaussian and Cliff's delta for non-Gaussian samples. GS, good sleepers; INS, insomnia patients; PVT, Psychomotor Vigilance Test; RT, reaction time; SD, standard deviation. P < 0.05 was considered significant between groups.

the experimental conditions between on-the-road driving and simulators studies are quite different in terms of awareness of danger, light exposure, proprioceptive feedback, and stimulating environment. We may hypothesize that a simulated environment has facilitated the detection of an impaired driving performance in the untreated group with insomnia. Nevertheless, this has no influence on the comparison between the insomnia and control groups because only the performance difference between both groups has a significant meaning, and both groups completed the simulated driving task in the same experimental conditions.

The secondary objective of this study was to assess performance of sustained attention by using the PVT, which is sensitive to sleep pressure.[43,44,55,56] The lack of impairment found in the insomnia group is in agreement with previous studies that used similar simple short duration reaction time tasks.[57] Orff et al.[58] used the same PVT as that used in the current study, and did not find any significant impairment although their sample size was larger than ours (32 insomnia patients and 17 good sleepers). In comparison, performance impairments in insomnia patients were observed only if complex short duration reaction time tasks were used.[59,60] The effect sizes reported for the PVT in the current study were small to medium, which may indicate that a larger sample size might be required to render the differences statistically significant. We subsequently carried out a Monte Carlo approach to check which sample size would have been required to obtain a sufficient level of power (0.8). The results obtained show that very large sample sizes are required (more than 90 participants for the variable number of lapses, which is the smallest sample size required among all variables). Thus, our findings indicate that both groups are subject to very small differences and that the PVT may not be the best method for highlighting cognitive dysfunction in insomnia.

The lack of impairment in the PVT in the current study is also in agreement with the lack of impairment observed during the first 20 min of the monotonous driving test, suggesting that patients with insomnia are able to maintain the same performance level as good sleepers during tasks of relatively short duration with low cognitive demand. Although the monotonous motorway driving test used in the current study is probably more complex than the PVT, it involves automatic processing and requires a low attentional demand.[61] These findings revealed that patients with insomnia are able to adequately perform a relatively simple task of short duration, but are not able to maintain their level of performance when the task is longer, even if it is simple. We hypothesized that patients with insomnia probably compensate their effort during the first 20 min of the driving task and during the PVT. This compensatory effort is probably because of the hyperarousal phenomenon,[62,63] which masks impairment when short or simple tests are used.

The subjective measures were used to characterize variations in driver performance and alertness level. The KSS measures did not show patients with insomnia to be sleepy. They only felt slightly less awake than good sleepers, which is in agreement with a previous study.[31] The VAMS revealed that the level of alertness was lower after the driving task in comparison to before for both groups, which is probably linked to the long duration of the driving task. Moreover, patients with insomnia felt less alert than good sleepers both before and after the driving test. It is interesting to observe that the level of alertness was on average more changed in the insomnia patients group than in the good sleepers group after the driving test. Although this interaction did not reach significance level, this result suggests that the monotonous driving test required more effort for the patients with insomnia than for the good sleepers. No correlation was found between the insomnia severity index and both objective and subjective measures of driving performance (data not shown). However, the subjective scale of driving performance revealed that the patients with insomnia seemed to be unaware of their driving difficulties because they estimated their driving performance as normal, as did good sleepers. This dissociation between objective evaluation and subjective perception is an important concept in traffic safety because drivers can overestimate their own ability to drive safely.

Table 6—Results of correlation between standard deviation of lateral position and sleep parameters

	Correlation with TST *r* (P value)	Correlation with SE *r* (P value)
SDLP (m)	-0.44 (0.011)	-0.44 (0.0096)

Linear correlation between SDLP and the main sleep parameters were obtained by using Pearson product moment correlation coefficient *r*. For none of the variables involved, normality was rejected by the Shapiro-Wilk test. $P < 0.05$ was considered significant between groups. SDLP, standard deviation of lateral position; SE, sleep efficiency; TST, total sleep time.

Sleep analysis showed that patients with insomnia objectively slept worse than did good sleepers in the laboratory, which confirmed subjective complaints measured by the PSQI. Findings on sleep architecture in primary insomnia are inconsistent.[64,65] Nevertheless, our results demonstrate that the simulated driving impairment was associated with both poor SE and quantity; the worse participants slept, the worse they drove. Interestingly, this link was found for both groups, with no intergroup differences observed. This result implies that the simulated driving performance depends on the quantity and the efficiency of sleep, independent of the participant status (being a patient with insomnia or a good sleeper). This relation between sleep quality and daily performance is thus in line with the study by Fernandez-Mendoza et al.,[66] which reported that only patients with insomnia with short sleep duration had objective cognitive dysfunction, which was not found in patients with insomnia with normal sleep duration.

Although the wide age range of the participants may be a limitation of the current study, no age effect was found in any parameter. However, a limitation of the study is the relatively small sample size of participants that may have prevented us from being able to assess whether young persons with insomnia experienced more impairments than older persons, as suggested by another study.[67]

Because most patients with insomnia are treated with hypnotics, further research is needed to study this population to assess whether the treatment has beneficial or deleterious effects on driving performance. This question remains to be addressed, as it has been clearly shown that hypnotics impair driving performance after a single intake in healthy young or older subjects,[17,19] or after 1 w of treatment in patients with insomnia,[16] but the effects of long-term treatment with hypnotics have not yet been studied.

In conclusion, the current study revealed that primary insomnia was associated with impaired driving performance during a simulated monotonous driving task. We also demonstrated that patients were able to drive for very short periods (less than 20 min), but when the duration of the task was longer, impairment occurred (probably because of decreased vigilance). The current findings highlight complaints expressed by patients regarding performance of daily tasks. It appears advisable for clinicians to warn patients about their impaired driving performance that could lead to an increased risk of driving accidents, particularly if they have to drive for relatively long periods of time in a monotonous environment. In addition, the current findings indicate that the driving impairments appeared to be associated with poor sleep efficiency and quantity without distinction between groups.

ABBREVIATIONS

BIC, bayesian information criteria
EEG, electroencephalographic
EOG, electroculogram
ISI, insomnia severity index
KSS, karolinska sleepiness scale
LC, lane crossings
LRT, likelihood ratio test
MLP, mean lateral position
MS, mean speed
PSG, polysomnography
PSQI, pittsburg sleep quality
PVT, psychomotor vigilance test
REM, rapid eye movement
SD, standard deviation
SDLP, standard deviation of lateral position
SDS, standard deviation of speed
SE, sleep efficiency
SOL, sleep onset latency
TST, total sleep time
VAMS, visual mood scale
WASO, wake after sleep onset

ACKNOWLEDGMENTS

Authors' contributions: Marie-Laure Bocca, Pierre Denise, Joy Perrier, and Sullivan Marie conceived, designed, and managed the study. Joy Perrier and Sullivan Marie performed experiments. Françoise Bertran, Colette Couque, and Pierre Denise recruited patients and controls, and Françoise Bertran and Colette Couque scored the polysomnographies. Joy Perrier, Marie-Laure Bocca, and Jan Bulla prepared, analyzed, and interpreted the data. Joy Perrier, Marie-Laure Bocca, Jan Bulla, Pierre Denise, and Françoise Bertran drafted the manuscript. Jan Bulla was in charge of development and selection of statistical procedures, and carried out the statistical analyses. The authors thank Gwenaelle Huet for her help during data collection, Valerie Fong-Constans for reviewing the English, and the participants for their involvement in the study.

DISCLOSURE STATEMENT

This was not an industry supported study. This work was conducted as part of the Driving under the influence of drugs, alcohol, and medicines (DRUID) research consortium funded by European Union grant TREN-05-FP6TR-S07.61320-518404-DRUID. This report reflects only the authors' view. The European community is not liable for any use of the information contained herein. The work was performed at the INSERM/UCBN, U1075 COMETE, Caen, 14032, France. The authors have indicated no financial conflicts of interest.

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SUPPLEMENTAL MATERIAL

Table S1—Detailed estimation results for mixed effects models

	Coefficients	Estimate	SE	df	*t*-value	P value	R^2
SDLP (m)	Intercept	0.36	0.022	146	16.27	< 0.0001	Marginal
	INS	0.051	0.029	35	1.75	0.089	0.12
	Last.30	-0.005	0.009	146	-0.53	0.60	Conditional
	INS × Last.30	0.022	0.008	146	2.70	0.008	0.83
Lane crossings	Intercept	0.48	0.13	146	3.63	< 0.0001	Marginal
	INS	-0.21	0.25	35	-0.83	0.42	0.09
	Last.30	-0.33	0.15	146	-2.26	0.025	Conditional
	INS × Last.30	0.77	0.25	146	3.034	0.003	0.12
VAMS	Intercept	1.79	0.33	36	5.44	< 0.000 1	Marginal
	INS	1.29	0.45	36	2.87	0.007	0.54
	Session 2	0.42	0.20	35	2.10	0.043	Conditional
							0.14

Detailed statistical results of the estimated mixed effects models used for the main driving parameters and the VAMS data. For the main driving parameters, a linear mixed effects model with two fixed effects, the group variable and a binary dummy variable corresponding to the last 30 min of driving, was estimated. The final model includes the group effect (INS), the dummy variable (Last.30), and their interaction (INS × Last.30). For the VAMS, a linear mixed-effects model with group (INS) and session variables (Session2, before versus after driving) as fixed effects was used. Marginal and conditional R^2 quantify the effect size and model fit in terms of proportion of explained variance by random and fixed effects, respectively. INS, insomnia patients; SDLP, standard deviation of lateral position; VAMS, Visual Analog Mood Scale.