HHS Public Access

Author manuscript

Clin Gastroenterol Hepatol. Author manuscript; available in PMC 2017 May 01.

Published in final edited form as:

Clin Gastroenterol Hepatol. 2016 May ; 14(5): 747–752. doi:10.1016/j.cgh.2015.11.007.

In Patients with Cirrhosis, Driving Simulator Performance is Associated With Real-life Driving

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Abstract

Background & Aims—Minimal hepatic encephalopathy (MHE) has been linked to higher real-life rates of automobile crashes and poor performance in driving simulation studies, but the link between driving simulator performance and real-life automobile crashes has not been clearly established. Further, not all patients with MHE are unsafe drivers, but it is unclear how to distinguish them from unsafe drivers. We investigated the link between performance on driving simulators and real-life automobile accidents and traffic violations. We also aimed to identify features of unsafe drivers with cirrhosis and evaluated changes in simulated driving skills and MHE status after 1 year.

Methods—We performed a study of outpatients with cirrhosis (n=205; median 55 years old; median model for end-stage liver disease score, 9.5; none with overt hepatic encephalopathy or alcohol or illicit drug use within previous 6 months) seen at the Virginia Commonwealth University and McGuire Veterans Administration Medical Center, from November 2008 through April 2014. All participants were given paper-pencil tests to diagnose MHE (98 had MHE, 48%), and 163 patients completed a standardized driving simulation. Data were collected on traffic violations and automobile accidents from the Virginia Department of Motor Vehicles and from participants' self-assessments when they entered the study, and from 73 participants 1 year later.

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Disclosures: none

Writing Assistance: none

Author contributions: Mette M Lauridsen: Analysis and interpretation of data and drafting of manuscript, Leroy R Thacker: Statistical analysis, Ariel Unser: Patient enrolment and data entry, Melanie B White: Patient enrolment and data entry, Jasmohan Bajaj: Conceptualization, funding, analysis, drafting and interpretation, Richard K Sterling, Richard T Stravitz, Scott Matherly, Puneet Puri, Arun J Sanyal, Edith A Gavis, Velimir Luketic, Muhammad S Siddiqui, Douglas M Heuman and Michael Fuchs: Patient enrolment

Participants also completed a questionnaire about alcohol use and cessation patterns. The driving simulator measured crashes, run-time, road center and edge excursions, and illegal turns during navigation; before and after each driving simulation session, patients were asked to rate their overall driving skills. Drivers were classified as safe or unsafe based on crashes and violations reported on official driving records; simulation results were compared with real-life driving records. Multivariable regression analyses of real-life crashes and violations was performed using data on demographics, cirrhosis details, MHE status, and alcohol cessation patterns, at baseline and at 1 year.

Results—Drivers categorized as unsafe had more crashes and made more illegal turns on the driving simulator than drivers categorized as safe; a higher proportion of subjects with MHE were categorized as unsafe drivers at baseline (16%) than subjects without MHE (7%, *P*=.02), and at 1 year follow up (18% vs 0%, *P*=.02). Alcohol cessation within less than 1 year and illegal turns during simulator navigation tasks were associated with real-life automobile crashes and MHE on in regression analysis; road edge excursions in the simulator were associated with real-life traffic violations. Personal assessment of driving skills improved after each simulation episode.

Conclusions—In a study of 205 patients with cirrhosis, we associated results from driving simulation tests with real-life driving records and MHE. Traffic safety counselling should focus on patients with cirrhosis who recently quit consuming alcohol and perform poorly on driving simulation.

Keywords

car crash; traffic violation; hepatic encephalopathy; public policy

Introduction

Minimal hepatic encephalopathy (MHE) is prevalent in cirrhosis and negatively affects psychomotor speed, visuo-motor coordination and reaction time stability [1–5]. It is associated with increased risk of overt hepatic encephalopathy (OHE), a high mortality and also adversely impacts driving skills [6–8].

Driving and navigation requires multiple and coordinated cognitive functions along with intact reflexes and response inhibition — functions that are often impaired in MHE patients. Previous smaller studies have reported MHE to be associated with poor navigation skills and a higher incidence of real-life crashes and violations compared to healthy controls and cirrhosis patients without MHE [9–11]. However, it remains unclear whether simulator and real-life crashes and violations are linked. This is an important validation point and we therefore aimed to examine this. In addition, we wanted to find out what characterises unsafe drivers apart from MHE by using prospective analyses of driving and clinical outcomes. This issue is important because identifying factors associated with a high risk of crashes and violations within cirrhotic subjects would allow clinicians to focus driving-related counselling to those specific groups. We also aimed to evaluate if driving simulator performance, MHE status, liver disease severity and self-rated driving skills changed concordantly over time[12, 13].

Patients and methods

Patients

In total, 205 patients with liver cirrhosis were prospectively enrolled after informed consent at VCU Medical Center between November 2008 and April 2014. The inclusion criteria were: age 18–65 years; current car driver, no overt mental impairment (Mini-mental status exam>25); and liver cirrhosis diagnosed by biopsy or unequivocal evidence of decompensation (history of ascites, variceal bleeding), presence of cirrhosis/varices on radiological examinations. The exclusion criteria were current or prior overt hepatic encephalopathy, infection or gastrointestinal bleeding within last 6 weeks, hepatocellular carcinoma, alcohol or illicit drug use within 6 months of enrolment and use of psychoactive drugs. None of the patients were on treatment for MHE/OHE at the time of enrolment or during the study. At inclusion and after 1 year patients' cognition was tested and MHE diagnosed using standardized psychometric testing. We also administered a questionnaire asking about any alcohol use over the last 5 years and divided those into those who stopped between 6–12 months and those who stopped >12 months prior to enrolment. All participants completed these tests and 163 also did a driving simulation (31 were unwilling and 11 developed simulator sickness) [14]. It was possible to retrieve information on demographics, cirrhosis severity (MELD score) and actual traffic violations/crashes from all 205 subjects. The Virginia Department of Motor Vehicles registry was used to corroborate the information.

Of the 205 included patients 73 were followed up after one year (51 had been recruited less than a year ago, 25 died, 12 were transplanted, 34 were lost to follow-up and 10 did not complete the driving questionnaires or provide permission to contact the driving authorities). Of these 73, 47 subjects repeated the driving simulation (17 were unwilling and 9 had simulator sickness). During the follow up period patients were excluded at transplant and death but continued in the study in spite of OHE episodes. Again at 1 year patients provided information on real life traffic violations (traffic violations and crashes) within the 1-year period. Also, MELD score and episodes of OHE since the last visit was also recorded.

Driving simulation

For driving simulation the STISim Drive simulation software was used (Systems Technology Inc., Hawthorne, California). The simulator consists of a computer screen, a steering wheel, brake and accelerator along with software that will time the performance and register accidents, speed and illegal turns. Throughout the simulation staff is present. The simulation takes up to 50 minutes including instructions and the test is divided into 3 sessions: Firstly, the patient completes a training session to make sure that the concept of the test is correctly understood. Next is a 25-minute driving simulation where the patient drives through the following settings: straight road, hill, mountain, highway, large city, beach town, suburban area and a small town. Lastly, the patient must navigate through a small town following a paper map indicating which route to take. If an illegal/wrong turn is made the staff notes it but the patient is not made aware. During the test the patients must try to comply with speed limits, stay on the road and follow instructions given on the screen and of course avoid crashes. Performance is evaluated based on the number of mistakes (speeding, collisions,

illegal turns, centreline crossings and road edge excursions). Up to 5 % were unable to complete the simulation due to simulator sickness/motion sickness [11]. Details are similar to prior published experience [11].

Standard psychometric testing

We used a validated paper pencil test battery consisting of 4 subtests to diagnose MHE: Digit-symbol test (DST), number connection test A (NCT-A), number connection test B (NCT-B) and the Block Design Test (BDT). The patient completed each test as fast as possible and a staff member, who was present throughout, noted the number of seconds spent on each test. Collective test performance was considered abnormal if 2 or more subtests were more than 2 SDs impaired beyond our established norms [7] that were adjusted to age, gender and education based on regression formulae derived from healthy community controls from Virginia.

Driving questionnaire

Before and after each driving simulation session patients were asked to rate their overall driving skills on a scale from 1 to 10 where 10 indicates best while 1 is the worst assessment of driving skills [13].

Statistical analysis

For statistical analysis GraphPad Prism 6.0 for Mac was used. In the cross-sectional analysis difference between parameters was estimated using t-test in case of endpoints with Gaussian distribution (age, education) and Mann-Whitney in other cases (MELD and driving simulator endpoints). Results were considered significant if $p<0.05$. A multi-variable analysis using backward logistic regression was performed with motor vehicle crashes and traffic violations within 1 year as the dependent variable. The potential predictors used were age, gender, duration of driving, education, MHE status, etiology of cirrhosis, alcohol use within 1 year, MELD score and simulator results (illegal turns, time, and crashes). Those with $p<0.10$ on univariate analysis were studied in the final model.

The VCU Medical Center Institutional Review Board approved the study protocol.

Results

Baseline characteristics of the 205 recruited subjects are shown in table 1.

MHE is linked to poor simulated driving skills and real-life crashes and violations

As anticipated, MHE patients had more simulator crashes, center of road crossings and road edge excursions (table 2). During navigation MHE patients made more illegal turns in spite of taking longer time to complete the driving and navigation tasks (table 2). Further, MHE patients reported more real-life motor vehicle crashes and traffic violations within 1 year prior to inclusion at baseline but also when the analysis was repeated at one year after being in the study (Table 3). None of the crashes were reported to be alcohol-related or had alcohol as a factor; which was verified by the state driving records. On analysis of the official driving records, all crashes except two (one occurred in North Carolina and one in Maryland

that were self-reported) and all traffic violations were found. The minority (30%) were associated with injuries, the rest involved damage to only the vehicle or surrounding structures. Most of the traffic violations were speeding tickets (n=31), followed by failing to stop at a sign (n=6) and others (n=3).

Driving simulator performance vs. real-life traffic crashes and violations

In subjects who had a real-life crash within one year prior to inclusion at baseline, there was a significantly higher number of simulation crashes (median 4 vs. 2, p=0.03) and illegal turns (median 1.0 vs. 0.5, p=0.05) compared to patients without a real-life crash. There was no significant difference in the MELD score, alcoholic etiology or other driving simulator outcomes.

Factors characterizing unsafe drivers

On univariate analysis, MHE, cessation of alcohol consumption less than 1 year and >6 months ago, and simulator illegal turns had p values <0.10 for real-life crashes. On multi-variable analysis, alcohol cessation less than 1 year and >6 months ago (OR 2.0, p=0.03) and simulator illegal turns (OR 1.3, p=0.01) remained significant predictors of real-life crashes within 1 year. When traffic violations within 1 year were considered, age, MHE and simulator road-edge excursions were significant on univariate analysis. On multi-variable analysis, age was protective (OR: 0.94, p=0.02) while MHE (OR: 2.01, p=0.05) and simulator road-edge excursions (OR: 1.1, p=0.04) were associated with real-life violations.

Changes at one-year follow-up

Of the 73 patients followed up after 1 year MHE/no-MHE diagnosis remained stable in 58 subjects; 7 subjects who were MHE positive at baseline were not at 1 year while the reverse happened in 8 subjects. None developed OHE. Subjects with MHE at 1 year continued to have a significantly higher rate of real-life crashes and traffic violations confirmed by official driving records compared to those without MHE (Table 3). Most violations were still speeding (11, 78%). None of the crashes were related to alcohol or resulted in bodily personal injury. There was no significant change between the groups with respect to driving simulation but the MHE patients increased MELD score (Table 4). Self-evaluated driving skills did not differ between no-MHE and MHE patients at baseline or at follow up. In both patient groups self–evaluated driving skills decreased (scale from 1–10) after the first simulation (7.5 to 6.3, p<0.0001 and 7.6 to 5.0, p<0.001). Interestingly, this pattern was repeated at the second driving simulation (7.2±1.2 to 5.9±1.6, p<0.001 and 6.8±1.3 to 5.9±2.1, p<0.001). Further, patients who had a real-life crash did not rate their driving skills significantly lower (7.6 vs. 7.0, p=0.45) or had a significantly different rate of reduction in self-evaluation after the simulation.

Discussion

In this largest-studied cirrhosis cohort, we found that MHE diagnosed using paper-pencil tests negatively impacts on simulated driving skills and is associated with more real-life crashes and traffic violations at baseline and at one year compared to those without MHE [9, 15], which was corroborated with traffic records. We found that these real-life crashes

and traffic violations are also linked to impaired driving simulator performance that remained stable over a year's follow-up. Further, our multi-variable analysis showed that specifically cirrhotic patients who performed poorly on simulated navigation and who had quit alcohol less than 1 year but >6 months ago were most likely to be responsible for crashes while those with MHE and increased road-edge excursions were likely to have traffic violations in real-life. This considerably narrows down subjects who should be the focus of driving-related counselling and restrictions and indicates that deeming every MHE patient unfit to drive is not necessary [10–12, 16].

The results from patients' self-rating of driving skills confirm that driving simulation seems to be an important method for subjects to increase insight into their driving skills: While self-assessed driving skills decline after testing; it goes up again before the second simulation a year later and drops again afterwards. This adds to our current knowledge and indicates that driving skills and other cognitive issues may need to be part of a constant dialogue between patients and clinicians, simply because patients tend to forget or neglect prior poor performances or have poor insight[13]. Of note, none of these patients were specifically counselled about their driving behaviour at the end of the research visit, so it is possible that with directed driving-related counselling, there would be a more realistic self-appraisal over time with patients. In that regard, driving simulation or review of the subjects' recent driving history may facilitate doctor-patient communication on the sensitive issues of driving and promote patients' receptiveness to counselling[17].

Several competing inputs are important while driving, the main factor behind most real-life crashes remains human error[18]. MHE can partly explain this human error by delaying response times to avoid crashes, and impairing attention and vigilance resulting in missed speeding and stop signs. It is interesting that patients with recent abstinence were likely to be unsafe drivers with violations/crashes that were not directly alcohol-related or driving under the influence. This could be related to a relatively reduced overall adherence to medical advice and clinic visits, which could extend to potential judgement errors while driving with alcohol use[19]. The crash rate in our MHE population was significantly higher than the 5% annual crash rate of all Virginia drivers[20]. This puts these results in context of the potential public health problem of car crashes and should encourage open dialogue into this condition. The impact of driving on the daily function cannot be discounted; therefore, MHE subjects with poor driving history and driving simulator performance and those with recent alcohol abstinence should be specifically targeted for counselling.

While currently there is no current firm legal basis for doing so, the need to address this issue is an ethical one towards preventing car crashes and violations[21–23]. Indeed in a recent survey, only a minority of clinicians were aware of their local driving laws[24]. Therefore approaching driving history as an important aspect of patient care, rather than simply in its legal context, may be helpful in reducing these outcomes.

Our analysis was based on patients' own reports of traffic events and the truthfulness of these data could be questioned. As a confirmatory measure we also obtained official driving records and found that they were actually less comprehensive because incidents outside state limits were missed in the public reports. Also, prior studies have shown that patients are

largely truthful although insight might be lacking[13]. Therefore gathering information from patients should suffice, provided it is sought in a non-judgemental way. At 1–year follow up we found that not only were the MHE patients likely to have more real-life crashes and violations, but also that there was little change in driving simulator performance in those who completed the visits. However, these results are limited by the loss of a large proportion of patients over time. While in this group the results indicate that driving simulation as well as the relationship between MHE and adverse real-life driving outcomes remains stable and that driving simulation remains a reliable measure of driving over time, further studies are needed to confirm this.

In conclusion, in this largest-studied cirrhosis cohort, MHE patients were likely to have worse simulator and real-life crash and traffic violation rates that remained stable over 1 year. Driving simulator performance and personal insight into driving skills remains impaired and stable over the follow-up period and simulator outcomes are linked to real-life traffic violations and crashes. Cirrhotic subjects with poor simulator and cognitive performance, and relatively short alcohol abstinence duration, are likely to be unsafe drivers in real life, and driving-related counselling should be focused on these individuals.

Acknowledgments

Grant support: The project was partly supported by VA Merit Review CX001076, RO1AA020203 from the National Institute on Alcohol Abuse and Alcoholism, by grant RO1DK087913 from the National Institute of Diabetes and Digestive and Kidney Diseases, and by the McGuire Research Institute.

Abbreviations

MHE	Minimal hepatic encephalopathy
MELD	Model for end stage liver disease
OHE	Overt hepatic encephalopathy
HCV	Hepatitis C virus
DST	Digit-symbol test
NCT-A	Number connection test A
NCT-B	Number connection test B
BDT	Block Design Test

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Table 1

Baseline characteristics of drivers with liver cirrhosis who underwent driving simulation and psychometric testing

Cohort	Cross-sectional (n=205)	Follow-up (n=73)
Age	55.6±6.5	56.0±5.6
Years of education	13.6±2.3	14.1±2.4
Years of driving experience	38.0±8.2	39.3±6.3
MELD score	9.5±3.8	8.9±2.5
Male/female	119/86	42/31
Etiology (%) (HCV/alcohol/HCV+alcohol/NASH/other)	49/7/3/24/17	38/7/3/33/19
No-MHE/MHE	107/98	40/33
Alcohol within last year but > 6 months ago	115 (56%)	0 (0%)

Table 2

Driving Simulation Results in Cirrhotic Subjects with and without MHE at baseline

Baseline simulation Mean ± SD	No MHE, n=90	MHE, n=77	P-value
Driving simulation			
Crashes	2.5 ± 1.7	3.1 ± 2.3	0.08
Centre of road crossings	11.8 ± 6.5	15.2 ± 10.1	0.05
Road edge excursions	4.8 ± 5.5	9.4 ± 14.0	**0.007**
Total run time (seconds)	1652 ± 325	1765 ± 324	**0.02**
Navigation Simulation			
Illegal turns	1.0 ± 1.4	2.3 ± 2.6	**<0.0001**
Crashes	0.3 ± 0.8	1.0 ± 1.3	**0.02**
Total run time (seconds)	904 ± 163	1084 ± 324	**< 0.0001**

Table 3

Demographics, cirrhosis severity and real-life crashes and traffic violations in cirrhotic patients with and without MHE at baseline

Baseline information	**No MHE, n=107**	**MHE, n=98**	**P-value**
Age (years)	55.6 ± 5.8	55.5 ± 7.5	0.96
Male/female	57/50	62/36	0.16
Education (years)	13.9 ± 2.2	13.4 ± 2.5	0.15
MELD score	8.6 ± 2.6	9.9 ± 3.7	0.07
Alcoholic etiology of cirrhosis	10 (10%)	13 (13%)	0.20
Stopped drinking alcohol<1 year but >6 months ago	62 (60%)	53 (54%)	0.43
Duration of driving experience	38.7 ± 6.6	37.0 ± 9.7	0.18
Real-life driving history			
Motor vehicle crashes in one year	7 (7%)	16 (16%)	**0.02**
Traffic violations in one year	16 (16%)	26 (26%)	**0.04**
At one year follow-up	**No MHE, n=40**	**MHE, n=33**	**P value**
Age (years)	55.7 ± 5.9	56.3 ± 5.5	0.47
Male/female	23/17	18/15	0.96
Education (years)	14.0 ± 2.1	13.7 ± 2.7	0.09
MELD score	8.5 ± 2.1	8.9 ± 2.9	0.85
Alcoholic etiology of cirrhosis	3 (7%)	4 (12%)	0.79
Stopped drinking alcohol>1 year ago	40 (100%)	33 (100%)	1.0
Real-life driving history			
Motor vehicle crashes in one year	0 (0%)	6 (18%)	**0.02**
Traffic violations in one year	4 (10%)	9 (33%)	**0.04**

Table 4

Driving simulation results change over one year in patients with and without MHE.f

	No MHE, n=29		P value	MHE=18		P value
	Baseline	**1 year**		**Baseline**	**1 year**	
MELD change	8.5±2	9±2	0.36	8±2	9±2	**0.03**
Crashes	2.4±1.7	2.3±1.5	0.75	2.9±2.3	2.5±1.9	0.46
Centre of road crossings	12.1±4.7	11.0±7.5	0.37	12.1±6.2	10.5±5.6	0.35
Road edge excursions	3.0±3.7	4.0±6.3	0.15	6.5±6.7	7.8±8.2	0.53
Total run time	1705±435	1704±319	0.98	1728±282	1811±478	0.24
Illegal turns	0.8±1.3	1.1±2.0	0.42	1.9±3.4	1.2±1.2	0.56
Navigation time	872±189	907±182	0.12	1080±360	1182±391	0.05

P value indicates paired t-tests compared to baseline

Clin Gastroenterol Hepatol. Author manuscript; available in PMC 2017 May 01.