1. BACKGROUND

Driving under the influence of alcohol or drugs causes a substantial part of road traffic fatalities. Legal prescription and over the counter medicines also may impair driving skills. De Gier (2005) states that a conservative estimate indicates that 10% of the adult population drives under the influence of impairing medicinal drugs, causing about 4500 deaths and 135,000 injuries each year in Europe. The problem is increasing with an elderly population, who expect to keep up their mobility despite an extensive use of medicines.

Research into the effects of various drugs on driving performance is becoming more important as epidemiological studies indicate that the incidence of drugs in drivers is increasing. This type of research often guides recommendations, laws and police intervention, hence it is important that the tests used to determine whether certain drugs are impairing are sensitive, valid and reliable.

Experimental research and large epidemiological studies have proven a strong relationship between blood ethanol concentrations (BAC) and accident risk. For other drugs and medicines, however, the associations between blood drug concentrations and crash risk are less certain. This is among other factors related to the methodological difficulties with assessing drugged driving and traffic safety issues. As epidemiological studies on the traffic safety effects of drugs and alcohol are rare and influenced by a number of confounding factors, experimental studies are of great importance.
To experimentally test the effect of drugs on driving we need to know the pharmacodynamic and pharmacokinetic properties of drugs and the nature of safe driving. Driving can be understood as a co-ordination of perception of the traffic environment, understanding the situation and acting accordingly. It is a skill requiring several abilities, among which vision, cognitive capacity and behavioural co-ordination are essential. The outcome of driving skill may not be fully dependent on the state of each subsystems involved (i.e. quality of vision, cognitive skills, body control), but rather relies on the integration of each dimension into an adaptive behavioural pattern in accordance with the surroundings. Drugs may have an impairing effect on one or several subsystems involved in safe driving.

The effects of alcohol on single driving relevant functions can be tested in a laboratory setting. The results of such studies have been summarized by i.a. Schnabel (2011). However, one may question how the results of laboratory tasks testing discrete cognitive or phsycomotor skills apply to the complex task of driving an automobile.

Furthermore there is no direct way to translate an impairment level into accident risk. The overall risk consists of an interaction of impairment with the demands of the driving situation and the individual abilities to compensate for the detrimental effects of alcohol or a specific drug. In experiments with alcohol, signs of impairment occurs frequently and at rather low BACs, whereas in reality accidents occur rarely and mostly at rather high BACs.

It has been questioned why the risk function is exponential whereas the impairment function is strictly linear. (Schnabel 2011). Two reasons for this are proposed. First, driving is a very special combination of subtasks, each with its own impairment function. Therefore, the exponential shape of the risk function may be the result of a weighted aggregation of task-specific impairment functions. Second, driving under the influence of alcohol has severe safety and legal consequences. Therefore, all drivers will try to compensate for the effects. This compensation may be successful at least for lower BACs, resulting in a slow increase of the risk, but breaks down with higher BACs.

Even the results of driving studies are limited with respect to their validity. Driving tests often last for relatively short time periods and require only the use of simple skills. Drivers under the influence may be able to keep concentration for a short time, while performance may suddenly drop after prolonged exposure to a driving task. The current reference method for
determining the impact of impaired driving is a Dutch standardized on-road test (Verster and Roth 2011). The main outcome variables in this test are measurements of standard deviation of lateral position (SDLP) as a measure of car “weaving” or the ability of the driver to keep a stable position and course under the influence of drugs, and the measurement of headway as an expression of the ability to keep safe distance to the vehicle ahead. Of the two main outcome measures, SDLP has been shown to be the most sensitive. However, the ability to maintain lane position represents only one of several levels of skills necessary for safe driving.

Within transportation research, driving behaviour is often understood as a hierarchically organised activity (Michon, 1989; Wickens, 1991; Keskinen, 1996; Walsh et al. 2008). The organisation of behaviour generally refers to three levels: The highest level refers to actions concerning strategic decisions. The middle level is a tactical level including responses to the immediate traffic scenario, whereas the lowest level is an operational level consisting of largely automated acts such as shifting gears, steering the vehicle etc. This description is in line with the skill-, rules-, knowledge- (SRK) taxonomy originating from cognitive engineering research (Rasmussen, 1983; Vicente and Rasmussen, 1992). The basic concepts in the taxonomy are skill-based behaviour, equivalent to the operational level, rule-based behaviour, equivalent to the tactical level, and finally knowledge-based behaviour, equivalent to the strategic level. The behaviours refer to a type of cognitive control, and the taxonomy can be grouped in two general categories: On one hand, there is fast, perceptual processing, and on the other hand there is slow, analytical problem solving. The perceptual processing is reckoned to be effortless, whereas the analytical problem solving is more laborious and comprehensive. Translated to the traditional workload terminology, one expects perceptual processing, as in skill-based behaviour, to place less strain upon the operator than the analytical problem solving of knowledge-based behaviour. These two cognitive control modes may be thought of as layers in a hierarchical organization. Behaviour constantly fluctuates between the states of control as the driver interacts with his/her context, where each state functions as a qualitatively different way of processing information.

In light of the theoretical perspectives above, SDLP mainly reflects automatic manoeuvring control, which represents the most basic behavioural level.

No successful test for driving under the influence of drugs has been established so far to assess impairment on a tactical or executive planning (strategic) level. The context of the standardized Dutch on-road test (one
hour’s monotonous motorway driving) may not be representative of other driving conditions that are associated with an elevated accident risk (i.e., rural narrow/winding roads, urban traffic). Further replication of the Dutch studies is hindered by ethical and legal barriers in most countries. Driving simulators may offer a more cost effective and replicable option to on-road studies. Simulators may recreate realistic surroundings testing behaviour at several levels in risk relevant contexts. Yet external validation of the simulator is imperative in order to interpret effects on drug impaired driving.

2. OBJECTIVE

A Norwegian research project conducted in collaboration by SINTEF Transport Research and St. Olav University Hospital/Norwegian University of Science and Technology, has developed and validated a driving simulator tool for future assessment of drug effects on driving performance. The purpose of the study was to establish a driving simulator test battery sensitive to ethanol effects, and to validate the sensitivity and reliability of the measures by comparison to data obtained in a real vehicle on a closed-circuit test track. The study is described in detail in a previous article (Helland et al. 2013), and the focus of this paper will be on the methodology for assessing driving impairment due to alcohol and drugs, discussing how the results from the validation study may be extended to include other sedative drugs as well, by using ethanol as a positive control.

3. METHODS

Materials and methods have been described in detail in a previous article (Helland et al. 2013). In the following, the trial design, the simulated and test track driving and measurements are briefly described.

A driving test scenario typical for accidents involving alcohol and sedative drugs were developed and a cross-over trial with 20 male drivers aged 25-35 years was conducted, comparing driving performance on the test track and in the driving simulator. Each subject underwent a total of six driving trials of one hour duration each; three in an instrumented vehicle on a closed-circuit test track and three in an advanced driving simulator with a driving scenario modeled as a virtual copy of the test track. The scenario consisted of narrow lanes with curves, hills, dips and straight road sections. Test subjects were titrated to BAC levels of approximately zero, 0,5 g/L and 0,9 g/L. The study
was conducted in a randomized, cross-over, single blind fashion, using placebo drinks and placebo pills as confounders. The intervention was concealed from study subjects, who also received a placebo pill before each driving session, which they were told may or may not contain a sedative drug. The outcome measures were standard deviation of lateral position (SDLP), mean speed, speed fluctuations, steering wheel movements, braking/acceleration, and reaction time to unexpected events. Statistical analyses were conducted, using a linear mixed model with SDLP as dependent variable, measuring BAC as covariate, and participant as random effect.

The test-track driving took place under frost-free conditions in the autumn, while the simulator driving took place about a month later. The 1.37 km long test-track resembled closely a typical narrow, hilly and curvy Norwegian road (see fig. 1)

![Test-track Outline](image)

Figure 1 Outline of the test-track. Trigger points refer to laser based recording of start and end of randomized events, and hazards which may or may not occur. E.g. 1s-10s is possible red light signal and 3c-11c is a curve where an obstacle may be present on some trial rounds.
Figure 2: Upper panel: Example of the driver’s visual impression of obstacle on the closed-circuit test track (left) and in the driving simulator (right). Lower panel: Visual Impression of pedestrian on test-track in daytime (left) and in driving simulator (right) during night-time. Note that the lower pictures are not taken in the same place or position.

The driving scenario in the simulator was a model of the test-track to ensure similar context and driving conditions. For detailed description of the simulator see Engen (2008).

The subjects drove a mean distance of 46.8 km during the one hour drive, equivalent to 34 laps per test/BAC level. The instrumented vehicle,
instruments and set-up for recording of speed, position with video and GPS etc. is described in detail in Helland (2013).

Obstacles in the form of foam cubes (size 1m³) were present in two locations on two occasions, one at the beginning and one towards the end of each test drive/BAC level. These surprise obstacles were supposed to be avoided by the test subjects. Traffic lights present in two locations turned red on one occasion during each trip. In addition the simulator scenario included two sudden incidents (a car suddenly entering the road and a pedestrian running across the road in front of the driver). The extra simulator incidents each occurred once at the end of the driving session. The participants were instructed to drive as they would normally have done. For safety reasons a professional driving instructor was present in the passenger seat at all times during test track driving.

4. RESULTS

Results are described and published previously (Helland et al. 2013). A short summary of main results are presented here.

A complete set of outcome data was obtained in 50 out of 60 driving sessions on the test track and 54 out of 60 driving sessions in the simulator. Two subjects withdrew from simulator testing, whereas SDLP data from 10 driving sessions on the test track were missing due to technical error. Data from all valid driving sessions were included in the analyses.

Ethanol concentrations were slightly lower than intended both in the simulator and on the test track, with concentrations closer to 0.4 g/L at the intended level of 0.5 g/L. The BAC also tended to be slightly lower in the simulator than on the test track, but the difference was small and not considered being of practical consequence.

Most subjects correctly identified the drink as containing/not containing alcohol. However, a few misidentified their drinks, and quite a few wrongly identified the pill as containing a sedative drug.

Figure 4 shows the individual SDLP values at the corresponding BAC, with the estimated regression line and its 95 % confidence interval.
Both simulated and test track driving showed significant positive correlations between BAC and SDLP, with the following estimated regression lines ($p<0.001$ for both).

**Simulator:** \[ SDLP_{(cm)} = 29.43(\pm 2.57) + 13.20(\pm 3.61) \times BAC \]

**Test track:** \[ SDLP_{(cm)} = 22.30(\pm 1.89) + 7.61(\pm 1.91) \times BAC \]

SDLP values were higher in the simulator than on the test track at baseline (placebo) conditions (29.4 cm vs. 22.3 cm, respectively), and showed a steeper increase with increasing BAC. SDLP variance was also larger in simulator driving than in test track driving.

The positive, linear relationship between BAC levels and SDLP on a group level, as well as positive individual slopes in most subjects (figure 5) point to a dose-response effect.
5. DISCUSSION

Dose-response correlation between BAC and SDLP

Our results show a positive dose-response correlation between BAC and SDLP in the simulator and on the test track, both for individual and mean data. A high degree of intra-individual similarity in the BAC-correlated increase in SDLP in the simulator and on the test track, suggests that SDLP is a valid and sensitive measure of ethanol-induced driving impairment in the simulator.

Absolute values of SDLP were higher in the simulator than on the test track, with mean SDLP at BAC 0 of 29 cm and 22 cm, respectively. SDLP values during placebo conditions in the simulator were also considerably higher than those seen in Dutch on-road driving tests, where mean baseline SDLP is approx. 19 cm (range 9 to 30 cm) and BAC levels of 0.5 g/L and 0.8 g/L on average increases SDLP from placebo conditions with 2.4 cm and 4.3 cm, respectively (Verster and Roth 2011). The relatively demanding driving scenario that was used in our experiment may account for the slightly higher SDLP values on the test track than those seen during previous on-road tests. Higher absolute SDLP values in the simulator compared to real driving may be explained by unfamiliarity with the driving experience in the simulator, a lack of perceived danger, and lack of gravitational cues and feedback that will normally adjust steering. This notion is also supported by the observation that

Figure 5: Relationship between BAC levels and SDLP results in individual subjects (Helland et al., 2013).
SDLP values were higher in curved sections than in straight sections in the simulator, whereas such a difference was not observed on the test track. Together with the more demanding driving scenario in our experiment, this may account for the considerably higher SDLP values than those seen for instance in the Dutch STISIM simulator employing a monotonous highway scenario (Mets et al. 2011b). Also, we cannot exclude the possibility that some participants’ SDLP scores were influenced by simulator sickness.

Technical limitation may also play a role, explaining why we see considerably larger increase in SDLP as a function of increased BAC in the simulator than on the test-track. We adopted the Dutch roof mounted video technique for SDLP measurement on-road. The video camera has a fixed angle and it was realized during post-test processing of data that the camera system does not record SDLP when it loses the reference edge line of the road, hence a cut-off effect in data may be present. Driving instructors noted several incidents at higher BAC levels on the test track where the drivers lost control in curves and the vehicle was outside road limits.
Figure 6: Example of plotted position in lane for one test person in the simulator on all 34 laps at increasing BAC level. Increasing deviations from lane is seen as thicker red lines especially in curves. Some of the red lines in curves at BAC level 2 and 3 indicate the vehicle has been outside the road edge line.

In the simulator all deviations in position are recorded and hence there is no potential cut-off effect.

**Concealment of intervention**

Most participants correctly identified their drink as containing/not containing ethanol. Previous experience suggests that concealment of ethanol is difficult in blinded studies. Quite a few of the participants misidentified the placebo pill, which indicates that the use of placebo pills to enhance blinding of the intervention in experimental trials with ethanol may be worthwhile.

**Predictive Validity**

We have designed a naturalistic test scenario which reflects the conditions in which 64% of police reported ethanol related accidents occur in Norway, i.e. nighttime driving on narrow winding roads with dips and curves. In real life this is a driving situation with low surveillance probability by police and most certainly not with a driving instructor in the front passenger seat. Uninhibited behavior combined with reduced impulse control and psychomotor retardation are well-documented pharmacological effects of ethanol.
For safety reasons and approval of authorities and ethical committee, it was required to have a driving instructor in the car as well as police present during the test drives. Hence, the validation presented here is between an experimental situation on a test track with the presence of a driving instructor and police versus an experimental situation in a driving simulator without the presence of a driving instructor in the car and police in the surroundings. With that in mind the observed driving behavior in the simulator is more valid for ethanol-influenced behavior when not being kept under surveillance than the test track driving. On the other hand subjects know that driving in a simulator is without crash risk. Thus, neither the simulator condition nor the test-track condition fully resembles real driving contexts associated with drug related traffic accidents. It may be argued that the test conditions in the simulator are more likely to elicit uninhibited risky behavior and thus the simulator has more predictive value.

Implications for the validity and further use of the simulator

External validity of a driving simulator refers to the test scenario’s ability to invoke similar reactions in the drivers as a real driving scenario. There was a large degree of similarity in the relationship between SDLP and BAC levels in the simulator and on the test track. However, the absolute values of SDLP in the simulator were consistently higher than on the test track. Thus, the relative (but not the absolute) external validity of the SINTEF simulator has been established when validated against test track driving in a driving scenario that is representative of the demanding rural driving conditions in Norway, using ethanol as a positive control. We believe that this validation may be extended to real driving under similar conditions; however, this assumption has not been proven.

A major problem in assessing the true public health impact of drug-use on driving and overall traffic safety is that the variables being measured across studies vary significantly (Walsh et al 2008). In studies reported in a growing global literature, basic parameters assessed, analytical techniques and drugs tested are simply not comparable due to lack of standardization in the field. Only a few studies fulfil all necessary requirements formulated in the ICADTS (International Council on Alcohol, Drugs and Traffic Safety) guidelines (Beghaus and Hilgers, 2009). Neither do test methods or test scenarios necessarily reflect typical drug related traffic accidents. These shortcomings
severely limit the value of research in the field. A set of standards to harmonize research findings are sorely needed, and utilisation of a methodology that reflects real accidents should be enhanced (Walsh et al 2008; Vollrath 2010; Schnabel 2011).

While the drug research publications of North American researchers reveal a predilection for tightly prescribed short performance tasks, the European tradition has been leaning more towards naturalistic studies in simulators. It has been argued that the final evidence that a drug in question would be safe or hazardous should be based on the combined results of conventional laboratory testing, driving simulators studies and actual driving tests on road (Owens and Ramaekers 2009).

As driving simulators improve in capabilities and realism, it has been argued that experimental designs must keep pace (Liguori 2009). The standard measures of lane deviation, speed and reaction time may be sufficient for identification of basic behavioural impairments, but simulated driving studies offer the opportunity to; a) vary weather, time of day and traffic conditions, b) create scenarios that test decision making and risk taking, c) create scenarios that demand divided attention (e.g. text messaging), and d) create scenarios that test the combined effect of sleepiness with drugs. Driving simulators can thus provide the scenario control and ethical management of risk to support experimental studies of drug impairment.

**Positive control**

The intentions of the validation procedure are to ensure; 1) that a "positive control" (i.e. an impact factor of the type of drug/prescription medicine with established performance-reducing effect) provides measurable effects, and 2) that effects are reproducible in realistic traffic scenarios.

Ethanol is well suited as "positive control" as there is a lot of experimental data relating ethanol exposure to impairment of driving related skills. Moreover, data from epidemiological research give precise and detailed measures of the relationship between a wide range of blood alcohol concentrations and relative accident risk. This means that the "calibration" of the simulator to alcohol exposure at different BAC levels allows reductions in simulated driving performance in simulator to be translated into relative risk increase in traffic.

The results from this validation study may be extended to include other sedative drugs as well, by using ethanol as a positive control. In contrast to
ethanol, there is a paucity of experimental data regarding the impact of commonly used, assumed performance-altering drugs. For instance, the debilitating effects of short-term use of benzodiazepines are well documented, but there is scant data on the effects of long term/chronic use of this class of compounds. There is also little experimental data on the driving performance effects of much-used drugs such as benzodiazepine-like hypnotics (z-hypnotics) and codeine.

6. CONCLUSIONS

The validation study presented here (Helland et al. 2013) concluded that the SINTEF advanced driving simulator is a sensitive and valid tool to assess driving impairment from ethanol. Results show that both on the test track and in the simulator, the SDLP increases significantly with higher ethanol levels in a dose dependent manner. Correlation between test track and simulator results, suggests that SDLP is a valid and sensitive measure of driving impairment under the influence of ethanol in the simulator. The results are also comparable to historical data from Dutch on-road motorway tests (Verster et al. 2004).

The simulator offers the possibility to create test scenarios representing motorway, rural and urban driving at various times of day and weather conditions, thus offering the possibility to replicate the context in which real drug related traffic accidents most often happen. We have validated a test scenario representing a rural road traffic context.

The observed driving behavior in the simulator is more valid for ethanol influenced behavior when not being kept under surveillance than the test track driving. Hence we can not rule out that the secondary outcome measures in the simulator may have more crash predictive value under the influence of ethanol than the test-track results.

7. ACKNOWLEDGEMENTS

The study presented here was funded by a grant from the Research Council of Norway
8. REFERENCES

De Gier, JJ (2005) Drugs other than alcohol and driving in the European Union. Study conducted with support of the European Road Safety Federation and the Directorate General for Transport of the Commision of the European Communities. Institute for Human Psychopharmacology (IHP), University of Limburg, Maastricht


Schnabel, E. (2011). Alcohol and driving related performance – A comprehensive meta-analysis focusing the significance of the non-significant naugural-Dissertationzur Erlangung der Doktorwürde derPhilosophischen Fakultät II der Julius-Maximilians-Universität Würzburg


