Drugs, Driving and Traffic Safety
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Drugs, driving, and models to measure driving impairment

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Abstract

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. Considering that this type of research is likely to guide laws and behaviours, it is important that the tests being used to determine whether certain drugs are impairing are sensitive, valid and reliable. This chapter presents the most common tests used in research to evaluate behaviours relating to driving. The research varies from the use of simple cognitive tasks, to simulators, and to driving in real traffic. The findings suggest that there are limitations to various methods of testing; however, considerations and precautions can be taken to ensure that we measure relevant processes and use sensitive tests for drug impairment.

Introduction

Driving is a complex task that requires control and coordination of a number of different behaviours. These behaviours are typically divided into three hierarchical levels of control [1]. At the top level or the strategic level, executive decisions such as route-choice and planning, setting of trip goals (e.g. avoid peak hour), observation, judgment and understanding of traffic and risk assessment are made. At the intermediate level or the manoeuvring level, negotiations of common driving situations occur. These behaviours are described as controlled and require conscious processing: reactions to the behaviour of other drivers, distance-keeping, speed adjustment, negotiation of curves and intersections, gap acceptance, and obstacle avoidance. At the lowest level or the operational level, the basic vehicle-control

processes occur, such as steering, braking and gear shifting, and are described as automotive behaviours. Automotive behaviours require little conscious mental activity and develop following extended practice. To gain a complete picture of the extent to which drugs affect driving performance, a variety of tests are used that measure behaviours across all three levels of control. The following chapter aims to identify the most common tests used to assess the impact of drugs on driving and how sensitive those tests are to drug effects.

There are three approaches used to assess driving impairment: on-road tests, driving simulators, and laboratory tasks. On-road driving tasks can be measured using two different methods. The first method, naturalistic driving scenarios, in which participants drive in actual traffic, are subjectively scored by trained raters. During these tests a licensed driving instructor, who has access to dual controls should an emergency situation arise, is accompanied by an observer who scores the participant according to a number of simple and strict criteria. The second method used to assess driver performance measures actual responses as driver inputs from steering, braking, and acceleration controls. These tests take place on both open and closed driving courses. It is often argued that on-road driving tasks are the gold standard tests to determine driver impairment. However, while these tasks effectively measure lower level behaviours, for obvious safety reasons they can not measure higher level functions such as response to emergency situations and risk taking behaviours.

Driving simulators offer the ability to assess higher level behaviours in a safe and controlled manner. However, they vary widely in research studies across different laboratories, thus making comparison difficult. They range from fully interactive systems, where the participant is seated in a complete vehicle mounted on a motion platform with 360-degree views, to desk top systems where the road environment is viewed on a computer screen and controlled by a steering wheel, keyboard or mouse. Driving simulators are often criticized for limited realism and it is questionable as to how well the results translate to real life driving situations. Additionally, the perceived risk of driving in the simulator is much less than on the open road, so participants may adjust their behaviour accordingly, e.g. driving less cautiously.

Cognitive tasks enjoy the benefit of permitting an assessment of a single, isolated aspect of driving performance in a controlled environment; however, there is a question as to whether they are comparable to real-life driving and whether they can be accurately used to predict accident risk.

Which tests are sensitive to drug effects on driver performance?

Automative behaviours

Road tracking task

The most common on-road test used to measure driver impairment is the road tracking task [2]. Participants are required to drive a 100 km course maintaining a constant speed of 95 km/h and a steady lateral position in traffic lanes: the standard deviation of lateral position or SDLP. SDLP is an index of road tracking error or weaving, swerving and overcorrecting. SDLP is measured using an electro-optical device mounted on the rear of the vehicle which continuously records lateral position relative to the traffic lane. An increase in SDLP, measured in centimeters, indicates driver impairment, as the driver's ability to hold the car in a steady lateral position diminishes.

A paper by Robbe [3] described three studies assessing the effect of marijuana on driving using the road tracking task. The first study utilised a shortened version of the road tracking task to assess the effects of marijuana containing three different THC (Δ-9-tetrahydrocannabinol) doses (100, 200 and 300 μg/kg) on driving. The test was undertaken on a restricted highway in which participants were required to maintain a constant speed of 90 km/h and a steady lateral position over a 22 km road-tracking course. SDLP, mean lateral position, and the mean and standard deviation of speed were recorded. The tests were undertaken at 40 minutes and one hour after smoking marijuana. The results revealed that all three THC doses significantly affected SDLP relative to placebo and that impairment after marijuana was equivalent at both time points. These results were compared to those of alcohol and suggest that THC consumption produces similar effects to BACs (blood alcohol concentration) of 0.03 % to 0.07 %. Other variables were not significantly effected by marijuana. The road tracking task in the second study involved driving on a 64 km highway course in the presence of other traffic, with the aim of maintaining a steady lateral position. The findings confirmed that driving performance was impaired in a dose related manner by THC, with SDLP increasing to 3 cm in the 300 μg/kg dose condition. The third study assessed the combined effects of alcohol and marijuana on driving ability and was conducted on an open highway in the presence of other traffic. Participants were administered alcohol (BAC 0.04 %) combined with a dose of THC (100 or 200 μg/kg), and either alcohol or marijuana alone. SDLP was measured over a 40 km section of highway and was found to increase compared to placebo in all drug conditions. The combination of alcohol and the low dose of THC resulted in an increase in SDLP equivalent to a BAC of 0.09 %, and the combination of alcohol and the higher dose of THC produced an effect equivalent to a BAC of 0.14 %.

The road tracking task has also been used to assess the effect of MDMA (3,4 methylenedioxymethamphetamine) (75 mg, 100 mg) and alcohol (BAC to reach

0.06), both combined and alone, on driving performance [4]. The results demonstrate that SDLP was significantly affected by all treatment groups. Alcohol increased SDLP by 2.5 cm and both MDMA doses decreased SDLP by approximately 2 cm relative to placebo. Both doses of MDMA significantly decreased the SD of speed by about 0.2 km/h compared to placebo. No other measures were significant. These findings were partially supported by Ramaekers et al. [5] who reported that participants administered 75 mg of MDMA showed a decrease in SDLP relative to placebo; however, no significant results were found for SD of speed. Once again lateral position and speed were not affected by MDMA.

Critical tracking task (CTT)

The critical tracking task is a psychomotor test that measures eye-hand coordination and delays in visual motor response. The CTT is a simple test that measures a subject's ability to control a displayed error signal. An error is displayed as a horizontal deviation of a cursor from the midpoint on a horizontal, linear scale. Compensatory joystick movements null the error by returning the cursor to the midpoint. The frequency at which the subject loses control is the critical frequency or Lambada-c. It has been suggested that the CTT is the closest laboratory alternative to the Road Tracking Task [5].

Research into the effects of marijuana have demonstrated that the CCT is sensitive to the impairing effects of marijuana. This is supported by recent literature that supports some impairment relative to placebo on CTT after the consumption of THC up to six hours after drug taking [5]. The CTT has also been used to assess impairment due to MDMA (75 mg, 100 mg) and alcohol (BAC to reach 0.06), combined and alone [4]. The authors reported that alcohol impaired tracking performance as shown by a decrease in Lambada-c in the alcohol conditions compared to the placebo condition. However, no significant effects were shown for MDMA or MDMA by alcohol.

Control behaviours

Object movement estimation under divided attention (OMEDA)

Assesses the participants ability to estimate speed of movement, and time to contact (TTC) of a moving object to a fixed point under divided attention. Participants are presented with a computer screen, the corners of which are covered by green triangles and the centre of the screen is occluded by a yellow circle. The participant views a target (a red dot) travelling from the corner of the screen to the edge of the yellow circle and the target then passes out of view behind the circle. The participant's primary task is to indicate, by using a foot pedal, when the target reaches the centre of the computer screen. While the target is moving, participants complete a secondary task; they are required to indicate whether a geometric shape that ap-

pears on the yellow occlusion circle is the same as any of the shapes which appear on the four green corners of the computer screen. The main variable is the absolute mean difference between the estimated and actual TTC.

Kuypers et al. [4] assessed the effect of MDMA (75 mg, 100 mg) and alcohol (BAC to reach 0.06), combined and alone on driving skills using the OMEDA. The authors report no significant effects for any of the conditions compared to placebo. However, using a more complex version of the OMEDA Lamers [6] found that a single dose of MDMA 75 mg decreased the subject's ability to estimate TTC, indicating that the complex version of OMEDA is more sensitive to drug effects. Additionally, the results suggest that assessing performance as close to T_{max} as possible renders best results.

Visual search task

Lamers and Ramaekers [7] assessed participants' eye movements in a City Driving Test using a head-mounted eye tracking system. The device records a subject's line of gaze with respect to the head, which is used to determine visual search for vehicles proceeding with right of way on the right of 58 intersections along the route. Checking for traffic at intersections was the dependent variable. The results revealed that only the combination of THC and alcohol significantly reduced visual search frequency compared to placebo (by 3 %).

Car following task

The car following task was developed to measure attention and perception performance, as errors in these areas often lead to accident causation [8]. In this task participants are required to match the speed of a lead vehicle and to maintain a constant distance from the vehicle as it executes a series of deceleration and acceleration manoeuvres. The primary dependant variable is reaction time to lead vehicle's movements and distance maintained during manoeuvres or headway. This test assesses a driver's ability to adapt to manoeuvres of other motorists.

Robbe [3] investigated the effects of marijuana (100, 200 and 300 µg/kg) on driving performance using the car following test on a 16 km segment of highway traffic (15 min test). The lead vehicle's speed varied between 80 and 100 km/h with one deceleration and acceleration manoeuvre taking approximately 50 seconds to complete. Depending on traffic density, six to eight of these manoeuvres were executed during one test. The results revealed that reaction time increased for each THC dose compared to placebo; however, the findings did not reach significance. In relation to the distance maintained, participants in the THC condition lengthened their headway (mean distance from the lead vehicle), indicating that participants were more cautious in the marijuana conditions. In a second study, using an improved car following test (microprocessor-driven cruise-control), a significant change increase) in the mean reaction time to speed adjustments of the lead vehicle

was found for the combination of alcohol and 200 THC µg/kg (4.65 s placebo to 6.33 s alcohol and THC). Headway distance was also significantly impaired by alcohol and THC conditions (5.69 min placebo to 7.78 min drugs).

Kuypers et al. [4] assessed the effect of MDMA (75 mg, 100 mg) and alcohol (BAC to reach 0.06), combined and alone on driving performance using the car following test. In addition to the method described above, the investigator in the lead car also randomly activated the brake lights. When this occurred, subjects were instructed to remove their foot from the brake pedal as quickly as possible. The results revealed that performance was unaffected by MDMA alone and that alcohol increased brake reaction time. When alcohol was administered alone or in combination with 75 mg MDMA, reaction time increased by 20 ms compared to placebo. When alcohol was combined with 100 mg MDMA reaction time further increased by 60 ms, indicating that MDMA may worsen the effects of alcohol. No significant effects were found for other measures.

Sobriety testing

Sobriety tests measure psychomotor performance, cognitive functioning, and divided attention. In addition to maintaining coordination and balance, the individual is required to remember instructions and simultaneously perform more than one task at a time. The most common battery of performance tests are known as the Standardised Field Sobriety Tests (SFSTs) and comprise the horizontal gaze nystagmus, one-leg stand, and walk and turn tests.

The SFSTs have been demonstrated to be a valid measure to identify alcohol intoxication [9–12]. A laboratory study by Tharp et al. [9] investigated the efficiency of the SFSTs in identifying alcohol intoxication and demonstrated that the SFSTs accurately classified 81 % of subjects as either above or below 0.10 % BAC. A later study by Burns and Anderson [11] examined field data collected from experienced police officers using the SFSTs. The results revealed that the police officers correctly classified 86 % of drivers with a BAC reading of above or below 0.1 %. Drivers over the limit were correctly identified in 93 % of cases, and drivers below the limit were correctly identified in 64 % of cases. The SFSTs have also been shown to be efficient (94 %) in detecting BAC levels between 0.04 and 0.08 % [11].

Papafotiou et al. [13] assessed whether the SFSTs (as used by Victoria Police, Australia) provide a sensitive measure of impairment following the consumption of a cannabis. Participants consumed cigarettes that contained either 0 % THC (placebo), 1.74 % THC (low dose) or 2.93 % THC (high dose). After smoking a cannabis cigarette, participants performed the SFSTs and a simulated driving test within two hours after the smoking cannabis. The results revealed that there was a positive relationship between the dose of THC administered and the number of participants classified as impaired based on the SFSTs. The percentage of participants whose driving performance was correctly classified as either impaired or not impaired based on the SFSTs ranged between 65.8 % and 76.3 %, across the two THC conditions. The results suggest that performance on the SFSTs provides a moderate predictor of driving impairment following the consumption of THC [14].

Executive planning

The Tower of London (TOL)

A decision-making task that measures executive function and planning [15]. The task consists of computer generated images of begin- and end-arrangements of three coloured balls on three sticks. The subject's task is to determine as quickly as possible whether the end-arrangement can be accomplished by "moving" the balls in two to five steps from the beginning arrangement by pushing the corresponding number coded button [16]. The total number of correct decisions is the main performance measure. Ramaekers, et al. [5] found that THC significantly decreased the number of correct decisions on the Tower of London task. Results also indicated that a longer planning time was required at 45 min after the consumption of a high THC dose.

The city driving task

Measures aspects at both the control level (e.g. maneuvering, distance keeping, speed adjustment) and the strategic level (observation and understanding of traffic, risk assessment, and planning).

A study by Robbe [17] was conducted in urban traffic with the aim of assessing whether THC impairment is greater using a more complex and demanding driving test. The test involved driving a 17 km course within the city limits of Masstricht, through heavy, medium, and low density traffic, under the influence of 100 μg/kg THC and alcohol 0.05% BAC. Tests were conducted during daylight hours at the same time and day of the week. Two different scoring methods were used: a "molecular" approach and a "molar" approach. The first "molecular" approach required a specially trained observer to record when the participant made or failed to make a series of observable responses at predetermined points along the route according to strict criteria. This method indicated that neither alcohol nor marijuana significantly affected driving performance. The second "molar" method involved the driving instructor retrospectively rating the subjects' driving performance using a shortened version of the Royal Dutch Tourist Association's Driving Proficiency Test. In total, 108 items were scored as either pass or fail and were categorized in the following subgroups: vehicle checks, vehicle handling, traffic maneuvers, observation and understanding of traffic, and turning. The percentage of items scored as "pass" was calculated as the total test performance measure. This approach proved to be more sensitive, with alcohol (0.034% BAC) significantly impairing driving when compared to placebo. However, the low dose of marijuana did not impair driving performance on any of the variables.

A similar city driving test was used by Lamers et al. [7] to assess the effects of alcohol (0.04 to 0.05% BAC) and marijuana (100 μg/kg) on driving and was scored using a 90 item version of the Royal Dutch Tourist Association's Driving Proficiency Test. Participants drove a constant route through business and residential areas on mostly two lane undivided streets and a 5 km, four lane divided section on a major cross-city thoroughfare. The study did not support Robbe's [17] findings,

with none of the driving variables significantly affected by alcohol, THC or the combination of the two.

Limitations of these tests or approaches include the fact that the recorded impairment is subjective and retrospective. In general, the results suggest that these approaches to testing for impairment are not always sensitive to drug effects. In addition, in naturalistic studies it is often difficult to control the testing scenario, whereby one participant's test may vary to the next depending on traffic, weather conditions and other factors. The potential effect of external factors should also be taken into consideration when assessing driving in real traffic.

Driving simulators

Assess behaviors across all three levels of control. Discussed below are a few recent studies which utilize driving simulators to assess driver performance.

A series of studies conducted at the Swinburne University assessed simulated driving performance after the administration of marijuana, marijuana and alcohol, dexamphetamine and methamphetamine using the CyberCAR LITE simulator. Participants were seated at a bench attached with a "force feedback" steering wheel with accelerator and brake pedals placed underneath the bench. The driving environment was projected on a 175 × 120 cm white screen, which placed the participant inside the vehicle with a view through the front windscreen and included a simulated car dashboard (speedometer, gears, rear-view mirror, and side-view mirrors). Participants completed four scenarios: freeway driving and city driving during both day time and night time conditions, with each taking approximately five minutes to complete. Thirty-four or fewer variables were continuously recorded to measure a range of driving behaviours and errors. They included collisions, signal errors, speed control, safe following distance, weaving, and response to an emergency situation (tree falling across road on freeway or car running a red light). Each variable score was then multiplied by a loading factor which represented the severity of the error. All adjusted scores were then summed to give an overall rating of "impaired" (76+) or "not impaired" (0–75). Marijuana significantly impaired performance on measures of lane weaving [14]. An overall reduction in driving performance was reported for the dexamphetamine condition compared to placebo in the day time scenario (in particular signalling errors and stop sign/lights adherence). This impairment was not observed for the night time condition [18].

To overcome some of the limitations of laboratory testing, such as low to moderate drug doses and unrealistic testing times and environment, Krueger & Vollrath [19] tested participants in a social setting in front of Discotheques. They selected participants who were under the influence of drugs and who indicated that they had been driving or would drive in similar circumstances (under the influence of recreational doses of drugs). Testing was undertaken on weekends between 10 p.m. and 6 a.m. at 29 discotheques across Bavaria, Germany. Participants were tested using a driving simulator that consisted of a 15-inch computer monitor and a commercial joystick steering wheel. The primary task involved the participant holding the vehicle in a steady lateral position while driving a curved road with a speed limit of

80 km/h. Four secondary tasks were also presented at random intervals. A simple reaction time task required participants to brake as fast as possible when they heard an acoustic signal resembling an ambulance horn. A peripheral attention task required participants to watch two traffic lights, one at each top corner of the screen. At random points in the simulation the traffic lights changed colour then turned red, at which point a bar appeared directly in front of the car. Only by reducing speed when the lights began to change could an accident be avoided. The third task assessed controlled reduction of speed; when a stop sign was presented, participants were instructed to come to a complete stop in front of the sign. The final task assessed risk-taking behaviour; a busy crossroad was presented and participants were to cross only when they thought the gap was large enough for them to do so safely.

Krueger & Vollrath [19] reported, using a factor analysis, that three factors representing driving performance: SDLP; speed; and performance in the secondary tasks. Blood sample results distinguished the following groups: THC (indicating recent cannabis use), THC-COOH (indicating past cannabis use), low concentration amphetamines (less than 0.05 mg/l), and high concentration amphetamines (greater than 0.05 mg/l). Results were analysed for each drug group alone and in combination with alcohol. In contrast to on-road studies, the results revealed that THC improved SDLP. Neither speed nor performance in the secondary tasks was affected. The THC-COOH group showed a further improvement in SDLP, as well as a reduction in speed. However, when combined with alcohol, performance was seen to deteriorate, especially in the THC-COOH group. For high concentration amphetamines, average speed increased slightly and performance in the secondary tasks deteriorated. In line with road tracking studies, low concentration amphetamine was associated with decreased SDLP. However, when combined with alcohol, SDLP increased dramatically. When cannabis was combined with high doses of amphetamines, SDLP increased and performance in the secondary tasks was impaired. When alcohol was combined with cannabis and amphetamines, performance was worse on all three measures. While the consumption of a single drug may variably affect driving performance, it is apparent that consuming a combination of drugs will have a dramatic and deleterious effect on driving performance.

A similar quasi-experimental methodology was used by Brookhuis et al. [20] who assessed volunteers after self administration of an MDMA tablet and after poly drug use. Participants completed a first ride in a driving simulator at the research institute one hour after the consumption of MDMA (average 59 mg). Participants then attended a party and were instructed that they could consume any psychoactive substance they liked, just as they normally would. A second ride in the simulator was undertaken after the party: the poly drug condition. The majority of participants consumed additional MDMA (70 %) and all had consumed other drugs at the party, most commonly marijuana (80 %) and alcohol (90 %). Participants returned for a final ride in the simulator on a separate evening when not under the influence of drugs. Driving behaviour was assessed in a fixed-based driving simulator consisting of a car with the original controls attached to a Silicon Graphics computer, the road environment was projected on a semi-circular screen. Road tracking (SDLP and speed) was assessed to reflect performance of automotive behaviours. Car following performance (delay in response to speed changes, headway) and per-

formance when lead traffic came to a standstill (brake reaction time) were measured to reflect control behaviours. Executive behaviours were assessed using a few scenarios: gap acceptance was measured while crossing a major road with traffic travelling in both directions, again whilst turning left with approaching traffic, and risk taking was assessed by the participant's response to a traffic light turning yellow. The results revealed that road tracking was sensitive to drug effects with SDLP increasing significantly in the multi drug condition. Speed measures also increased significantly from the no drug condition to the MDMA condition to the poly drug condition. Participants in the poly drug condition were more likely to accept less clearance than in the no drug condition. Car following performance revealed a trend for smaller headway in the poly drug condition (not significant). Reaction time when the lead car came to a standstill did not differ between conditions; however, the standard deviation in reaction time increased from no drug to MDMA to the poly drug condition. In the no drug condition, accidents occurred in two of the 20 no drug drives (10%). Under the influence of MDMA participants crashed four times (20%) and when under the influence of multiple drugs participants crashed five times (25%) while driving. The main limitation of previous quasi-experimental methods is the lack of experimental control; however, they do benefit from greater realism and testing the effects of realistic ('street') drug doses.

Validity of tests measuring driving or skills related to driving

A wide range of experimental studies have assessed drug effects on laboratory test performance over the last three decades. Although various investigators have claimed that their task or task battery taps driving related skills, most studies show no proof for such a claim or even a reasonable theoretical rationale. In general, investigators have employed a wide range of laboratory tests measuring aspects of perception, attention, motor control, cognitive function or CNS arousal that are assumed to underlie safer driving. However, none of these tests has ever been shown to closely predict driving performance or traffic accidents. Experimental laboratory tests may predict driving impairment, but until now it simply has not been demonstrated.

Two causes can be identified that have hampered attempts to demonstrate the predictive validity of performance testing for real-life crash risk: 1) a lack of theoretical performance models integrating all aspects of the driving task, and 2) a lack of epidemiological data demonstrating a conclusive relation between drug use and traffic accidents. The former refers to the fact that investigators have never been able to truly define the basic components of the driving task and their underlying psychological and neuropharmacological principles. Instead, investigators have turned to the multi-faceted approach for measuring isolated skills in laboratory task, driving simulators or on-the-road driving. The latter refers to the fact that availability of reliable epidemiological surveys on drug-induced crash risk accelerates attempts to validate any kind of driving performance tests against a real-life occurrence, such as crash risk. To date however, epidemiological data on the association

between drug and crash risk are still very limited. Consequently, the construction of a well-founded task battery to evaluate drug effects on performance always has been, and still is, a major research priority.

Nevertheless, there are a number of performance tests with demonstrated sensitivity to both beneficial and detrimental drug effects on driving performance. Most notable is the standardized road tracking task [2] that is conducted on the road in normal traffic to measure lateral position control and which has been used in over 90 experimental studies to date. Some laboratory tests, measuring tracking ability, impulse control, and cognitive function have shown exceptional drug sensitivity as well. It is postulated here that it is also possible to establishing the reliability and validity of these tests for predicting crash risk by applying some basic psychometric principles.

Reliability

Test reliability covers several aspects of consistency. It indicates the extent to which differences in test scores are attributable to true differences in the characteristic under consideration or to change errors. The measurement of test-retest reliability is essentially simple. The scores from a set of subjects tested on two occasions are correlated. Test-retest correlations have been repeatedly calculated for the standardized, on-the-road driving test by comparing driving performance of subjects who completed the driving test on two occasions during placebo treatment. These analyses show that mean values of the dependant variable obtained during these driving tests (i.e. the standard deviation of lateral position, SDLP) were highly comparable among individual subjects. Consequently, test-retest correlations or reliability of the driving test have been shown to be very high (i.e. $r > 0.85$ [21]).

Test reliability is a valuable construct that should be relatively easy to calculate for any measure claimed to assess driving or skills related to driving.

Validity

A test is valid if it measures what it claims to measure [22]. The validity of a test, however, can be described from several angles.

Content validity

Content validity is concerned with a test's ability to include or represent all of the content or a representative sample of the behavior domain [23]. Content validity is usually a bottleneck problem when measuring driving or skills related to driving because a broadly accepted reference framework or model integrating all basic skills underlying the driving task is missing. To date, no single performance test exists that comprises all relevant aspects of the driving task. Even one the most accepted tests for measuring drug-induced driving impairment, i.e. the standardized

road tracking task as described above, validly measures only a part of the driving task and a part of total drug action. Likewise, laboratory tests usually assess single aspects of the driving task and none of them is capable of encompassing all the potential danger areas for the effects of drugs. Consequently, investigators have usually decided to include a wide range of laboratory tests comprising performance areas such as: motor control, decision making, risk taking, vigilance and attention, perception, among others. The final evidence that the drug in question would be safe or hazardous should subsequently be based on the combined results of laboratory tests, simulator tests and actual driving tests [24].

Predictive validity

Predictive validity is the ability of a measure to predict something it should theoretically be able to predict. A high correlation between changes in the measure and changes in the construct that it is designed to predict would provide good evidence for its predictive validity. Thus, in the field of experimental drugs and driving research, we should consider whether actual driving tests or laboratory tests of skills related to driving actually predict crash risk in real life.

The predictive validity of performance tests in drugs and driving research is usually unknown, primarily due to a lack of real-life epidemiological (crash risk) data in general. The absence of such data has made attempts to correlate laboratory data to real life driving accidents extremely difficult. However, it should also be noted that, in the past, investigators have often neglected to calculate the predictive validity of their performance tests for alcohol induced crash risk, even though a wealth of epidemiological data is available. This can be considered a major deficiency in experimental drugs and driving research, since any performance task with demonstrated predictive validity for alcohol induced crash risk is also likely to be sensitive to drug induced crash risk.

In the case of the standardized, on-the-road driving test, sufficient alcohol calibration data are available to calculate the relation between alcohol induced changes in SDLP and alcohol related crash risk as a function of blood alcohol concentration (BAC). It is noteworthy that both SDLP and crash risk rise exponentially with increasing BAC, and it thus comes as no surprise that alcohol induced changes in SDLP are highly correlated with alcohol induced changes in crash risk ($r = 0.99$). The conclusion is thus warranted that the validity of the road tracking task for predicting alcohol induced crash risk is very high (Fig. 1).

Recent epidemiological data on THC and BZD (benzodiazepine) induced crash risk also offer the opportunity to calculate the predictive validity of the driving test with respect to these drugs' potential for crash risk. Figure 2 demonstrates that diazepam-induced changes in SDLP do correlate highly with diazepam-induced crash risk as a function of time after dosing ($r = 0.97$).Together, these data demonstrate that the standard road tracking task is a very reliable predictor of alcohol and drug-induced crash risk.

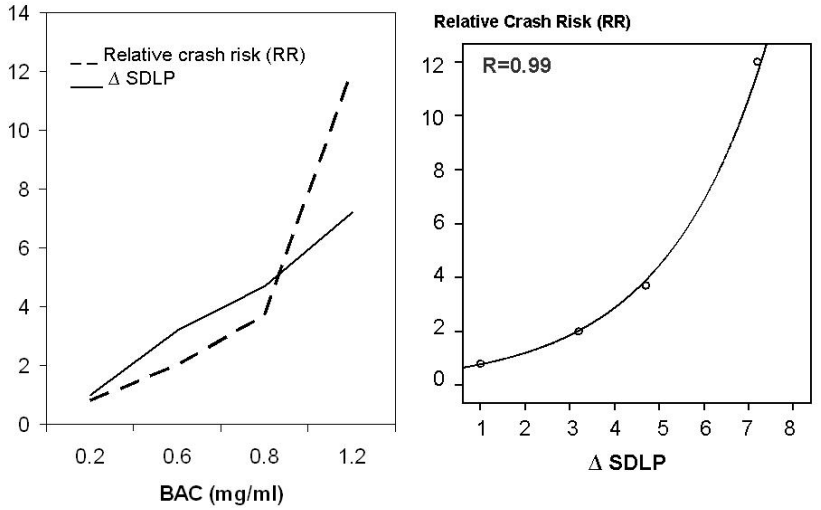

Figure 1 Curve fitting (right panel) of changes in SDLP (road tracking task) and relative crash risk as a function of blood alcohol concentration. SDLP and crash risk data were taken from Louwerens et al. [24] and Borkenstein [25].

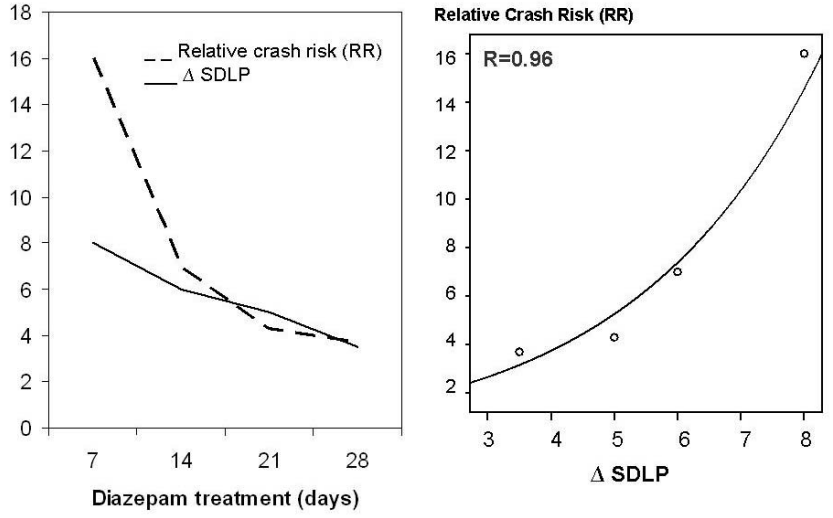

Figure 2 Curve fitting (right panel) of changes in SDLP (road tracking task) and relative crash risk as a function of blood alcohol concentration. SDLP and relative risk data were taken from Van Laar et al. [27] and Neutel [28].

Despite these impressive data on the predictive validity of the actual driving test, it should be recognised that the SDLP measures only partial aspects of the driving task, i.e. tracking ability and vigilance. Obviously these are keys aspects of driving that should never be neglected; however, other aspects of driving may be important as well.

External validity

External validity is related to generalising. External validity is the degree to which the conclusions from a study or measure would hold for other persons in other places and at other times. The issue is particularly relevant in studies assessing medicinal drug effects on driving, because these are usually conducted with healthy volunteers. It has been argued that patients do not experience side effects to the same degree as healthy volunteers. For example, most driving studies on the effect of antidepressants on actual driving performance have been conducted in healthy volunteers. It could be argued that healthy volunteers respond differently to antidepressant treatment than depressed patients and that one response does not predict the other. The obvious example is that depressed patients may respond favorably to antidepressant treatment, whereas healthy volunteers do not. Nevertheless, the rationale for studying antidepressant effects in healthy volunteers is that they experience side effects just like patients. This is certainly important at the beginning of depression therapy and in the minority of patients who do not respond to antidepressant treatment. It is assumed that somnolence or sedation is by far the most important cause of driver impairment in patients treated with antidepressant drugs. Regression analyses of elevations in SDLP observed in experimental driving studies, and the number of patients in clinical trials complaining of somnolence with the same antidepressants, strongly support this notion. Elevations in SDLP caused by antidepressants in healthy volunteer trials sharply increase as a linear function of the percentage of depressed patients complaining of somnolence in clinical trials ($r = 0.95$). These data thus indicate that the external validity of the actual driving test applied in a healthy volunteer model is very high [21].

Propositions

- Investigators should be able to justify the use of a performance test on the basis that it provides valid indices of a specified pharmacological effect and a specified mental/behavioral reaction relevant to driving.
- A test battery should measure as many of the relevant pharmacological aspects of a drug as possible, and as many of the mental and/or behavioral reactions of relevance to driving as possible.
- In general, performance measures used to define the effect of drugs on driving should posses a high test – retest reliability coefficient for raw scores measured in the absence of a drug effect (e.g. $r > 0.70$).

- Investigators should always fit experimental performance data with epidemiological crash risk data in order to define the reliability of a specific performance test for predicting drug-induced crash risk.
- Studies to show a drug effect on driving or skills related to driving should be designed to establish a dose-effect as well as a concentration-effect relation (i.e. multiple doses and quantification of drug concentration in blood)
- It is possible to attain results of practical relevance from studies employing healthy volunteers as subjects. This is not only the case when it is known or strongly suspected that healthy volunteers and ambulant patients experience different drug reactions capable of influencing their driving ability.
- Studies to establish the driving hazard potential of a particular drug should proceed from conventional laboratory testing to driving simulators and actual driving tests. The final evidence that the drug in question would be safe or hazardous should be based on the combined results of these tests [24].

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