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Driving simulator and neuropsychological testing in OSAS before and under CPAP therapy

M. Orth*, H-W. Duchna*, M. Leidag*, W. Widdig#, K. Rasche*, T.T. Bauer*, J.W. Walther*, J. de Zeeuw*, J-P. Malin#, G. Schultze-Werninghaus* and S. Kotterba#

ABSTRACT: Patients with obstructive sleep apnoea syndrome (OSAS) have an increased car accident rate. Investigations on accident frequency are based on case history, insurance reports and driving simulator studies. The present study combines neuropsychological testing of different attention aspects engaged in driving a car and driving simulation to evaluate a suitable instrument for assessing therapeutic effects of continuous positive airway pressure (CPAP).

Driving simulator investigation and neuropsychological testing of alertness, vigilance and divided attention were performed in 31 patients with polysomnographically confirmed OSAS (apnoea–hypopnoea index 24.8±21.5·h^{-1}) before, and 2 and 42 days after initiation of CPAP.

Divided attention and alertness improved significantly during CPAP, whereas vigilance remained unchanged. However, accident frequency (OSAS before therapy: 2.7±2.0; 2 days after CPAP: 1.5±1.4; 42 days after CPAP: 0.9±1.3) and frequency of concentration faults (OSAS before therapy: 12.4±5.1; 2 days after CPAP: 6.5±3.9; 42 days after CPAP: 4.9±3.3) decreased in the simulated driving situation after 2 and 42 days of therapy. There was no relation between accident frequency, concentration faults and daytime sleepiness, as measured by the Epworth Sleepiness Scale, and polysomnographic or neuropsychological findings, respectively.

In conclusion, the present results suggest that driving simulation is a possible benchmark parameter of driving performance in obstructive sleep apnoea syndrome patients.

KEYWORDS: Accident frequency, continuous positive airway pressure, driving, driving simulator, neuropsychological testing, obstructive sleep apnoea syndrome

Motor vehicle accidents are one of the major causes of death in modern society [1]. Whereas factors such as excessive speed and alcohol consumption are primary and obvious causes of accidents [2], the incidence of sleepiness as a reason for accidents is rarely reported in official statistics; 0.14% of accidents in 1999 in Germany [3], 3.2% in Italy [4] and 1–3% in USA [5]. Driver sleepiness may be under-recognised in official databases because the police often do not ask about sleepiness and the drivers do not report this difficulty. This results in a discrepancy between low rates of road accidents ascribed to sleepiness in databases and the higher percentage reported in studies conducted by police officers sensitised on sleepiness as a determinant of accidents [4, 5]. Nevertheless, studies on motorway accidents have indicated that 20–25% appear to be sleep-related, and these are particularly likely to occur in the early morning or mid-afternoon [5, 6].

Obstructive sleep apnoea syndrome (OSAS) represents the most common untreated cause of excessive daytime sleepiness. Several studies have shown that patients with OSAS have an increased accident rate in driving simulation tests [7–10], and tend to have an accident rate between two- and seven-times higher than patients without OSAS [5, 11–14]. Furthermore, it has been shown that continuous positive airway pressure (CPAP) treatment can reduce the number of accidents in patients with OSAS, both in simulated driving situations [7] and in reality [14–17].

These data clearly identify OSAS as a significant contributing factor to road traffic accidents, with important consequences both for the individual's and public safety. Therefore, physicians are often asked to assess an individual's ability to drive a car. However, as yet, there are no generally accepted regulations within Europe concerning driving licensing and OSAS. Diagnostic tools to

AFFILIATIONS
*Dept of Internal MedicineDivision of PneumologyAllergology and Sleep Medicine, and
#Dept of NeurologyUniversity Hospital Bergmannsheil, Bochum, Germany.

CORRESPONDENCE
M. Orth
University Hospital Bergmannsheil
Dept of Internal Medicine
Division of Pneumology
Allergology and Sleep Medicine
Bürkle-de-la-Camp-Platz 1
44789 Bochum
Germany
Fax: 49 2343026420
E-mail: Maritta.Orth@ruhr-uni-bochum.de

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assess a person's sleepiness include subjective measures (*e.g.* Epworth Sleepiness Scale (ESS)) and objective assessment of sleepiness by Multiple Sleep Latency testing or Maintenance of Wakefulness testing. Driving performance can be simulated and the different components of attention involved in driving a car may be assessed by neuropsychological investigations. However, there is still no consensus regarding the adequate and best diagnostic tool. The present study was performed to assess accident rates in patients with OSAS before and during CPAP therapy, and to estimate the predictive value of different diagnostic tools in assessing a simulated accident rate.

PATIENTS AND METHODS

In total, 31 consecutive male patients (age: 55.3 ± 10.2 yrs; body mass index: 29.9 ± 2.2 kg·m^{-2}) with polysomnographically (Alice IV; Respironics®, Pittsburg, KS, USA) confirmed OSAS were included in the study. Sleep apnoea was defined as an apnoea–hypopnoea index of $\geqslant 5$ events·h^{-1} and the presence of clinical symptoms *e.g.* daytime sleepiness and drowsiness.

Exclusion criteria were as follows: cerebral diseases (head injuries, cerebral ischemia and encephalitis); central nervous stimulating or relaxing medication; alcohol or drug abuse; disability to drive a car; chronic obstructive pulmonary disease; and pregnancy. The study was approved by the Ethics Committee of the Ruhr-Universität Bochum (Bochum, Germany), and all patients gave their written informed consent prior to the study. Subjects were instructed to avoid caffeine and alcohol during the study period. They were also informed that all results were confidential, had no legal impact and no influence on their driving licence. All participants of the study were active drivers.

Patients were asked to rate on the ESS, an eight-item questionnaire, the likelihood of dozing in a variety of sedentary situations. Computer-assisted neuropsychological testing was performed using the Wiener test system [18] and the Zimmermann test battery [19]. Tests were chosen to explore the following cognitive functions which are utilised when driving a car. 1) Vigilance: subjects have to watch a beam on a screen moving up and down. They have to react on rarely occurring higher swings by pressing a button. The test lasts 10 min [19]. 2) Alertness: simple reaction on a lamp flashing upwards. The test lasts 80 s [18]. 3) Divided attention: the patient has to press coloured lamps when the corresponding colour flashes on a board. Additionally they have to react to acoustic signs by pressing buttons and foot pedals when indicated by signals. During the test, velocity was increased. The test was then repeated for another 760 tasks for the best velocity achieved. The median reaction time was then recorded. This test resembles a driving simulator and lasts 10 min [18].

Test results were scored automatically by the computer. Results were expressed as a percentage related to normative data evaluated by the system providers (age-matched patients without physical handicap). ''Percentage 20'' for example indicates that 80% of age-matched controls would achieve a better test result.

Patients underwent a driving simulator test. The C.A.R.® (Computer Aided Risk Simulator; I. R. Foerst, Gummersbach, Germany) was used in conjunction with the German traffic board (Deutscher Verkehrsrat) in order to examine its clinical relevance (fig. 1). At present, the maximal number of errors that should be tolerated (normative data) is under debate. In brief, sitting in the simulator, after a trial period of 15 min, subjects have to drive on a highway for 60 min with a mean speed of 100 km·h^{-1}. A monotonous condition despite different weather (rain, sunshine, snow, mist) and daytime conditions is presented in a random sequence on a computer screen. Obstacles (deer, pedestrians, other vehicles) occur infrequently, randomised by the computer. Drivers experience real car reactions (*e.g.* aquaplaning during rain conditions, feedback by automobile noise and reaction of the car seat to speeding and slowing down).

FIGURE 1. Diagram showing the driving simulator Computer Aided Risk Simulator (C.A.R.®).

Computer analysis of the simulator only scores accidents (*i.e.* crashes with other cars, pedestrians and other obstacles, and driving off the road) and some concentration faults (*e.g.* using the headlights). In order to evaluate all concentration deficits (*e.g.* driving with headlights switched off at night; driving with headlights switched on in the daytime; disregarding the speed limit; driving with dimmed headlights; tracking error (turning too extensivly to the right or left side of the road, touching the curb or the opposite lane); not using the flash of the headlights; disregarding traffic lights; and disregarding right of way) a technician watches the road situation on a video screen and observes the patient from behind, registering all the concentration faults manually. All these items represent important errors because they can lead to near-miss accidents. The technician is not allowed to motivate the patient, but can take action if problems with handling of the simulator occur.

Driving simulation and neuropsychological testing were performed before, and 2 days and 42 days after initiating CPAP therapy in polysomnographically confirmed OSAS patients. The testing was performed either between 09:00–11:00 h or between 16:00–18:00 h, according to the circadian rhythm and representing the daytime periods in which alertness is highest. The time of testing was the same for each patient in the follow-up investigation. ESS was assessed before each test. The investigation on day 42 was chosen according to the German Society of Sleep Research and Sleep Medicine, which recommends application of CPAP therapy for $\geqslant 6$ weeks before allowing professional drivers to work again [20].

Intra-individual comparisons were made with the paired t-test or the Wilcoxon signed-rank test for variables without normal distribution. Multivarate analyses were carried out with multiple linear regression analyses (backward selection, inspiratory pressure 0.05, outflow pressure 0.1). Dependent variables in this analysis were accident frequency and frequency of concentration faults. The following independent variables were investigated: subjective sleep quality (ESS score); sleep architecture (arousal index, stage 1/2 sleep, stage 3/4 sleep, rapid eye movement sleep); ventilatory parameters (apnoea index, apnoea–hypopnoea index, oxygen saturation); and results of neuropsychological testing. In cases with significant associations, univariate regression analyses were performed. Statistical significance was assumed with a p-value <0.05. As no published results of sequential testing were available at the time of the study, sample size calculation was based on the following assumptions. For the neuropsychological testing, mean alertness reaction time was expected to be 431 ms with SD of 15% (60.6 ms) [21]. The study was then designed to establish a difference of 15% with an α-error of 5% and a β-error of 10% (minimal required sample size: n=22).

RESULTS

Polysomnography, ESS, neuropsychological testing and driving simulator performance were evaluated before, and 2 and 42 days after initiating CPAP therapy. Out of the 31 patients enrolled in the study, 24 (77%) agreed to CPAP therapy and completed the investigations on day 2, and 21 (68%) also completed the study 42 days after initiating CPAP.

Average ESS scores improved significantly during CPAP after 2 days of therapy (10.1±4.2 before CPAP *versus* 8.9±4.5 day 2; $p<0.05$) and were still significantly lower compared with baseline after 42 days (6.1±3.3; $p<0.001$).

Sleep architecture was not changed during CPAP (table 1), with the exception of arousal index (12.6±19.0·h^{-1} before CPAP *versus* 3.7±4.1·h^{-1} day 42; $p<0.05$). However, ventilatory parameters, such as apnoea–hypopnoea index (24.8±21.5·h^{-1} before CPAP *versus* 8.2±9.6·h^{-1} day 42; $p<0.001$), and medium (93.5±3.1% before CPAP *versus* 95.3±0.8% day 42; $p<0.001$) and minimal oxygen saturation (80.5±10.9% before CPAP *versus* 88.4±5.0% day 42; $p<0.001$) improved significantly. Table 2 shows the results of neuropsychological performance before and during CPAP. Significant improvements were seen in terms of alertness and divided attention, whereas vigilance remained unchanged throughout the course of CPAP therapy.

TABLE 1 Sleep architecture in patients with obstructive sleep apnoea syndrome before and during continuous positive airway pressure (CPAP)

	Before CPAP	After CPAP	
		2 days	42 days
TST min	345±64.6	347.4±53.6	347±57.7
REM min	55.7±33.3	61.7±37.4	58.3±25.7
REM % of TST	16.1±8.5	17.4±9.0	17.8±6.2
Stage 3/4 sleep min	31.2±28.4	69.9±21.8	40.0±28.3
Stage 3/4 sleep % of TST	9.9±8.7	12.1±7.9	10.9±8.3
Arousal index·h^{-1}	12.6±19.0	4.8±4.9	3.7±4.1*

Data are presented as mean±SD. TST: total sleep time; REM: rapid eye movement. *: $p<0.05$ when compared with before CPAP.

TABLE 2 Neuropsychological test results in patients with obstructive sleep apnoea syndrome before and during continuous positive airway pressure (CPAP)

	Before CPAP	After CPAP	
		2 days	42 days
Alertness			
Reaction time ms	432.1±90.5	405.9±62.1*	391.9±56.8*
PR	30.2±29.7	36.5±30.2	43.9±30.3
Divided attention			
Reaction time ms	1.3±0.5	1.0±0.2***	1.0±0.2***
PR	48.1±34.6	77.8±29.1***	78.6±28.5***
Vigilance			
Reaction time ms	511.7±86.5	479.1±130.6	477.2±130.8
PR	76.6±19.1	79.6±13.3	80.7±13.2

Data are presented as mean±SD. PR: percentage related to normative data. *: $p<0.05$ when compared to before CPAP; ***: $p<0.001$ when compared to before CPAP.

Figures 2 and 3 show the comparison of driving simulator performance (accidents, concentration faults) of patients with OSAS before and during CPAP. There was a significant reduction of both accidents (before CPAP: 2.7±2.0; 2 days after CPAP: 1.5±1.4, $p<0.01$; 42 days after CPAP: 0.9±1.3, $p<0.001$) and concentration faults (before CPAP: 12.4±5.1; 2 days after CPAP: 6.5±3.9, $p<0.001$; 42 days after CPAP: 4.9±3.3, $p<0.001$) even after 2 days of CPAP therapy and this improvement continued throughout the course of CPAP therapy.

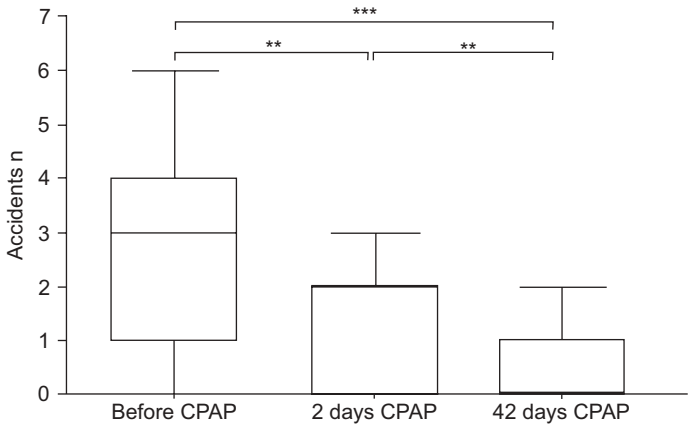

FIGURE 2. Box-whisker plots representing comparison of accident frequency (driving simulation) in obstructive sleep apnoea syndrome patients before continuous positive airway pressure (CPAP) initiation (n=31), and after 2 and 42 days of CPAP (n=24 and n=21, respectively). **: $p<0.01$; ***: $p<0.001$.

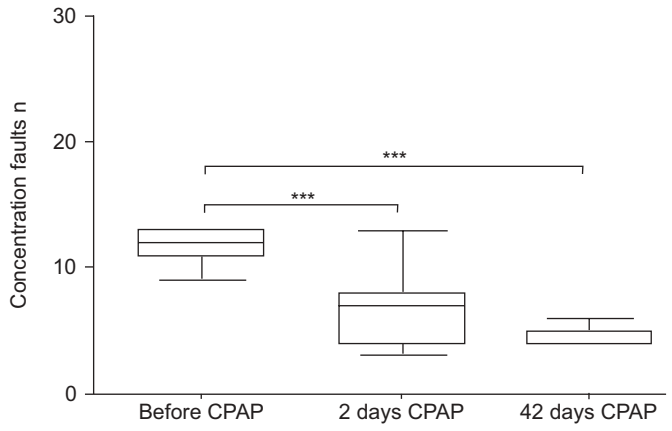

FIGURE 3. Box-whisker plots representing comparison of frequency of concentration faults (driving simulation) in obstructive sleep apnoea syndrome patients before continuous positive airway pressure (CPAP) initiation (n=31), and after 2 and 42 days of CPAP (n=24 and n=21, respectively). ***: $p<0.001$.

Multiple linear regression analysis revealed no significant association between ESS score, neuropsychological test results and driving simulator performance. Furthermore, there was no relationship between polysomnographic parameters (neither sleep architecture nor ventilatory parameters) and driving performance (data not shown).

DISCUSSION

The present study demonstrates that in a simulated monotonous driving situation, the frequency of accidents and concentration faults in patients with OSAS were reduced significantly in the short- (2 days) and long-term (42 days) course of CPAP therapy. Likewise there was an improvement in alertness and divided attention, which are both crucial to car driving performance. Vigilance, as a parameter of attention in monotonous situations created during the car simulation, did not improve after CPAP.

Sleepiness is a major contributing factor to road traffic accidents and is often ignored because the accident seems to be attributable to other more obvious causes, such as alcohol, bad weather or impairment due to drug abuse. OSAS patients have an increased risk of road accidents, which is between two- and seven-times higher than in normal subjects [5, 11, 22–24]. Accident frequency can be evaluated by different tools, *e.g.* clinical history, analysis of databases of insurance companies or legal authorities, neuropsychological testing and driving simulation. Questionnaire studies and clinical history have revealed an increased accident risk in OSAS [13, 24] and an improvement during CPAP [14, 17, 25]. However, self-reporting of automobile crashes due to sleepiness by patients may not be reliable, because drivers are reluctant to report their car crashes because of the potential of losing their driving licence. FINDLEY *et al*. [15] showed that two out of three patients with sleep apnoea syndrome did not report their accidents. Furthermore, databases may be biased, because only those accidents that have been reported by the driver are registered and near-miss accidents will not be registered.

The present study was conducted in order to combine neuropsychological testing of different attention aspects engaged in car driving and driving simulation in order to find the most suitable instrument for assessing accident frequency and therapeutic effects. Multiple regression analysis revealed that simulated accident frequency and number of concentration faults were not associated with sleep architecture, ventilatory parameters, ESS score and/or neuropsychological testing. In the current authors' opinion this underlines the fact that car driving, and its simulation, is a comprehensive task which cannot be reflected in neuropsychological testing investigating specific aspects of attention one at a time. Therefore, accident frequency can probably not be predicted by neurophysiological testing, and driving simulation has to be performed to document the benefits of CPAP therapy. These findings correspond with the recent data provided by MAZZA *et al*. [10], who demonstrated significant attention deficits in OSAS patients as compared with controls. However, the authors were also unable to find a correlation between performance in any of the vigilance tests and ESS score, respiratory disturbance index or any sleep variables measured. Therefore, the authors recommended that a single test of vigilance is not sufficient and could underestimate impaired vigilance and attention in some patients.

Nevertheless, physicians are often asked to make recommendations about an individual's ability to drive a car after initiation of CPAP. Consequently, there is need for sensitive and objective tools to ascertain attention, namely driving, impairment. Driving simulators may help to identify drivers at risk for car crashes. In OSAS, several driving simulators have been evaluated, and have been able to discriminate between patients and controls [8, 9, 12] and to demonstrate improvement in driving simulation under CPAP [16]. However, most simulators test only one attention aspect engaged in driving a car, such as divided attention (Divided Attention Driving test) or sustained attention (''steer clear''). With regard to neuropsychological testing, there are hints to impairments in general intellectual measures, verbal fluency, and performance in executive and psychomotoric tasks [27], as well as vigilance impairments which may persist after initiating CPAP [28]. In a former study on OSAS patients, deficits in alertness and continued attention were found, which are important attention factors when driving a car [29].

In the intra-individual comparison, ventilatory parameters and oxygen saturation improved significantly during CPAP. However, with regard to sleep architecture, there was only a reduction of arousal index, whereas stage 3 and 4 sleep did not improve. This lack of acute influence of CPAP on deep sleep is not an unusual finding. LOREDO *et al*. [26] showed similar results when treating patients with effective CPAP compared with placebo CPAP for 7 days in a double-blind study. They found that effective CPAP was able to reduce arousals, but did not improve sleep architecture when compared with sham CPAP. Similar results were found during follow-up of the current study patients after 42 days, corroborating the results of LOREDO *et al*. [26]. However, subjective parameters of sleep quality, such as the ESS, improve significantly during the study period. There are many reasons for the lack of improvement of sleep architecture, *e.g.* patients are not accustomed to the sleep laboratory situation. Additionally,

the patient has to become familiar with the new CPAP device. Despite these factors, sleep architecture in the present study showed a trend towards improvement even shortly after initiating CPAP, which is demonstrated by a reduction in arousal index.

As demonstrated, follow-up of neuropsychological deficits during CPAP revealed an improvement in terms of alertness and divided attention in the present study. However, vigilance, which is the predominating factor in long-term monotonous car driving, remained unchanged. The driving simulator, C.A.R.®, was able to demonstrate the effect of CPAP therapy with regard to concentration faults and accident frequency in the short and long term. In contrast to other simulators, C.A.R.® combines tracking and visual search with several attention dimensions and is not focussed on one aspect. C.A.R.® imitates all attention aspects that are involved in driving a car (*e.g.* alertness, divided attention and vigilance). Weather conditions change only rarely and obstacles are seldom, so that the emphasis is on vigilance testing. Additionally, time of testing was 60 min, bearing in mind that vigilance tests have to last $\geqslant$30 min. To summarise, C.A.R.® imitates the classic situation in which OSAS patients doze-off when driving a car for a long and monotonous period of time. The technical handling, feedback by automobile noise, reaction of the car seat on speeding and slowing down, and several daytime and weather conditions offer a relatively realistic driving situation. In a former study with C.A.R®, accident frequency and concentration faults were increased in patients with multiple sclerosis as compared with controls [21]. The results of the present study suggest that C.A.R.® is a useful additional instrument to document the improvement of simulated driving capabilities before and after CPAP therapy in OSAS patients.

Some possible limitations of the current study deserve consideration. The test battery in the combination used has not been validated for sleep deprivation as it occurs, *e.g.* in commercial truck drivers. This study is the first to investigate the association between neurophysiological parameters and improvement of sleep fragmentation as it occurs in sleep apnoea. ESS was assessed before each test and an improvement in this measure of long-term sleep quality was shown. Moreover, the results of neuropsychological testing and driving performance could have been influenced by acute sleep disturbance in individuals. However, a large number of patients were included and the average improvement of neuropsychological testing and driving simulation suggests that the present results are valid despite this possible drawback. One other possible limitation of C.A.R.® is the need for additional manual scoring by a technician who may have problems with his own vigilance. This only applies to concentration faults, because all other errors (*e.g.* accidents, obstacles hit) were scored automatically. The technician was the same throughout the study and the number of tests was limited to one per day. Therefore, the authors would like to exclude a bias for the intra-individual comparison. In the study, 21 out of 31 patients (68%) accepted CPAP therapy and completed the study on day 42. Of the remaining 10 patients, seven (70%) refused CPAP therapy initially and three during the course of the study. This figure corresponds to a rejection rate of 32%, which is comparable to the average rejection rate reported in the literature [30–32].

In conclusion, neuropsychological testing was not significantly associated with simulated driving performance in patients with obstructive sleep apnoea syndrome. Effective continuous positive airway pressure therapy improved ventilatory parameters and nocturnal oxygenation, as well as neuropsychological functioning and driving performance, as measured by the driving simulator. For example, the German Society for Sleep Research and Sleep Medicine recommends $\geqslant$6 weeks of continuous positive airway pressure therapy for commercial drivers with obstructive sleep apnoea syndrome [19]. From the socioeconomic view this is hardly practical and most of the drivers continue driving immediately after initiating continuous positive airway pressure therapy. The present results suggest driving simulation as a possible benchmark parameter of driving performance in these patients.

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