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EFFECTS OF FATIGUE ON REAL-WORLD DRIVING IN DISEASED AND CONTROL PARTICIPANTS

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Summary: This study evaluated real world driver errors and sleepiness in 66 drivers with Obstructive Sleep Apnea (OSA) and 34 matched controls (24 younger and 22 older). Driving errors and driver state were derived from analyses of video data from "black-box" event recorders. Sleep fragmentation data in OSA was derived from actigraphy for 15 days prior to beginning standard treatment (positive airway pressure, PAP) and 15 days after beginning PAP treatment. Prior to starting PAP, OSAs appeared sleepier than controls in general and particularly at intersections, while making safety errors following nights with high levels of fragmented sleep compared to matched controls. Adverse effects of sleep fragmentation during the pre-PAP phase were reduced post-PAP. Greater hours of PAP-use were associated with lower sleepiness and errors on the road. PAP-use was associated with a decrease in high sleep fragmented nights. Findings suggest reduction in acute sleepiness is unlikely to be the only mediating factor that explains the driving safety benefits of PAP in OSA.

OBJECTIVES

Meta-analytic studies indicate that obstructive sleep apnea (OSA) is associated with increased crash risk (Treagear et al., 2009). Positive airway pressure (PAP), the standard treatment for OSA, appears to mitigate crash risk (Tregear et al., 2010). A major weakness of the studies to date is how crash risk is estimated. 67% of the studies in Tregear et al., (2009) were based on self-report, 22% on state records, and remaining 11% on insurance company records. Only 22% of PAP effectiveness studies were based on objective reports of crash risk (Tregear et al., 2010). Even when crash risk is estimated using state/insurance company records, it remains a poor measure of driving safety because crashes represent a fraction of the variability in driving safety (Heinrich et al., 1980). Many near-misses, other safety relevant errors that do not result in a crash because of the evasive maneuvers of other drivers are not reflected in crash statistics.

These meta-analytic studies are inconclusive on why untreated OSA drivers may be at increased crash risk. While sleepiness from a variety of causes has been shown to be associated with increased crash risk (Connor et al, 2002), measures of chronic sleepiness such as the Epworth Sleepiness Scale have not shown significant associations with crash risk in OSA drivers (Tregear et al., 2009). In contrast, small sample and short-term (1-2 weeks) PAP-treatment studies show significant reductions in excessive daytime sleepiness and crash risk compared to pre-treatment baseline (Tregear et al., 2010) and improved vigilance in driving simulator outcomes for OSA drivers (e.g. Orth et al., 2005; Turkington et al., 2004). Chronic sleepiness may not be the main reason for decreased driving safety in OSA. Rather crash risk may depend more on the effects of

acute sleep deprivation associated with sleep fragmentation/ poor sleep hygiene. Connor et al., (2002) found that acute rather than chronic sleepiness based on retrospective interview data was associated with objective crash data in the general population. Acute sleep deprivation has also been shown to worsen simulated driving performance in both treated and untreated OSA to a greater extent than in matched controls (Filtness et al, 2011; Vakulin et al, 2009). Hence, OSA drivers may have an exaggerated deterioration in driving safety when sleep duration or quality is reduced. This study evaluated the effects of poor sleep quality (high sleep fragmentation) on driving safety and driver state in OSA. We examined these effects for 15 days before and 15 days after PAP-therapy. We examined whether PAP-dose (measured by hours of use) was associated with driving outcomes in the post-PAP period and levels of sleep fragmentation. Compared to previous work, this study: a) measured driving safety errors and driver state including sleepiness from video using black-box event recorders, b) observed both OSAs for a two-week period prior to and a two-week period after PAP therapy, c) collected objective sleep quality data from actigraphy in both OSAs and controls d) presence/absence of OSA was confirmed with overnight polysomnography in both OSA and control drivers. We used these data to address two broad questions:
1) Does sleep fragmentation adversely influence driving safety the next day in drivers with untreated OSA and matched controls pre-PAP period? Are the adverse effects of sleep fragmentation on driving safety larger for untreated OSA drivers than controls?
2) How does PAP-treatment affect sleep fragmentation and the effects of sleep fragmentation on driving safety among OSAs? Are those relationships dependent on PAP-dose?

METHOD

Subjects

Two groups of subjects, 66 diagnosed with OSA (26 female, age M = 46.8 years, SD = 7.47) and 34 control participants (17 male, age = M = 44.2 years, SD = 8.4) from an ongoing study of real-world driving in OSA were included in current report. In the broader study control participants were matched with OSA drivers at the group level on age within 5 years, education within 2 years, and distribution of gender, county of residence for rural vs. urban driving. Patients met ICSD-2 clinical criteria for OSA and had a Respiratory Distress Index > 15, while controls had no sleep complaints and an RDI < 5 as confirmed by overnight sleep study.

Study Procedures

The design of the broader study called for naturalistic observations of OSA subjects driving their own vehicles using an instrumented vehicle data acquisition system (IV-DAS) for a 2-week period prior to beginning PAP treatment, and a period of 3-months after beginning PAP-use. Control drivers were evaluated at the same schedule to assure comparable data acquisition. To standardize PAP-use data collection, all OSA subjects were prescribed the same PAP-machine. Both control and OSA participants were also given actigraphy watches for the duration of the study. The data from the PAP-machines and watches were downloaded at monthly intervals. For the current report, only the 15 day-periods before and after the commencement of PAP-therapy were used.

*Procedures Pertinent to Driving Data Collection***.** IV-DAS contains three devices: an internal camera cluster (ICC), a GPS, OBD-II, and accelerometers. The cameras are located underneath the rear view mirror, with one pointing forward toward the road (a driver's eye view) and the other at the face and upper body of the driver. Electronic drive files and associated video clips were transmitted to a remote server daily. Video data collection was triggered intermittently based on accelerometer exceedances and a baseline data collection schedule (see Aksan et al., 2011). Each ignition on-off cycle could be associated with three types of clips: one-minute ignition clips, trigger clips of minimum 20-seconds duration when the driver exceeded .35 g's, and baseline clips of 20-seconds duration every 15-minute into a drive. Electronic data on vehicle state were not used in this report (see McLaurin et al., 2014).

Measures

PAP-adherence and objective sleep quality statistics. Nightly PAP-use data were downloaded during monthly visits in the post-PAP phase. Average minutes of use per night were used in the current report. Actigraphy watches report several statistics pertinent to sleep quality. In the current report, number of awakenings and number of minutes awake after sleep onset were used to index level of sleep fragmentation in the pre-PAP and post-PAP periods.

Driving measures. Clips were evaluated in 20-second segments in three broad domains: safety, exposure, and driver state. Table 1 provides examples of coded dimensions (Klauer et al., 2006; Neale et al., 2005; Wierville & Elsworth, 1994). Coders were trained on sample clips illustrating the range of behaviors in each of the dimensions listed in Table 1 until they showed the following minimum levels of inter-rater reliability: on categorical scales a Kappa of .61 and on continuously distributed scales minimum intra-class correlation of .71 for absolute agreement. All coders were blind to PAP-use and actigraphy data, some coders were also blind to group status. Presence/ absence of distracted behavior in several categories, safety errors, and facial/ bodily indicators of sleepiness were noted in 20-second segments. These binary judgments were transformed into relative frequency variables within a day, e.g. % time the driver appeared sleepy, distracted, made safety errors. In addition to these simple events, relative frequency of joint events was computed, e.g. % time the driver was negotiating an intersection while sleepy, % time driver made a safety error while sleepy, % time distracted at intersection or making safety errors while distracted at the day level. Because distraction can be a source of safety errors, these measures were included to permit an examination of whether the effects of sleep fragmentation and PAP-use on driving safety were specific to drivers' sleepiness.

Data reduction. Each night's sleep statistics and PAP-use was linked with the following day's driving data (e.g. relative frequency of safety errors while sleepy). Based on actigraphy data, each night was characterized as a low-to-moderate sleep fragmentation night or a high sleep fragmentation night. Sleep fragmentation was categorized as high if subjects had more than 30 awakenings and more than 43 minutes awake after sleep onset. OSA and controls showed similar patterns of high vs. low-to-moderate sleep fragmentation in pre-PAP and post-PAP periods. Among controls, 79% in pre-PAP and 91% in the post-PAP period experienced high fragmentation, and among OSAs 85% in the pre-PAP and 89% in the post-PAP period experienced high fragmentation. Corresponding percentages for low-to-moderate sleep fragmentation were also similar across the groups and across pre to post-PAP periods.

Table 1. Coded dimensions in 20-second segments from each video clip in three domains of interest

Domain	Dimension	Examples
Safety	Errors	Running stop signs/ lights, other traffic sign violations, turn errors, lane keeping, accelerating or braking hard enough to exceed .35 g's
Driver State	Distraction	Included several categories, e.g. talking, singing, dancing, eating/ drinking, tending to personal hygiene (hair, teeth), cell-phone, etc.
	Sleepiness	Slow eye lid closure, fixed gaze, rubbing eyes, yawning, low facial and bodily muscle tone, leaning/ holding neck/head
Road Culture	Intersection	Sign or light controlled and uncontrolled intersections

RESULTS

Mixed linear models with maximum likelihood were fit to each of the joint and single event measures of driving. Group and level of sleep fragmentation the night before were the predictors. Unlike traditional ANOVA/ regressions these models accommodate various error covariance structures and missing data, permitting less biased inferences. The models were fit separately for the pre- and post-PAP periods. Table 2 shows p-values associated with the fixed effects. In all cases, the within and between subject variance components were statistically significant showing substantial intra- and inter-individual differences (not shown). The pre-PAP models (Figure 1) showed several interaction effects between sleep fragmentation and group. Of note, OSA drivers showed a pattern opposite that of matched controls on driving measures as a function of the level of sleep fragmentation the night before. OSA drivers appeared sleepier, made more safety errors while sleepy, and appeared sleepy during intersection negotiations on days following high levels of fragmented sleep. In contrast, the matched controls appeared less sleepy during intersection negotiation and less likely to make safety errors while sleepy following high levels of fragmented sleep in the pre-PAP period. None of these effects were observed in the post-PAP period (the last 3 columns of Table 2). However, there were significant main effects of group on overall sleepiness and likelihood of making a safety error while sleepy (see Figure 2). Controls were sleepier and made more safety errors while sleepy than OSAs in the post-PAP period. Importantly, effects of sleep fragmentation prominent for OSAs in the pre-PAP period were no longer observed in the post-PAP period.

Table 2. Mixed model p-values for fixed effects as a function of sleep fragmentation and group on driving measures obtained the next day during the pre- and post-PAP periods

Outcome measures	pre-PAP			post-PAP		
	Group	Sleep Fragmentation	Group X Sleep Fragmentation	Group	Sleep Fragmentation	Group X Sleep Fragmentation
Driving measures the next day						
Single events (% time)						
Safety errors	.125	.510	.628	.067	.599	.213
Distracted	.941	.960	.689	.586	.599	.833
Sleepy	.296	.413	**.035**	**.025**	.080	.133
Joint events (% time)						
Sleepy & safety error	.189	**.005**	**.007**	**.035**	.214	.334
Sleepy during intersection negotiation	**.009**	**.038**	**.001**	.248	.113	.126
Distracted & safety error	.148	.404	.073	.134	.648	.778
Distracted during intersection negotiation	.181	.785	.724	.290	.485	.949

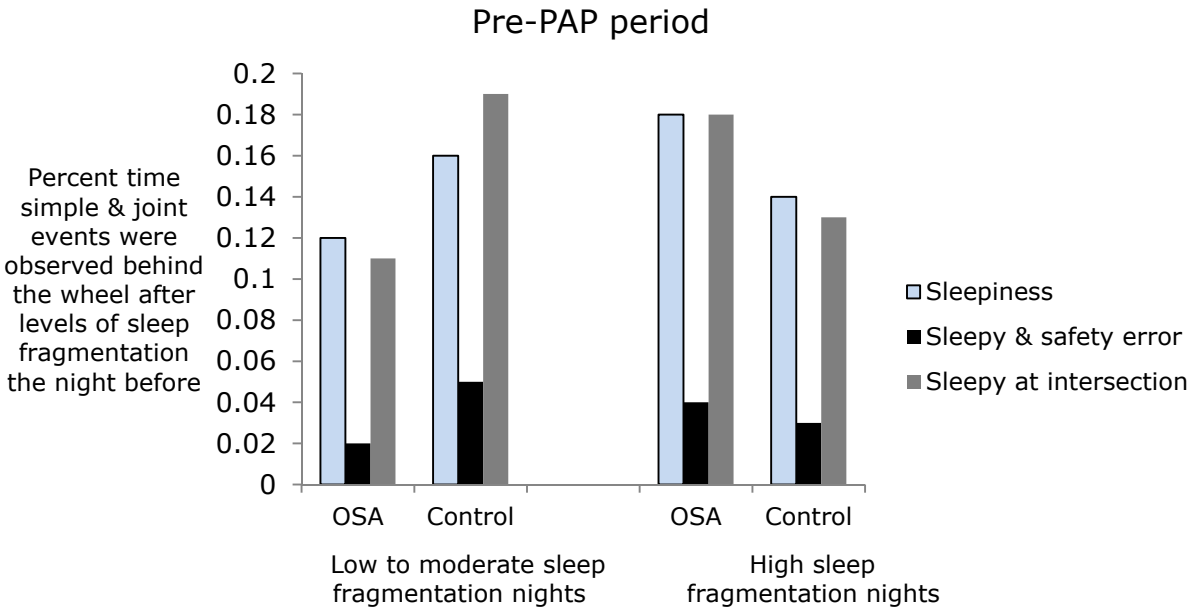

Figure 1. Effects of sleep fragmentation on real-world driving performance in untreated OSA and controls

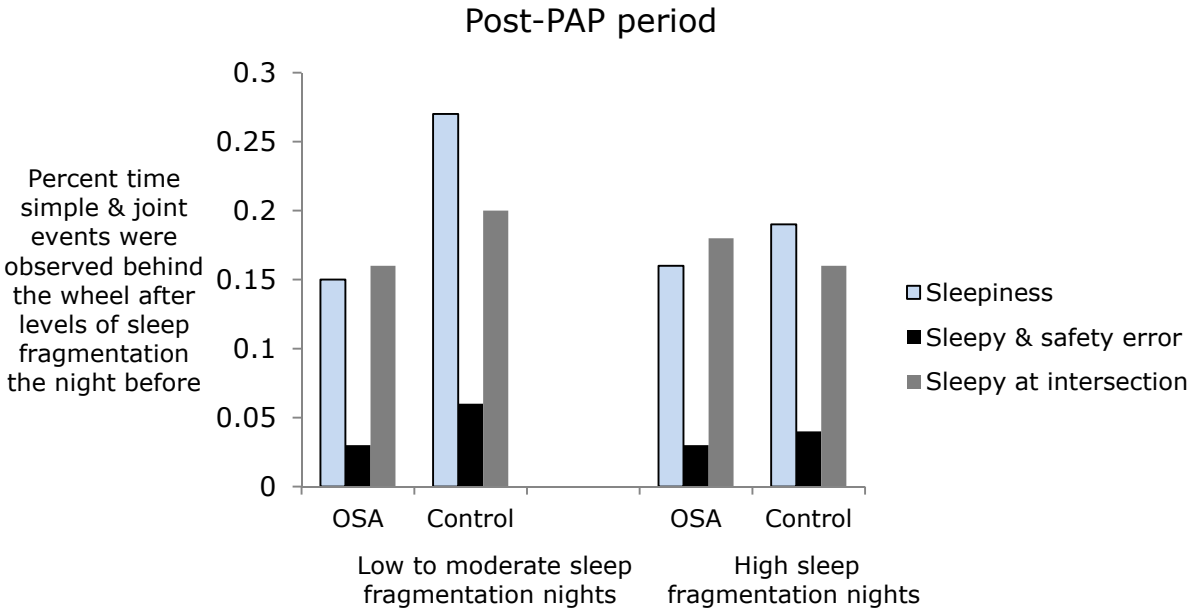

Figure 2. Effects of sleep fragmentation on real-world driving performance in OSA and controls post-PAP

These findings *suggest* that PAP treatment itself may have diminished the adverse effects of sleep fragmentation on driving for OSAs. Higher hours of PAP-use were associated but at the trend level with lower levels of sleepiness in general ($r = -.27$, $p < .10$), lower levels of sleepiness both during safety errors and intersection negotiations (both r's $= -.30$, $p < .10$). Mixed models examined changes in the number of days of high or low-to-moderate sleep fragmented from pre to post-PAP periods for OSA and controls (Table 3). In the pre-PAP period, OSAs and controls had similar numbers of days classified as high versus low-to-moderate sleep fragmented, all fixed effects ns. OSAs experienced an increase in low-to-moderate sleep fragmentation nights ($p < .001$ for the interaction of group by period), and a slight decrease in high fragmentation nights

(p = .05) from pre to post-PAP, while controls did not show a significant change in that time period. OSAs were not using PAP for shorter hours on low-to-moderate than high sleep fragmentation nights (3.85 and 3.6 respectively, ns).

Table 3. Mean (SD) for number of days characterized as high versus low-to-moderate sleep fragmentation nights pre and post-PAP for OSAs and controls

	Pre-PAP		Post-PAP	
	OSA	Control	OSA	Control
High sleep fragmentation	6.1 (3.2)	5.7 (3.1)	5.3 (3.0)	6.2 (3.1)
Low-to-moderate sleep fragmentation	5.1 (3.3)	6.1 (3.4)	6.7 (3.4)	5.2 (3.4)

CONCLUSION

This study provided novel information on whether sleep fragmentation adversely influences driving safety the next day in drivers with OSA and matched controls prior to PAP and after PAP treatment. They also showed how PAP-dosage affected association of sleep fragmentation with driving safety.

Of note, OSA drivers appeared sleepier, made more safety errors while sleepy, and appeared sleepy during intersection negotiations on days following high levels of fragmented sleep prior to PAP treatment. In contrast, the matched control participants appeared less sleepy during intersection negotiations and less likely to be making safety errors while sleepy, possibly because they were driving more carefully by increasing following distance, stopping earlier at intersections, driving less rushed than OSAs following poor quality sleep nights. In contrast, the adverse sleep fragmentation effects were not observed for OSAs in the post-PAP period. In fact, controls were sleepier and made more safety errors while sleepy than OSAs post-PAP. The findings showed that the effects of sleep fragmentation as well as PAP were specific to drivers' sleepiness behind the wheel, and were not associated with other possible sources of driver safety errors such as distraction. Collectively, those findings indicate that PAP-therapy changed the adverse effects of sleep fragmentation prominent for OSAs in the pre-PAP period. However, the mechanisms of change remain unclear. For example, PAP-dose was associated with driver state and safety but only at the trend level. Pre- vs. post-PAP period was associated with fewer high fragmentation nights and greater low-to-moderate fragmentation nights for OSAs in the post-PAP period but they did not receive larger PAP-doses on low-to-moderate than high sleep fragmentation nights. It is important to note that the effects of sleep fragmentation on driving outcomes for OSAs versus controls remained in the opposite direction from pre-PAP to post-PAP period. For controls, greater sleep fragmentation was associated with greater safety suggesting the presence of self-regulatory influences. It is possible PAP-use increases drivers' alertness in ways which are only partially or poorly captured by sleepiness measures (Tippin et al., 2012). Future studies will need to rely on more refined data reduction schemes that include alertness among driver state measures to better understand how the effects of PAP and sleep fragmentation affect driver safety in OSA and controls.

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