Arch Bronconeumol. 2017;53(6):336–341

Sociedad Española de Neumología y Cirugía Torácica SEPAR

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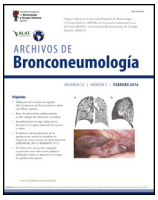

Special article

Sleep Apnea and Driving. Recommendations for Interpreting Spanish Regulations for Drivers☆

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ARTICLE INFO

Article history:
Received 9 September 2016
Accepted 16 November 2016
Available online 28 April 2017

Keywords:
Sleep apnea
Sleepiness
Driving
Accidents

ABSTRACT

Road traffic accidents are one of the main causes of death worldwide and are clearly associated with sleepiness. Individuals with undiagnosed sleep apnea–hypopnea syndrome (SAHS) are among the population with a high risk of experiencing sleepiness at the wheel and, consequently, road traffic accidents. Treatment with continuous positive airway pressure (CPAP) has been shown to reduce the risk of accidents among drivers with SAHS. For this reason, the European Union has included this disease in the psychological and physical criteria for obtaining or renewing a driving license. To comply with this European Directive, Spain has updated its driving laws accordingly. To facilitate the implementation of the new regulations, a group of experts from various medical societies and institutions has prepared these guidelines that include questionnaires to screen for SAHS, diagnostic and therapeutic criteria, and physician's report templates.

Apnea del sueño y conducción de vehículos. Recomendaciones para la interpretación del nuevo Reglamento General de Conductores en España

Palabras clave:
Apnea del sueño
Somnolencia
Conducción
Accidentes

RESUMEN

Los accidentes de tráfico son una de las principales causas de mortalidad en todo el mundo, y la somnolencia está claramente relacionada con ello. Entre la población con alto riesgo de padecer somnolencia al volante, y consecuentemente accidentes de tráfico, se encuentran las personas que tienen síndrome de apnea del sueño (SAHS) sin diagnosticar. El tratamiento con CPAP ha demostrado una disminución en el riesgo de accidentabilidad de conductores con SAHS. Es por ello que la Unión Europea ha incluido esta enfermedad entre los requisitos psicofísicos para obtener o mantener el permiso de conducción. Para cumplir con esta Directiva Europea, España ha actualizado el Reglamento de Conductores de manera acorde. Con el fin de facilitar la implementación de la nueva norma, un grupo de expertos de diferentes sociedades médicas e instituciones han elaborado la presente guía, que contiene cuestionarios de cribado de SAHS, criterios de diagnóstico y tratamiento y modelos estandarizados de informes a completar por los médicos.

☆ Please cite this article as: Terán-Santos J, Egea Santaolalla C, Montserrat JM, Masa Jiménez F, Librada Escribano MV, Mirabet E, et al. Apnea del sueño y conducción de vehículos. Recomendaciones para la interpretación del nuevo Reglamento General de Conductores en España. Arch Bronconeumol. 2017;53:336–341.

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1579-2129/

Sleep Apnea and Driving. Scientific Evidence

Traffic accidents are one of the major worldwide causes of death among individuals aged between 5 and 50 years. The death rate on the roads in the European Union (EU) is 52 deaths per million inhabitants, and in economic terms have been estimated to account for 1%–3% of the GDP of the respective countries, representing up to 500 billion dollars on a worldwide level.[1]

There is clear evidence that sleepiness, irrespective of its cause, is a significant risk factor for traffic accidents, although it is difficult to determine the exact figures. The National Highway Traffic Safety Administration calculates that 2.5% of fatal accidents and 2% of non-fatal accidents are related to sleepiness, although these numbers may be underestimated.[2]

Sagaspe et al.[3] conducted a telephone survey among 4774 drivers, and found that 5.8% of the respondents had had an accident, 3.2% of which were related to sleepiness.

In a Spanish study of 4002 vehicle drivers, 3.6% regularly experienced sleepiness when driving; of these, 81% had fallen asleep at the wheel at some time, and 25% regularly did so. One of the main causes of habitual sleepiness while driving was sleep apnea.[4]

Goncalves et al.[5] also provided interesting data associated with the prevalence of sleepiness and driving in Europe: in 12 434 questionnaires completed in 19 EU countries, the mean prevalence of "falling asleep at the wheel in the last 2 years" was 17%, and of these, the median accident rate was 7% (3.2% of which were fatal).

Sleepiness among professional drivers is a particularly sensitive issue, in view of the possible consequences.[6]

The population at high risk of experiencing sleepiness at the wheel includes not only professional drivers, due to their longer times of exposure, but also people who work very long shifts or who drive at night, individuals who drive in a state of sleep deprivation, especially young people, or who sleep less than 6 h, patients taking hypnotic drugs or other sleep-inducing medications, and finally, individuals with symptoms associated with undiagnosed sleep apnea.[7]

Various diseases, such as diabetes mellitus, cardiovascular diseases, psychiatric and neurological diseases, obesity or impaired vision, are associated with a higher incidence of traffic accidents,[8] but sleep apnea–hypopnea syndrome (SAHS) is the disorder that most frequently causes sleepiness and an increased risk of accidents. Poor sleep hygiene must be added to this group of diseases.

A systematic review and metaanalysis[9] of the risk of accidents among drivers of commercial vehicles published in 2009 showed that the mean risk was in the range of 1.21–4.89, and that the predictive factors for accidents among drivers with SAHS include body mass index (BMI), apnea–hypopnea index (AHI), oxygen saturation, and possibly daytime sleepiness. Young et al.[10] showed that individuals with an AHI>5 were significantly more likely to have at least 1 accident in a 5-year period, and that men and women with AHI>15 had significantly more multiple accidents in the same period (odds ratio: 7.3).

Although the published studies differ, most of the evidence suggests that the risk of traffic accidents and sleep apnea is related more closely with sleepiness than with disease severity measured by AHI. The significance of sleepiness as a primary factor contributing to traffic accidents was recently supported by Karimi et al.[11] who found that excessive daytime sleepiness (Epworth scale>15) is significantly associated with accident rates. Other studies, meanwhile, such as those of Terán-Santos et al.[12] and the *European Sleep Apnea Database* (ESADA), associate AHI with accident rates.[13]

Several studies have evaluated the effect of continuous positive airway pressure (CPAP) on reducing motor vehicle accident rates in patients with SAHS, and in most studies, effective treatment will result in a substantial reduction or even normalization of the accident rate.[14]

The fact that untreated SAHS patients have a higher risk of traffic accidents has prompted some countries in the EU, including Spain, to list this disease among those that must be controlled before a driving license can be obtained or renewed. More recently, the EU Commission Driving License Directive 2014/85,[15] modifying Directive 126/2006, has included SAHS among the criteria that appear in Annex III on the criteria for psychophysical aptitudes that must be evaluated in all Member States. This regulation was published in the EU in June 2014 and sets down the minimum criteria that must be applied in all countries.

Spain, which already included SAHS in the General Regulations for Drivers, specifically in Annex IV, specifying criteria for psychophysical fitness for obtaining or renewing a driver's license, has updated their criteria in accordance with the European Directive with Royal Decree (RD) 1055/2015, 20 November 2015, modifying the General Regulations for Drivers approved by Royal Decree 818/2009, 8 May 2009, that became effective in January 2016 (Table 1). The annex regarding obtaining or renewing a driving license now includes criteria for moderate (AHI 15–29) and severe (AHI>30) SAHS, both associated with excessive sleepiness, and establishes that individuals with SAHS (diagnosed in a Sleep Unit [SU]) with an AHI of 15 or more associated with sleepiness cannot obtain or renew their driving license, unless they submit a favorable report from the SU stating that they comply appropriately with treatment and that their disease is clinically controlled to a satisfactory degree, particularly with regard to sleepiness. The period of validity of these licenses is limited to 3 years for group 1, and up to 1 year for group 2.

Fitness to Drive in Patients With Sleep Apnea

Studies in SAHS and driving show that the risk of a traffic accident in subjects with a diagnosis of SAHS depends not only on the diagnosis of the disease, but also on the different parameters that are also associated with a greater driving risk, and which might affect an individual's fitness to drive.[13] This requires a personalized evaluation of the driver in Driving Examination Centers (DACs) and, consequently, the medical staff of these centers must be fully apprised of the impact of the disease on the subject before issuing the psychophysical fitness report.

Annex IV of the General Regulations for Drivers, RD 818/2009, modified by RD 1055/2015, states that to obtain or renew a driving license, drivers with a diagnosis of SAHS must provide the DAC with a report from an SU, which is taken into account in the definitive report on the individual's fitness to drive. The aim of the SU report is to inform the DAC physician of the diagnostic details, clinical manifestations of the disease (primarily sleepiness), and efficacy of treatment, so that the impact of the disease on driving can be evaluated and a report on the fitness of the subject to drive issued. Both the patient and doctors working in SUs must be aware of the need to present this report to the DAC at the time of either obtaining or renewing a driving license, since failure to present the report at the time of license renewal will lead to suspension of the process until such time as it is presented, with the consequent personal and professional inconveniences that such a situation may cause the driver.

Individuals who need to renew their driving license may face difficulties and variable access to SUs, depending on their healthcare areas, our group recommends that a standardized report template is issued for the purposes of obtaining and renewing a license, and that the patient is informed of the importance of such a report and their obligation to present it to the DAC. This report should be valid for a period of 6 months, unless the DAC detects any changes when administering their standard questionnaire.