Identification and treatment of professional drivers at risk of road accidents from excessive daytime sleepiness. A population-based survey on drivers transporting dangerous goods

S. Garbarino (1), D. Pizzorni (2), B. Mascialino (3), F. Ferrillo (1)
(1) Sleep Disorder Center, DISMR, University of Genoa, Italy (2) ENI Spa (3) Department of Medical Epidemiology and Biostatistics, Karolinska Institutet, Stockholm

Excessive daytime sleepiness (EDS) in drivers accounts for approximately 22% of road accidents. Such accidents result in higher mortality than from other causes: 11.4% vs. 5.6%.
Obstructive Sleep Apnea Syndrome (OSAS), a disease that most often involves EDS, has a significantly high prevalence (12%) among more than 40-year-old males. Moreover, it is a risk factor for cardio- and cerebro-vascular diseases. Recent data confirm that in professional drivers the occurrence of OSAS is significantly higher (17%) than in the general population. Adequate treatment of this disease can drastically reduce the risk of road accidents among the population affected.
The aim of the study was to obtain a diagnostic tool for OSAS screening, to be applied on a large scale for effective prevention in a typical homogenous population of dangerous goods drivers in North-western Italy.
The outcome of the survey was: A) high and unexpected prevalence of OSAS, ~ 30% with RDI>10 (number of apnea+hypopnea/hour) reveals some pathological features and, more importantly, 8.5% with RDI>30 shows values that can be associated to a severe condition. B) analysis of the results of the questionnaire, the clinical examinations and the polysomnography (PSG) and elaborate a simple and effective diagnostic tool in order to identify these disorders, applicable on a large scal,e for the prevention of the above mentioned risk factors among professional drivers.
Occupational physicians and or general practitioners might detect OSAS on the basis on the score obtained from the answers to a some items in the questionnaire and on easily measurable anthropomorphic parameters. Still keeping PSG as the "gold standard" examination for confirming the diagnosis of the cases previously identified.

Introduction

The public body U.S. National Transport Safety Board (NTSB) has stressed the importance of excessive daytime sleepiness (EDS) as a cause of road accidents (IS) of heavy vehicles [1]. In a survey it showed that 52% of road accidents in which only one heavy vehicle was involved, was linked to fatigue, in 17.6% of cases the driver admitted that he had fallen asleep. A previous survey [2] showed how the main EDS was the cause of 31% of fatal accidents with death of the driver. The EDS while driving is

reported by about a driver on 30 [3], and it increases by eight times the risk of serious IS [4].
Studies conducted over the past 20 years show a clear relationship between sleep disturbance and IS involving professional drivers [5-6]. Most IS involving professional drivers are tied OSAS, this high incidence may be due to several reasons: First, the high prevalence of this syndrome among the general population (2-4%) [7] that among the selected samples reaches extremely high percentages (26 - 50%) [8]. The studies investigating the effects of the OSAS therapy on the risk of IS, showed that in addition to a surgical approach [9] the application of a continuous positive pressure in airways (CPAP device) showed a marked improvement in driving performance and a significant reduction of IS in patients with sleep respiratory diseases involving EDS [10]. Few are the studies that have investigated the risk of IS and sleep non-breathing disturbances, Aldrich showed in a clinical tests that patients suffering from narcolepsy were involved in IS more frequently than the general population [11].
There are no studies on the risk of IS in patients with Nocturnal Myoclonus / Periodic Limb Movement Disorder (PLMD) or with Restless Legs Syndrome (RLS), although they both frequently involve EDS [12].
The link between insomnia and risk of IS has never been well documented. An American survey showed that 5% of people who complained insomnia had been involved in IS caused by EDS, while the percentage of those who had not suffered was 2% [13].

Objectives of the study

These premises have given birth to this study, which is meant to:
A. Assess the exact incidence of sleep disorders involving EDS.
B. Elaborate a simple and effective diagnostic tool in order to identify these disorders, applicable on a large scale, both by the Doctors of Medicine and the General Labour MD's for the prevention of the above mentioned risk factors among professional drivers transporting dangerous goods for G & A Spa Company Operating in Northern Italy, particularly in regions Valle d'Aosta, Piemonte, Liguria, Lombardia, Emilia Romagna. In the general and working population (periodic health surveillance former Leg. 626/94 as amended).
In this context preliminary results regarding the OSAS will be presented, being OSAS recognized as a disease involving EDS greater prevalence in the general population and particularly in the population of drivers of dangerous goods we taken into consideration.

Materials and Methods

The project is divided into 4 phases:
1. Clinical examination and administration of the questionnaire to all professional drivers of dangerous goods identified as components of a "universe" homogenous and representative of an extended Italian area, in order to identify individuals carrying diseases involving sleep EDS.

2. Confirmation through diagnostic scans (home-based multiple graphical sleep recording) of clinical suspicion in positive subjects.

3. Preparation of therapeutic measures necessary to eliminate or reduce the number of apnoeic events and thus EDS (without interruption of the work).

4. Prevention through training and informing the population about the risks associated with these disorders

The first phase is preceded by:

- Establishment of a specialized technical team pertaining to the Sleep Disorder Center, University of Genoa.

- Preventive public awareness on the workplaces, given to the groups of drivers and their leaders.

PHASE I at clinical cabinets located in a working environment or on adequately equipped mobile medical units, the study managed to:

- Give the professional drivers a questionnaire validated and assisted, in order to highlight data:
  I. Age-administrative;
  II. Hystorical physiological and pathological;
  III. Sleep habits;
  IV. Sleep disturbance involving EDS
  V. Road accidents and / or injuries at work associated with EDS

- Validated scale that explored the EDS track (Epworth Sleepiness Scale - ESS) [14].

- To clinically examinate drivers in order to identify possible carriers of these diseases (screening):
  I. Hystorical data through structured interview;
  II. Meaningful anthropometric parameters:
  A. Body mass index (BMI> 29).
  B. Neck circumference (♂> 43 cm.).
  C. Neck-chin angle measurement.
  III. Presence of craniofacial dysmorphism
  IV. Presence of clogging hypertrofies at the inspection of the nasal cavity and throat.
  V. Mallampati classification.

PHASE II has consisted of: home polysomnography (PSG) registration of subjects with clinical suspicion of sleep disorder, previously notified by a doctor.

PHASE III implies for individuals with certain diagnosis, the access to Sleep Disorder Center for further investigation and treatment of the case:

- clinical or instrumental tests, possibly in mode of day-hospital/night-hospital (Multiple Sleep Latency Test - MSLT, multiple graphical sleep recording during the whole night - PSG, respiratory device titration, Continuous Positive Air pressure - CPAP etc.).
- Validate with objective scans (multiple graphical sleep recording etc..) any clinical suspicion.
- Arrange the necessary treatment to heal the EDS.

The population had 283 male subjects. An amount of 254 drivers have taken part in the survey (ca. 90%); the 10% has not, because unable for health reasons (approx. 4%) or unwilling to give their consent (approx. 6%).
From a statistical point of view, the sub-group recordered (R) by PSG was compared with that of subjects not to record (NR) by the test Kologorov-Smirnov. For categorical variables, the test of square-chi has been used.
Multiple regression analysis has been used to assess the relation between the value measured objectively by RDI, PSG and predictor variables extracted from personal data (age), data obtained by the medical checkups (Mallampati Scale, neck-chin corner, neck circumference) and answers to the questionnaire (ESS, indicators of OSAS, insomnia, hypersomnia and myoclonus).
In all cases the level of significance has been fixed at 0.05.

Results

The sample had 283 male subjects of the average age of 43.3 ± 8.3 years, with a working seniority of 17.9 ± 10.7 years.

Comparison Recordered *vs* Non-recordered

According to the clinical criteria adherent to international guidelines [*Sleep. 1999 Aug 1; 22 (5) :667-89*], 142 on 283 subjects, equal to 50.2% of the population taken into consideration, were identified as requiring an in-depth complete diagnostic examination, with clinical suspicion of sleep disorder.
Table 1 summarizes the descriptive statistics for the two groups. The two groups (P & NR) were compared using test Kolmogorov-Smirnov, the results are summoned up in Table 2.
A statistically significant difference ($p < 0.05$) has been detected between the two groups for demographic variables (age, length of working time), physical parameters (BMI, neck circumference, neck-angle) and answers to the questionnaire (indicators insomnia , OSAS, myoclonus and global sleep disorder).

VARIABLE	**R**	**NR**
Eta' +	(43.7 ± 8.5) years	(41.0 ± 8.0) years
Working seniority +	(18.8 ± 11.3) years	(17.0 ± 10.0) years
BMI *	(29.4 ± 4.8) kg/m^2	(26.1 ± 2.7) kg/m^2
Circumference neck *	(42.3 ± 3.3) cm	(40.5 ± 2.5) cm
Neck-chin angle *	(113.6° ± 10.5°)	(106.3° ± 10.0°)
ESS +	(7.0 ± 3.5)	(6.1 ± 3.6)
Insomnia indicator+	(8.3 ± 3.7)	(6.9 ± 3.0)
OSAS indicator +	(10.0 ± 5.0)	(6.2 ± 3.2)
Hypersomnia indicator +	(3.4 ± 3.4)	(2.4 ± 2.4)
Myoclonus indicator +	(1.8 ± 2.2)	(0.9 ± 1.5)
Questionnaire score +	(23.5 ± 10.2)	(16.4 ± 7.0)

Table 1. Descriptive statistics for the two groups P (N = 142 subjects) and NR (N = 141 subjects). The variables marked with a * were collected during the medical examination, the variables marked with + derived from the questionnaire administered.

Analysis Group A: PSG

Twenty-three subjects (16.2%) refused the multiple sleep graphic examination at home); 110 to 119 records were used for statistical analysis. From the hystorical-clinical examination and from the questionnaire, there emerged the diagnostic suspicion of:
Obstructive Sleep Apnea Syndrome (OSAS) (76%), Restless Legs Syndrome (RLS) with Periodic Limb Movement Disorder PLMS) (7%), Overlap of the two diseases (RLS; PLMS) (16%), Narcolepsy (1%).
The OSAS has confirmed to be the most common disorder among sleep-related breathing problems (76%), both in our case and in the general population.

VARIABLE	**D (p-value)**	**Results**
Age +	0.22 (0.001)	Significant highly
Working seniority +	0.18 (0.02)	Significant highly
BMI *	0.33 (10^{-7})	Difference highly significant
Circumference neck *	0.30 (10^{-6})	Difference highly significant
Neck-chin angle *	0.36 (10^{-8})	Difference highly significant
ESS +	0.13 (0.21)	No significant difference
Insomnia indicator+	0.20 (0.008)	Difference highly significant
OSAS indicator +	0.40 (10^{-10})	Difference highly significant
Hypersomnia indicator +	0.16 (0.05)	No significant difference
Myoclonus indicator +	0.20 (0.005)	Significant Difference
Questionnaire score +	0.39 (10^{-10})	Difference highly significant

Table 2. Results of tests Komogorov-Smirnov between the two groups R and NR. D The second column shows the numerical value of statistical tests and p-value, the third column outcome of the test. The variables marked with a * were collected during the medical examination, the variables marked with + derived from the questionnaire administered.

The PSG performed on subjects with OSAS, even with possible overlaps, confirmed the presence of pathological indices (respiratory events per hour of sleep - RDI) exceeding 5 in 87.6% of subjects.
A RDI exceeding 30, indicates that a severe disease was present in 22% of observed subjects equal to 8.5% of the studied universe [Figure 1].

THE PREVALENCE AND GRADE OF OSAS

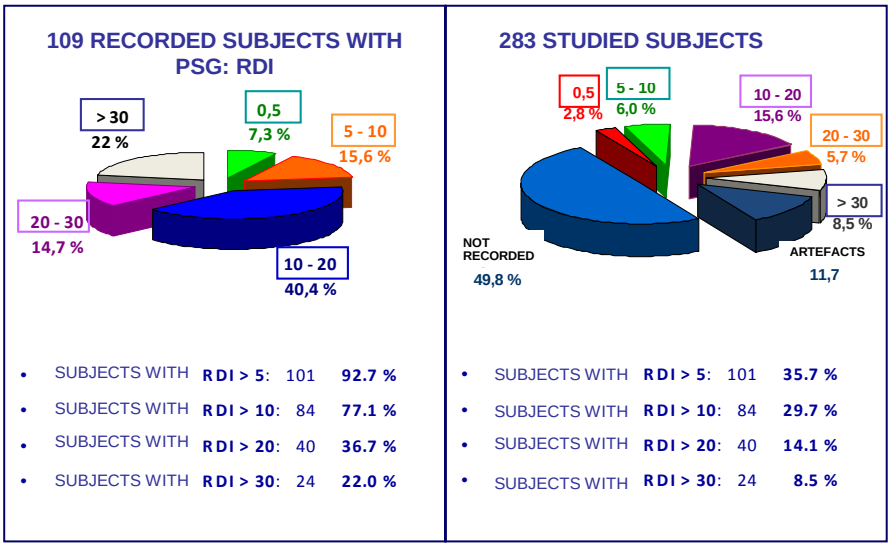

Figure 1: The left pane shows the group of recordered subjects. In the right pane, the entire population studied. In particular, a greater than 30 RDI, indicator (defined as severe disease) was present in 22% of registrants equal to 8.5% of the population initially studied.

The regression analysis with RDI has considered as dependent variables:

- Personal information (working age and seniority)
- Data derived from the medical checkup(body mass index, neck angle-chin, neck circumference and Mallampati)
- Data derived from the questionnaire (ESS indicators insomnia, myoclonus, and hypersomnia OSAS)

An initial analysis showed that the RDI depends significantly from the Body Mass Index. Consequently a study of collinearity was executed, to see if some of the independent variables could be significantly correlated with each other. The variables "body mass index" and "working seniority" were not entirely independent from the others (related particularly to size of the neck angle + neck-and age).
The multiple regression analysis was then repeated after eliminating the variables "body mass index" and "working seniority. The bio-mathematic model resulted highly significant from a statistical point ($p < 0.0001$), with a R^2 equal to 0.26.
In particular, the RDI depends significantly from:

-- OSAS Indicator ($p < 0.0001$),

-- Neck-chin angle ($p = 0{,}014$),

-- Size of the neck ($p = 0{,}003$).

The scale of Mallampati is found at the very limit of statistical significance (p = 0,067).
The model is reliable as highly significant (p <0.0001).
The detection of these parameters becomes therefore the tool that enables diagnostics to identify subjects with OSAS (pathology far more frequent and dangerous among the disorders involving EDS) and define with good approximation the severity of the pathology itself.

Discussion

The preliminary results of this study confirm a higher prevalence of OSAS in professional drivers (35.7%) than in general population (2-4%) [7] probably due to an underestimate of the OSAS in the general population, which is not unexpected, being generated by the extreme lack of methodology in these studies, often affected by numerous and apparent bias [8].
These data are consistent with the percentage reported in literature (26% - 50%) when compared with similar studies carried out on selected samples of professional drivers [10-15]. Remarkable is the high incidence of OSAS that can be defined severe (RDI exceeding 30) in 22% of registrants equal to 8.5% of the studied universe. The awareness of the presence of excessive sleepiness while driving is not significant because the disease starts subtly and gradually over the years. In this study the common morphological configuration adherent to the stereotype of 'driver (obese, overweight etc… of Pickwickian memory) seems to be partially confirmed. There remains to be proven today if such physical habitus is already present in the initial phase of working as drivers or it is primarily due to the interaction between predisposing factors and lifestyle as a circumstance capable in time to increase the physical characteristics of the stereotype of the "truck driver". In our population subjects suffering from OSAS showed a statistically significant neck circumference> 43 cm. , High BMI. The inspection of the first airway, assessed by Mallampati scale, showed pathological scores(> 2) at the edge of statistical significance (p = 0,067). For the presence of craniofacial dysmorphisms and / or diseases obstructing the first airways.
From our study, becomes known the possibility to produce a predictive model to identify potentially apnoeic subjects through the use off tools available in the Phase I of the project (clinical checkup and questionnaire). Statistical analysis were carried out along with the application of mathematical models in order to predict the possible presence and the degree of severity of the syndrome using RDI as a measuring parameter. In this study the bio-mathematical model thus developed has proved to be highly significant from a statistical point (p <0.0001), with a R^2 equal to 0.26.
In particular, the RDI depends significantly, as well as from the body mass index, by:

- OSAS indicator(few items derived from the questionnaire) (p <0.0001)
- Neck-chin angle measuring (p = 0,014),
- Size of the neck (p = 0,003).

This mathematical model may then be developed as a diagnostic tool to help suspecting swiftly OSAS (pathology far more frequent and dangerous among the disorders involving EDS) and foreseeing with good approximation the level of importance.
The power of "tool" and its usefulness in terms of human and economic investment introduce a new approach in prevention strategies and screening of OSAS on a large scale, an important and misunderstood risk factor of IS and cardiovascular diseases

cerebrovascular (acute myocardial infarction, ischemic heart disease, stroke etc..). One diagnostic tool simple and effective, that can be performed in an ambulatory as it is based on easily measurable anthropomorphic parameters and responses to items relating to the OSAS in the questionnaire. This still requires preliminary validation records with PSG on a sample of the control group of healthy subjects still underway. The results over the indisputable interests directly related to the Occupational Medicine (training activities, information given to professional drivers about the risks associated with these diseases; Health Surveillance former DLs 626/94 as amended) acquire, in our opinion, a much broader interest and importance in the prevention of cardio-cerebrovascular diseases in the general population.

Considering that today the only possible diagnostic approach to this disease is the polygraphic recording of all subjects with this disorder; without any "sustainable" proposal for screening (because of the high social and health costs), we believe that the results of this study have gone far beyond the initial expectations, namely to protect psycho-physical health of the professional drivers and more specifically the reduction in the risk of traffic accidents related to sleepiness.

A recent survey conducted by the (SIS- Ministry of Health Italy) on the social impact of OSAS (*Source CREMS; SIS*) has estimated its total cost to a figure between 3.5 and 5 billion euro, and a population potentially affected by the pathology of 1,600,000 (a sort of silent epidemic comparable to diabetes mellitus) corresponding for the years 2002 to a rate between 0.29 and 0.4 of GDP (*Source: ISTAT years 2002 GDP = 1,295,225 billion euro*) [16]. Even from the perspective of those figures of the Superior Institute of Health, the results of our study have a significant and essential value in helping create a network of mass screening and primary diagnosis, able to treat clinically and adequately these patients for the good of the national and international community.

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