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Impact of rail medical standard on obstructive sleep apnoea prevalence

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Background	The 2004 edition of the National Standard for Health Assessment of Rail Safety Workers (the standard) used the Epworth Sleepiness Scale (ESS) to screen for excessive daytime sleepiness related to obstructive sleep apnoea (OSA). The 2012 edition of the standard expanded the OSA screening matrix to include body mass index, comorbid hypertension and type 2 diabetes as triggers requiring a sleep study to be undertaken irrespective of the ESS.
Aims	To assess the impact of the new standard on the estimated prevalence of OSA in railway workers.
Methods	An analysis of data on safety critical employees referred for rail safety health assessment during the 2013 calendar year and meeting the criteria for sleep study referral. Sleep study outcomes were used to assess the predictive value of screening under the new standard.
Results	A total of 200/4311 workers were investigated with a sleep study. One hundred and ninety-three met the new risk factor criteria and 182 (91%) were newly diagnosed with OSA. The prevalence of OSA in the study population was 7%, compared with 2% in 2009. No worker reported an elevated ESS. The false positive to true positive ratio was 0.1 (95% CI 0.06–0.16).
Conclusions	The new medical standard has resulted in an increased estimate of the prevalence of OSA in rail workers. This study supports the use of objective clinical risk factors to select workers for further investigation, aiming to minimize the risk of accidents associated with excessive daytime sleepiness and other comorbid conditions of OSA.
Key words	Medical standards; obstructive sleep apnoea; rail; safety critical work; screening.

Introduction

Obstructive sleep apnoea (OSA) is a disorder characterized by repeated episodes of apnoea and hypopnoea during sleep, related to upper airway obstruction. OSA is a potentially incapacitating medical condition associated with excessive daytime sleepiness, inattention and fatigue. It can lead to, or exacerbate, cognitive deficits and increases the likelihood of errors and accidents [1]. The presence of OSA in safety critical workers presents a risk to the safety of the general public and to the health and safety of individual workers.

The 2004 edition of the *Australian National Standard for Health Assessment of Rail Safety Workers* [2] ('the standard') introduced screening for OSA in safety critical rail workers by use of the Epworth Sleepiness Scale (ESS). The ESS is a self-administered questionnaire developed in the early 1990s to assess daytime sleepiness with a view to investigation of sleep disorders, particularly OSA. It has remained a popular screening tool as it is simple, cheap and can be rapidly administered. However, the ESS is subjective in nature, leading to reports that it may be influenced by employment and other factors. As such, there is some debate regarding its use as a screening tool [3–7]. Previous studies of Australian train drivers [8,9], conducted after the introduction of the 2004 edition of the standard, found the prevalence of OSA to be 2%, as opposed to 4% in the general male population, suggesting under-diagnosis of OSA despite the screening programme and despite the workforce having a higher prevalence of obesity.

The estimated prevalence of OSA associated with daytime sleepiness is 3–7% in adult men and 2–5% in women [10] but the prevalence is higher if the diagnosis is based solely on the Apnoea Hypopnoea Index (AHI). In a sample of 30–60 year olds, 9% of women and 24% of men had

OSA when defined as an AHI ≥5 per hour [11]. Another study in the USA found a higher prevalence of OSA in commercial vehicle drivers (28%) than in the general population [12]. There is a strong relationship between OSA, obesity, hypertension and the metabolic syndrome [13].

The Australian standard was updated in October 2012 [14] to include objective clinical risk factors that would trigger further investigation for underlying OSA. These include high body mass index (BMI), type 2 diabetes, hypertension requiring two or more medications to control it and a history of habitual loud snoring during sleep or of witnessed apnoeic events (Table 1).

This study aimed to assess the potential change in the prevalence of OSA as a consequence of this recent introduction of clinical risk factors into the assessment of rail safety critical workers.

Methods

Rail workers are required to undergo either periodic (age-dependent) or triggered (comorbidity-dependent) assessments at intervals of 1–5 years. A retrospective cross-sectional study was carried out on safety critical employees referred for their rail safety health assessment during the 2013 calendar year who met the study inclusion criteria outlined in Table 1. During review of these cases, a predefined data collection sheet was populated with de-identified data (specified in Table 2) for both the current assessment and the previous assessment, where available, in order to ensure that all aspects of the medical history were considered.

Sleep studies were conducted to evaluate the presence of OSA in workers who met the clinical risk factor criteria outlined in Table 1. A type 1 sleep study is an overnight technician attended study conducted in a sleep laboratory. A type 2 study measures the same variables as a type 1 study but is not performed in a sleep laboratory. The type 2 device used in this study records an electrocardiogram, electroencephalogram, electromyogram and electro-oculogram and measures respiratory effort, sleep position, oxygen saturation and nasal flow.

The choice of type 1 versus type 2 study was mainly dependent on the location of the workers' residence, availability of sleep laboratories, availability of appointment times and other logistical factors. Type 3 devices, whilst still meeting the minimum requirements outlined in the standard, were not used as they were not able to measure sleep time and were hence unable to calculate an apnoea hypopnea index (AHI).

The results of the type 1 and type 2 studies were reviewed by a sleep physician to ascertain whether or not OSA was present, calculate the AHI and classify severity. AHI was defined as the total number of apnoeic and hypopnoeic events that occurred divided by the number of hours slept. For the purpose of this study, AHI was grouped using the criteria developed by the American Association of Sleep Medicine: 0–4 (no OSA), 5–15 (mild), 16–30 (moderate) and >30 (severe OSA) [15]. In cases where OSA was confirmed, further review and treatment recommendation by a sleep physician was requested.

Data analyses were performed using Microsoft Excel for Mac 2008. The relative accuracy analysis was performed

Table 1. Study inclusion criteria

Workers who are at risk of OSA due to clinical risk factors	Workers with reported or suspected sleepiness
• BMI ≥ 40 • BMI ≥ 35 and either: - Type 2 diabetes; or - High blood pressure requiring two or more medications for control; or - History of loud snoring or witnessed apnoea events	• Self-reported moderate to severe excessive daytime sleepiness (ESS score of 16–24) • A history of self-reported sleepiness whilst driving or working • Work performance reports indicating excessive sleepiness • Incident reports plausibly explained by inattention or sleepiness

Table 2. Data collection variables

- Date of assessment
- Age
- Gender
- Rail safety work classification (category 1 or 2)
- Height
- Weight
- BMI
- Declared diagnosis of type 2 diabetes and type of treatment
- Declared diagnosis of hypertension and number of medications prescribed
- Epworth sleepiness score on day of assessment
- Declaration of known history of sleep disordered breathing or witnessed apnoeic episodes
- Type of sleep study referred for:
  – Type 1 polysomnography versus type 2 home study
- AHI
- Classification of severity of OSA by the sleep physician

in SAS using methods described by Chock *et al.* [16] for estimating relative accuracy of screening tests.

The research protocol was reviewed and approved externally by the University of New South Wales Human Research Ethics Committee as well as by an internal clinical governance committee.

Results

During the study period, 4311 safety critical health assessments were completed. A total of 416 workers were identified as having one or more clinical risk factors listed in Table 1. Of these 416, 126 were workers with pre-existing OSA and three were applicants undertaking a pre-employment health assessment who subsequently withdrew from the process. The remaining 287 individuals were referred for a sleep study. Data were incomplete for 87 subjects: three had inconclusive or incomplete sleep studies; 81 cases (28%) were still awaiting sleep studies at the time of data collection and three did not have the sleep study performed, as the reviewing sleep specialist felt the pre-test probability was too low to warrant it. Data on clinical risk factors, ESS and sleep study results were thus available for 200 individuals and were included in the study. A summary of the demographics and anthropometrics of this cohort are presented in Table 3.

Of the 200 cases included, 193 workers strictly met the clinical risk factors outlined in the standard and in the first column of Table 1. Of the remaining seven, six workers with BMI <35 were sent for sleep studies as they had disclosed either a history of witnessed apnoeic episodes (n = 4) or work-related accidents potentially related to fatigue (n = 2). Five of these six were subsequently diagnosed with OSA. One worker with a BMI ≥35 who was only treated with a single antihypertensive medicine was also sent for a sleep study and was subsequently found to have severe OSA (AHI = 91). No worker reported an ESS of 16 or more.

Of the 200 workers referred for a sleep study, 182 (91%) were subsequently diagnosed with OSA when defined as an AHI ≥5 (Figure 1). The treatment recommended by the reviewing sleep specialist is shown in Figure 2. Conservative treatment was defined as weight loss, improved sleep hygiene and control of other risk factors. One worker was advised to consider surgical intervention for snoring after a normal sleep study. Four individuals in the moderate and severe OSA groups underwent maintenance of wakefulness testing (MWT) to ascertain if there was any objective evidence of sleepiness. On review, referral for MWT occurred if the worker was reluctant to commence continuous positive airways pressure (CPAP) treatment. All four of these workers returned a MWT within the normal range and conservative management and a repeat sleep study in 12 months were recommended. Sleep specialist opinion varied with respect to treatment strategy, particularly in the moderate

Table 3. Demographics and anthropometrics of the study sample

Sex	Male (n = 177)	Female (n = 23)
Age (years): mean (SD)	47 (11); range 20–69	41 (10); range 28–61
Height (m): mean (SD)	1.76 (0.07)	1.66 (0.07)
Weight (kg): mean (SD)	129.9 (21.6)	120.2 (18.1)
BMI (kg/m^2): mean (SD)	41.5 (5.8)	43.3 (5.2)
BMI <35: N (%)	6 (4)	0
BMI ≥35 to <40: N (%)	61 (34)	2 (9)
BMI ≥40: N (%)	110 (62)	21 (91)
ESS: mean (SD)	1.9 (2.1); max 9	2.2 (2.5); max 9
AHI: mean (SD)	32.9 (25.9)	16.5 (16.3)
Type of study	77 type 1 and 100 type 2	9 type 1 and 14 type 2

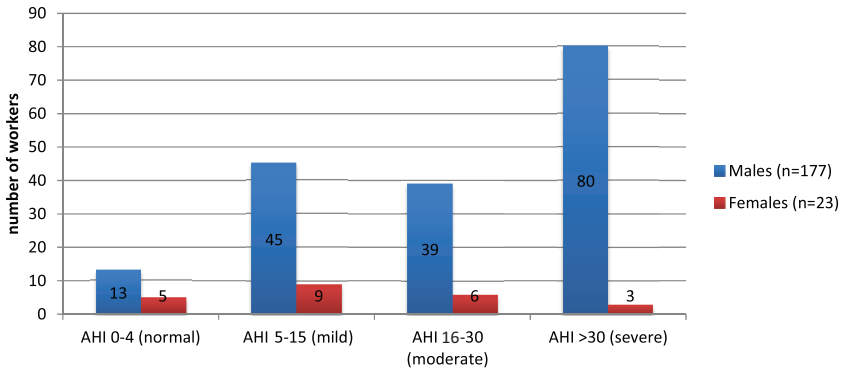

Figure 1. Outcomes of sleep studies.

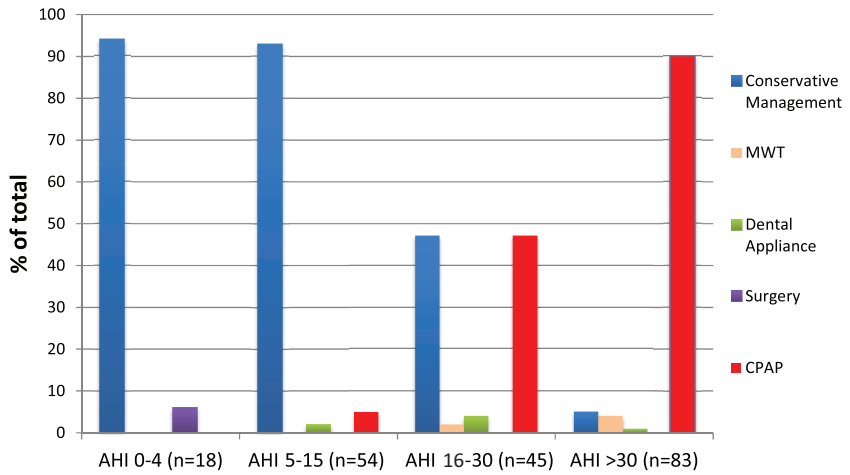

Figure 2. Recommended treatment.

OSA group. CPAP was recommended more frequently as the severity of OSA increased and, in total, 54% of those diagnosed with OSA were commenced on CPAP.

Of the 62 cases with BMI ≥35, 19 had hypertension, 20 had type 2 diabetes and 23 had both hypertension and diabetes (Figure 3). Of the 131 cases with a BMI ≥40, 83 had an elevated BMI as the sole clinical risk factor, 19 had hypertension, 17 had type 2 diabetes and 12 had both hypertension and diabetes. Eighty-nine per cent of those with a BMI ≥40 and 93% of those with BMI ≥35 were subsequently diagnosed with OSA.

As indicated above, from the study population of 4311 employees, 126 had pre-existing OSA and a further 182 were diagnosed with OSA, leading to a prevalence in this population of 7%. Of the 182 individuals diagnosed with OSA, 176 had clinical risk factors noted on screening. Of the remaining 18 individuals who had an AHI <5, 17 had clinical risk factors noted on screening. The false positive:true positive ratio is therefore 17:176, or 0.10 (95% CI 0.06–0.16) [16]. This means that for every 100 cases of OSA correctly identified by screening with clinical risk factors, a further 10 individuals without OSA underwent a sleep study.

Discussion

This study found that 91% of workers referred for a sleep study on the basis of clinical risk factors were diagnosed with OSA, as defined by an AHI ≥5, and the prevalence of OSA increased from 2% to 7% following the introduction of the new standard. No worker reported an ESS score >9 during the study period. Of those diagnosed with OSA, 54% were commenced on CPAP.

The strength of this study lies in the mandatory screening and investigation for sleep apnoea under the standard and the Rail Safety National Law 2012, thus overcoming the limitation of relying on self-reported symptoms as the main trigger for referral and enabling the prevalence of OSA in the study population to be calculated as completely as possible.

Corollary limitations of this study are the possibility of false negatives in workers not meeting the clinical risk factor criteria in Table 1. Additionally, 87 of 287 cases were incomplete at the time of data collection, which may potentially affect the estimated prevalence. However, objective measures for referral for sleep studies in the incomplete cases were similar to those who had completed sleep studies, which suggests the incomplete cases are not biasing the results presented here. Hypopnoea episodes may be scored differently across different centres, relating to the length and amount of reduction in airflow and oxygen saturation. These differences were not controlled in this study and, as such, variations in AHI reporting could have altered the overall grading of some cases. Furthermore, there were variations in how sleep physicians reported the severity of OSA, relating to rapid eye movement (REM) versus non-REM AHI and other comorbidities. This was controlled by classifying OSA severity by total AHI for the purposes of this study.

Type 2 sleep studies are, by definition, unsupervised and thus the identity of the person undertaking the study cannot be confirmed. The theoretical risk of person substitution for type 2 sleep studies seems low considering that 91% of workers were diagnosed with OSA.

The ESS is a screening tool developed to measure excessive daytime somnolence. It has been used over the years as a screening tool for OSA in the road transport, rail and aviation industries. However, the ESS relies on self-report and this can be unreliable for symptoms with an insidious onset and where financial and employment factors are at play. The average ESS was 1.89 in the male study participants and 2.2 in females. This is very low for a population undertaking rotating shift work and with a high prevalence of clinical risk factors.

A number of studies have not confirmed an association between the severity of OSA and the ESS [5,17–19]. The ESS has been found to have large discrepancies

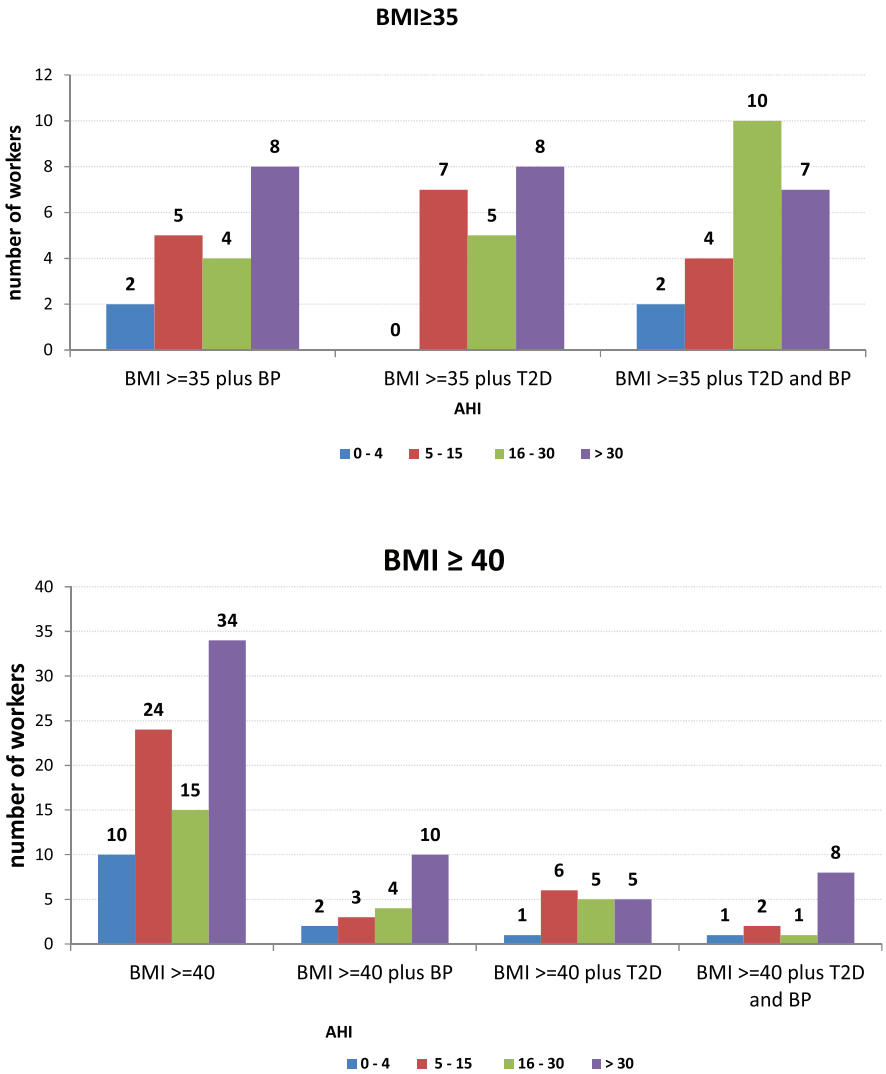

Figure 3. Clinical risk factors versus AHI. BP, hypertension requiring treatment with two or more medications; T2D, type 2 diabetes mellitus.

when used in the clinical setting, suggesting that it should not be used as the sole tool for screening patients for possible OSA [4]. Subjective sleepiness may not actually be present in many individuals with significant sleep disordered breathing [3] and this is supported by the results of this study, with no individuals reporting an elevated ESS. Other screening tools, such as STOP-Bang and the Berlin questionnaire, have been used in industry and health care settings with inconsistent results [20]. These questionnaires are also based on self-reported symptoms.

There is a strong association between OSA and other clinical risk factors such as age, male gender, increased neck circumference (>43 cm in males and >40 cm in females) and waist-to-hip ratio (>1 in males and >0.85 in females). Obesity is also a well-documented risk factor for OSA in both males and females [21–23]. OSA is associated with diabetes and hypertension, which may be due to risk factors that are common to all three conditions, as well as reflecting a role of OSA in the aetiology of these diseases [21,24]. In this study population, 89% of those with a BMI ≥40 and 93% of those with BMI ≥35 who met the inclusion criteria were subsequently diagnosed with OSA.

The current standard requires individuals with a BMI of ≥40 or of ≥35 with comorbid type 2 diabetes or hypertension requiring two or more medications, to undertake a sleep study. Our results demonstrate the high predictive value of these screening measures. Due to the strong association between OSA and obesity and the higher prevalence of OSA reported in other studies [11,12], further consideration could be given to extending the clinical risk factor criteria to include a BMI ≥30, which defines obesity. A study conducted on train drivers found that 47% of those employed had a BMI ≥30, yet the corresponding prevalence of OSA was only 2% [8]. That study suggested that under-reporting on the ESS or failure to declare a history of OSA may have been occurring and proposed more active screening for OSA in asymptomatic individuals with risk

factors. The possibility of inter-observer variability in measuring neck circumference and waist-to-hip ratio is a potential barrier to the use of these measures in the national standard and, given the high positive predictive value of the clinical risk factors currently included, may not add significant additional information.

With respect to sleep disorders, the aim of the rail safety health assessment is to minimize the risk of accidents or near misses from inattention due to excessive sleepiness. This study has been able to show that the use of objective clinical risk factors to identify rail safety workers with potential OSA is more effective than using the ESS alone.

The use of clinical risk factors in this fashion will inevitably identify individuals who deny symptoms and are reluctant to commence treatment but have severe sleep apnoea on a sleep study. In this study, four individuals were reluctant to commence CPAP, were referred for a MWT, returned results in the normal range and were permitted to work subject to review in 12 months. We propose a role for MWT in the routine management of such cases. Additionally further investigation is required to assess whether identifying OSA in this population leads to a demonstrable reduction in rail accidents and near misses.

In summary, this study has found a high predictive value of objective clinical risk factor measures for OSA confirmed by sleep study. The introduction of objective clinical risk factor measures in the 2012 edition of the standard has resulted in the identification of rail safety workers with OSA who previously would not have been required to undergo further investigation based on their ESS scores. This study supports the ongoing use of objective clinical risk factors to identify workers with OSA and minimize the risk of accidents associated with potential excessive daytime sleepiness and other comorbid conditions associated with OSA.

Key points

- Ninety-one per cent of workers referred for a sleep study on the basis of their clinical risk factors were diagnosed with obstructive sleep apnoea.
- The prevalence of obstructive sleep apnoea in the workforce increased from 2% in 2009 to 7% following the introduction of new medical standards.
- No worker in the study population reported an elevated Epworth Sleepiness Scale.

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Conflicts of interest

None declared.

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