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Original Article

Positional therapy in ischemic stroke patients with obstructive sleep apnea

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ABSTRACT

Background: Obstructive sleep apnea (OSA) is common in stroke patients and is associated with poor functional outcome. The effects of positional therapy in ischemic stroke patients with OSA have not been investigated. We tested the hypothesis that ischemic stroke patients have less severe OSA during positional therapy that promotes nonsupine positioning.

Methods: We conducted a randomized, controlled, cross-over study. Sleep apnea screening studies were performed on two consecutive nights, using a portable respiratory monitoring system, on 18 subjects within the first 14 days of ischemic stroke. An apnea–hypopnea index (AHI) $\geqslant 5$ established the diagnosis of OSA. Subjects were randomized to positional therapy that included the use of a therapeutic pillow on either the first or second night. On the control night, subjects used the hospital pillow and were positioned *ad lib*. Treatment effect on AHI was estimated using a repeated measures model.

Results: All ischemic stroke subjects studied had OSA. The predominantly male group had a median age of 58 years, BMI of 29 kg/m^2, NIH Stroke Scale score of 3, and a median AHI on the nontherapeutic night of 39 (interquartile range: 21–54). Positional therapy reduced the amount of supine positioning by 36% (95% CI: 18–55% ($P < 0.001$)). The AHI was reduced by 19.5% (95% CI: 4.9–31.9% ($P = 0.011$)), when using positional therapy compared to sleeping *ad lib*.

Conclusions: Positional therapy to avoid supine positioning modestly reduces sleep apnea severity after ischemic stroke, and may therefore improve outcomes.

1. Introduction

Obstructive sleep apnea (OSA), a very common condition in stroke patients [1], has recently been recognized as an important independent risk factor for stroke [2–4]. Furthermore, a large body of evidence suggests that OSA has a negative impact on the immediate and long-term functional outcome after stroke [5,6]. Greater severity of sleep apnea is associated with more severe functional impairment, greater prolongation of hospitalization, longer rehabilitation, and higher mortality [6–8]. The apnea–hypopnea index (AHI), a common measure of sleep apnea severity, is an independent predictor of mortality in stroke patients [9,10]. These important associations between OSA and stroke, and stroke outcomes underscore the need to understand the role that OSA treatment may play in stroke.

Continuous positive airway pressure (CPAP) therapy is the most effective treatment for OSA. Despite its beneficial effects on sleep, adherence is poor, particularly in stroke patients [11]. Palombini and Guilleminault reported that only 22% of stroke patients were compliant with CPAP treatment 8 weeks after initiation [12]. Despite the imperative to assess the benefits of CPAP for stroke, some researchers have challenged the feasibility of randomized trials of CPAP after stroke [13]. Thus alternative therapies for sleep apnea in stroke patients should be assessed.

Body position during sleep influences the severity of sleep apnea in more than half of OSA patients [14,15]. Supine positioning is associated with an increase in upper airway collapsibility [16] and thus an increase in apnea frequency and duration [17]. Positional therapy, designed to minimize supine sleep, has a beneficial effect in the general sleep apnea population [18–20], although not as great as CPAP [21]. As supine sleep is very common in acute stroke patients [22,23], positional therapy that reduces supine sleep may have particular relevance to the stroke population. Although positional therapy seems to target obstructive apneas, the predominant type of apnea in stroke patients, non-supine positioning may also improve central apneas [24]. Given differences between stroke patients with sleep apnea and the general sleep apnea patient, such as body mass index and daytime sleepiness [25], positional therapy

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results in the general population may not be applicable to the stroke patient.

The effects of positional therapy in ischemic stroke patients with OSA have not been investigated. We therefore performed a pilot randomized, controlled, cross-over study to test the following hypotheses: (1) positional therapy reduces the amount of nocturnal supine positioning after ischemic stroke, and (2) ischemic stroke patients have less severe sleep apnea, as reflected by AHI, during positional therapy. We also sought to explore the tolerability of positional therapy over a 3 month period.

2. Methods

2.1. Patients

We prospectively recruited subjects 18 years or older, who presented with acute ischemic stroke or probable ischemic stroke to the inpatient Neurology service at the University of Michigan. In all cases, a final diagnosis of ischemic stroke was reached during the hospitalization based on standard criteria [26]. We excluded subjects with any medical condition that precluded the avoidance of supine posture or dictated the need for a particular position, and those currently using positive airway pressure therapy, mechanical ventilation, or supplemental oxygen. Following consent, overnight sleep apnea screening studies were performed on all subjects within the first 14 days of stroke symptom onset. Those with an AHI of 5 or more on either night were considered to have OSA [27] and were therefore included in the final data analysis. The study was approved by University of Michigan's Institutional Review Board and written informed consent was obtained from the patient ($n = 19$) or a proxy ($n = 1$).

All participants were interviewed and their medical records reviewed to obtain baseline demographic characteristics and personal medical history. Height was self-reported and weight was self-reported or measured. Stroke severity was measured by the National Institutes of Health Stroke Scale (NIHSS) performed by certified personnel at the time of enrollment.

2.2. Sleep apnea studies

Sleep apnea screening was performed with a portable monitoring system (Stardust II, Respironics, Inc.) for two consecutive nights during the stroke hospitalization. The Stardust II has been validated against full polysomnography, has been used in previous studies [28,29], and as a type III portable monitor can now often qualify a patient for OSA treatment under Medicare or other medical insurance plans. The Stardust II system records oxygen saturation, pulse rate, nasal pressure, chest excursion, and body position (supine or non-supine) and uses software to analyse these data. The raw data were reviewed for each study to adjust the start sleep time and stop sleep time, both based on subjective information obtained from the patient and as suggested by review of the recorded data. Respiratory events were confirmed or invalidated based on standard methods as described in the Stardust Host Software Manual 2002 Respironics, Inc. Any periods of poor quality recordings were also excluded from analysis. The study was then analysed by the Stardust Host Software, Respironics, Inc.

An apnea was defined as a complete cessation of breathing for $\geqslant$10 s. An hypopnea was defined as a reduction of airflow for at least 10 s associated with oxygen desaturation of $\geqslant$4%. Sleep apnea severity was measured by the AHI, calculated as the total number of apneas, both obstructive and central, and hypopneas per hour of post-processed recorded time. Positional sleep apnea was defined by an AHI that was at least twice as high while supine as while non-supine on the non-therapeutic night.

2.3. Intervention

Avoidance of supine positioning was achieved by use of the commercially available SONA Pillow®, which is designed to prevent supine sleep. The pillow has been shown to reduce the AHI in patients with mild to moderate sleep apnea and to reduce snoring [20]. The pillow has a flat base and a double incline on the top surface that promotes lateral positioning. Recesses in the base create a space for the lower arm to extend under the head. Additionally, at the beginning of the therapeutic night, the patient, family, and nurses were instructed that the subject was to avoid supine sleep. Subjects were initially positioned to sleep on the side least affected by the stroke.

On the control night, subjects used the standard hospital pillow and were positioned *ad lib*. The head of the bed angle was set to the same degree at the beginning of each of the two nights, though the subject was not precluded from manipulation of the head of the bed angle during the night.

2.4. Study design

This study was conducted in two phases. The first phase, performed on two consecutive nights during the acute stroke hospitalization, followed a randomized, controlled, two-period cross-over study design (AB/BA). Subjects were randomized on a 1:1 basis to the order of treatment: positional therapy either on the first or the second night. Given that OSA may improve over the months following stroke [23,30], two consecutive nights were used. This also allowed the first phase to be completed during subjects' stroke hospitalizations.

In the second phase of the study, subjects were randomized on a 1:1 basis, in a parallel group design, to 3 months of therapeutic pillow use or standard positioning, which started immediately after completion of the first phase. At 3 months post-stroke we conducted a telephone interview with all subjects to determine functional outcome measured by the modified Rankin Scale (mRS) and classified as good (0–1) or poor (2–6). Those randomized to the therapeutic pillow were also queried about pillow adherence using a Likert scale: use of the pillow all nights, most nights, some nights, or no nights.

2.5. Sample size calculation

A sample size of 18 was planned a priori based on the desire to detect a 10-point difference in the AHI assuming power of 80%, an alpha of 0.05, and a 2-sided test. This was based on the assumption that the within-patient standard deviation of AHI (based on night-to-night variability) is 10 [31], and that there would be negligible carryover effects of positional therapy.

2.6. Statistical analysis

The results are reported as medians with interquartile ranges or as numbers and percentages. The absolute difference in percentage of time spent in the supine position and mean oxygen saturation were estimated using a linear repeated measures model, which accounts for the correlation of repeated measures within subject [32]. The relative treatment effect on AHI (events per hour) was assessed using generalized estimating equations (GEE) for a Poisson regression model. GEE allows for correlation of repeated measures in the model. To adjust for the subjects acting as their own controls, the period effect (whether they had the intervention on the first or second night) was included in the model as a covariate. A treatment by period interaction was added to assess for crossover effect, but was removed because it was not significant. Descriptive statistics were used to report 3-month outcomes ($n = 18$) and