Sleep Medicine 15 (2014) 269–272

Contents lists available at ScienceDirect

Sleep Medicine

journal homepage: www.elsevier.com/locate/sleep

Brief Communication

Prevalence of residual excessive sleepiness during effective oral appliance therapy for sleep-disordered breathing

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ARTICLE INFO

Article history:
Received 28 May 2013
Received in revised form 4 October 2013
Accepted 1 November 2013
Available online 30 December 2013

Keywords:
Obstructive sleep apnea
Mandibular advancement device
Epworth Sleepiness Scale
Daytime sleepiness
Dental sleep medicine
Sleep disordered breathing

ABSTRACT

Background: Oral appliance therapy with a mandibular advancement device (OA_m) can yield to complete therapeutic response (apnea–hypopnea index [AHI] < 5 events/h), though some patients show little or no improvement in daytime sleepiness. The prevalence of residual excessive sleepiness (RES) despite effective treatment with OA_m therapy is unknown. We aimed to determine the prevalence of RES in patients treated with a titratable custom-made duobloc OA_m.

Methods: A prevalence study was performed, collecting data from 185 patients with an established diagnosis of sleep-disordered breathing (SDB) under OA_m therapy with a titratable custom-made duobloc device (baseline data were male:female ratio, 129:56; age, 48 ± 9 years; body mass index [BMI], 27 ± 4 kg/m^2; Epworth Sleepiness Scale [ESS] score, 10 ± 5; and AHI, 19 ± 12 events/h). A full-night polysomnography was performed at baseline and after 3 months of OA_m therapy. Daytime sleepiness was assessed using the ESS with RES defined as an ESS score of 11 or higher out of 24, despite complete therapeutic response.

Results: Out of 185 patients, 84 patients (45%) showed a complete therapeutic response with an AHI of <5 events per hour after 3 months of OA_m therapy. Despite this normalization of AHI, 27 out of these 84 patients (32%) showed RES and had a significantly higher baseline ESS (15 ± 4 vs 9 ± 4; $P < .001$) and were younger (43 ± 9 vs 47 ± 9; $P = .028$) compared to patients without RES.

Conclusion: RES under OA_m therapy showed a prevalence of up to 32% in SDB patients effectively treated with respect to AHI. Patients with RES were younger and had higher baseline daytime sleepiness.

1. Introduction

Sleep-disordered breathing (SDB) is a highly prevalent public health issue affecting 9–24% of the middle-aged population [1]. It spans a wide pathophysiologic continuum of severity, ranging from snoring over obstructive sleep apnea (OSA) to obesity hypoventilation syndrome [2]. OSA is the most common type of SDB and is characterized by recurrent episodes of partial or complete collapse of the upper airway, resulting in intermittent hypoxemia, hypercapnia, and disruption of the normal sleep pattern [3]. The consequences associated with undiagnosed or untreated SDB include excessive daytime sleepiness (EDS), cardiovascular morbidity, reduced quality of life, and increased risks for motor vehicle and occupational accidents [1].

Continuous positive airway pressure (CPAP) is the current standard of therapy for moderate to severe OSA [4]. However, its clinical effectiveness is limited by poor patient acceptance and tolerance and unsatisfactory compliance [5]. Oral appliances are considered to be the main alternative to CPAP therapy for patients with mild to moderate OSA and for patients who do not comply with or refuse long-term CPAP treatment [6]. Within the group of oral appliances, the most commonly prescribed is the type of oral appliance that brings the mandible in a protruded position during sleep (OA_m). The aim of this treatment is to prevent upper airway collapse by increasing the cross-sectional pharyngeal area, thereby reducing snoring and OSA. The use of OA_m therapy has been reported to be effective in reducing patients' hypersomnolence [6]. However, a number of patients show little or no improvement in

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http://dx.doi.org/10.1016/j.sleep.2013.11.781

daytime sleepiness despite complete response with OA_m therapy for SDB severity. The prevalence of residual excessive sleepiness (RES) under OA_m-therapy currently is unknown. Therefore, the aim of our study was to explore the prevalence of RES during effective OA_m therapy.

2. Methods

Our cross-sectional single-center study evaluated the prevalence of RES in SDB patients treated with a titratable, custom-made OA_m. For the evaluation of daytime sleepiness, the Epworth Sleepiness Scale (ESS) was used. The ESS is a self-administered well-validated questionnaire that measures how likely patients are to fall asleep in eight different sedentary situations, previously determined to be soporific. Total ESS scores range from 0 to 24. Scores of $\geqslant$11 or $\geqslant$16 are indicative of EDS or severe EDS, respectively [7,8].

Baseline ESS and anthropomorphic and polysomnographic data were collected for 185 consecutive SDB patients treated with a custom-made, titratable OA_m (Resident Butterfly, Dormoco, Belgium [9] (n = 143) or SomnoDent Flex, Somnomed AG, Australia [10] (n = 42). The characteristics of the patients are shown in Table 1. All patients were evaluated at baseline and reevaluated after 3 months of OA_m therapy, including a full-night polysomnography with the OA_m in situ. Effective treatment was defined as a complete response with a reduction of apnea–hypopnea index (AHI) to less than five events per hour [11]. The other patients were considered as nonresponders. Ethical approval for our study was obtained from the institutional review boards of the Antwerp University Hospital.

2.1. Statistics

Data were statistically analyzed using SPSS (SPSS version 17.0, SPSS Inc, Chicago, Illinois, USA). Descriptive statistics for clinical characteristics of patients were presented as mean ± standard deviation (SD). The significance level was set at .05. Normality of distribution was assessed using Q–Q plots and the Shapiro–Wilk normality test. Continuous data between groups were compared with an unpaired t test if the data were normally distributed and with the nonparametric Mann–Whitney U test if the data were not. A paired t test or Wilcoxon signed-rank test were used to

Table 1
Patient characteristics. Bold values represent statistically significant values (P < .05)

Variable	All patients (n = 185)	Complete responders (n = 84)		P value
		RES (n=27)	Non-RES (n=57)	RES vs non-RES
Men (n; %)	129; 70%	16; 59%	37; 65%	.295
Age (y)	47.7 ± 8.9	42.7 ± 8.7	47.4 ± 8.9	**.028**
Baseline				
BMI (kg/m^2)	26.8 ± 4	26.1 ± 3.8	26.2 ± 3.4	.818
ESS (mean ± SD; range)	10 ± 5.1; 1–20	14.5 ± 3.6; 7–19	8.6 ± 4.4; 1–20	**<.001**
AHI (events/h)	19.1 ± 12.2	13.6 ± 16.9	14.9 ± 9.8	.981
Sleep efficiency (%)	83.4 ± 10.4	86.1 ± 9.3	82.4 ± 10.9	.08
TST (min)	384.5 ± 61.6	395.1 ± 61.4	381.4 ± 72.6	.4
St N1 (%TST)	6.8 ± 4.4	6.8 ± 3.4	7.8 ± 5.1	.85
St N2 (%TST)	51.4 ± 12.1	51.1 ± 13.3	48.7 ± 10.8	.13
St N3 + N4 (%TST)	20.4 ± 10.4	19.8 ± 13.4	22.1 ± 8.9	.06
St REM (%TST)	19.7 ± 6.2	21.9 ± 7.8	19.8 ± 5.8	.2
Time awake (min)	53.8 ± 46.1	43.7 ± 33.8	57.2 ± 49.4	.28
LMI (events/h)	21.1 ± 21.9	17.7 ± 15.9	17.9 ± 15.0	.9
PLMI (events/h)	13.5 ± 18.6	14.0 ± 15.8	11.2 ± 12.9	.6
ODI (events/h)	6.3 ± 7.5	3.4 ± 4.2	4.0 ± 4	.3
Mean saturation (%)	95.1 ± 1.4	95.6 ± 1.6	95.4 ± 1.2	.6
Minimum saturation (%)	85.1 ± 8.1	87.5 ± 6.7	86.3 ± 7.1	.3
With OA_m				
BMI (kg/m^2)	27.0 ± 4.0	26.3 ± 4.0	26.1 ± 3.4	.365
ESS (mean ± SD; range)	7.9 ± 4.6	14.0 ± 2.6	5.4 ± 2.9	**<.001**
AHI (events/h)	9.3 ± 9.4	2.5 ± 1.7	2.6 ± 1.3	.445
Sleep efficiency (%)	82.9 ± 11	83.0 ± 10.3	84.2 ± 9.6	.5
TST (min)	385.7 ± 58.1	380.7 ± 53.5	388.8 ± 55.3	.5
St N1 (%TST)	6.1 ± 3.8	6.2 ± 3	5.9 ± 3.7	.5
St N2 (%TST)	52.1 ± 11.1	55.3 ± 9.7	50.7 ± 11.3	.11
St N3 + N4 (%TST)	20.4 ± 9.3	17.1 ± 7.5	22.7 ± 10.0	**.01**
St REM (%TST)	21.3 ± 6.4	21.4 ± .6.8	20.7 ± 6.5	.7
Time awake (min)	52.3 ± 43.7	60.1 ± 42.1	45.3 ± 36.8	.06
LMI (events/h)	19.9 ± 21.6	18.1 ± 3.4	16.6 ± 17.4	.7
PLMI (events/h)	11.4 ± 15.9	10.9 ± 16.2	10.0 ± 14.7	.8
ODI (events/h)	3.2 ± 3.7	1.1 ± 0.9	1.4 ± 1.1	.1
Mean saturation (%)	95.1 ± 1.3	95.8 ± 1.3	95.1 ± 1.3	**.035**
Minimum saturation (%)	87.6 ± 4.9	89.6 ± 3.9	88.5 ± 4.9	.2
Δ AHI (events/h)	9.7 ± 11.7	11.0 ± 6.9	12.2 ± 9.8	.97
Subjective compliance (d/wk)	6.6 ± 1.1	6.9 ± 0.5	6.6 ± 1.1	.1
Subjective compliance (h/night)	6.9 ± 1.1	6.8 ± 1.2	7 ± 0.7	.4
Adjusted subjective compliance (%)	96.7 ± 11.4	100 ± 0	99.3 ± 13.5	.51

Abbreviations: RES, residual excessive sleepiness; OA_m, mandibular advancement device; y, year; BMI, body mass index; ESS, Epworth Sleepiness Scale; SD, standard deviation; AHI, apnea–hypopnea index; h, hour; TST, total sleep time; min, minutes; St, sleep stage; REM, rapid eye movement; PLMI, periodic limb movement index; LMI, limb movement index; ODI, oxygen desaturation index; d, day; wk, week.
RES: AHI OA_m < 5 events/h and ESS OA_m $\geqslant$ 11.
Non-RES: AHI OA_m < 5 events/h and ESS OA_m < 11.
Adjusted compliance: mean rate of OA_m use corrected for subjective TST.
Data are presented as mean ± SD unless otherwise stated.