ISSN: 1520-9512 Volume 3, Number 2

Sleep & Breathing

International Journal of the Science and Practice of Sleep Medicine

Official Journal of the Sleep Disorders Dental Society (SDDS)

The Society of Applied Sleep Medicine (Germany)

Sleep Medicine Section of the German Society of Otolaryngology (Head and Neck Surgery)

Thieme
New York • Stuttgart

SLEEP AND BREATHING-VOL. 3, NO. 2, 1999

ORIGINAL ARTCLE

A Randomized Double-Blind Placebo-Controlled Evaluation of the Safety and Efficacy of a Natural Over-The-Counter (OTC) Medication in the Management of Snoring

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ABSTRACT: More than 40 million American adults snore. Habitual snoring afflicts 44% of adult males and 28% of females.[1] Uncomplicated snoring is generally due to vibration of the palatal soft tissues or the tongue base, causing intermittent airway obstruction. Loudness is correlated with the degree of vibration and/or obstruction. The tendency, frequency, duration, intensity, and sequelae of snoring are influenced by myriad structural, physiological, environmental and pharmacological factors. Uncomplicated, nonapneic snoring is treated in a wide variety of ways, ranging from self-help methods, such as positional therapy, to laser surgery. The purpose of this report is to evaluate the safety and efficacy of a natural medication for snoring in a randomized double-blind placebo-controlled trial. The treatment is significantly more effective than placebo. Neither side effects nor intolerance to the product was reported.

KEYWORDS: snoring, naturopathic, homeopathic, Snore Stop

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Introduction

Subjects (n = 100) from the Portland, Oregon metropolitan area were recruited to participate in a randomized double-blind placebo-controlled trial to evaluate the safety and efficacy of a natural medication as a treatment for chronic snoring. The objective was to ascertain whether a homeopathic medicine can influence the incidence and intensity of snoring, and whether the use of such a product effects the quality of sleep for the snorer and his/her sleepmate. The product tested (**Snore Stop**, The Green Pharmacy, Wilsonville, OR) is a tablet manufactured in accordance with the Homeopathic Pharmacopoeia of the United States (HPUS) containing the following natural substances: Nux vomica 4X & 6X, Belladonna 6X, Ephedra vulgaris 6X, Hydrastis canadensis 6X, Kali bichromicum 6X, Teucrium marum 6X, and Histaminum hydrochloricum 12X.

Methods

Randomization and Double Blinding

Study subjects were recruited from the Portland Oregon metropolitan area through newspaper advertising and submitted to a confidential medical history and screening examination (at no charge) by a local otolaryngologist. After suitable informed consent was obtained, qualified study participants received a bottle of study medication randomly numbered from 101 to 201. All containers and labels were identical with the exception of their assigned number. Each amber glass bottle contained 20 tablets, identical in color, odor, taste, shape, markings, and other physical characteristics. Both the active treatment and placebo tablets were prepared and packaged in sealed bottles in an FDA-registered manufacturing facility licensed to produce homeopathic medicines under GMP controls. Containers remained unopened until delivery to study participants. Neither the patient nor any persons having direct patient contact knew the identity of active and placebo containers. Codes were broken only at the conclusion of the study. The randomized placebo group (n = 46) comprised 32 men and 14 women, with a mean age of 47.6 (SD 9.6) years. The treatment group (n = 44) contained 35 men and 9 women, with an average age of 49.3 (SD 10.3) years. The body mass index for the placebo and treatment groups were 29.5 (SD 5.5) and 29.7 (SD 6.6), respectively. Body mass indexes correlated with weights in the Metropolitan Life Tables.

TABLE 1. Subject Characteristics

Characteristic	Placebo n	Placebo Mean (SD)	Treatment n	Treatment Mean (SD)
Gender(% men)	46	69.5	44	79.5
Age (years)	46	47.6 (9.6)	44	49.3 (10.3)
Body Mass Index	36	29.5 (5.5)	34	29.7 (6.6)
Addiction[a] (% with addiction)	41	24.4	40	22.5
Allergies(% yes)	44	29.6	44	38.6
Surgery(% yes)	46	34.8	43	41.9
# of years with chronic snoring	44	11.6 (10.2)	43	16.6 (12.8)*

[a] Addiction to cigarettes and/or alcohol. *p = 0.026.

There were no significant differences between the treatment and placebo groups in subject characteristics (Table 1) or responses to the pretreatment Snoring Questionnaire (Table 2) with the exception of “Number of years snoring” in which the treatment group had experienced 16.6 ± 12.5 years of snoring as compared to 11.6 ± 10.2 years for the placebo group (p = 0.026).

TABLE 2. Snoring Questionnaire[a] (% Response)

Group	N	Score 1	2	3	4	5	Question No.
Placebo	46	0	0	4.4	39.1	56.5	1. How often?
Treatment	44	0	0	0	40.9	59.1	
Placebo	46	0	0	4.4	32.6	63.0	2. Disturb partner?
Treatment	44	0	0	2.0	29.6	68.2	
Placebo	44	20.5	29.6	22.7	22.7	4.6	3. Disturb others?
Treatment	42	16.7	19.1	40.5	16.7	7.1	
Placebo	45	15.6	11.1	20.2	40.0	13.3	4. Snore constantly?
Treatment	44	4.6	9.1	27.3	36.4	22.7	
Placebo	45	24.4	8.9	13.3	20.0	33.3	5. Snore on back?
Treatment	42	28.6	14.3	9.5	9.5	38.1	
Placebo	46	2.2	4.4	10.9	26.1	56.2	6. All positions?
Treatment	44	2.3	6.8	15.9	25.0	50.0	
Placebo	46	58.7	8.7	13.0	13.0	6.5	7. Stop breathing
Treatment	44	43.2	9.1	22.7	20.5	4.6	
Placebo	45	24.4	20.0	35.6	17.8	2.2	8. Wake suddenly?
Treatment	41	22.0	22.0	39.0	12.2	4.9	
Placebo	46	13.0	15.2	21.7	23.9	26.1	9. Partner leave?
Treatment	43	9.3	18.6	27.9	20.9	23.3	
Placebo	46	30.4	19.6	26.1	10.9	13.0	10. Embarrassment?
Treatment	43	37.2	14.0	22.3	18.6	7.0	

[a]1 = Never; 2 = Very infrequently; 3 = Occasionally; 4 = Often;
5 = Always or almost always (Fisher’s Exact test).

Inclusion Criteria

Adult snorers of both genders between the ages of 18 and 55 with uncomplicated medical histories and sleepmates whose sleep is adversely affected by their partner’s snoring.

Exclusion Criteria

Sleep apnea, deviated septum, nasal polyps, and other structural conditions, alcoholism or other chemical dependency, COPD, concurrent medications and other factors predisposing to neuromuscular, postural or vascular related airway/respiratory dysfunction which may complicate patient assessment were listed. Unwillingness or inability to adhere to the study protocol was also included.

Intervention

Over a 10-day period, study subjects were asked to consume two tablets, dissolved in the mouth before bed time, taking care to avoid any food, beverages, or other factors that could confound the interpretation of product efficacy. Patients and their sleepmates were asked to faithfully and accurately maintain a nightly diary to record outcome measures. Study nurses conducted follow-up by telephone on days 3 and 7 to ensure compliance and answer questions.

Outcome Measures

On the case report forms for 10 consecutive nights, snorers were asked to assess their quality of sleep and daytime alertness, and sleep mates were asked to grade their partner's snoring on a scale of 1-5 for each night.

- 1 = snoring unchanged 0%
- 2 = snoring slightly reduced 25%
- 3 = snoring moderately reduced 50%
- 4 = snoring significantly reduced 75%
- 5 = snoring completely resolved 100%

Additional comments requested from the nonsnoring sleep partner included any noticeable changes in quality or frequency of their partner's snoring pattern, on which nights, and how the nonsnoring partner slept.

Results

The first 5 nights of treatment were viewed as a run-in phase to allow for treatment effects to reach steady state. The last 5 nights were viewed as representing the steady-state treatment effect. In order to examine whether there was a change in snoring ratings, the average rating for the first 5 nights was compared to the average rating for the last 5 nights using a paired t-test for each group. There was no significant change in the placebo group ($p = 0.4665$). The treatment group showed an improvement in snoring score between the first and last part of the study ($p = 0.053$). We interpret this as indication that the steady state had not been completely attained within the first 5 days of the study. This is characteristic of the gentle and gradual therapeutic effect of homeopathic medicines.

Primary Analysis

Primary comparisons between the two groups were based on the average snoring score computed from the responses to the Snore Diary (Table 3) over the last 5 nights for each of group. The average score for the placebo group was 0.73 (SD= 0.94) indicating no significant change in snoring. The average for the treatment group was 1.58 (SD = I .20) representing a noticeable reduction overall. These differences were statistically significant (p = 0.0009).

TABLE 3. Distribution (% Response) of Responses to the Snore Diary

		Rating[a]						
Group	N	-1	0	1	2	3	4	Night
Placebo	46	0	65.2	23.9	4.4	4.4	2.2	1
Treatment	44	2.3	40.9	25.0	11.4	13.6	6.8	
Placebo	46	2.2	54.4	26.1	10.9	4.4	2.2	2
Treatment	43	0	32.6	27.9	23.3	16.3	0	
Placebo	46	2.2	45.6	26.1	15.2	8.7	2.2	3
Treatment	44	0	29.6	22.7	13.6	27.3	6.8	
Placebo	45	2.2	50.0	30.4	13.0	4.4	0	4
Treatment	44	0	31.8	15.9	27.3	18.2	6.8	p = 0.010
Placebo	46	2.2	47.8	28.3	13.0	8.7	0	5
Treatment	44	0	29.6	15.9	22.7	22.7	9.1	p = 0.019
Placebo	45	0	48.9	28.9	8.9	11.1	2.2	6
Treatment	44	0	25.0	18.2	22.7	29.6	4.6	p = 0.018
Placebo	44	0	47.7	36.4	9.1	2.3	4.6	7
Treatment	43	0	25.6	20.9	18.6	30.2	4.7	p = 0.001
Placebo	46	2.2	56.5	21.7	8.7	8.7	2.2	8
Treatment	43	0	30.2	16.3	20.9	27.9	4.7	p = 0.020
Placebo	46	0	54.4	30.4	8.7	2.2	4.4	9
Treatment	43	0	39.5	18.6	9.3	20.9	11.6	p = 0.025
Placebo	44	2.3	59.1	20.5	13.6	2.3	2.3	10
Treatment	43	0	38.6	22.7	9.1	18.2	11.4	p = 0.031

[a] -1= worse; 0 = no change; 1 = slightly reduced; 2 = moderately reduced; 3 = significantly reduced; 4 = completely resolved (p-values from Fisher's Exact test).

TABLE 4. Global Rating (%)

Rating	Group[a]			
	Placebo		Treatment	
	%	(n)	%	(n)
No change	54.4	(25)	20.5	(9)
Slightly reduced	23.9	(11)	18.2	(8)
Moderately reduced	6.5	(3)	18.2	(8)
Significantly reduced	10.9	(5)	27.3	(12)
Completely reduced	4.4	(2)	15.9	(7)
Totals		(46)		(44)

B. Summary Results

Rating	Group			
	Placebo		Treatment	
	%	(n)	%	(n)
No improvements	54.4	(25)	20.5	(9)
Improvements	45.6	(21)	79.5	(35)
Totals		(46)		
(44)				

[a] The groups are significantly different in their response, p = 0.0024 (X2 = 16.54,4df).

Secondary Analysis

Comparing “improvement” versus “no improvement’’ in the global assessment rating (Table 4), 79.5% of the treatment and 45.5% of the placebo group showed overall improvement in their snoring (p = 0.0009). In the treatment group, 61.4% reported moderate to excellent improvement versus 21.7% of the placebo group (p = 0.0001).

Discussion

In this randomized, double-blind, placebo-controlled trial, the evaluating physician was also blinded to the responses in the patient diary when calculating the overall results and determining the global assessment (Table 4) of success or failure for each participant. In this rating the treatment group was significantly better ($p = 0.0024$).

Although the trial lasted a short period, it demonstrated a clear treatment effect for a chronic condition (mean 16.6 years for the treatment group). There is no consensus on the scientific basis for the mechanism of action of homeopathic medicines. Controlled trials have confirmed the efficacy of homeopathic medicines in the management of acute diarrhea[2] and influenza.[3] Similarly, this study suggests that a safe, inexpensive homeopathic treatment may be of benefit to socially disruptive snorers.

References

1. Young T, Palta M, Dempsey J, et al. The occurrence of sleep-disordered breathing among middle aged adults. N Engl J Med 1993;328:1230

2. Ferley JP, Smirou D, D' Adhemar D, Balducci F. A controlled evaluation of a homeopathic preparation in the treatment of influenza-like syndromes. Br J Clin Pharmacol 1989;27: 329- 335

3. Jacobs J, Jimenez M, Gloyd S, Gale J, Crothers D. Treatment of acute childhood diarrhea with homeopathic medicine: A randomized controlled clinical trial in Nicaragua. Pediatrics 1994; 93:719-725