A Unique Internal Nasal Dilator Device (Brez® by AirWare®) for the Treatment of Primary Snoring

Barbara A. Harris, PhD,1 Michael J. Breus, PhD,2 Thomas Minor, MD3 and Yiran Hu, MS1

Abstract

Background: Snoring is a problem that affects a large number of people around the world. Not only can snoring be a health risk for the snorer, but also research now indicates that individuals sleeping next to a snoring bed partner will lose between 1 and 2 hours of sleep each night. The present study tests the hypothesis that use of a unique internal nasal dilator will reduce snoring, improve sleep quality and sleep quantity of their bed partner.

Methods: 26 primary snorers with AHI< 6 (12 men and 14 women), with bed partners, were recruited from the community to participate in this within-subject study. Participants underwent at least three (3) nights of snoring evaluation with a validated three (3) channel home sleep-testing device (ApneaLink™). Pre-treatment and post treatment questionnaires (Bed partner rating scales and Epworth Sleepiness Scale) were used to measure sleepiness and bed partner sleep quantity and quality.

Results: The average number of snoring events, when wearing the device (defined as > 0.3 sec. vibration at the nasal canula) decreased by 52% from 1247 (SD 830) to 654 (SD 495) which was statistically significant at the p = 0.0037 level. The mean value of two post-treatment snoring event measurements was used in comparison with the pre-treatment measurements.

Logistical regression analysis showed that participants wearing the treatment device had only 22.4% likelihood of persistent snoring and disturbing their bed partner’s sleep quality, which was statistically significant at the p = 0.0217 level. The bed partners’ self-reported sleep quality was 7 times more likely to improve (p = 0.0006). Additionally, summation of the total “improved” observations divided by the total number of observations (23/26, see Table 3) shows that 88% of the bed partners reported some improvement in their quality of sleep. Epworth Sleepiness Scale Score, while reduced, was not clinically significant for the snorer.

Conclusions: The results of this pilot study are suggestive of a significant therapeutic effect of the unique internal nasal dilator device (Brez® by AirWare®) for the reduction of snoring events. In addition, these results strongly suggest improvement of bed-partner sleep quality and quantity. Further clinical studies should include evaluation of the quality of sleep in snoring participants over a longer treatment period, decibel level reduction in snoring when using the device, and further evaluation of the mechanism of action for this unique and effective device.

Introduction

Snoring is defined as the sound made by the vibration of tissue residing in the naso and oropharynx during inhalation or exhalation while sleeping. The vibration is often due to obstructed air movement due to deviations in the septum or a relaxation of tissue during breathing while sleeping. The pathogenesis of snoring can be related to the combination of physiological, environmental and gender causative factors. Epidemologic data on snoring suggests at least 30% of adults and perhaps as many as 50% of people in some demographics snore.1 The nose accounts for 50% of nasal breathing resistance while the remaining resistance is associated with upper sinus and throat tissue and tissue relaxation. Snoring is a sign of increased upper airway resistance, and it is an auditory reminder that obstruction of the airway is occurring.

Snoring has been linked to increases in blood pressure, heart attack, and stroke.5,6,16,24,28 Not only can snoring be a health risk for the snorer, but research now indicates that individuals sleeping next to a snoring bed partner could lose between 1 and 2 hours of sleep each evening themselves.3 Although snoring is often considered a minor affliction, snorers can sometimes suffer severe impairment of life-style.19 In a between-subjects trial, Armstrong and colleagues discovered a statistically significant improvement in marital relations after snoring was surgically corrected, and that snoring strains interpersonal relationships; concerns for its effects were often voiced above a medical malady.4

Many of the treatments for snoring revolve around opening the breathing passage. This is the reason snorers are advised to lose weight (to stop fat from pressing on the throat), stop smoking (smoking inflames mucosal tissue and lining narrowing the airway), sleep on their side (to prevent the tongue from blocking the throat), use mandible advancement dental devices (to open the posterior airway space), avoid alcohol (a muscle relaxant) and surgery (to remove structures and tissue).4,8 All of these treatments have significant obstacles for successful adoption as indicated by adherence research in the areas of alcohol consumption, smoking cessation and weight loss. In addition, surgical treatments, while effective

1 PsyPharma Global, Phoenix, AZ.
2 Michael J Breus, PhD, DABSM, FAASM, SouthWest Spine and Sport, Scottsdale, AZ.
3 Thomas Minor, MD, Boulder Valley Pulmonology, Boulder, CO. Correspondence to Michael Breus: Dr.Breus@Gmail.com.
in some cases, can be painful, have significant side effects and eventual tissue re-growth. Dental devices can also have side effects including tooth movement and jaw pain.\textsuperscript{4} 

The economics of snoring treatments can include high costs such as non-reimbursed surgery, appropriate dental evaluation and correction, device expense and implementation, and follow-up care can be expensive.\textsuperscript{18} There is clearly a need for an economically feasible, reliable and effective solution for simple snoring with few side effects.

The present study tests the hypothesis that use of this unique internal nasal dilator will reduce snoring and improve the sleep quality and quantity of the bed partner.

The Device

The device under study is an intra-nasal dilator. (See picture below) The unique patented shape opens nasal passages to make breathing easier. The device is molded with a soft, FDA approved, food-grade, hypoallergenic plastic. It comes in three sizes to accommodate most human nasal structures. It is free of drugs and latex, disposable and recyclable.

Pre-treatment and post treatment questionnaires (Bed partner rating scales)\textsuperscript{1-5} were used to measure sleep quantity and quality of the bed partners. The snoring participants completed pre and post treatment Epworth Sleepiness Scales. Baseline measurements were recorded and all measurements were conducted for an additional two nights with snoring participants wearing the treatment device. Adverse events were collected.

The outcome variables include snoring events, bed partner’s subjective quantity of sleep, bed partner’s subjective quality of sleep, and the Epworth Sleepiness Scale (ESS) for the snorers. The self-reported bed partner’s quality of sleep disturbed by the snorer contained five levels of snoring effect: (1)- not at all to, (5) – more than anything else. The bed partner’s quantity of sleep disturbed by the snorer contained five levels; (1)- not at all, to (5) – greatly disturbs. The Epworth Sleepiness Scale score contained four levels: no chance of dozing (0), slight chance of dozing (1), moderate chance of dozing (2), to heavy chance of dozing (3), all levels were listed in an increasing order.

The primary variable is the study treatment, which has two levels: wearing the treatment device and no treatment device. A comparison of the pre-treatment and post-treatment observations for the above-mentioned outcome variables was performed with adjustment for participants’ demographic information (i.e., age and gender). The mean value of two post-treatment measurements of snoring events was used in comparison with pre-treatment measurement.

Due to participants’ improper sizing or manipulation of the device, 74 of 78 observations for snoring events were used, and 50 of 52 observations for ESS scores were used. An $\alpha$-level of 0.05 was used to determine significance of all statistical tests.

Results

Descriptive statistics of variable snoring events are given below in Table 1. We observed that the snoring events after the treatment had a smaller mean value (decreased by 52%) as well as a smaller standard deviation than the snoring events before the treatment.

The graph below also shows that the median post-treatment snoring events are lower than the median pre-treatment snoring events; there seems to be some but not severe variability between pre-treatment and post-treatment groups. No outliers were statistically observed. Assumptions for Analysis of Variance were examined and no violation of the assumptions was found.

With adjustment for the participants’ demographic information (i.e. age, gender), the analysis indicated that there is strong evidence of a post treatment effect of

<table>
<thead>
<tr>
<th>Variables</th>
<th>Pre-Treatment</th>
<th>Post-Treatment</th>
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<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>Stand Deviation</td>
</tr>
<tr>
<td>Snore events</td>
<td>1247</td>
<td>830</td>
</tr>
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</table>
the intra-nasal dilator on reducing snoring events with a P-value of 0.0037, < 0.05.

Logistic regression analysis was performed to test the effect of wearing the treatment device on the bed partner’s subjective quantity of sleep. Particularly, with participants’ demographics adjusted, analysis showed that participants wearing the treatment device had only a 22.4% likelihood of persistent snoring and bothering their bed partner’s sleep compared to their pre-treatment snoring quantity, with a P-value of 0.0217 < 0.05.

In testing the effect of snoring participants wearing the treatment device on the bed partner’s quality of sleep, logit analysis for ordered outcome categories showed their sleeping quality as improved compared to before the subject received the treatment with a P-value of 0.0006 < 0.05.

Descriptive statistics of ESS total scores are given below in table 4. We observed that the ESS total scores after the treatment had a slightly smaller mean value as well as a smaller standard deviation than the ESS total scores before the treatment. However, this difference was not statistically significant.

There were two adverse events recorded: Mild irritation of the nares (probably related to the device), and head congestion (not related to device).

**Discussion**

It was found that the Brêz® by AirWare® had a significant effect on objectively measured snoring in a selected group of non-obese primary snorers (AHI <6). The number of snoring events was reduced. It is assumed that the mechanism of action for the reduction in snoring events was that the placement of the device inside the nostrils decreased nasal resistance during sleep. Historical data have shown that nasal dilation in general does in fact reduce nasal resistance (Hornung et. al. 2001). However, this hypothesis cannot be proven since nasal resistance was not evaluated during sleep.

**Table 2. Table of Bed Partner’s Quantity of Sleep Effect before and after the Study Treatment; the Number in each Cell is the Number of Observations that Fall into each Situation. Percentages are Calculated by Dividing the Number in each Cell by the Total Number of Observations (52)**

<table>
<thead>
<tr>
<th>Frequency (%)</th>
<th>Occasional Soft Snoring: not Bothersome to Partner</th>
<th>Persistent Snoring: Bothersome to Partner</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-treatment</td>
<td>13 (25%)</td>
<td>21 (42 %)</td>
</tr>
<tr>
<td>Post-treatment</td>
<td>13 (25%)</td>
<td>5 (10%)</td>
</tr>
</tbody>
</table>

**Table 3. Table of Improved Sleeping Quality of the Bed Partner against the Study Treatment; the Number in each Cell is the Number of Observations that Fall into each Combined Situation. Percentages are Calculated by Dividing Number in each Cell by the Total Number of Observations (52). In Addition, Summation of the Total “Improved” Observation Divided by the Total Number of Observations (23/26) Shows that 88% of the Bed Partners Reported some Improvement in their Quality of Sleep**

<table>
<thead>
<tr>
<th>Frequency (Percent)</th>
<th>Great Improvement</th>
<th>Moderate Improvement</th>
<th>Slight Improvement</th>
<th>No Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-treatment</td>
<td>3 (6%)</td>
<td>3 (6%)</td>
<td>9 (18%)</td>
<td>11 (22%)</td>
</tr>
<tr>
<td>Post-treatment</td>
<td>9 (18%)</td>
<td>11 (22%)</td>
<td>3 (6%)</td>
<td>3 (6%)</td>
</tr>
</tbody>
</table>
or wake. A reduction in snoring with internal nasal dilation appears to depend upon individual patient characteristics, that is to say non-obese, normal airway individuals. Thus, those patients with snoring etiology other than nasal resistance (i.e., obesity, tonsilar hypertrophy, redundant palate, etc) may have a positive reaction to treatment, only if their snoring etiology is in combination with nasal resistance.

Bed partner ratings of sleep quality and quantity were also effected post treatment with Brêz® by AirWare®. Bed partner subjective sleep quality and quantity was overwhelmingly reported as improved, when snorer was using the treatment device. It is assumed that the reason for improved quantity and quality of bed partner sleep was the observed reduction in snoring events since environmental conditions, other than snoring, were constant, as described by the bed partners. However, since this was an in-home study, it cannot be assumed that environmental factors other than the reduction in snoring contributed to these effects. Some of the partner comments post-treatment include: the nights were so much better, the partner didn’t have to leave the room, snoring was eliminated, usually wears earplugs and sleeps in another room but not with Brêz®, and the partner kept waiting for snoring which didn’t occur.

Epworth Sleepiness Scale scores were equivocal in snorers while using Brêz® by AirWare® during the study. Multiple reasons for these results can be put forth including: insufficient duration of use of treatment device, accumulated sleep debt, or sleepiness due to something other than snoring. Further study is required.

Further clinical studies should include an evaluation of sleep quality in snoring participants and bed partners over a longer treatment period, decibel level reduction in snoring when using the device, evaluation of nasal resistance both during wake and sleep, full-nighttime polysomnography while wearing treatment device and further evaluation of the mechanism of action for this unique and effective device. This study was funded by AirWare, Inc.

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Table 4. Descriptive Statistics of ESS Scores

<table>
<thead>
<tr>
<th>Variables</th>
<th>Pre-Treatment</th>
<th>Post-Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>ESS total scores</td>
<td>Mean</td>
<td>Stand Deviation</td>
</tr>
<tr>
<td></td>
<td>9</td>
<td>4.36</td>
</tr>
</tbody>
</table>

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