Use of Hybernite Universal Heated Breathing Tube during PAP Titration Improves Acceptance and Reduces End Therapeutic Pressure

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Executive Summary
This study observed perceived patient benefit from using Hybernite Heated Breathing Tubing during standard titration protocols with heated humidification versus standard hose with heated humidification. Results showed that end pressures were reduced on average by 0.9 cm H_2O with eighty-five percent of patients in the "heated tube" control group reporting a high amount to very high amount of comfort. With using the heated tubing thus eliminating the condensation issues, technicians were also able to increase humidifier settings allowing for greater ease of breathing with fewer complaints of congestion, nasal/oral dryness, and/or sinus type headaches. Higher humidification treatment with reduced pressures has shown to provide patients greater comfort which has in turn been linked to greater continued use of PAP therapy.

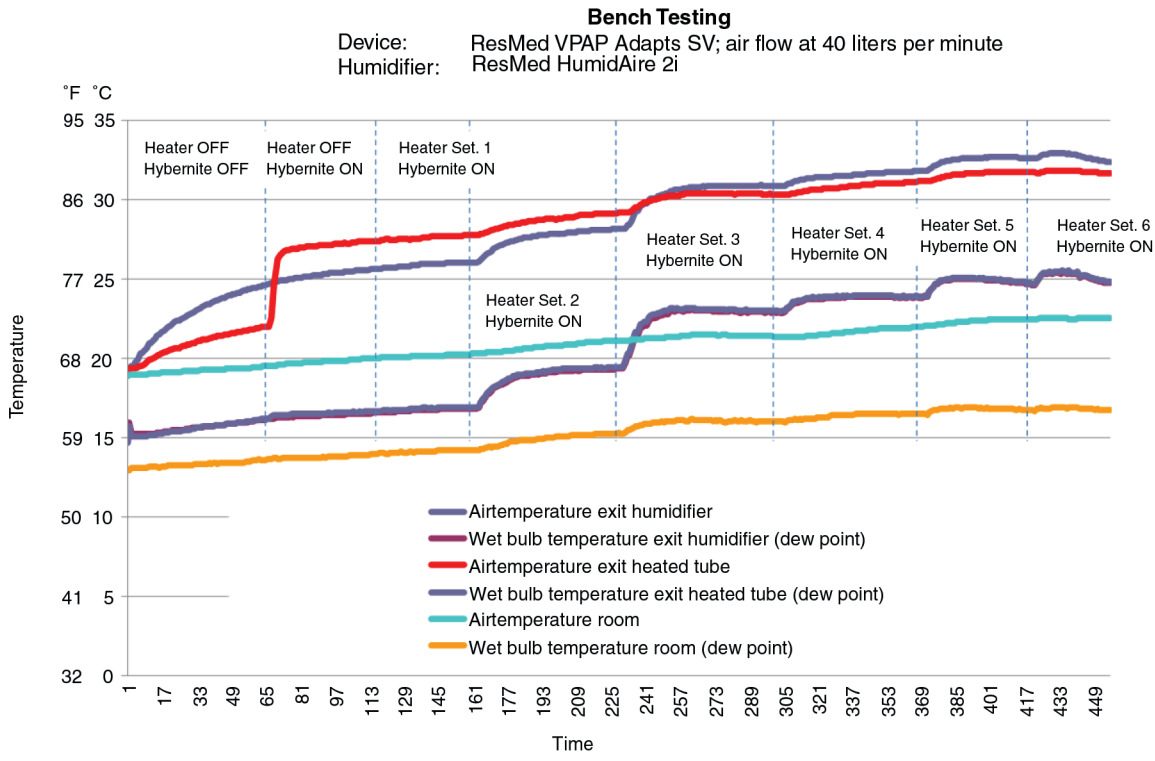
Introduction

In a changing and more stringent health care environment delivery of optimal PAP therapy cannot be based only on instinct, intuition or historical experience. To gain maximum benefit from night to night usage of PAP therapy, humidification needs to be interfaced with pressure. Termination of PAP therapy or limited usage often is due to common problems of oral/nasal dryness as well as nasal congestion. This can be due to the interaction of low humidity and higher pressure. One needs to be more active in leading the patient to an understanding of the value of humidification as an aid to achieve early acceptance and prolonged benefit.

Masks have been the focus of resolving early difficulties with acclimatization to PAP therapy. Masks will remain a primary focus to improve comfort and increase nightly usage of PAP therapy, but pressure and humidification needs to be adjusted as well. Manufacturers in the sleep industry have tackled many challenges long ago by gaining deeper patient insights through analytics to improve interfaces – replacing gut feeling and intuition with fact-based decisions.

In the mid 1990's heated humidification was introduced as an integrated device with the PAP blower leading to clinically significant improvement in treatment efficacy and usage.[1,2] Expected drop in patient complaints of progressive drying of the upper airway due to cold air, increased nasal resistance and return of daytime upper airway symptoms[3,4] was the benefit. However, the full benefit of humidification was not realized due to the persistent problem of "rainout".

The amount of humidification available at the mask has been limited by condensation leading to water forming in the tubing due to cooling of the air as it passed down the hose. Ambient temperature and humidity also affected the percentage and amount of humidification. The consequence of this physical process led to discomfort and awakenings from the water droplets to reducing the therapeutic pressure to sub-optimal levels.[5] The only remedy was to lower the temperature of the heater plate of the heated humidifier thus reducing the amount of humidity at the mask. The result was reduced humidity for many patients leading to reduced total time of usage. Limited use due to persistent complaints and discomfort often



contributed greatly to stoppage of PAP therapy.[6] Engineers working at the company Plastiflex, verified that heated breathing tubes avoided condensation and hence allow increasing the temperature of the heater plate of the heated humidifier. This results in an increased amount of humidification at the mask.

This white paper describes the assessment of the initial introduction of heated breathing tubing at the time of PAP titration in the sleep lab while challenging it against traditional heated humidification. Many patients fail or struggle with the initial experience due to the problems mentioned above compromising their future compliance with PAP therapy.[7] It is our hypothesis that the patient's initial acceptance of PAP therapy is enhanced by the ease of breathing with a higher relative humidity at a relative lower of pressure needed to reduce the apneas and hypopneas at the end of the titration study with Hybernite's heated breathing tubing.

Additionally, Hybernite heated breathing tubing by Plastiflex was developed and validated to improve relative and absolute humidification at the mask with any heated humidifier on the market, especially the specialty device used in most sleep labs for titration (i.e., VPAPtx™ and OmniLab™).

Clinical Challenge Trial

The aim of the challenge trial was to assess first time users reaction and acceptance to Hybernite HBT benefits of improved humidification with HBT as well as the difference in end pressure titrated by the technologist following standard titration protocols between standard hose with heated humidification and heated breathing tubing (Hybernite) with heated humidification; started at a predetermined heated humidification setting.

Method

This was a multi-center clinical challenge trial that was conducted in five facilities in Kansas, Nebraska and Texas on 225 paired patients. All diagnosed with Obstructive Sleep Apnea with an average AHI of 28, average BMI of 36. All patients were titrated following a standard titration protocol or split-night protocol consistent with AASM practice parameters. One group

was titrated using only heated humidification (patients studied prior to the availability of HBT) and the other group was titrated using heated humidification (HH) with heated breathing tubing (HBT). All patients were titrated using the ***OmniLab*** blower device. The heated humidifier setting for the HH only group (HH group) was 2 and the HH with HBT (HBT group) was initiated at a HH setting of 4. End pressure was considered the highest pressure at the conclusion of the titration protocol. Subjects' preferred mask choice was divided up into three groups, nasal interface, full face interface and nasal pillows. Patient comfort questionnaire was recorded using a 4-point Likert scales. Objective data was analyzed using the Paired t-test. Technicians were asked to complete a brief questionnaire assessing patient complaints and comfort at the conclusion of the titration study.

The purpose of this clinical challenge is to compare the effect of HBT on common side effects and perceived patient comfort by the attending technician and end titration pressure. The survey was designed to protect privacy. No name was stored or linked to any patient information.

Results

The average end CPAP pressure was different between the two groups, HBT group average was 11.2 cm H_2O, SD- 4.0 and the HH group was 12.1, SD- 4.4, a difference of 0.9 cm H_2O. End pressure range for both groups ranges from 5 – 23 cmH_2O. Number of patients titrated to a pressure greater than 12 cm H_2O was similar with a slight reduction in the number of patients using HBT with HH. Mask selection was different only with regards to increased usage of nasal Pillows in the HBT group. HBT group saw a reduction in nasal interface and both groups used the same percentage of full face interfaces. No gender differences or general demographic parameters were significantly different. The HBT group saw a reduction in problems associated with condensation in the mask and tubing as well as reduced oral/nasal dryness (average score of 1.3). Eighty five percent of the patients report a high amount to a very high amount of comfort when using HBT (average score 3.9). A consistent response of patients to the titrating technologist was how easy it was to breath. Headaches were less reported when HBT was utilized with higher humidifier settings. After completion of the trial all facilities chose to continue with HBT in the lab for all future titration protocols.

Conclusions

This preliminary clinical challenge trial compared a new universal heated breathing tube (Hybernite) connected to a heated humidifier during titration of nasal CPAP for the treatment of Obstructive Sleep Apnea. Using standard titration protocols end pressure was assessed between traditional heated humidification at a setting of 2 with standard tubing. End pressure was used due to the fact most prescribed pressures for static CPAP is the final or end pressure. In this trial end pressures eliminated sleep disordered breathing events to within normal limits. The initial heated humidifier setting of 4 was a concern for many technicians due to their perception that the delivery of warm air did not meet expectations of the patient thus leading to a complaint. This was not found to be a consistent finding, but rather a strategy to prevent potential "rainout" necessitating a return to the bedside to drain the excess water in the tubing. The patient response to higher humidifier settings was that of greater ease of breathing with fewer complaints of congestion, nasal/oral dryness and/or sinus type headaches. After further review of technician observation fewer patient at optimal humidification were reported to persist with mouth breathing or puffing. Only 6 events were reported to have any condensation in the mask or tubing (primarily full face masks and pillow type interface with a portion of the tubing not heated). Dry mouth/nose was the only complaint noted and that was less than 4.3 percent of the time. Only in 1.2 percent of these events of

reports of oral/nasal dryness did the technician choose to increase the heated humidifier setting. It should be noted that all patients did not have any experience using PAP therapy prior to this titration experience.

The new Hybernite heated breathing tube was developed to eliminate "rainout" (tube condensation) and reduce symptoms of oral/nasal dryness, nasal congestion and mouth leaks that contribute to patient complaints and discomfort. It is well accepted that progressive drying of the upper airway releases inflammatory mediators which increases nasal blood flow leading to increased nasal resistance as well as daytime upper airway problems. These side effects can and do require higher PAP pressure to maintain a patent airway. This clinical challenge trial demonstrated that end pressures were lower with the use of Hybernite HBT to a clinically significant degree. One observation that confounded the results may have been that the matched controls were titrated during the early winter months versus the late winter early spring of the HBT group. Seasonal issues may impact the outcomes and further review of seasonal as well as geographical differences (altitude) is needed to determine the most effective settings of heated humidifier settings used with Hybernite HBT.

The decreased difference in end pressure was 0.9 and others have found a difference of 1.1 cm H_2O pressures between the use of HBT and a standard non heated breathing tube.[8] When the pressure exceeds 12 cm H_2O, the difference in end pressure increases to 1.8. Suffice it to say the obvious trend is toward lowering of therapeutic pressure with the use of Hybernite HBT. A lowering of pressure has also been clinically seen to potentiate usage.

The amount of available distilled/filtered water became important the longer the titration study. Depending on the volume of water in the humidifier reservoir and the settings of the humidifier, the amount of available water is likely to reduce the amount of humidification during the latter part of the night at which time the pressures are the highest. This could contribute to early awakenings and reducing total sleep time thus eliminating the last REM period.

The three take home messages of this clinical challenge trial are, one, heated humidifier setting needs to be in the top third of the range, two, least obtrusive mask interface needs to be used and three, adequate water (fill the tub to max level) will go a long way in effecting initial acceptance and efficacy of PAP therapy. Lastly, the technicians introducing heated breathing tubes to PAP therapy need to see the relation between pressure and humidification: higher pressures need higher relative humidity initiated by higher heated humidification settings.

References

1. Hoffstein V, Viner S, Mateika S, Conway J. "Treatment of obstructive sleep apnea with nasal continuous positive airway pressure. Patient compliance, perception of benefits, and side effects." *Am Rev Respir Dis* 1992; 145(4 Pt): 841–845.
2. Massie CA, Hart RW, Peralez K, Richards GN. "Effects of humidification on nasal symptoms and compliance in sleep apnea patients using continuous positive airway pressure." *Chest* 1999; 116(2): 460–465.
3. Strohl, KP, Arnold JL, Decker MJ, Hoekje PL, McFadden ER. "Nasal flow-resistive responses t challenge with cold dry air." *J Appl Physiol* 1992; 72(4): 1243–1246.
4. Hayes, MJ, McGregor FB, Roberts DN, Schroter RC, Pride NB. "Continuous nasal positive airway pressure with a mouth leak; effect on nasal mucosal blood flux and nasal geometry." *Thorax* 1995; 50(11); 1179–1182.
5. Rakotonanahary D, Pelletier-Fleury N, Gagnadoux F, Fleury B. "Predictive factors for the need for additional humidification during nasal continuous positive airway pressure therapy.": *Chest* 2001; 119(2): 460–465.
6. Almasri E, Kline L. "The addition of heated wall tubing provides more humidity and comfort than standard heated humidifier CPAP units." *Sleep*, Vol. 30, *Abstract Supplement* 2007; 0562; A190.
7. Virag R. "Evaluation of the performance of CPAP heated humidifiers for use in sleep apnea therapy; A comparative study of humidification effectiveness." *Sleep* Vol. 31, Abstract Supplement, 2008; 1159; A38
8. Massengill J and Lewis KL. "Effect of humidification on titration pressures in obstructive sleep apnea." *Sleep* Vol. 32, Abstract Supplement, 2009; 0666; A217.