LOWER AIRWAY HUMIDIFICATION IN SPONTANEOUSLY BREATHING TRACHEOSTOMIZED PATIENTS: COMPARATIVE STUDY OF TRACHEA SPRAY VERSUS HEATED HUMIDIFIER

Tilman Keck, MD, Ajnacska Rozsasi, MD, Richard Leiacker, Eng, Marc Oliver Scheithauer, MD

Department of Otorhinolaryngology, University of Ulm, Ulm, Germany. E-mail: kecktill@aol.com

Accepted 3 August 2007
Published online 4 December 2007 in Wiley InterScience (www.interscience.wiley.com). DOI: 10.1002/hed.20742

Abstract: Background. Our aim was to compare inhalation with molecular water (vaporizing humidifier) and particulate water (trachea spray) in spontaneously breathing tracheostomized patients.

Methods. We performed a randomized, 2-way crossover study and a prospective, comparative, nonblinded study. Tracheal humidity and temperature were measured before and after use of a humidifier and spray for 1 week.

Results. After both inhalation and spray, the tracheal temperature and total water content increased significantly (study 1). The temperature gradient between ambient and tracheal air was significantly higher after spray, but not after inhalation (study 2). The water gradient increased nonsignificantly after spray and inhalation. The water gradient after inhalation or spray did not differ significantly.

Conclusions. Molecular water is not superior to particulate water because of temperature and humidity increase after both forms of water delivery. Because of its easy use, portability, and moisturizing effect, a trachea spray may offer additional options in postoperative tracheostomy care. ©2007 Wiley Periodicals, Inc. Head Neck 30: 582–588, 2008

Keywords: tracheostomy; humidification; respiratory pathophysiology; air conditioning

Patients after tracheostomy or laryngectomy often suffer from dry tracheal mucosa and tracheal crusting when staying or working in dry ambient air or in air-conditioned rooms. In these patients, the ability of the upper airways to warm and moisturize the inspiratory air is bypassed. Because of a measurable decrease of heat and moisture transfer to the respiratory mucosa, the lower airway mucosa can be damaged.1–4 However, an external supply of humidity is frequently not available in these situations, but an artificial way of adding moisture to the tracheal airways might reduce clinical symptoms of crust formation of the lower airways and increase breathing comfort.5–9

When the upper respiratory tract is bypassed, the inhaled air being delivered to the lower respiratory tract has to be as close to physiologic levels as possible.10–14 Until now, only little is known on the optimal form of delivered water (ie, aerosol or particulate form [300 μL H₂O/Lair], vapor or molecular form [30 μL H₂O/Lair]) of inhaled air administered to tracheostomized patients.14–17

Our working group has recently demonstrated that delivery of both molecular and particulate water significantly increases the tracheal climate and conditioning in the tracheal airways. We could also show that the tracheal humidity
remained on a higher level after aerosol spray than after use of a vaporizing humidifier. However, measurements of the tracheal climate after use of a newly available and hand-held trachea spray have not been performed.

This study was therefore done (1) to examine if a portable trachea spray is appropriate to supply moisture in particulate form to the lower airways and (2) to compare the influence of water delivery by a trachea spray and a heated humidifier to the lower airways in patients after tracheostomy. The increase in tracheal temperature and humidity after humidification was the primary outcome variable. Secondary outcome variables included a symptom score and an endoscopic score of the tracheobronchial mucosa.

PATIENTS AND METHODS

Subjects. In this study, patients after tracheostomy due to completely obstructing malignancies of the larynx or total laryngectomy were studied. The inclusion criteria were existence of a permanent tracheal opening for at least 6 weeks and age >18 years. The study was approved by the Ethics Committee of the University of Ulm, Germany, and informed consent was obtained from all patients.

Experimental Protocol.

Study 1. The first part of the study involved the evaluation of the efficacy of a trachea spray compared with a heated humidifier. For this purpose, a randomized, 2-way, crossover study design comparing the effects of 1-week use of a trachea spray and 1-week use of a heated humidifier on the tracheal climate was chosen. The randomization of the patients was accomplished according to a randomization list generated by the Department of Biometry and Medical Documentation of the University of Ulm. The study patients received delivery of molecular water in a vapor stream (32°C and approximately 100% relative humidity; 30 μL H₂O/Lair; inhalation device SUPER, Heimomed GmbH, Kerpen, Germany; Figure 1) for 20 minutes or delivery of particulate water in an aerosol stream via 2 puffs of the new trachea spray HeimoAIR (26°C and 90% relative humidity; 300 μL H₂O/Lair; Heimomed GmbH, Kerpen, Germany; Figure 2) for 1 week. All patients had to carry out humidification 4 times daily for 1 week. After 1 week without use of humidifier or trachea spray, the other method of airway humidification was performed. All patients had to carry out again humidification 4 times daily. A time interval of 1 week between both moisturizing therapies was kept to minimize possible carry-over effects.

Study 2. The second part of the study involved the comparison of both types of tracheal humidification in different patients. For this purpose, a randomized, comparative, nonblinded study was performed. Patients had to perform inhalation (INH group) for 20 minutes by use of a heated humidifier or to use 2 puffs of the trachea spray (SPRAY group). All patients had to carry out...
humidification 4 times daily for 1 week. The randomization of the patients to the INH group or the SPRAY group was accomplished according to a randomization list generated by the Department of Biometry and Medical Documentation of the University of Ulm.

Before beginning the study, the patients and their relatives were informed to control the ambient climate at home and to adjust it to the room temperature and humidity that is regularly measured in our research laboratory (range of temperature, 20.3–24.1°C; range of relative humidity, 33% to 48%).

**Tracheal Conditioning.**

**Study 1.** Before the start of each type of humidification for 1 week, baseline values of tracheal conditioning were obtained. At the end of each week of humidification, tracheal conditioning measurement was repeated.

**Study 2.** Before use and after 1 week of humidification by inhalation (INH group) or spray (SPRAY group), tracheal conditioning was measured under the same laboratory conditions and daytime.

Measurement of tracheal conditioning has been described in detail previously. First, the patients were brought to the laboratory. Following an equilibration period at an ambient temperature of 22.4°C (range, 20.3–24.1°C) and a relative humidity of 41% (range, 33% to 48%), the tracheostomy tube was removed and each patient was instructed to breathe calmly through the tracheal opening for 15 minutes. A thermocouple and a suction probe that was connected to a relative humidity sensor outside the body were placed into the upper part of the trachea. The thermocouple measured the temperature within the tracheal lumen close to the tip of the suction probe. Relative humidity was detected at the end of the suction probe in the air that was sampled in the trachea. To minimize errors due to any slight condensation within the suction system and the sensor box, a heat map was wrapped around the sensor box and warming of the suction system was achieved. The suction tube outside the trachea was also warmed, whereas the tip of the suction system within the trachea was without active heating. Temperature and relative humidity in the tracheal airstream were obtained during respiration at quiet breathing for 2 minutes. Signals of this device were compared with temperature and relative humidity signals that were simultaneously recorded directly in front of the patient’s tracheal opening. Data of relative humidity and temperature obtained simultaneously in front of the tracheal opening and in the tracheal lumen were used for calculation of the total water content of the air in the trachea and the water gradient across the upper tracheal airway. The water gradient (and the temperature gradient) was defined as the difference of the total water content (temperature), measured in the tracheal airway using sensor 2, minus the total water content (temperature), detected in front of the tracheal opening using sensor 1. The phase of inspiration and expiration was continuously detected using a stress-sensitive belt around the thorax of each patient.

**Symptom Score.** In both studies, the subjective perception of tracheobronchial irritation, formation of crusts, hypersecretion, need for suctioning, coughing, and tracheal dryness before and after 1 week of humidification were evaluated using 10-cm-long visual analog scales (VAS). Positive values indicated an increased level of discomfort. Values 1 to 4 were defined as acceptable (category 1), values 5 to 7 indicated moderate complaints (category 2), and values 8 to 10 indicated severe and unacceptable complaints (category 3).

**Endoscopic Score.** In both studies, rigid or flexible tracheobronchoscopy was performed before and after 1 week of humidification whether the clinical signs evaluated were present or not. Clinical signs of irritation of the tracheobronchial mucosa were mucosal swelling, edema, redness, and amount of secretions.

**Statistical Analysis.** Absolute values of tracheal temperature, total water content, and water gradient at various detection times are calculated and shown. Results are presented as a median ± range where appropriate. Intergroup and intragroup comparisons were performed using non-parametric tests: Wilcoxon and Friedman’s tests where appropriate. Significant differences were determined using the 2-sided Fisher’s exact test for categorical data. Significance was accepted at the 95% confidence level (p ≤ .05).

**RESULTS**

**Study 1.** Ten patients were included in the study, but in only 4 patients were complete results avail-
able after total laryngectomy (Table 1). Four patients living in the vicinity of Ulm were not able to appear 4 times in the 3-week investigation for transportation reasons. Two patients did not follow the humidification protocol correctly and, therefore, had to be excluded from the final analysis.

Baseline values of tracheal temperature and total water content before both inhalation and spray application did not differ significantly (pre-study 1 median temperature$_{INH}$, 25.2°C; pre-study 1 median temperature$_{SPRAY}$, 25.4°C; pre-study 1 median total water content$_{INH}$, 11.1 mg/L; pre-study 1 median total water content$_{SPRAY}$, 12.2 mg/L, Table 2). After inhalation and spray application, the temperature and total water content increased significantly compared with baseline values before humidification (post-study 1 median temperature$_{INH}$, 26.4°C; post-study 1 median temperature$_{SPRAY}$, 26.0°C; post-study 1 median total water content$_{INH}$, 15.1 mg/L; post-study 1 median total water content$_{SPRAY}$, 14.1 mg/L; Table 2). The same was true for the water gradient in the upper trachea (data not shown). Values of temperature, total water content, and water gradient (data not shown) after 1-week humidification did not differ significantly between both types of water delivery to the lower airways.

Table 1. Characteristics for 4 patients (study 1).

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>60.5 (47–75)</td>
</tr>
<tr>
<td>Sex, no. M/F</td>
<td>4/0</td>
</tr>
<tr>
<td>Weight, kg</td>
<td>74.5 (74–103)</td>
</tr>
<tr>
<td>Height, cm</td>
<td>176 (175–187)</td>
</tr>
<tr>
<td>Time after tracheotomy, mo</td>
<td>74 (24–156)</td>
</tr>
</tbody>
</table>

Note: Values represent median (range), except as otherwise stated.

After 1-week use of spray, coughing (although of minor subjective relevance) was significantly more often a complaint after spray than after inhalation. The other symptoms evaluated did not differ between both types of humidification (Figure 3). No symptom was from category 2 (moderate complaints) or category 3 (severe complaints). No differences in endoscopic scoring between both types of water delivery were observed (data not shown).

Study 2. Ten patients were included and divided into the INH group and the SPRAY group according to prior randomization (Table 3). In this part of the study, 1 patient after tracheostomy due to a completely obstructing malignancy of the larynx and 9 patients after total laryngectomy were studied.

Baseline values of tracheal temperature and total water content before inhalation and spray application did not differ significantly (pre-study 2 median temperature$_{INH}$ group, 25.5°C; pre-study 2 median temperature$_{SPRAY}$ group, 25.7°C; pre-study 2 median total water content$_{INH}$ group, 16.5 mg/L; pre-study 2 median total water content$_{SPRAY}$ group, 17.9 mg/L). The temperature gradient, calculated from the values measured in the trachea and in front of the tracheal opening, increased nonsignificantly after trachea spray and inhalation for 1 week (Figure 4, Table 4). After both inhalation (INH group) and spray (SPRAY group), the total water content increased nonsignificantly compared with baseline values before humidification. The water gradient, calculated from the values measured in the trachea and in front of the tracheal opening, after spray application for 1 week increased significantly (Figure 5, Table 4). The water gradient after inhalation for 1 week did not differ significantly.

Table 2. Statistical analysis (p values) of temperature and total water content values before and after application of spray and inhalation for 1 week (study 1).

<table>
<thead>
<tr>
<th>Groups</th>
<th>Temperature</th>
<th>Total water content</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline pre-SPRAY versus</td>
<td>0.35</td>
<td>0.23</td>
</tr>
<tr>
<td>Baseline pre-INH</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline pre-SPRAY versus</td>
<td>0.03</td>
<td>0.03</td>
</tr>
<tr>
<td>Post-SPRAY</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline pre-INH versus Post-INH</td>
<td>0.03</td>
<td>0.03</td>
</tr>
<tr>
<td>Post-SPRAY versus Post-INH</td>
<td>0.50</td>
<td>0.07</td>
</tr>
</tbody>
</table>

Abbreviations: INH, inhalation by vaporizing humidifier; SPRAY, humidification by trachea spray.

FIGURE 3. Study 1. Median symptom score, evaluated by a visual analog scale, after inhalation and spray in 4 patients. *p < .05; n.s. = not significant.
No differences in VAS scoring and in endoscopic scoring between the INH group and the SPRAY group were observed (data not shown). No subjective symptom reached category 2 or 3 (moderate or unacceptable severity). Overall, the patients were more satisfied with the trachea spray because of its easy handling and immediate humidification effect.

DISCUSSION
In patients with a permanent tracheal opening, respiratory problems such as excessive sputum production, coughing, crusting, and recurrent tracheobronchitis frequently occur. To regenerate the tracheobronchial mucosal surface and to improve the tracheobronchial climate, humidification via inhalation has been recommended in selected patients as part of postoperative care after tracheostomy or laryngectomy. In a recent study of this working group, 2 forms of water delivery to the lower airways have been investigated. One type of humidity supply was “optimal” humidity in molecular form at normal conditions of air entering the tracheobronchial region. The other type of humidification was particulate form between ambient and tracheobronchial condition. The result of this previous study was that, after use of both a vaporizing humidifier (molecular form) and an aerosol spray (particulate form), the end-inspiratory total water content and water gradient in the upper trachea increased significantly, compared with baseline values before application of humidity. After end of use of the vaporizing humidifier, the total water content and the water gradient decreased significantly faster than after application of the aerosol spray.

The aim of the present study was to compare the humidifying effect of a commercially available vaporizing humidifier, supplying molecular water, with a newly available trachea spray, supplying particulate water to the lower airways. In the present investigation, 2 studies comparing these 2 forms of water delivery to the lower airways have been performed. The primary intention of the working group was to compare the moisturizing effect of both forms of humidification after 1-week use in all patients after a 1-week interval between each week of moisture therapy. However, 4 patients with laryngeal cancer after laryngectomy, of 10 patients included, were living in the vicinity of Ulm and were not able to visit our institution 4 times in the 3-week investigation for transportation reasons. Two patients did not follow the humidification protocol correctly and, therefore, had to be excluded from the final analysis.

To increase the number of study patients with complete conditioning measurements and endoscopic and subjective symptom scoring, an easier study design with comparison of 2 study groups, 1 performing inhalation therapy by vaporizing humidifier only and 1 using the trachea spray only for a 1-week study period, was chosen. All patients included in the second part of the investigation finished the study according to the protocol and were included in the final analysis.

The tracheal temperature and humidity values before use of the vaporizing humidifier and trachea spray measured in our study were similar to the values from previous studies. After use of both the vaporizing humidifier and the trachea spray for 1 week (study 1), the temperature and total water content in the upper trachea increased significantly, compared with baseline values before application of humidity. After end of use of the vaporizing humidifier, the total water content and the water gradient decreased significantly faster than after application of the aerosol spray.

The aim of the present study was to compare the humidifying effect of a commercially available vaporizing humidifier, supplying molecular water,
increased significantly, compared with baseline values before humidification. In the first part of the study, increase in airway humidity was not significantly different between the 2 forms of humidity delivery after a 1-week period. In the second part of the study, the temperature gradient between ambient and tracheal air was nonsignificantly higher after trachea spray and after inhalation for 1 week. The water gradient between ambient and tracheal air increased nonsignificantly after trachea spray and inhalation for 1 week. The water gradient after spray application for 1 week increased significantly, whereas the water gradient after inhalation for 1 week did not differ significantly. No relevant differences in the impact of water in molecular versus particulate form on the respiratory mucosa have been found. We conclude that aerosols via trachea spray (water volume, 10–500 mg/L) that deposit in the tracheobronchial airways sufficiently provide water that can be evaporated to condition subsequent breaths.

In the present study, no clinical signs of tracheobronchial irritation or subjective complaints after both forms of humidity supply were found. After administration of the trachea spray, a short irritation, accompanied by coughing, occurred in the study patients, without the need for suctioning or further tracheobronchial irritation. Both after inhalation and trachea spray, the study patients were satisfied with the humidification therapy after a 1-week period. The patients with spray were even more satisfied and were asking to continue the spray therapy because of a subjectively increased feeling of tracheobronchial comfort. We, therefore, believe that an increase in humidity after a 1-week delivery of molecular or particulate water is beneficial for the integrity of the tracheal mucosa and mucosal function. After both moisturizing therapies, the water content of the respired air is increased, with an increased amount of water that can be transferred to the tracheobronchial mucosa and with possible impact on mucociliary clearance. Even after a 1-week study period, no negative effect on the mucociliary function2,3,11 and no clinical signs of disturbance of the ion-associated and osmotically driven water transport of the tracheobronchial mucosa13 were seen.

In conclusion, the results of the present study support the fact that humidification via a vaporizing humidifier and trachea spray is effective in tracheostomized patients after a 1-week use. Molecular water is not better than particulate water, because of temperature and humidity increase after both forms of water delivery. Because of its easy use, portability, and significant humidifying effect, a trachea spray may offer additional options in postoperative tracheostomy and laryngectomy care.

REFERENCES