Novel approaches to performance assessment of heat and moisture exchangers for pulmonary protection and rehabilitation in laryngectomized patients
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Chapter 5

Water uptake performance of hygroscopic heat and moisture exchangers after 24-hour tracheostoma application

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ABSTRACT

Background: After total laryngectomy, patients suffer from pulmonary complaints due to the shortcut of the upper airways which results in a decreased air conditioning. Laryngectomized patients are advised to use a heat and moisture exchanger to optimize the inspired air. According to manufacturers’ guidelines, these medical devices should be replaced every 24 hours. Aim of this study is to determine whether heat and moisture exchangers still function after 24-hour tracheostoma application.

Methods: Three hygroscopic heat and moisture exchanger types were tested after use by laryngectomized patients in long-term follow-up. Water uptake of 41 used devices (including 10 prematurely replaced devices) was compared with that of control (unused) devices of the same type and with a control device with a relatively low performance.

Results: After 24 hours, the mean water uptake of the three device types had decreased compared with that of the control devices. For only one type this difference was significant. None of the used heat and moisture exchangers had shown a lower water uptake than that of the low performing control device.

Conclusions: The water uptake capacity of hygroscopic heat and moisture exchangers is clinically acceptable though no longer optimal after 24-hour tracheostoma application. From a functional point of view the guideline for daily device replacement is therefore justified.
INTRODUCTION

After total laryngectomy, inspired air is no longer sufficiently humidified and warmed due to the shortcut of the upper respiratory tract. Consequently, patients develop pulmonary complaints such as mucus hypersecretion, forced expectoration, and frequent coughing, significantly contributing to a decreased quality of life. Heat and moisture exchangers (HMEs) are medical devices specially developed for the treatment and prevention of these pulmonary complaints. These devices help to optimize the conditioning of the inspired air and therefore to reduce pulmonary complaints and other pulmonary side effects of total laryngectomy. Different types of HMEs are commercially available. Some HMEs contain hygroscopic salt. The main function of this salt is to attract a layer of water on the core material. Since water has a high heat capacity, the performance of the HME increases with increased salt amount.

According to manufacturers’ guidelines, patients are advised to replace the HME device after 24-hour tracheostoma application because of an increased risk of infections after prolonged use due to bacterial colonization in the foam. Kramp et al\textsuperscript{10} showed that using HME devices in patients with a permanent tracheostoma with daily replacement does not cause additional exposure to pathogenic microorganisms. This shows that using an HME for 24 hours is bacteriologically safe, but whether HME function is still acceptable after 24-hour tracheostoma application in patients has not yet been studied. In vitro measurements with a mechanical lung model (ISO-standard 9360) have shown that HMEs still have an efficient performance after 24 hours.\textsuperscript{11,12} However, patient factors that cannot be simulated in this model might influence HME performance, such as mucus production (causing HME blockage), frequent coughing, repeated compression of the HME during airtight occlusion for voicing, possible voice prosthesis leakage, and changes in environmental conditions. For hygroscopic HMEs, it cannot be excluded that over time a device loses some of its hygroscopic salt (e.g. due to dilution in water by condensation during breathing), which would result in a reduction of the water uptake and a decrease in heat and moisture exchange.

The aim of this study was therefore to measure the HME water uptake capacity after 24-hour tracheostoma application in patients and to determine whether
there was a significant reduction in water uptake in used devices compared with control (unused) HMEs of the same type. Additionally, devices that were replaced by patients after less than 24 hours of tracheostoma application due to obstruction/blockage by mucus/phlegm and causing uncomfortable breathing were tested and compared similarly.

**MATERIAL AND METHODS**

The study was approved by the ethical review board of our institute and informed consent was obtained from all patients.

*Patients and HMEs*

Table 1 shows the patients’ characteristics. Devices were obtained from 10 laryngectomized patients. All patients were daily HME users with stable disease and in long-term follow-up at the Netherlands Cancer Institute- Antoni van Leeuwenhoek (a tertiary, comprehensive cancer center), Amsterdam, The Netherlands.

Four hygroscopic HME types were tested: Provox XtraMoist (XM-HME), Provox XtraFlow (XF-HME), Provox Normal (R-HME) and Provox Hiflow (L-HME) (Atos Medical, Hörby, Sweden). The abbreviations used for these devices are similar to published studies performed previously in our institute. These HMEs contain a CaCl$_2$-impregnated foam in a plastic case. The HME performance (water uptake, water exchange and end-inspiratory humidity performance) are shown in Table 2. The L-HME can be prescribed if a patient does not tolerate the resistance of the better performing HMEs. Due to the larger foam pores in the core material (causing lower airflow resistance), this HME type has a relatively low heat and moisture performance. The L-HME was not used by patients in this study but only included as a control HME for comparison.
Table 1. Overview of patient characteristics.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Patients (median; range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td>10</td>
</tr>
<tr>
<td>Gender</td>
<td>9 male: 1 female</td>
</tr>
<tr>
<td>Radiotherapy</td>
<td>10</td>
</tr>
<tr>
<td>Mean age in years (median; range)</td>
<td>64.4 (62.5; 56-81)</td>
</tr>
<tr>
<td>Mean post-TLE in years (median; range)</td>
<td>10.6 (9; 2-24)</td>
</tr>
<tr>
<td>Mean HME use in years (median; range)</td>
<td>10.2 (9; 2-20)</td>
</tr>
</tbody>
</table>

TLE= total laryngectomy, HME = heat and moisture exchanger

Table 2. Performance parameters for each HME type: water uptake, water exchange and end-inspiratory humidity performance.9

<table>
<thead>
<tr>
<th>Water uptake</th>
<th>Water exchange*</th>
<th>End-inspiratory Humidity performance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>at operating conditions (see text), mg (SD)</td>
<td>at ambient humidity 5 mg/L, mg (SE)</td>
</tr>
<tr>
<td>XM-HMEs</td>
<td>172.5 (28.5)</td>
<td>3.61 (0.13)</td>
</tr>
<tr>
<td>XF-HMEs</td>
<td>89.2 (11.0)</td>
<td>2.89 (0.11)</td>
</tr>
<tr>
<td>R-HMEs</td>
<td>53.1 (8.4)</td>
<td>2.66 (0.13)</td>
</tr>
<tr>
<td>L-HME</td>
<td>47.7 (4.5)</td>
<td>2.04 (0.11)</td>
</tr>
</tbody>
</table>

*Water exchange is the amount of water taken up and released by an HME during each breath.

HME collection

Patients were asked to collect the following within a 2-week time period:

- Three HME samples that had been used approximately 24 hours (referred to here as “24-hour” HMEs)

- If possible, an HME that had been changed prematurely (well within 24 hours) due to blockage by mucus and/or uncomfortable breathing (referred to here as “mucus” HMEs)
Patients were instructed to send each HME in an airtight plastic bag to the hospital on the same day that the device was changed.

**Measurements**

The water uptake is the difference between the wet HME weight (at operating conditions) and the dry HME weight (at 0% ambient relative humidity) and was measured as has been described previously\(^8\) with minor modifications as described in the appendix (available at www.otojournal.org).

A Freeze Drying Chamber (FDC206, SpeedVac system, Savant, Farmingdale, New York) was used to create a vacuum for 0% relative humidity (RH) conditioning. Higher humidity conditions were created using a Plexiglas climate room containing an electromotor-driven propeller for air mixture (26x42x16 cm\(^2\) as described earlier by J.K. Zuur et al\(^{15}\)). A commercial, calibrated humidity sensor (Testo, Almere, the Netherlands) with an accuracy of ± 0.6°C and ±2.5% RH was used to record the ambient humidity during the measurements. Weighing of HMEs was performed using a Micro Balance (Sartorius MC210P, Göttingen, Germany) with an accuracy of 0.1 mg. HMEs were placed in airtight boxes during weighing to prevent evaporation similar as described for previous weight measurements.\(^{16}\)

**Analysis and statistics**

HMEs of the same type were analyzed together. The water uptake of the used HMEs per type was compared with the water uptake of the corresponding control HMEs and with the control L-HMEs. The Wilcoxon-Mann-Whitney test was used to calculate significance with p-value of 0.05.

**RESULTS**

All together, 43 HMEs were collected. For all types of the 24-hour HMEs, a sufficient number of devices were available for analysis, but for the mucus HMEs only the XF-HME was available. An overview of the average water uptake measurements with standard deviations of all tested HME types together with the number of collected HMEs is shown in Table 3.
The water uptake capacity of the 24-hour XM-HMEs was significantly lower than that of the control XM-HMEs (p-value < 0.001). The water uptake values of the 24-hour XF-HMEs, the 24-hour R-HMEs and the mucus XF-HMEs were lower, but not significantly different from those of their respective control HMEs (p-value = 0.13, 0.45, and 0.43 respectively).

The 24-hour XM-HMEs, and both the 24-hour XF-HMEs and mucus XF-HMEs, had a significantly higher water uptake than the control L-HMEs (p-value = < 0.001, 0.006 and 0.01 respectively). The water uptake of the 24-hour R-HMEs was comparable to that of the control L-HMEs (p-value =0.14).

Table 3. Overview of the mean water uptake results for the control HMEs, the collected 24-hour devices and the mucus XF-HMEs.

<table>
<thead>
<tr>
<th>Used HMEs</th>
<th>“24-hour” HMEs</th>
<th>&quot;mucus&quot; HMEs</th>
<th>Control HMEs</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number of collected HMEs/ patients</td>
<td>Median hours used (range)</td>
<td>Mean water uptake (SD)</td>
</tr>
<tr>
<td>XM-HME</td>
<td>9 / 3</td>
<td>24 (24-26)</td>
<td>88 (30) *^</td>
</tr>
<tr>
<td>XF-HME</td>
<td>15 / 5</td>
<td>24 (19.5-26)</td>
<td>69 (20) ^</td>
</tr>
<tr>
<td>R-HME</td>
<td>7 / 2</td>
<td>24 (21.5-25)</td>
<td>48 (7)</td>
</tr>
<tr>
<td>L-HME</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

N/A: not applicable
* Significantly lower than control XM-HME
^ Significantly higher than control L-HME
+ Not analyzed (insufficient number of HMEs received)
Figure 1 shows the water uptake measurements of the HMEs used by patients and the control HMEs of the same type and the control L-HME. The water uptake values of the 24-hour XM-HMEs were very heterogeneous, but this was also the case for the control XM-HMEs (Figure 1A). Both the 24-hour and mucus XF-HMEs showed a higher variance in the water uptake than their control device (Figure 1B). The variance of the 24-hour and control R-HME was similar (Figure 1C).

**Figure 1.** Water uptake measurements:
A: 24-hour XM-HMEs, n=9 (blue diamonds)
B: 24-hour XF-HME, n=15 (blue diamonds) and mucus XF-HMEs, n= 10 (blue circles)
C: 24-hour R-HME, n=7 (blue diamonds)
Closed data points indicate the mean water uptake.
DISCUSSION

The mean water uptake of all three tested HME types was lower after 24-hour tracheostoma application than the water uptake of the corresponding control devices, but only for the XM-HME was this difference significant. The 24-hour XM-HME and 24-hour XF-HME as well as the mucus XF-HME still had a higher mean water uptake than the control L-HMEs. After 24 hours, the R-HME water uptake was comparable to that of the control L-HME type.

The results suggest that the XM-HME was the only device type that lost a significant amount of hygroscopic salt after 24 hours, resulting in the decreased water absorption. The XM-HME is capable retaining considerably more water than are the other HME types, as can be seen in Figure 1. In our previous study, we presumed that a large water uptake may lead to dripping of water into the trachea or onto clothes or skin by condensation. The present study confirms that the XM-HME (with the highest water uptake) loses part of its salt during use. Despite this apparent loss of salt, the XM-HMEs still have a water uptake after 24 hours of tracheostoma application similar to that of the control XF-HMEs. As this is also significantly higher than the mean uptake capacity of the control L-HMEs, we consider this reduced water uptake as clinically acceptable and no reason for early replacement.

All used XF-HMEs (both the 24-hour and the mucus devices) had a water uptake capacity similar to the control XF-HMEs and a significantly higher water uptake than the control L-HMEs. Only three samples seemed to have lost most of their salt, as can be seen in Figure 1B.

HMEs that have lost all their salt, or devices that do not contain hygroscopic substance in the first place, still have a (minimal) water exchange/humidity performance (based on the heat capacity of the remaining core material and case) as published previously. Some patients in our clinic (not included in this study) report that they wash their HMEs (personal communication). The results of our study indicate that washing of hygroscopic HMEs should be discouraged as this will lead to the loss of salt and therefore to a decreased water uptake associated with a decreased HME performance.
For HME-Fs (HMEs that are used for mechanical ventilation in intensive care units), both bacteriological safety (no significant alterations in bacterial colonization after prolonged use of the devices or in cultures of respiratory flora\textsuperscript{17-22}) and a constant humidity performance after 24-hour use has been shown.\textsuperscript{17,19,21-24} These performance studies used a direct in vivo measurement for humidity performance. The intensive care unit humidity data are not entirely representative for spontaneous breathing patients, though, because tracheal mucus suction is used in ventilated patients.

For the present study we chose a rather indirect method to measure HME performance after 24-hour tracheostoma application: measurement of the water uptake capacity of hygroscopic HME devices. The reason is that in vivo measurements are technically challenging\textsuperscript{15,25-27} and would have meant a severe burden to patients because these measurements must be repeated for multiple HMEs and require several hospital visits.\textsuperscript{16} Ex vivo measurement of the water exchange capacity requires breathing through the HME.\textsuperscript{9} Using a healthy volunteer to test HMEs used in patients was not possible for hygienic reasons. Asking patients themselves to participate in these ex vivo measurements would have imposed a severe burden on them.

Previously, we have shown that the water uptake of hygroscopic HMEs is associated with their performance.\textsuperscript{9} However, water uptake capacity is only measurable in HMEs containing hygroscopic material and not in HMEs without salt in their core material, which are also available for laryngectomized patients.

In conclusion, this study shows that the hygroscopic XM-HME, XF-HME and R-HME still have a clinically acceptable water uptake performance if they are replaced after 24-hour tracheostoma application following the guideline. The results indicate that HME use greater than 24 hours may be feasible and considered from a water uptake perspective. It has to be kept in mind, though, that even the best performing HME presently available does not fully close the physiological gap with upper respiratory tract breathing\textsuperscript{9,14} and that any decrease in water uptake performance will lower the clinical benefits of HME use. Therefore, aside from obvious hygienic reasons (e.g. mucus/phlegm contamination), daily replacement of an HME still is recommended. Given that the bacteriological safety of this guideline had already been shown\textsuperscript{10}, the current guideline is both safe and justified.
APPENDIX 1

Calculation of the wet HME weight at operating conditions

For each HME, the weight increase gradient (weight increase with increasing relative humidity: mg/ %RH) was calculated from the HME weight increase as a function of relative humidity.

In our previous study, for each HME type one sample was conditioned by breathing by a healthy volunteer to determine a fictive average relative humidity under operating conditions. It is used to calculate the weight under operation (breathing) conditions from a linear extrapolation of the weight increase as a function of relative humidity. Due to the non-linear weight increase above 55% relative humidity in reality the true average relative humidity in HMEs will be much lower than this fictive average relative humidity.

For the used HMEs in this study it was not possible to determine the fictive average relative humidity for hygienic reasons. Using the fictive average relative humidity of the control HMEs might lead to overestimation of the weight for HMEs that lose a considerable amount of salt (these HMEs consequently have a lower performance and will also have a lower fictive relative humidity under operating conditions). Instead we used the relationship between weight increase gradient and fictive average relative humidity from our previous study to estimate the fictive relative humidity for the used HMEs.

The impact of estimated fictive relative humidity on the water uptake of the used HMEs is largest for the HMEs which have lost almost all their salt. For these HMEs the water uptake value calculated using the fictive relative humidity is about 10% lower than water uptake value calculated using the operating relative humidity of the control HMEs (but note that these used HMEs have a water uptake which is more than three times less than the controls). Significance of testing the differences using the latter values instead of the values that are shown in Figure 1 yielded identical results.
REFERENCE LIST


