The influence of heat and moisture exchangers on tracheal climate in laryngectomized individuals: toward optimal pulmonary rehabilitation
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CHAPTER 8

General discussion
Laryngectomized patients frequently experience problems of the lower airways, such as irritation of the tracheo-bronchial mucosa, excessive sputum production, crusting and coughing. Regular use of a Heat and Moistening Exchanger (HME) is the most important treatment option for pulmonary rehabilitation in laryngectomized patients, and has proven to significantly reduce pulmonary complaints. It has become also obvious, that, although pulmonary complaints are diminished, they are not yet fully eliminated. Clinical experience reveals that quite some patients after total laryngectomy are struggling, although at a lower level, with excessive mucous production, despite 24/7 use of HME devices. These persistent pulmonary complaints suggest that HMEs are suboptimal substitutes for the heat and moisture exchanging capacity of the normal upper airways. Therefore, further improvement of the heat and moistening capacity of these medical devices is still required, but it is not yet known what temperatures and humidity levels should be targeted at for an ideal HME in these patients.

Normal upper respiratory tract values at about the level of the tracheostoma (i.e. subglottic level) have been established by Ingelstedt [56] in the early 1950s in young and healthy individuals. This was an invasive study as a puncture in the trachea had to be made to prevent interaction with the upper airways. In contrast with these young subjects, laryngectomized patients are generally elderly and most of them have been smokers and/or treated with radiotherapy. It is known that the elderly have lower intranasal temperature and humidity values than younger individuals, probably due to involution atrophy of the nasal mucosa. As such, the results reported by Ingelstedt [56] may not be fully representative for many laryngectomized patients.

More appropriate target temperature and humidity values for laryngectomized patients are described in Chapter 2. To avoid the invasive procedure performed by Ingelstedt these target values were obtained from head and neck cancer patients with a precautionary tracheotomy. Through the tracheotomy, endotracheal temperature and humidity values could be measured. Temperature and humidity values during nose and mouth breathing are compared with those of tracheotomy breathing (see Table 2.2). The end-inspiratory values of nose breathing are most relevant as they can be considered as target values for HME devices. These temperature and humidity values were 31.1 °C (SE 0.36) and 29.3 mgH₂O/L (SE 1.9), respectively. Even if not invasive, this study was a considerable burden to these recently operated and generally still recovering
patients. Therefore, only a limited number of patients could be included, leading to rather wide error margins.

Although it is not known how nicotine and radiotherapy may have affected the endotracheal temperature and humidity, it can be argued that these parameters may have damaged mucociliary epithelium, leading to a reduced moisturizing capacity. As the limited number of patients did not allow for multivariate analysis, we compared the calculated model estimates of temperature and humidity values of different subgroups. We found (non-significant) indications that radiotherapy and "compromised" mucosal epithelium (due to oral or pharyngeal surgery) may have lowered moisturizing capacity, without affecting temperature. Why only humidity seemed to be affected by these parameters (and not temperature) can perhaps be explained by a larger humidity gradient that must be conditioned (from 8 mgH₂O/L environmental humidity to 44 mgH₂O/L in the peripheral pathways) compared to the temperature gradient (from 25 °C to 37 °C).

Although the effects of radiotherapy and surgery-induced "compromised" mucosa on the endotracheal humidity did not reach statistical significance, it must be considered that these parameters could have lowered endotracheal humidity. Therefore, perhaps (slightly) higher temperature and humidity than the presented target values should be aimed at.

For accurate HME improvement, repeated testing and comparison of different HME devices is indispensable. Ideally, in vivo measurements are required. For this purpose, the Airway Climate Explorer (ACE) has been developed so that endotracheal temperature and humidity in laryngectomized patients could be measured. However, these measurements require a selected group of laryngectomized individuals, who are physically able and willing to participate, and to sit still for at least half an hour. Therefore, it is highly desirable to limit the number of patients in such studies. For accurate assessment of the power of these studies we investigated the intra- and inter-patient variability of the endotracheal temperature and humidity values measured by the ACE, and the influence of different seasons on endotracheal climate (see Chapter 3). The short-term intra-patient variability was particularly large for the end-inspiratory humidity (2.04 mgH₂O/L), whereas that of end-inspiratory temperature was somewhat smaller (0.73 °C). Interestingly, the intra-patient variations were found to have the largest contribution to the overall variability, whereas the
inter-patient temperature and humidity variations were much smaller (0.04 °C and 0.39 mgH₂O/L, respectively). From these results it follows that more repetitions in a few patients are just as useful as a few repetitions in many patients. Therefore, it would be sufficient to include a limited number of laryngectomized patients (for example only 1 or 2 patients) in future studies provided that a sufficient number of repetitive measurements are accomplished. In general about ten repetitions or measurements will be required then.

A likely cause of the relatively large intra-patient variability is inconsistency in the positioning of the catheter tip in the trachea at the beginning of each measurement. In practice, it appeared to be rather difficult to position the catheter tip at exactly the same position in the tracheostoma. In the presence of an HME, correct positioning of the catheter tip is even more difficult as visual inspection of the catheter tip is impossible. Another possible reason for the relatively large intra-patient variability is the body temperature of the patients themselves. Higher patient temperature leads to a higher capacity of the trachea to hold water vapor so that end-inspiratory humidity will increase. In future studies, therefore, the patient’s body temperature should be measured as well and taken into account in the interpretation of the data.

Long-term (“seasonal”) intra-patient variations in both (end-inspiratory) temperature and humidity were of the same magnitude as the short-term intra-patient variations (1.06 °C and 1.60 mgH₂O/L). These variations may have been caused by patient-related changes such as the influence of environmental factors on the tracheal mucosa.

Most studies investigating the endotracheal temperature and humidity in laryngectomized patients were performed in room climate conditions. Using the ACE equipment at room environment, it was found that the increase in end-inspiratory humidity was about 6 mgH₂O/L (see Chapter 3). The end-inspiratory temperature, however, decreased slightly, but significantly (-1.6 °C). Measurements in a cold (near freezing) environment already had revealed that the humidifying effect of an HME increases, and that the HME actually heats inspired air (in contrast to the cooling effect in room climate conditions). Not only in a cold, but also in a hot environment, the mucosa in the trachea in laryngectomized patients will also be at risk of drying out if it is dry outside. However, the effect of an HME in hot and dry climate conditions was not known. It was anticipated that an HME would not contribute anything in a hot and dry
climate as the environmental temperature are then almost equal to the climate in the trachea. During expiration water condenses on the surface of the HME material, if its temperature is sufficiently low. At temperatures at and above body temperature, therefore, condensation would seem unlikely. Interestingly, the study results (Chapter 4) revealed that an HME further humidifies the inspired (dry) air, even at temperatures above body temperature. The underlying cause is probably the water absorbing effect of the hygroscopic salt (such as calcium chloride), so that condensation may still occur even if the temperature is at or above body temperature. Evaporation of this conserved water during inspiration leads also to cooling of inspiratory air, which seems to be desirable in high environmental temperature. Based on these results, using HME devices also can be recommended in hot and dry environments.

If we compare the HME effect in cold, room and warm climate conditions, the effect of the HME appears to be almost linear, with a very strong heating at near freezing, and strong cooling at temperatures near body temperature. Both at low and at high environmental temperatures an HME enhances the effect of the trachea itself. In all climate conditions both the trachea and HME have an almost constant humidifying effect compared to the environmental humidity. Considering the end-inspiratory temperature, it was found that an HME enhances the effect of the trachea: an HME further warms inspired air in a cold environment (near freezing) and further cools in a warm environment (close to body temperatures). Unfortunately, the thus-far tested HMEs cool end-inspiratory air already at or probably even slightly below room temperature, which limits the possible humidification of the inspired air in most living conditions. Future HMEs, thus, should heat inspired air also at room climate conditions.

Basically, HMEs are designed as air conditioners, not as antimicrobial filters. However, for instance during flu epidemics an HME with appropriate filtration capacities may be desirable. For this reason, an HME in series with an antimicrobial filter was developed. Although the filtration layer of this F-HME (Provox® Micron HME) primarily was intended for antimicrobial filtering, it also appeared to be a very effective “preheater” of inspired air (Chapter 6). Interestingly, parallel to the increased end-inspiratory temperature, the amount of sputum production decreased already within 3-weeks of use. Although the antimicrobial effect of this HME on the decreased sputum production cannot be excluded, it seems more likely that this short-term positive clinical effect is more due to the
improved heating of inspired air than to the decreased exposure to airborne contaminants. One important limiting factor in this kind of HME design for laryngectomized patients was found to be its size as this HME is at least three times as large as the normal HME. Many laryngectomized disliked the shape and size as such that they did not want to use the Micron HME at all. Basically, any additional isolation layer will increase its size, potentially leading to cosmetic inconvenience and decrease in patient compliance. Another disadvantage of such construction is that an additional layer will increase breathing resistance. High breathing resistance leads to uncomfortable breathing (particularly during physical activities) and reduces patient compliance. From clinical experience, it is known that breathing resistance should be moderate (about 0.13–0.18 kPa.s/L) to achieve sufficiently comfortable breathing. Although normal upper airways (the nose in particular) provide higher breathing resistance (about 0.37 kPa.s/L), there is no unambiguous evidence that HMEs should also strive for such high breathing resistance. We have found that a moderate breathing resistance of about 0.18 kPa.s/L slightly increases tidal volumes (about 70 ml or 15%) (Chapter 5). Therefore, we suggest that a breathing resistance of an HME should be close to or at 0.18 kPa.s/L to keep this clinical beneficial effect and compliance optimal, but also provide HMEs with lower airflow resistance to optimize compliance for example during physical activities.

Improving the heat and moistening capacity of an HME device generally means that the mass of its basic material should be increased. The challenge was to increase the heat and moistening capacity of an HME without enlarging the dimensions and size of the HME, and without increasing the breathing resistance (i.e. enlarging the density of the foam material). Based on these considerations, the Provox® normal HME was redesigned, resulting in the XtraMoist HME with quite low breathing resistance (0.14 kPa.s/L) and the XtraFlow HME with even lower breathing resistance (0.06 kPa.s/L). The low breathing-resistance could be achieved by adding more hygroscopic foam material with somewhat larger pores. The space formerly taken by the spring mechanism for the speaking valve in the R-HME and L-HME was substituted with foam. The spring mechanism is now based on the recoil properties of the foam (Figure 6.1b). The in vivo measurements (see Chapter 7) show that the new generation HME devices indeed performed better than the earlier generation HMEs, with a further increase in humidification and without the decrease in temperature in room climate conditions of the former. This was substantiated in a 3-weeks clinical trial, showing a reduction in pulmonary complaints in 54%
of the patients. Figure 8.1 shows the result of these new devices together with the older ones and the target values. The end-inspiratory values for nose breathing (Chapter 2), are probably an underestimation, as discussed before, but the end-inspiratory temperature, the end-expiratory temperature, and the end-expiratory humidity values for nose breathing are realistic for head and neck cancer patients. It is thus obvious that the R-plus HME, although showing a considerable improvement in comparison with its predecessor, still does not compensate in full for the lost nose function.

**Figure 8.1** End-inspiratory and end-expiratory temperature (\(T_{\text{insp}}\) and \(T_{\text{exp}}\), respectively) and humidity (\(A_{\text{insp}}\) and \(A_{\text{exp}}\), respectively) values of different HMEs and open stoma (without HME). Also the target values (nose breathing in head and neck cancer patients with temporary tracheotomy) are shown in this Figure. The values for the various HMEs are given in relation to the R-HME values, which acted as the ‘reference’ HME in every study.

Summarizing we propose the following guidelines for the further improvements of HMEs:

1. The endotracheal temperature and humidity during HME breathing should try to close in to at least the end-inspiratory target values (31.1 °C and 29.3 mgH\(_2\)O/L).
2. The limiting factor for the humidifying capacity of an HME device is the heating capacity. The primary focus should be improving heat capacity, without enlarging the dimensions of the HME cassette or increasing the breathing resistance.

3. A breathing resistance of an HME of 0.13–0.18 kPa.s/L is sufficient. Even lower breathing resistance may be aimed at to achieve comfortable breathing even during physical activities.

4. In addition to these technical aspects, HME devices must be comfortable and (cosmetically) acceptable for daily use in laryngectomized patients. Generally, this implicates that the HME must be limited in size, weight, easy airtight closure needed for speech, changeable, disposable and affordable.