

# Randomized Controlled Trial on Postoperative Pulmonary Humidification After Total Laryngectomy: External Humidifier Versus Heat and Moisture Exchanger

Jean-Claude Mérol, MD; Anne Charpiot, MD; Thibault Langagne, MD; Patrick Hémar, MD;  
Annemieke H. Ackerstaff, PhD; Frans J. M. Hilgers, MD, PhD

**Objectives/Hypothesis:** Assessment of immediate postoperative airway humidification after total laryngectomy (TLE), comparing the use of an external humidifier (EH) with humidification through a heat and moisture exchanger (HME).

**Study Design:** Randomized controlled trial (RCT).

**Methods:** Fifty-three patients were randomized into the standard (control) EH (N = 26) or the experimental HME arm (N = 27). Compliance, pulmonary and sleeping problems, patients' and nursing staff satisfaction, nursing time, and cost-effectiveness were assessed with trial-specific structured questionnaires and tally sheets.

**Results:** In the EH arm data were available for all patients, whereas in the HME arm data were incomplete for four patients. The 24/7 compliance rate in the EH arm was 12% and in the HME arm 87% (77% if the four nonevaluable patients are considered noncompliant). Compliance and patients' satisfaction were significantly better, and the number of coughing episodes, mucus expectoration for clearing the trachea, and sleeping disturbances were significantly less in the HME arm ( $P < .001$ ). This was also the case for nursing time and nursing staff satisfaction and preference.

**Conclusions:** This RCT clearly shows the benefits of immediate postoperative airway humidification by means of an HME over the use of an EH after TLE. This study therefore underlines that HMEs presently can be considered the better option for early postoperative airway humidification after TLE.

**Key Words:** Total laryngectomy, postoperative airway humidification, external humidifier, heat and moisture exchanger, pulmonary rehabilitation.

**Level of Evidence:** 1a.

*Laryngoscope*, 122:275-281, 2012

## INTRODUCTION

Total laryngectomy (TLE) causes profound changes in the pulmonary physiology of the patient because the upper and lower respiratory tracts become permanently separated.<sup>1,2</sup> This precludes the normal conditioning and filtration of the inhaled air in the nose and pharynx, and allows unconditioned air to flow directly into the trachea.<sup>3</sup> Unconditioned in this respect means that

normal humidification and warming of the inhaled air no longer takes place,<sup>4</sup> and thus mostly significantly colder and dryer air will enter the trachea and bronchi, causing often bothersome pulmonary problems.<sup>5</sup> These consist of excessive phlegm production, involuntary coughing, and increased need to clear the airway from mucus by forced expectoration.<sup>2</sup> Clinical research has shown that these problems negatively effect many quality of life aspects and also negatively influence voice quality, irrespective of the mode of communication (prosthetic tracheoesophageal or esophageal voice).<sup>2</sup>

These effects of the changes in the pulmonary physiology will commence immediately after the TLE, and therefore it has become common practice to provide extraneous airway humidification directly following the surgery.<sup>3</sup> This underlines that most clinicians are well aware of the necessity to compensate for the loss of the upper airway function. In the far past, this was accomplished with an electric steamer in the room, but in the last decades mostly with an external humidifier (EH) consisting of an electrical heater and air-driven (often oxygen from a wall outlet) evaporator, directly applying moisturized and warmed air over a tube and a mask to the stoma. This is, unlike systems used in intubated patients,<sup>6</sup> an open system with little control over the actual amount of water applied to the breathing air. Moreover, compliance is troubled by the uncomfortable

From the Service d'ORL et de Chirurgie Cervico-Faciale, Hopital Robert Debré (J.-C.M., T.L.), Reims, France CHRU Hôpital de Hautepierre (A.C., P.H.), Service d'ORL et de Chirurgie Cervico-Faciale, Strasbourg, France, The Netherlands Cancer Institute (A.H.A., F.J.M.H.), Amsterdam, The Netherlands, Institute of Phonetic Sciences/ACLC University of Amsterdam (F.J.M.H.), Amsterdam, The Netherlands, Academic Medical Center (F.J.M.H.), University of Amsterdam, Amsterdam, The Netherlands.

Editor's Note: This Manuscript was accepted for publication on March 2, 2011.

Atos Medical AB, Sweden, provided the heat and moisture exchanger and cannula material for this study. The Netherlands Cancer Institute (employer of A.H.A. and F.J.M.H.) receives an unrestricted research grant from Atos Medical AB, Sweden. The authors have no other funding, financial relationships, or conflicts of interest to disclose.

All authors were involved in the conception and design of the project, analysis of the manuscript data, drafting or critically revising the content of the manuscript submitted for publication, and giving final approval of the version to be published.

Send correspondence to Frans J. M. Hilgers, MD, Netherlands Cancer Institute, Plesmanlaan 121, 1066CX Amsterdam, The Netherlands. E-mail: f.hilgers@nki.nl

DOI: 10.1002/lary.21841

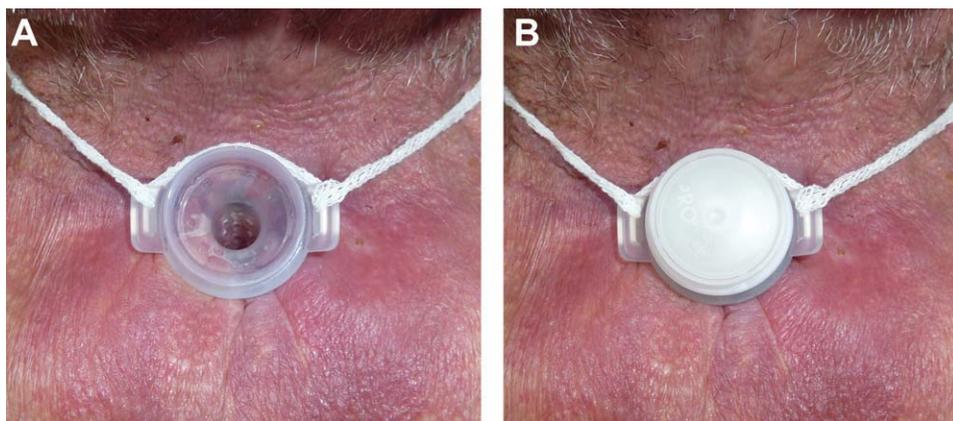


Fig. 1. (A, B) Patient postoperative with LaryTube and HME (Provox) and neck strap to keep the cannula in position.

24/7 noise production of these humidifiers when applied continuously, and by the necessity for the patient to remain at or at least close to the humidifying system, thus leaving the patient more or less bedridden.

To improve compliance and comfort, therefore, it would be beneficial to be able to use another means to humidify the lower airways immediately postoperatively, independent of a wall-mounted humidifier. Potentially, this could be achieved with a so-called heat and moisture exchanger (HME). Extensive clinical research, including several randomized clinical trials, has shown that HMEs have a positive influence on the aforementioned bothersome pulmonary problems and also improve quality of life and voice.<sup>7-10</sup> Moreover, it could be shown that by starting the use of HMEs as early as possible after total laryngectomy, these pulmonary problems can be significantly diminished and to some extent also prevented.<sup>11,12</sup> Furthermore, direct measurements of humidity in the trachea, right behind the HME, have shown that HMEs indeed significantly increase water content in the inhaled air.<sup>12,13</sup> This has led to the clinical practice in many head and neck departments to start with HMEs as early as possible after total laryngectomy. Often the HME is already applied to the stoma at the operation table before moving the patient to the ICU, replacing there the use of an EH.<sup>3</sup> Although this practice is already widespread in The Netherlands and several other European countries, thus far no studies have been carried out to substantiate that an HME clinically is at least equally effective as an EH for early airway humidification and/or comparable from a compliance point of view. Therefore, a prospective randomized controlled trial, comparing EHs and HMEs during postoperative hospital care, was conducted in two university teaching hospitals in France in collaboration with The Netherlands Cancer Institute. The results of this study with respect to compliance, pulmonary effects, cost-effectiveness, and patients' and nursing staff satisfaction and preferences will be presented.

## MATERIALS AND METHODS

### Patients

In total, 53 consecutive patients scheduled for TLE, 44 men and 9 women, with a mean age of 60 years (range,

40-81 years) participated in this multicenter, prospective, randomized controlled trial (RCT) between April 2006 and September 2007. Twenty-six patients were randomized for using the standard EH (control arm), and 27 patients were randomized for using an HME (experimental arm). The study was carried out in two teaching university hospitals in France: the Hôpital Robert Debré in Reims (N = 34) and the Hôpital de Hautepierre in Strasbourg (N = 19). Patients were randomized per study site. In 32 patients, voice prosthesis insertion was carried out as a primary procedure during the TLE, in one as a secondary procedure at a later date after the initial hospital stay, and in 20 patients no voice prosthesis was inserted. Eight patients were laryngectomized for recurrent disease after radiotherapy, and the other 45 were primary TLEs. There were no statistically significant differences with respect to age, gender, stage, voice prosthesis insertion, or radiotherapy between the two arms of the study. Following surgery all patients in both arms of the study used a soft silicon cannula (LaryTube; Atos Medical, Hörby, Sweden) with straps around the neck in their stoma (Fig. 1).

The study was approved by the local medical ethical committees, and all patients gave written informed consent. Patient data are summarized in Table I and the randomization specification in the Consort 2010 flow chart in Figure 2.

## Methods

**Trial-specific questionnaires and tally sheets.** Assessment concerning the short-term use and effects of each of the two pulmonary humidification systems was based on study-specific structured questionnaires and the use of tally sheets. One questionnaire addressed demographic data of each patient, information about radiotherapy, voice prosthesis, cannula use, and randomization. This questionnaire was completed by the nursing team and/or the physician immediately after the TLE. Tally sheets were used to keep a record on a daily basis of frequency of coughing and mucus expectoration, number of HMEs used, and nursing time spent on patient care related to the humidification device (including replacements of the device, suctioning, and skin care).

At discharge from the hospital (at approximately 12 days) the nursing team completed a final evaluation questionnaire concerning their preferences for either of the two airway-humidification systems. At discharge from the hospital, the patient also completed a final evaluation questionnaire related to the humidification system. These questions concerned daily life aspects (i.e., pulmonary problems such as coughing and mucus production, sleeping comfort, and mobility) in relation to the

TABLE I.

Clinical Data of the Patients Enrolled in the Randomized Clinical Trial on Postoperative Pulmonary Humidification After Total Laryngectomy.

	N = 53
Gender	
Male	44
Female	9
Age, yr	
Mean	60
Range	40–81
Institution	
Reims	34
Strasbourg	19
Randomization	
External humidifier	26
HME	27
Voice prosthesis	
Primary	32
Secondary	1
None	20
Radiotherapy	
Before TLE	8
Postoperative	30
No	14
Missing	1

HME = heat and moisture exchanger; TLE = total laryngectomy.

system used, compliance, practical aspects of the system and opinion about that.

### External Humidifier

The EH used was a regular medical device with a heater and a bottle containing sterile water, which was applied over a tube, a water droplet container, and a stoma mask (comparable to the system shown in Fig. 3).

### Heat and Moisture Exchanger

The HMEs used were the Provox Normal HME or the HiFlow HME (Atos Medical), the latter having a somewhat lower airflow resistance, making it more suitable for use in combination with a cannula.<sup>14</sup> The cannula was a soft silicone trachea cannula (LaryTube), which has a special retainer for application of the HME.

### Statistics

The analysis is mainly descriptive. Differences between means were assessed by means of the Student *t* test, and associations were measured by Pearson correlation coefficients. A 2-tailed *P* value <.05 was taken to indicate statistical significance.

## RESULTS

### External Humidifier (Control Arm)

The compliance with the EH system was low, with only 11 of the 26 patients in the standard arm using this

humidification system every day during the total hospital stay, and with only three of these 11 (12% of the total) using it continuously during the day and night (24/7). The remaining 15 patients used it every now and then during the day and/or night. The main reasons (more than one reason could be given) for not using the humidifier 24/7 reportedly were that it was too noisy (*n* = 17), was wetting clothing (*n* = 7), and/or was limiting patient's mobility (*n* = 18). The device was turned off during the night by 17 patients (63%) because the noise compromised their sleeping comfort.

With respect to the frequency of pulmonary complaints, 19 patients (73%) had two to 10 spontaneous coughing episodes per day, whereas two patients had 20, another two had 30, and one had 72 episodes a day (for two patients this information was missing). The mean frequency of mucus expectoration (deliberately coughing to clear the trachea from mucus) was 5.5 times per day (range, 0–15).

Patient satisfaction with this EH system was also quite low: only three patients reported that they were satisfied with it, two reported they liked it somewhat, and 21 patients (81%) reported that they did not like this system.

### Heat and Moisture Exchanger (Experimental Arm)

Of the 27 patients randomized for HME use, data were incomplete for four patients (due to early discharge, in one case due to a fistula, one or more questionnaires and/or tally sheets were missing), leaving 23 patients for proper evaluation in the HME arm.

The compliance in experimental arm was high, with all evaluable patients being compliant with every day use and with 20 of them (87%) using the HME 24/7. The other three patients (13%) used the HME irregularly during the day and/or night. Even when considering the four nonevaluable patients as completely noncompliant, the 24/7 compliance rate would have been 77% (20/26).

Numbers of HMEs used per day were available for 22 patients. Eighteen of them (82%) used one or two HME cassettes per day, and the remaining 4 patients used three to five HME cassettes per day. The average daily use was 1.74 HME cassettes per patient over the total hospitalization period. Eighteen patients (82%) used the HiFlow cassette, whereas four patients used the Normal filter cassette. Even though the breathing resistance of the Normal HME is somewhat higher than that of the HiFlow HME, none of the four patients using the Normal HMEs complained about shortness of breath, whereas three HiFlow users reported some problems in this respect.

With respect to the frequency of pulmonary complaints, the majority of patients (*N* = 21, 90%) had one to five spontaneous coughing episodes per day, whereas one patient had 10 and another one 20 of such episodes per day. The mean frequency of mucus expectoration (deliberately coughing to clear the trachea from mucus) was 2.5 times per day (range, 0–5.5).

Nineteen patients in the HME arm did not experience any sleeping discomfort over the hospitalization

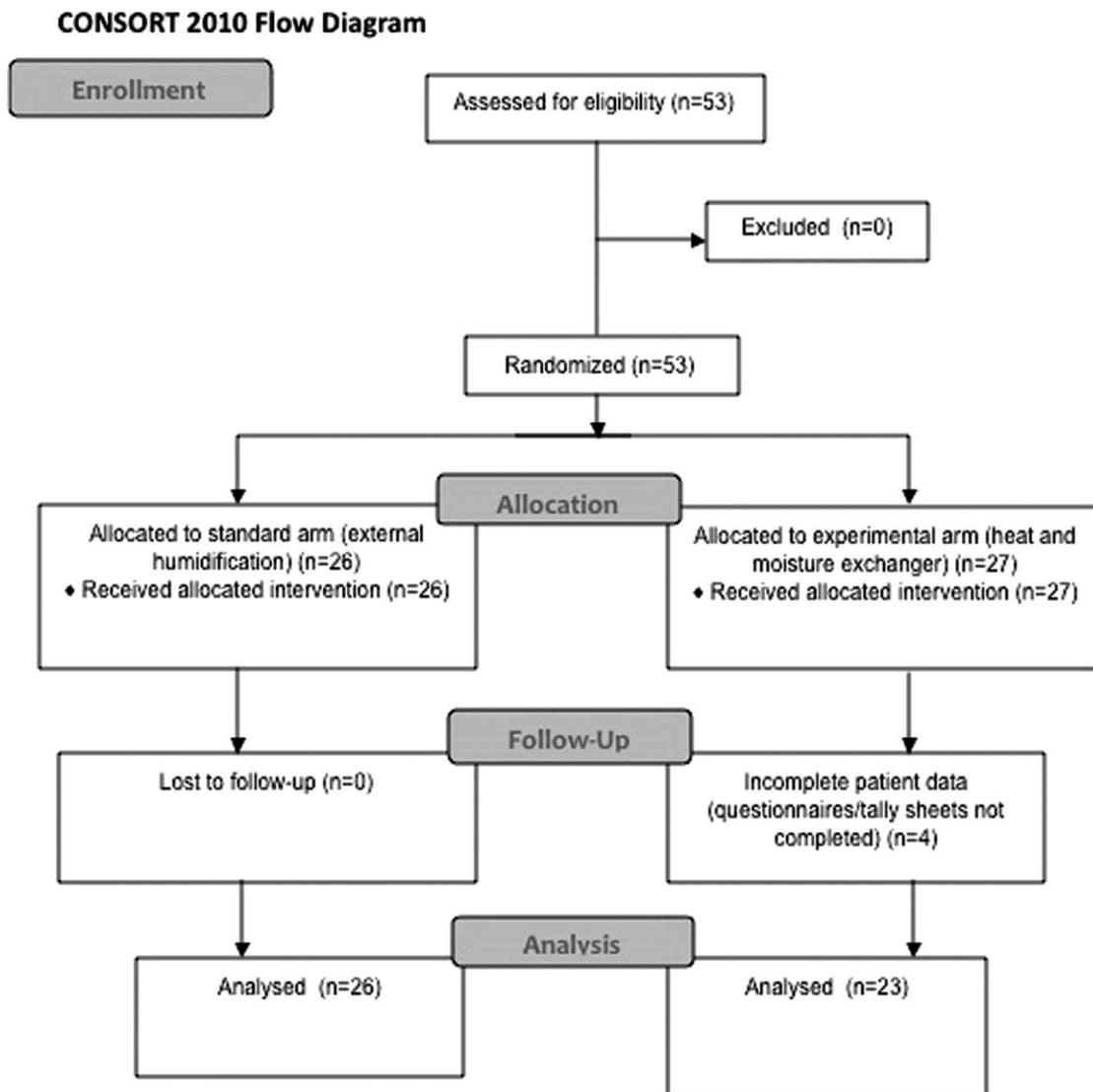


Fig. 2. Consort 2010 flow diagram of the study population of the randomized controlled trial on postoperative pulmonary humidification after total laryngectomy, comparing the use of an external humidifier with the application of a heat and moisture exchanger.

period, whereas four of them mentioned some sleeping discomfort (three a little and one quite a bit) due to obstruction by mucus and/or having to get used to the cannula and HME system. Only one of them removed the HME during the night. All 23 patients reported that they were satisfied with this humidification system.

A Student *t* test revealed that all outcome parameters, as shown in Table II, were significantly better (problems with coughing, phlegm expectoration, and sleeping; compliance; patients' and nursing staff satisfaction) in the HME arm than in the EH arm ( $P < .001$ ).

### Nursing Evaluation

The evaluation of the tally sheets completed by the nursing staff showed that patient care related to the EH took significantly more time than the care related to the HME (EH: mean 30 minutes per day; HME: mean 20 minutes per day,  $P < .001$ ). Moreover, all nurses

preferred the HME humidification system, and none of them favored the EH system.

### Humidification-Related Costs

With respect to the EH, the main costs come from the disposable parts of this system, which need to be replaced every 24 hours. The device controlling the oxygen mixture coming from the wall outlet especially is quite expensive (approximately €30). Total costs (if oxygen control device is not replaced every day, but only once during the hospitalization period) are calculated on €11.54 per day. With respect to the HME system, the actual cassettes cost between €1.92 (Normal HME) and €2.05 (HiFlow HME), which means that with an average of 1.74 cassettes per day the daily costs are between €3.34 and €3.57. The costs for the trachea cannula and the neck straps are similar in both arms. Thus, the daily costs for the HME system are considerably

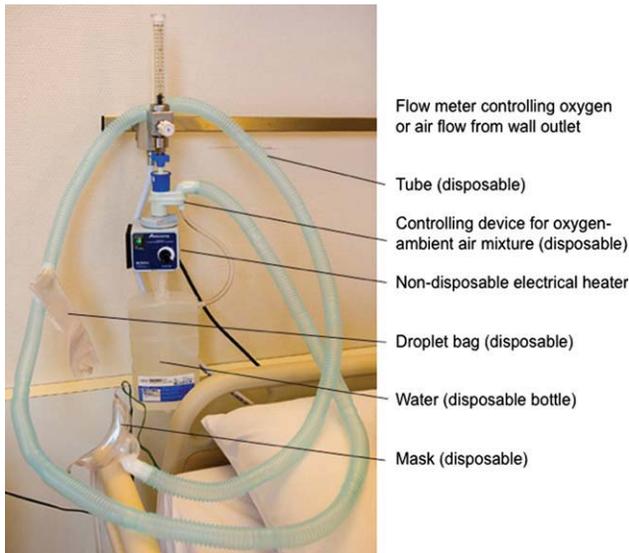


Fig. 3. Example of a widely used external humidifier system. The disposable attributes such as air-oxygen mixture controlling unit and the plastic parts (i.e., tube, droplet bag, water bottle, and mask) have to be replaced every 24 hours for infection prevention, resulting in much waist. The flow meter and the electrical heater are reusable.

lower than for the EH system, also in view of the significant reduction in nursing time from 30 to 20 minutes.

## DISCUSSION

This is the first RCT addressing airway humidification during the postoperative hospitalization after TLE, comparing the traditional use of an EH with the immediate postoperative application of an HME. The results of this trial show quite positive outcomes in favor of the application of an HME. The compliance with HMEs is significantly better considering the 87% 24/7 use with the HME compared to the only 12% with the EH. Furthermore, the use of an HME results in significantly fewer pulmonary complaints (fewer coughing episodes and less need for active mucus expectoration), better sleeping because noise disturbance does not play a role, and thus not surprising, a higher patient satisfaction. Moreover, HMEs appear to require less nursing time, and also therefore are preferred by the nursing staff. An obvious and additional reason for the higher patient satisfaction is that an HME does not keep the patient bedridden and therefore allows for earlier remobilization in the postoperative phase without compromising airway humidification. Also interesting is that despite the fact that an HME is a passive, nonheated humidifier,<sup>15</sup> whereas the open EH system used here actively provides moisturized and heated air, the former conditioning seems to be more effective in laryngectomized patients considering the significantly lower number of coughing and expectoration episodes.

This study fills the gap between the already existing evidence of the long-term necessity and benefits of restoring the lost nasal functions because of TLE by means of HMEs, and the earliest possible start with this

pulmonary humidification/rehabilitation method. Many studies, including several randomized phase III studies, most recently the study of Dassonville et al., already have substantiated the validity of this concept, lifting the prescription of HME up to level I evidence.<sup>8,10,15</sup> The present RCT underlines that in many respects it is also beneficial to start the application of HMEs immediately following TLE. It has to be stressed that this study was not designed to study potential effects on hospitalization time, reduction of short-term pulmonary infections, or use of antibiotics during the hospitalization period. Nevertheless, the clear reduction in pulmonary complaints at least suggests that (subclinical) infection pressure is most likely reduced by the early HME use, if not already because of the better compliance. Long-term reduction of pulmonary infections was already demonstrated in an RCT by Jones et al. in 2003.<sup>16</sup> Whether the short-term cost-effectiveness of using HMEs is also obtained long-term remains to be seen, but in view of all the present evidence it is very likely to be so.

Humidification of the airway after TLE still seems a somewhat underestimated issue. Most anesthesiologists nowadays agree that the airway in intubated patients needs to be humidified optimally, not only to prevent blockage of the tube with mucus, but primarily to improve the pulmonary condition of the patient.<sup>6</sup> Although the discussion about the relative benefits of active, closed humidifier circuits versus the use of passive humidifiers (i.e. HMEs) is not yet settled, one of these forms of humidification is considered mandatory for intubated patients.<sup>17,18</sup> Yet, for comparable patients with a short-circuited upper respiratory tract (i.e., TLE

	EH (n = 26)*	HME (n = 23)†
Compliance, no. (%)‡		
Daily use	11 (42)	23 (100)
24/7	3 (12)	20 (87)
Coughing, no. (%)‡		
1–5×	14 (58)	21 (90)
6–10×	6 (21)	0 (0)
>10×	6 (21)	2 (10)
Mucus expectoration‡		
Mean daily frequency	5.5	2.5
Range	0–15	0–5.5
Sleeping problems, no. (%)‡	20 (77)	4 (17)
Satisfaction, no. (%)‡		
Not favorable	21 (81)	
A little favorable	2 (8)	
Favorable	3 (11)	23 (100)
Nursing time involved in patient care*§	30 min/d	20 min/d

\*Reasons for irregular or nonuse (more options possible): too much noise, n = 17; wet clothing, n = 7; limitation to move around, n = 18.

†Four dropouts.

‡Significant advantage of HME over EH ( $P < .001$ ).

§All nurses had a preference for the HME system.

EH = external humidifier; HME = heat and moisture exchanger; 24/7 = continuous use during day and night.

patients), an open humidifier system or nothing at all still seems to be acceptable. The relevance of this RCT in this respect is that it pays attention to the important issue of airway humidification after TLE and it shows that an HME is at least equal and probably better than an open EH system in terms of improved compliance and reduction of postoperative pulmonary complaints.

An additional advantage of the immediate application of an HME instead of first applying EH is that it is accentuating for the patient the importance of this medical device in aftercare and pulmonary rehabilitation after TLE. This certainly enhances overall compliance, as could be shown before.<sup>19</sup> It familiarizes the patients in an early postoperative phase with this essential medical device, and enables the nursing staff to use the hospitalization time to counsel and instruct the patient properly. It also precludes patients getting used to breathing through an open stoma without any airflow resistance, which later on can decrease compliance with HME use because the patients need to get used to a (beneficial) higher breathing resistance again.<sup>20</sup> In this respect it is important to mention that, in general, a cannula like the LaryTube, which has an inherent airflow resistance, is used in combination with an HME with a slightly lower airflow resistance, such as the HiFlow HME.<sup>14</sup> This results in a combined airflow resistance comparable to that of the Normal Provox HME. The fact that, in this RCT, several patients had no problem of using the LaryTube in combination with the Normal HME underscores that immediate postoperative application of the HME does not require much adaptation to the HME in the first place, because the airflow resistance of the upper respiratory tract is still higher than that of the HME-LaryTube combination.<sup>20</sup>

In this study, the HME was used in combination with a soft silicone cannula (Provox LaryTube) with a neck strap, but it is also possible to use adhesive clips, which prevents unintentional compression of the vessels in the neck (especially of relevance in cases of free flap reconstruction).<sup>21</sup> When the stoma is stable, the HME can also be used in the postoperative phase without a cannula, by applying a hydrocolloid adhesive, suitable to be taped over the freshly operated/sutured stoma region, such as the Provox OptiDerm adhesive (Atos Medical).<sup>22</sup> Such an adhesive also keeps the stoma open because it stabilizes the peristomal skin, especially the cranial skin flap, which sometimes tends to be edematous and to bulge over the stoma.

As already mentioned in the Introduction, an increasing number of hospitals have used HMEs in the immediate postoperative phase for quite some years now. After the clinical proof of their effectiveness,<sup>11</sup> this immediate postoperative HME use was already introduced in The Netherlands in the mid-1990s at the Radboud Academic Medical Center Nijmegen (Professor H. Marres, personal communication), and subsequently adopted by many other head and neck centers in The Netherlands and throughout Europe. This RCT now has confirmed the soundness of this so far more or less subjective appraisal of the advantages of immediate postoperative HME humidification.

A potential advantage of the EH is that, when it is managed through the oxygen port of the wall outlet, any level of additional oxygen, if necessary, can be regulated through the oxygen-controlling device. However, oxygen also can be delivered over the HME by using a small catheter placed under the lid of the device or via a mask, with the added advantage that the oxygen will be humidified while passing through the HME material.

In addition to patient and nursing staff outcomes, the direct costs for humidification appear to be in favor of the HME system. Not only does it appear that HMEs save nursing time, but they also cut the daily costs by more than one half and produce considerably less waste, as can be deducted from Figure 2, when looking at all the disposables involved. It has to be taken into account that for this study the costs related to both systems for France were used, but these are most likely also valid for other European countries, such as The Netherlands and Germany, and also for the United States and Canada for that matter, where costs are quite similar.

Recently, a new generation HME (Provox XtraHME) has been developed that further improved humidification capacities in comparison to the HMEs used in this RCT.<sup>23</sup> It is conceivable that these would have shown an even greater difference in favor of HMEs over EH.

A limitation of this RCT is that data were incomplete for four patients (due to early discharge, in one case due to a fistula, and one or more questionnaires and/or tally sheets were missing), leaving only 23 patients for proper evaluation in the HME arm. Even when considering these patients as noncompliant, the 24/7 compliance rate is 77% and all outcomes are still in favor of the HME arm.

## CONCLUSION

This RCT clearly shows the benefits of immediate postoperative airway humidification by means of an HME over the use of an EH after TLE. Not only is compliance better, but there is also a reduction in pulmonary and sleeping problems, and higher patients' and nursing staff satisfaction. Moreover, there is a reduction in nursing time, costs, and waste production. This underlines that presently HMEs should be considered the better option for early postoperative airway humidification after total laryngectomy.

## Acknowledgments

Maya Bou Hayla, SLP, and Dana Kronick-Buttler, SLP (Atos Medical AB), are acknowledged for their dedicated study monitoring and help with data management.

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