

# The effect of a Heat and Moisture Exchanger (Provox<sup>®</sup> HME) on pulmonary protection after total laryngectomy: a randomized controlled study

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**Abstract** The goal of this randomized controlled study was to investigate the effect of Heat and Moisture Exchanger use on pulmonary symptoms and quality of life aspects in laryngectomized patients. Eighty laryngectomized patients were included and randomized into an HME and Control group. The effect of the HME was evaluated by means of Tally Sheets and Structured Questionnaires. The results showed a significant decrease in the frequency of coughing, forced expectoration, and stoma cleaning in the HME group. There were trends for the prosthetic speakers to report more fluent speech with the HME and for the HME group to report fewer sleeping problems. In conclusion, this study, performed in Poland, confirms the results of previous studies performed in other countries, showing that pulmonary symptoms decrease significantly with HME use and that related aspects such as speech and sleeping tend to improve, regardless of country or climate.

**Keywords** Total laryngectomy · Heat and Moisture Exchanger · Provox · HME · Pulmonary rehabilitation · Quality of life

## Introduction

Knowledge concerning the influence of the upper respiratory tract on the physiology of the entire respiratory system is well-documented [1–3]. Humidification of inhaled air, retention of a significant amount of water from exhaled air, balancing the optimal temperature of the air at the level of the lower respiratory tract, and filtration of inhaled air by trapping dust particles and microorganisms on the surface of the nasal mucosa, all support the defense mechanisms of the respiratory system and are for a significant part based on the mucociliary clearance function.

After total laryngectomy, the upper and lower airways are permanently disconnected and the patient breathes through a permanent tracheostoma. During normal nasal breathing, ambient air with a temperature of 22°C and 40% relative humidity (RH) is conditioned by the upper airways and reaches a temperature up to 32°C and RH up to 99% at the level of the trachea, thereby creating an optimal condition for the mucociliary clearance function of the tracheobronchial tree. The air with the same parameters inhaled through a tracheostoma reaches a temperature of 27–28°C and 50% RH at a level of the trachea, which significantly reduces mucociliary clearance [1, 4]. The loss of nasal function leads to impaired function of the cilia, thickening and crusting of the mucous, irritation of the mucosa of the tracheobronchial tree, and overproduction of mucosal secretions. This, in turn leads to a wide range of pulmonary complaints such as increased coughing and forced expectoration, excessive sputum production, crusting of the sputum and shortness of breath [5]. The symptoms increase during the first 6–12 months after permanent tracheostomy, and tend to stabilize later on [6]. The histological changes of tracheobronchial mucosa include squamous metaplasia of the ciliary epithelium and chronic

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inflammatory changes of the lamina propria of mucosal membrane [7]. In laryngectomized patients, lower respiratory tract infections significantly increase, especially during winter [5]. In normal individuals, clearing of the lower airways from secretions takes place instinctively, and with a minimal effort. This instinctive action in patients with tracheostoma often requires forceful coughing and subsequent cleaning of the stoma. These pulmonary symptoms, together with the loss of the natural voice, significantly reduce quality of life of laryngectomized patients [5, 8].

The use of Heat and Moisture Exchangers in laryngectomized patients as a treatment option for the pulmonary symptoms has become the gold standard of care in many countries. Various studies have demonstrated the positive effects of HME use on pulmonary function and tracheal climate [9–17]. HME use has been found to significantly reduce coughing, forced expectoration, and stoma cleaning and it has been found to have a positive effect on quality of life [9–11, 13–15]. Application of an HME changes the intratracheal temperature and humidity [16, 17]. With the use of an HME, water loss due to tracheostoma breathing is reduced from about 500 to 250–300 ml per day [18].

Only one of the clinical studies was randomized and included a control group [10], but the HME used in that study is not available anymore. In addition, this one randomized controlled study was carried out in early postoperative period, while HMEs are often applied in long-term laryngectomees as well. Thus, there is a need for randomized controlled studies that involve HMEs that are currently available on the market in long-term laryngectomees.

Therefore, we conducted a randomized controlled study on the effects of HME use in laryngectomized patients that are in long-term follow up (longer than 6 months post laryngectomy). The HME that was used in this study has shown to be clinically effective in several prospective studies in different countries and climates [12–15] and has shown to have a positive effect on intratracheal temperature and humidity [16]. The study was carried out during winter and in a group of patients that is representative of the typical Polish laryngectomized patient, mostly representing a group with low socio-economic status.

## Patients and methods

### Patients

In total, 80 laryngectomized patients were entered into the study and randomized for the HME ( $n = 40$ ) or Control ( $n = 40$ ) group. The patients in the Control group were all offered the option to try the HME system after the study was finished.

The study took place from December 2007 to February 2008. The average temperature at that time in Poland ranged from  $-1$  to  $+2^{\circ}\text{C}$  (29–35 degrees Fahrenheit). The age of the patients ranged from 38 to 80 years, with an average of 62 years. The time since surgery varied from 10 months to 31.25 years, with an average of 5 years. Male to female ratio was 68:12. Forty-nine patients had received postoperative radiotherapy, 11 had received radiotherapy as a primary treatment before salvage laryngectomy, and 20 patients had never received radiotherapy. Sixty-three patients were married and 17 were living alone. The majority of the participating patients were retired ( $N = 70$ ), eight were unemployed, and only two were full-time employed. Forty-five patients had elementary/high-school education level and 35 college or university. None of the patients had used HME's, foam pads or foam bibs before the study. Sixty-one patients used tracheoesophageal speech by means of a Provox<sup>®</sup> voice prosthesis as their main communication method, 14 used esophageal speech, and 5 used 'whispering' (i.e. mouthing words without sound production). In Table 1, the most important patient characteristics are presented.

### Methods

All patients were asked to record their daily number of coughs and forced expectorations during the first and the last week of the study on a Tally Sheet. In addition to the Tally Sheets, the patients completed structured questionnaires (adapted from the ones used in [10]) to report on stoma cleaning, shortness of breath, fatigue, sleeping problems, voice and speech, and psychological well-being. The patients in the HME group completed an additional Tally Sheet in the first and last week that recorded the amount of adhesives and HME cassettes that they used, and they answered a structured questionnaire about their compliance and experience with the HME system.

The HME System that was used in this study was the Provox HME System (Atos Medical, Hörby, Sweden, <http://www.atosmedical.com>). It contains porous foam treated with calcium chloride and a lid to facilitate stoma occlusion. The foam traps the heat and humidity from the exhaled air and thereby conditions the inhaled air.

The clinical investigation was approved by the Ethical Committee (National Oncology Center, Warsaw), and has been conducted in accordance with International and European Standard for Clinical Investigations (EN-ISO 14155-2:2003).

The primary outcome measures of the study were the changes in coughing and forced expectorations as recorded in the Tally Sheets. Factors that were considered when evaluating the effect of the HME were age of the patient, time since surgery, and compliance with the HME system.

**Table 1** Patient characteristics for all patients ( $n = 80$ ) and the Control and HME group separately

Characteristic	All patients	Control group ( $n = 40$ )	HME group ( $n = 40$ )
Age			
Range (years)	38–80	45–80	38–75
Average (years)	62	64	60
Post op follow up			
Range	10 months–31 years	11 months–26 years	10 months–31 years
Average (years)	5	5	5.5
Gender			
Male	68	38	30
Female	12	2	10
Radiotherapy			
Primary	11	4	7
Post op	49	25	24
None	20	11	9
Speech method			
Provox	61	31	30
Esophageal	14	4	10
‘Whispering’	5	5	0
Stoma cover			
Cloth bib	64	31	34
None	16	9	6

The structured questionnaires aimed to give some insight in other factors that might possibly be affected by HME use.

#### Statistical analysis

The compliance data obtained from the HME users were used to create two subgroups: one with fully compliant users who used the device day and night and one with reduced compliant users. The coughing and forced expectoration frequencies reported on the Tally Sheets were analyzed using Splus (Version 6.2, Insightful Corp). The expectation is that the frequencies will decrease with HME use over time, and as such, the interaction between time and HME use is included in the model. Two linear mixed effects models were constructed (one for coughing and one for forced expectorations) to examine the associations between these two variables and HME use. Possible confounders (patient age and time since total laryngectomy) were included in the models. The interaction with HME use was also included for these two confounders since they could possibly influence the response of the patient to HME use. To account for the skewed and clustered nature of the data, we respectively took the square-root transform of the outcome variables and used patient identifier as a grouping variable. All other analyses were carried out with SPSS Version 15.0. Mean, standard deviations, and range were computed for the reported frequencies of coughing, forced expectoration, stoma cleaning, and adhesives and cassettes

used. Frequency Tabulations were made for all questions separately. The separate questions regarding fatigue and depression were Likert items and after being tested for reliability by means of Cronbach’s alpha ( $\alpha > 0.70$ ; see [19]) they were summated into Likert scales that were used for further reporting. Paired  $t$  tests were carried out to compare the outcomes for the different aspects covered in the questionnaires within the Control group, within the HME group, and within the fully compliant and reduced compliant HME group. When available the summated Likert items were used for the tests. A  $P$  value below 0.05 was considered statistically significant.

## Results

### Compliance

Four patients (10%) dropped out of the study (those patients did not want to come in for the post-study questionnaire). Of those four patients, one patient was hospitalized for a recurrence, one could not use the HME due to anxiety when his stoma was covered, and two could not use the HME due to skin allergy/irritation from the adhesive. Since they refused to come in to complete the post study questionnaires, their results were excluded from analysis.

The remaining 36 patients had used the HME for 3 months. After a period of getting used to the HME, 25

patients (70%) used the HME on a daily basis and 18 of them used it day and night. Patients were asked whether they used the HME never, sometimes, often, or always during the day and during the night. Patients were considered compliant users when they used the HME day and night. For practical reasons such as skin irritation, some patients every now and then discontinued use of the HME during the night. This was not considered non-compliance. For further analysis, the patients were divided into a compliant and a non-compliant subgroup.

Based on this 'ideal compliance' which was based on the fact that normal individuals continuously enjoy the benefits of conditioning of the inhaled air by the upper airways, 18 patients (50%) were considered fully compliant and the other 18 (50%) were considered 'reduced compliant'.

#### Frequency of coughing and forced excretions—HME effect

All patients recorded their coughs and forced excretions during the first week and the last week of the trial. The results of the Tally Sheets show that the coughing frequency in week 1 for all patients together averaged 52 (SD 41) and the frequency of forced excretions averaged 53 (SD 44). In Table 2, the frequencies for coughing and forced excretions in the first and the last week, are shown for the Control group, the 'fully compliant' HME users and the 'reduced compliant' HME users.

As can be seen in Table 2, there is a slight reduction in the average coughing and forced excretion frequencies in the control group, a larger reduction in the 'reduced compliance' HME group, and a substantial reduction in the 'full compliance' HME group. As can be seen from the standard deviations and ranges in this Table, the variation among patients is large.

**Table 2** Coughing and forced excretions frequencies in week 1 and week 12 in different subgroups

	Control		HME			
	Week 1	Week 12	Reduced compliance		Full compliance	
	Week 1	Week 12	Week 1	Week 12	Week 1	Week 12
<b>Coughing frequency</b>						
Average	60	56	39	29	48	30
SD	41	37	27	22	48	21
Range	0–195	0–154	6–90	4–80	6–214	7–68
<b>Forced excretions</b>						
Average	59	53	37	28	56	27
SD	39	38	26	27	63	27
Range	7–177	7–189	10–110	2–101	0–284	0–98

Two linear mixed effects models were constructed (one for coughing and one for forced excretions) to examine the associations between these two variables and HME use. The results of both models were similar. In both cases, HME use causes a decrease in coughing and forced excretions ( $P < 0.001$  in both cases). This decrease is larger in patients with full HME compliance. Patients with reduced HME compliance have a reduction; however, this reduction is not significantly different from the control group. Older patients experienced more coughing and excretions than younger patients ( $P = 0.02$  for week 1 data,  $P = 0.0001$  for week 12 data). In the aspect of coughing and forced excretions there was no significant difference between patients that were shorter, versus longer after their surgery. There was no detectable association between the outcome variables and age and time since total laryngectomy, indicating that the HME effect is similar in older and younger patients and is not related to the time of living with the tracheostoma.

#### Questionnaires

All 80 patients entered into the study completed the baseline questionnaires. After 3 months, all patients, except the four (all from the HME group), who dropped out, completed the same questions again.

#### Stoma cleaning

At baseline, patients reported to clean their stoma on average 2.8 times per day (SD 1.8). Paired  $t$  tests between the baseline and follow up data showed no significant changes in the Control group. In the HME group, the number of times the stoma was cleaned per day decreased significantly [average 2.1 times per day (SD 1.2);  $P = 0.001$ ]. Paired  $t$  tests showed that this was significant both for the compliant group ( $P = 0.031$ ) and the non-compliant group ( $P = 0.013$ ).

#### Shortness of breath

The patients were asked about shortness of breath while climbing steps, walking, and while at rest. Both the HME users and the control group experienced a decrease in shortness of breath at rest. Paired  $t$  tests show that this is significant for both groups (HME group:  $P = 0.033$ ; Control Group:  $P = 0.006$ ). The HME users experienced a significant increase in shortness of breath while climbing steps ( $P = 0.012$ ). This is not unexpected, since the HME causes an objective increase in breathing resistance that the patient might experience during physical activity. Almost 60% of the patients indicated that they sometimes remove the cassette when they experience increased resistance.

### Fatigue

Fatigue was recorded on three Likert items that concerned feeling the need to rest, feeling weak, and feeling tired during the past week. Cronbach's alpha was 0.905 at baseline and 0.881 for the follow up data. Overall, most patients (about 80%) reported no or only a little fatigue problems. A paired *t* test did not show any differences in fatigue over time between the Control and the total HME group or between the full and reduced compliant HME users.

### Sleeping problems

With regards to sleeping problems, the patients were asked about waking up at night and the use of sleeping medication. In the control group, almost all patients (97.5%) had sleeping problems and this did not change over time. In the reduced compliant HME group, 89% of the patients had this problem at baseline and it was the same 3 months later. In the full compliance group, 79% of the patients had sleeping problems at baseline and 72% had this problem after 3 months. This reduction was not significant, but noteworthy: compliant use of an HME might reduce the need to cough during the night and therefore reduce waking up at night. At baseline, 27.5% of the patients in the control group used sleeping pills and they still used those 3 months later. In the HME group, 16.7% of the patients used sleeping pills at baseline, and only 11% used sleeping pills 3 months later.

### Voice and speech

The patients were asked to rate five different aspects of their speech (intelligibility, pitch, volume, fluency, and intelligibility over the phone), and overall voice quality. Paired *t* tests did not show a significant change in voice and speech aspects over time in the Control or the HME group. The HME group was analyzed in its entirety for the voice and speech aspects, since compliance is not expected to influence the aspects of speaking with the HME. Since not all patients in our study used a voice prosthesis to speak and since it is known that the HME contributes to maximum phonation time and dynamic range in prosthetic speakers [20], the group of patients ( $n = 61$ ) using a voice prosthesis was analyzed separately. Paired *t* tests on the voice and speech aspects for the prosthetic speakers in the Control and HME group, showed a trend for the prosthetic speakers to report more fluent speech with HME use ( $P = 0.073$ ).

### Psychological well being

The Likert scale for psychological well-being consisted of four items: feeling tense, worried, irritable, and depressed

during the past week. Cronbach's alpha was 0.813 at baseline and 0.800 at follow up. Most patients (80–90%) were reported no or only slight problems with anxiety and depression at baseline. Paired *t* tests showed that feelings of anxiety and depression had significantly increased in the Control group ( $P = 0.003$ ), but in the HME groups no significant changes in the feelings of anxiety and depression could be found.

### HME use

The usage of HME cassettes and adhesives decreased over time. During the first week of the study, on average 12.5 cassettes and 7.8 adhesives were used and during the last week on average 9.5 HME cassettes and 6.1 adhesives were used. The usage decreased for both products, as the patients learned how to apply the adhesives and secretions decreased. About half of the patients used a round shaped adhesive and the other half an oval shaped one. Most patients used a combination of various types of adhesives (Regular, Flexiderm, Optiderm, XtraBase). Only one patient used a LaryButton.

Table 3 shows the results that the HME users reported about their experience with the HME system. The reasons that patients gave for their problems with loosening or leakage of the adhesive were that they had a deep stoma, mucus was coming in between the adhesive and the skin, or a combination of both.

Overall, all HME users were very positive about their experience. All patients felt that they had benefitted from using the HME and all but one would use the HME if it were prescribed by their physician and were covered by insurance.

### Discussion

When discussing pulmonary symptoms in laryngectomized patients, one should keep in mind that most of them have coexisting impairments of unspecified protective mechanisms of the tracheo-bronchial tree, not only due to the loss of nasal function, but also due to impaired pulmonary function prior to the laryngectomy (i.e. most patients have been long-term cigarette smokers). The mechanisms of an unspecified protection of the tracheo-bronchial mucosa are then chronically impaired, which is especially evident during wintertime.

In our study, that was carried out during winter, frequency of coughing and forced expectoration decreased significantly in patients who used the HME for 3 months. This decrease was most significant in patients who used the HME day and night. The clinician plays an important role in educating the patient about the importance of

**Table 3** HME experience

Experience	
<b>Breathing</b>	
More difficult	52%
Equal	17%
Less difficult	31%
Removal of cassette when too high resistance is experienced	58%
<b>Speaking</b>	
More difficult	19%
Equal	31%
Less difficult	50%
<b>Stoma occlusion</b>	
Quite good–very good	100%
<b>Leakage of adhesive</b>	
Never	39%
Sometimes	57%
Often	4%
<b>Removal of adhesive painful</b>	
Not–a little	94%
Quite painful	6%
<b>Skin irritation</b>	
None–A little	77%
Quite a bit	17%
Very Much	6%
<b>Loosening of adhesive</b>	
Not–A little	89%
Quite often	11%
<b>Get used to HME</b>	
Average	3 to 4 days
Range	1 to 14 days
<b>Benefit from HME</b>	
Yes	100%
<b>Use HME if reimbursed</b>	
Yes	97%

compliance, and in supporting and advising the patient to overcome problems that may reduce compliance such as skin irritation and adhesion of the base plate. The importance of compliance has also been found in previous studies [11, 13]. In our study, 70% of the patients used the HME daily and 50% used it day and night, a similar outcome was found in previous studies using the Provox HME [13, 15]. The majority of laryngectomized patients in our study did have a deep stoma since we did not routinely perform additional surgical procedures during the total laryngectomy to create a flatter peristomal area. Some patients reported this as a problem for getting a good seal with the adhesive, but overall we did not record significant

problems with adhering the baseplate to the skin. Application of the adhesive requires some experience from the patient, but after a short time, they become an expert in their own particular case.

The structured questionnaires showed some changes in stoma cleaning, fluency of speech, waking up at night, anxiety, and depression. However, the changes were not as significant as in previous studies. The frequency of daily stoma cleaning, reflecting crusting and overproduction of mucosal secretions in the tracheobronchial tree, reduced significantly in the HME group. A trend showed fluency has improved in prosthetic speakers who use an HME. This is in concordance with earlier findings [11]. About half of the patients found speaking with the HME easier and all patients found stoma occlusion easier. Problems with waking up at night reduced in the fully compliant HME users, although not significantly. The results of our study with regard to the separate aspects of voice and speech, sleeping, and depression are not as evident as the results found by others. Compliant HME users in our study reported a reduction in waking up at night, but this was not significant. Previous studies have shown that seasonal fluctuations in pulmonary symptoms exist in laryngectomized patients [5, 21] and that pulmonary symptoms tend to decrease further with longer HME use and that psychosocial functioning tends to improve over a longer period of time [6]. Perhaps the pulmonary symptoms in the laryngectomized patients during our study that was carried out in a cold climate and during winter were quite severe at baseline and a longer HME use might have revealed more significant improvements in related aspects such as sleep, fatigue, depression and voice and speech. Interestingly, symptoms of depression increased significantly in the Control group while they remained constant in the HME group. There is no clear explanation for that, but it might be that patients in general show more symptoms of depression during the wintertime. This might have caused the increase of depressive mood in the Control group, whereas it was somehow prevented in the patients involved in the active part of the study (HME group). One important aspect that might also have caused the differences in results for the structured questionnaires compared to previous studies [10–15] is that we used Tally Sheets to record the frequencies of coughing and forced expectorations. For logistical reasons, we asked the patients to complete the Tally Sheets during the first and the last week of the study. Thus, at baseline the questionnaire was completed prior to the Tally Sheets and at follow up the order was reversed. This might have caused a more negative outlook at follow up. We recommend that in future studies the Tally Sheets and structured questionnaires should be in the same order at baseline and follow up.

## Conclusions

The results of our randomized controlled study in long-term Polish laryngectomized patients show that HME use significantly reduces pulmonary problems such as coughing and forced excretions. Compliance is crucial to achieve this reduction in symptoms. There are some trends showing that some quality of life aspects, like fluency of speech, ease of speech and stoma occlusion, sleeping, and feelings of anxiety and depression are positively affected by HME use.

**Conflict of interest statement** One of the authors, who had a consulting role in this study (last author *-blinded*) is part time employed at one of the Sponsors (*blinded*) The remaining authors do not have a financial relationship with the organization that sponsored the research.

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