Patients' experiences with HMEs and attachments after total laryngectomy

Macri, G.F.,* Bogaardt, H.,[†] Parrilla, C.,[‡] Minni, A.,* D'Alatri, L.,[‡] de Vincentiis, M.,* Greco, A.* & Paludetti, G.[‡]

*Universita degli Studi La Sapienza di Roma, Rome, Italy, [†]Speech Pathology, Faculty of Health Sciences, The University of Sydney, Sydney, Australia[‡]Universita Cattolica del Sacro Cuore di Roma, Rome, Italy

Accepted for publication 22 October 2015 Clin. Otolaryngol. 2016, **41**, 652–659

Objectives: The short-term and long-term beneficial effects of HME use by laryngectomees are well described in literature. In this study, we document how laryngectomised patients, who previously did not use an HME, get accustomed to the use of HME and attachments.

Participants: Thirty patients, who were at least 3 months post-laryngectomy and previously did not use an HME, were followed for 12 weeks and were asked to complete questionnaires about their experiences with the HME and attachments.

Results: Results show that when patients start using an HME, they report some difficulties with breathing resistance

Total laryngectomy causes significant anatomical changes that interfere with normal physiological processes. Separating the alimentary and respiratory tracts with the creation of a permanent stoma at the base of the neck precludes normal pulmonary driven voice and speech, and lack of a nasal airflow leads to olfaction and pulmonary problems.¹ To reduce pulmonary symptoms, such as involuntary coughing and excessive phlegm production, patients normally use a heat and moisture exchanger (HME).

The short-term and long-term beneficial effects of HME use by laryngectomees are well described in literature.^{2–4} Zuur *et al.* concluded that in a cold environment, the presence of an HME significantly increases both inspiratory and expiratory temperature and humidity values.² In a warm environment, however, the presence of an HME has a cooling effect on the temperature, while it still humidifies the inspired air.³ An earlier study by the same researchers on endotracheal temperature and humidity and tidal volumes in laryngectomised patients significantly improved tracheal climate when an HME was used.⁵ The study by Brook *et al.*

during the first 2 weeks of use. However, after 6 weeks, they have become accustomed to the breathing resistance and after 12 weeks over 96% reports that breathing was equal or less strenuous compared with breathing though an open stoma. Only a small proportion of patients experienced problems with increased coughing when starting HME use. **Conclusions:** This study provides insight in the way laryngectomised patients are experiencing the use of HMEs in the first weeks. These outcomes can contribute to a better knowledge of HME use by healthcare providers and help them to manage patient expectations and improving support to patients in achieving compliant HME use.

showed compliant HME users tend to make less use of external humidifiers and vaporisers, and have better pulmonary status and lower healthcare costs.⁴ The HME devices in these mentioned studies can be attached to the tracheostoma in two different ways: peristomally (base plate) or intraluminally (laryngectomy tube or stoma button). For peristomal attachment, the HMEs can be attached into a variety of available adhesives. Additionally, some patients may require the use of silicone glue to improve the seal of the adhesive to the skin.⁶ For intraluminal attachment, the HME device can be attached into a so-called laryngectomy tube or tracheostoma button.^{7,8} Many laryngectomised patients require a laryngectomy tube to maintain stoma patency, especially in the early post-surgical days and during postoperative radiotherapy. Some patients experience permanent problems with stoma patency, requiring permanent use of a laryngectomy tube.⁹ A recent study showed that 68% of long-term HME users only use one type of attachment of which 76% used adhesives and 24% used a laryngectomy tube or stoma button.⁴

A recent Spanish study showed that 78% of laryngectomised patients that were prescribed HMEs used the HME consistently, while 22% abandoned its use despite the wellknown beneficial effects of HME use. The most common causes of desertion were adhesion problems due to mucus

Correspondence: H. Bogaardt, SLP, PhD, Speech Pathology, Faculty of Health Sciences, The University of Sydney, 75 East Street, Lidcombe NSW 2141, Australia. Tel.: +61 2 9351 9334; Fax: +61 2 9351 9163; e-mail: hans. bogaardt@sydney.edu.au

and skin irritation.¹⁰ Van der Houwen *et al.* studied in detail (peri) stomal geometry data of a diverse population of laryngectomised patients in relation to adhesive use.¹¹ This study showed that there is a wide variation in (peri)-stomal anatomy, a wide variability in the use of stoma patches and a possible mismatch between the (peri) stomal anatomy and shape of the then available adhesive patches.¹¹ Therefore, their recommendation was that adhesives should be better designed to cover the wide variation of stoma anatomies, especially for patients with deeper stomas.

We hypothesised, however, that if compliance to HME use and attachments could be improved, one should investigate in detail how patients get accustomed to HMEs and attachments. Brook *et al.* describe that most patients learned about HME use from a speech language pathologist (50%) or a physician (42%) and over 98% stated that they had received instruction on how to use an HME.⁴ Next to this limited data, no studies have published data on the process of how patients get accustomed to HMEs and the problems they may encounter. In this study, we document how laryngectomised patients, who previously did not use an HME, get accustomed to the use of HME and attachments and we will discuss clinical implications.

Patients and methods

Patients

Patients were recruited at the Universita Cattolica del Sacro Cuore di Roma, Faculty of Medicine and Surgery 'Agostino Gemelli', and at the Universita degli Studi La Sapienza di Roma - Outpatient Clinic Umberto I. The study was approved by the relevant local Ethical Boards. All patients received written information and signed informed consent prior to inclusion. Included were adult laryngectomised patients with a stable pulmonary situation, who were longer than 3 months post-treatment and did not use an HME. Excluded were patients with decreased level of consciousness and patients with reduced mobility of arms and/or hands, unable to insert and remove an HME independently.

Methods

The study was carried out as a multicentre time-series design. The design of the study allowed the patients to act as their own control in order to reduce bias, allow for a control period, and eliminate possible climate effects. After consenting to participate in this study, all patients used the Provox XtraHME[™] (Atos Medical AB, Horby, Sweden) for 12 weeks in total. During these 12 weeks, data collection took place after using the HME for 2, 6 and 12 weeks. As there is to date no standardised questionnaire for the evaluation of the use of HMEs and attachments in laryngectomised patients, the questionnaire for this study had to be developed by the researchers themselves. The first set of questions about the patients' experiences with the XtraHME were based on the article by Bien *et al.*, where in a randomised controlled trial the effects of HME use was evaluated.¹² In this study, a limited number of questions were asked about the patients' personal experiences with the HME and nine questions were selected to evaluate the personal experience of the patients participating in this study.

Hilgers *et al.* evaluated patients' experiences with a novel adhesive¹ and four questions that were used in this study were selected from this publication. A fifth question was added and asked whether the patient had used an adhesive. For the patients' report of their pulmonary function, relevant questions used in the study by Herranz *et al.*¹³ were selected and eight questions were used in this study, totalling the number of questions in the questionnaire to 22 questions.

HME and attachments

During the 12-week intervention period, patients were provided with the two versions of the Provox[®] XtraHMETM: the XtraMoistTM HME Cassette, which can be worn day and night under normal physical effort, and the XtraFlowTM HME Cassette with a lower breathing resistance intended for use during physical activities. The XtraFlow can also be used during the period of getting used to the increased breathing resistance of the HME. To attach the HME to the stoma, a variety of available Provox[®] adhesives (Provox[®] OptidermTM, RegularTM, FlexidermTM, XtraBaseTM and StabiliBaseTM, Atos Medical AB, Horby, Sweden) were available for the patients. For intraluminal attachment, the LaryTubeTM or LaryButtonTM (Atos Medical AB, Horby, Sweden) was available.

All patients were provided with the possibility to use all different products in order to trial which would suit them best. To accommodate their choices and provide training on the different products, in the first 2 weeks of the intervention period, they were also seen by the speech language pathologist.

Statistical analyses

Statistical analysis was performed using IBM SPSS 21.0 (SPSS Inc., Chicago, IL, USA). Data analysis took place on base of the treatment-per-protocol principle. All analysed data are presented with mean, standard deviations and range of collected data. Reliability of the used questionnaire was determined by calculating Cronbach's alpha. All statistical tests are two-tailed and are evaluated with a 5% level of significance.

Results

Patients were included between April 2012 and July 2013. Forty-one patients were initially included (38 males, three females): twenty-one at the Universita Cattolica del Sacro Cuore di Roma, Faculty of Medicine and Surgery 'Agostino Gemelli' and twenty at the Universita degli Studi La Sapienza di Roma - Outpatient Clinic Umberto I. Eleven patients dropped out of the study. One patient did not want to change his daily care, one patient did not want to travel anymore for this study, one patient had a recurrence of cancer in the neck and was excluded, one patient underwent a secondary puncture during the study and was excluded from the study, one patient withdrew due to skin irritation from the used adhesive, three patients found participation in this study too demanding and three patients deceased prior to the end of the study (no relation to this study). Subsequently, the data of 30 patients (28 males, two females) were analysed.

Demographic data of the included patients are presented in Table 1. Average age at inclusion was 68.7 years old (SD \pm 11.2; range 40.8–90.3). Average time since laryngectomy was 51.7 months (SD \pm 56.5; range 4–223). Of these patients, 29 had undergone a neck dissection (26 bilateral, three unilateral). Four patients had undergone reconstructive surgery. Twenty-five patients had received radiotherapy (24 post-operative, one patient pre-operative) and 10 patients had received chemotherapy post-surgery. Ten patients had a voice prosthesis *in situ* at inclusion; seven patients used the Provox^{2TM}-prosthesis and three patients used the Provox[®] VegaTM.

| | n | % |
|---------------------------------------|-----------|----------------|
| Male | 28 | 93.3 |
| Female | 2 | 6.7 |
| Age in years (\bar{x} , SD, range) | 68.7 (±11 | .2; 40.8–90.3) |
| Time since laryngectomy | 51.7 (±56 | .5; 4–223) |
| $(\bar{x}, SD, range)$ | | |
| Neck dissection | | |
| No neck dissection | 1 | 3.3 |
| Unilateral neck dissection | 3 | 10.0 |
| Bilateral neck dissection | 26 | 86.7 |
| Reconstruction | | |
| Yes | 4 | 13.3 |
| No | 26 | 86.7 |
| Radiotherapy | | |
| No radiotherapy | 5 | 16.7 |
| Pre-operative/primary | 1 | 3.3 |
| Post-operative | 24 | 80.0 |
| Chemotherapy | | |
| No chemotherapy | 20 | 66.7 |
| Pre-operative/primary | 0 | 0.0 |
| Post-operative | 10 | 33.3 |

Table 1. Patients' characteristics (n = 30)

General perception and experiences with HMEs

The patients' experiences with the HME are presented in Table 2. Patients reported that (on average) it took them 6.8 days (SD \pm 6.1; range 0–24) to get used to the XtraHMETM. All patients used the HME during the 12-week intervention period for more than 20 h per day. Although a trend was visible in an increase of the number of hours of HME use over time (20.2, 21.1 and 22.2 resp.), a repeated measurements ANOVA revealed no statistical difference in the hours of use of the HME at 2, 6 and 12 weeks (P = 0.240).

During the intervention period, 23 patients (76.7%) started with the use of a combination of the XtraMoistTM and the XtraFlowTM, six patients (20.0%) started with the XtraFlowTM and one patient (3.3%) started with the XtraMoistTM. After 12 weeks, 19 patients (65.5%) still used a combination of XtraFlowTM and XtraMoistTM, seven patients (24.1%) used the XtraFlowTM only and three patients used the XtraMoistTM only (10.3%). During the intervention period, there was no significant change in the incidence of the use of the type of HMEs or in the use of a combination of both (P = 0.060).

At the start of HME use, 13 patients (43.3%) reported that breathing had become more difficult during use of the HME. Seven patients (23.3%) reported no changes and ten patients (33.3%) found breathing through the HME less difficult. After 12 weeks, only one patient (3.4%) found it more difficult to breathe through the HME, seven patients (24.1%) felt no difference and 21 (72.4%) patients found breathing through the HME less difficult (P = 0.002). The number of patients that sometimes would remove the HME when breathing became too difficult dropped from an initial 22 (73.3%) to seven (24.1%) after 12 weeks (P = 0.001).

Noise coming from the HME when breathing was noticed by nine patients (30.0%) at the start of HME use. After 12 weeks of HME use, only three patients (10.3%) reported noise when breathing (P = 0.037).

A majority of patients rated their appearance with an HME consistently better or equal to their appearance with an open stoma with no significant changes over the 12 weeks (P = 0.088). Throughout the 12 weeks, a large majority of patients consistently found breathing through an HME more hygienic than through an open stoma after 2 weeks of HME use (P = 0.203). Twenty-five patients (83.3%) rated the use of an HME to cover the stoma as 'pleasant' after 2 weeks with a non-significant increase to 96.6% after 12 weeks (P = 0.165).

Initially, six patients (20.0%) had a little difficulty in placing the HME into the holder. At the end of the study, this number dropped to one patient (3.4%) (P = 0.251). The main reason to replace an HME with a new one was when it was saturated with secretions. This reason was reported by 21

| Table 2. | Patients' | experiences | with | the | XtraHME |
|----------|-----------|-------------|------|-----|---------|
|----------|-----------|-------------|------|-----|---------|

| | 2 week | s | 6 weeks | s | 12 wee | ks | Р |
|---|----------------|----------------|------------|------|--------|-------|-------------------|
| Do you like your appearance better or w | orse? | | | | | | |
| Better | 18 | 60.0 | 22 | 78.6 | 14 | 48.3 | 0.088^{*} |
| Worse | 0 | 0.0 | 0 | 0.0 | 2 | 6.9 | |
| Same | 12 | 40.0 | 6 | 21.4 | 13 | 44.8 | |
| Pleasant or unpleasant to cover your stor | na by means | of this HME | ? | | | | |
| Unpleasant | 1 | 3.3 | 0 | 0.0 | 0 | 0.0.0 | 0.165* |
| The same | 4 | 13.3 | 2 | 6.7 | 1 | 3.4 | |
| Pleasant | 25 | 83.3 | 28 | 93.3 | 28 | 96.6 | |
| Do you find breathing through the HME | more hygie | nic than an op | oen stoma? | | | | |
| Not at all | 2 | 6.7 | 0 | 0.0 | 0 | 0.0 | 0.203^{\dagger} |
| A little | 1 | 3.3 | 1 | 3.3 | 0 | 0.0 | |
| Quite a bit | 5 | 16.7 | 5 | 16.7 | 5 | 17.2 | |
| Very much | 22 | 73.3 | 24 | 80.0 | 24 | 82.8 | |
| Do you hear noise coming from the HM | E when you | are breathing | | | | | |
| Yes | 9 | 30.0 | 2 | 6.7 | 3 | 10.3 | 0.037^{*} |
| No | 20 | 66.7 | 28 | 93.3 | 25 | 86.2 | |
| Don't know | 1 | 3.3 | 0 | 0.0 | 1 | 3.4 | |
| Has your breathing with using the HME | been easier of | or more diffic | ult? | | | | |
| More difficult | 13 | 43.3 | 3 | 10.0 | 1 | 3.4 | 0.002^{*} |
| Equal to without HME | 7 | 23.3 | 8 | 26.7 | 7 | 24.1 | |
| Less difficult | 10 | 33.3 | 19 | 63.3 | 21 | 72.4 | |
| Do you sometimes remove the HME who | en breathing | becomes too | difficult? | | | | |
| Yes | 22 | 73.3 | 10 | 33.3 | 7 | 24.1 | 0.001^{*} |
| No | 8 | 26.7 | 20 | 66.7 | 22 | 75.9 | |
| Do you have problems inserting the HM | E into/onto | the placehold | er? | | | | |
| Not at all | 24 | 80.0 | 26 | 86.7 | 28 | 96.6 | 0.251^{+} |
| A little | 6 | 20.0 | 3 | 10.0 | 1 | 3.4 | |
| Quite a bit | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | |
| Very much | 0 | 0.0 | 1 | 3.3 | 0 | 0.0 | |
| Do you have problems removing the HM | IE from the | placeholder? | | | | | |
| Not at all | 26 | 86.7 | 27 | 90.0 | 27 | 93.1 | 0.659^{\dagger} |
| A little | 4 | 13.3 | 3 | 10.0 | 2 | 6.9 | |
| A bit | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | |
| Very much | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | |
| What is the main reason for you to repla | ce an HME | with a new on | e? | | | | |
| Routine replacement every 24 h | 5 | 17.9 | 10 | 34.5 | 8 | 27.6 | 0.320* |
| When it is blocked with secretions | 21 | 75.0 | 16 | 55.2 | 19 | 65.5 | |
| For increased breathing resistance | 2 | 7.1 | 3 | 10.3 | 2 | 6.9 | |

*Related samples Friedman's two-way analysis of variance by ranks.

[†]Rep. measurements ANOVA.

patients (75.0%) at the start of the study and reduced to 65.5% at the end of the study; however, this change was not significant (P = 0.320).

Patients' experiences with adhesives

At the start of the intervention period, three patients (10.0%) used the Regular adhesive, nine patients (30.0%) used the FlexidermTM adhesive, six patients (20.0%) used the OptiDermTM adhesive, one patient (3.3%) used

StabiliBaseTM and ten patients (33.3%) used other attachments, like the LaryButtonTM (one patient) and the LaryTubeTM (nine patients). All data regarding the use of adhesives are presented in Table 3. None of the patients used a combination of adhesives. At the end of the study, only six patients (20.7%) still used the LaryTubeTM and none of the patients used a LaryButtonTM. The number of patients that uses an adhesive to attach the HME increased from 18 (60.0%) at the start to 24 patients (82.8%) after 12 weeks (P = 0.014).

Table 3. Patients' experiences with attachments

| | 2 w | veeks 6 weeks | | reeks | 12 weeks | | Р | |
|--------------------------|--------|---------------|-------|--------|----------|------|-------------------|--|
| Did you use an adhesive? | | | | | | | | |
| Yes | 18 | 60.0 | 19 | 63.3 | 24 | 82.8 | 0.014^{*} | |
| No | 12 | 40.0 | 11 | 36.7 | 5 | 17.2 | | |
| Removal of adhesi | ive p | ainful? | | | | | | |
| Not at all | 8 | 44.4 | 5 | 26.3 | 13 | 54.2 | 0.331^{\dagger} | |
| A little | 9 | 50.0 | 11 | 57.9 | 9 | 37.5 | | |
| Quite a bit | 0 | 0.0 | 2 | 10.5 | 1 | 4.2 | | |
| Very much | 1 | 5.6 | 1 | 5.3 | 1 | 4.2 | | |
| Non-applicable | 12 | | 11 | | 6 | | | |
| Troubled by skin i | irrita | tion du | ie to | adhesi | ve | | | |
| Not at all | 9 | 50.0 | 7 | 36.8 | 16 | 66.7 | 0.525^{+} | |
| A little | 6 | 33.3 | 11 | 57.9 | 7 | 29.2 | | |
| Quite a bit | 1 | 5.6 | 0 | 0.0 | 0 | 0.0 | | |
| Very much | 2 | 11.1 | 1 | 5.3 | 1 | 4.2 | | |
| Non-applicable | 12 | | 11 | | 6 | | | |
| Did adhesive loos | en w | hen co | ughii | ıg? | | | | |
| Not at all | 11 | 64.7 | 10 | 52.6 | 20 | 83.3 | 0.166^{\dagger} | |
| A little | 2 | 11.8 | 6 | 31.6 | 4 | 16.7 | | |
| Quite a bit | 3 | 17.6 | 3 | 15.8 | 0 | 0.0 | | |
| Very much | 1 | 5.9 | 0 | 0.0 | 0 | 0.0 | | |
| Non-applicable | 13 | | 11 | | 6 | | | |
| Did adhesive stick | well | to the | skin | ? | | | | |
| Not at all | 2 | 11.8 | 2 | 10.5 | 1 | 4.2 | 0.029^{+} | |
| A little | 2 | 11.8 | 4 | 21.1 | 0 | 0.0 | | |
| Quite a bit | 9 | 52.9 | 8 | 42.1 | 9 | 37.5 | | |
| Very much | 4 | 23.5 | 5 | 26.3 | 14 | 58.3 | | |
| Non-applicable | 13 | | 11 | | 6 | | | |

*Related samples Friedman's two-way analysis of variance by ranks.

[†]Rep. meas. ANOVA.

At the start of the study, two patients (11.8%) reported that the adhesive did not stick well to the skin, while at the end of the study this was only the case in one patient (4.2%) (P = 0.029).

Other questions regarding the use of adhesives showed no statistical differences between 2, 6 and 12 weeks. Initially, 35.5% experienced problems with loosening of the adhesive when coughing, which reduced to 16.7% at the end of the study (P = 0.166). At the start of the study (when 18 patients used an adhesive), the removal of the adhesive was not all painful or a little painful in 17 patients (94.4%). After 12 weeks of HME use (when 24 patients used adhesives), 22 patients reported the removal of the adhesive was not at all painful or a little painful (91.7%; P = 0.331). Nine patients (50.0%) reported no skin irritation due to the adhesive at the beginning of HME use. At the end of the study, 16 patients (66.7%) did not report any skin irritation, seven (29.2%) a little irritation and one patient (4.2%) very much irritation (P = 0.525).

Table 4. Patients' report on pulmonary function

| Compared to the start of the study | 2 weeks 6 weeks | | 12 weeks | | P^{*} | | | |
|---|-----------------|----------|----------|--------|---------|-----------|----------|--|
| Did the air you breathed in feel more or less warm? | | | | | | | | |
| More | 17 | 56.7 | 21 | 72.4 | 21 | 72.4 | 0.294 | |
| Less | 5 | 16.7 | 2 | 6.9 | 2 | 6.9 | | |
| Same | 8 | 26.7 | 6 | 20.7 | 6 | 20.7 | | |
| Did you have more | e or l | ess trac | heal | drynes | s/irr | itation? | | |
| More | 18 | 60.0 | 1 | 3.4 | 1 | 3.4 | 0.013 | |
| Less | 12 | 40.0 | 23 | 79.3 | 24 | 82.8 | | |
| Same | 0 | 0.0 | 5 | 17.2 | 4 | 13.8 | | |
| Did you have more | e or l | ess drie | ed up | mucu | s/cru | ists in y | our | |
| trachea/stoma? | | | _ | | | | | |
| More | 3 | 10.0 | 2 | 6.9 | 2 | 6.9 | 0.273 | |
| Less | 20 | 66.7 | 27 | 93.1 | 23 | 79.3 | | |
| Same | 7 | 23.3 | 0 | 0.0 | 4 | 13.8 | | |
| Did you have more | e or l | ess mu | cus p | roduc | tion? | | | |
| More | 1 | 3.3 | 2 | 6.9 | 2 | 6.9 | 0.368 | |
| Less | 21 | 70.0 | 22 | 75.9 | 23 | 79.3 | | |
| Same | 8 | 26.7 | 5 | 17.2 | 4 | 13.8 | | |
| Did you have to cle | ear yo | our airv | vays | more o | or les | s often l | by means | |
| of deliberate, force | eful | coughi | ng? | | | | | |
| More | 4 | 13.3 | 1 | 3.4 | 1 | 3.4 | 0.895 | |
| Less | 19 | 63.3 | 23 | 79.3 | 22 | 75.9 | | |
| Same | 7 | 23.3 | 5 | 17.2 | 6 | 20.7 | | |
| Did you cough mo | re or | less of | ten? | | | | | |
| More | 3 | 10.0 | 2 | 6.7 | 0 | 0.0 | 0.337 | |
| Less | 19 | 63.3 | 25 | 83.3 | 26 | 89.7 | | |
| Same | 8 | 26.7 | 2 | 6.7 | 3 | 10.3 | | |
| Was coughing more or less difficult? | | | | | | | | |
| More | 2 | 6.7 | 1 | 3.4 | 1 | 3.4 | 0.336 | |
| Less | 18 | 60.0 | 21 | 72.4 | 22 | 75.9 | | |
| Same | 10 | 33.3 | 7 | 24.1 | 6 | 20.7 | | |
| Did you have to clean the stoma more or less often? | | | | | | | | |
| More | 5 | 16.7 | 2 | 6.9 | 2 | 6.9 | 0.807 | |
| Less | 15 | 50.0 | 22 | 75.9 | 21 | 72.4 | | |
| Same | 10 | 33.3 | 5 | 17.2 | 6 | 20.7 | | |

*Related samples Friedman's two-way analysis of variance by ranks.

Patient experience with the effect of HMEs on pulmonary function

After two, six and 12 weeks of XtraHMETM use, patients were asked to compare their present situation (i.e. with the XtraHMETM) to their previous situation (i.e. without the XtraHMETM). When asked whether patients had more or less tracheal dryness/irritation, after 2 weeks, 18 patients (60.0%) reported less irritation and 12 patients (40.0%) reported no changes. After 12 weeks, 24 patients (82.8%) reported less irritation, four patients (13.8%) reported no changes and one patient (3.4%) reported more irritation (P = 0.013) (Table 4).

After 2 weeks of HME use, 19 patients reported less coughing (63.3%) compared with the baseline period. In the following visits (after resp. six and 12 weeks of XtraHMETM use), the patients did not reported any further change in coughing (P = 0.337). This was also seen for difficulty with coughing: 60.0% of the patients reported less difficulty after 2 weeks of XtraHMETM use and throughout the rest of the study there were no changes (P = 0.336). Patients reported less mucus production and less frequent cleaning of the stoma after 2 weeks of XtraHMETM use.

Overall, when asked after 12 weeks of use, 17 patients (60.7%) were 'very satisfied' with the use of the XtraHMETM, and 11 patients (39.3%) were 'satisfied' with the use of the XtraHMETM. None of the patients was dissatisfied with the XtraHMETM. Sixteen patients (55.2%) responded that they would continue to use the XtraHMETM after the study has ended, 13 patients (44.8%) responded that they would continue to use the XtraHMETM after the study has ended but only could do so if the use of the XtraHMETM is reimbursed. None of the patients stated that they would not like to continue with the use of the XtraHMETM.

As the direction of the questions in each of the three tables was different, it was not possible to calculate Cronbach's alpha as a measure of reliability over the total questionnaire. Analysis showed that the reliability using Cronbach's alpha of the questions presented in Tables 2, 3 and 4 was 0.565, 0.226 and 0.791 respectively.

Discussion

Although the effects of the use of an HME has been described in the literature, describing both short-term^{2,14} and longterm^{4,15} positive effects on pulmonary function, so far no indepth study has been conducted how patients get accustomed to these products. This is the first attempt to describe patients' experiences when starting with HMEs after laryngectomy.

Our data show that in the first 2 weeks, patients will experience some discomfort of HME use like experiencing an increased breathing resistance (reported by 43% of our patients) and the need to remove the HME when breathing becomes too difficult (reported by 73%). However, after 6 weeks of HME use, patients seem to be more accustomed to the HME and after 12 weeks only one patient (3%) reported that breathing was more difficult with the HME. Interestingly, after 12 weeks of HME use over 70% of the patients reported that breathing with an HME is easier than breathing through an open stoma (P = 0.002). An explanation might be that an HME (partially) restores the breathing resistance of the nose and restores normal lung function, allowing the patient to breathe more in accordance with normal physiology. HMEs have been shown to

show significant improvements in inspiratory flow and volume values following use of the HME,¹⁶ making it easier for the patient to breathe. However, our data suggest that a patient will need 6 weeks to experience this effect. The findings that over time breathing is experienced to be easier, are similar to the findings by Bien *et al.*¹² and Brook *et al.*⁴ who both reported this long-term effect in compliant HME users. Merol *et al.* found in their study that patients who use an HME experience better sleep as well.¹⁶ In our study, patients reported easier breathing through an HME after 6 weeks of HME use, which would be an explanation for the results found by Merol, as easier breathing during the night most likely will correlate to a better sleep.

There are some limitations to this study, as this study solely describes a cohort of patients without the use of control group. Based on the studies by Bien *et al.*¹² and Dassonville *et al.*¹⁷ (with a maximum follow-up time of 12 weeks), one could argue that our inclusion criterion of minimum of 3 months after laryngectomy would provide this study with a cohort of stable patients.

Another limitation is that no specific and validated questionnaire investigating the experience of laryngectomised patients with HMEs and attachments exists yet. Although the questions were developed by experienced speech language therapists and ENT surgeons with numerous years of experience with laryngectomised patients, the psychometric validity of the questions, as presented in this study, might be questioned. When interpreting the reliability analysis, one should take in account that Cronbach's alpha is highly influenced by the test length and dimensionality.¹⁸ This would suggest that a very short number of questions (like Table 3 with four questions only) inevitably will result in a low alpha, making the result of the reliability analysis not lower than we expected for this number of questions per construct. However, the results of this study suggest the need for the development for a psychometric valid tool to evaluate this specific area of care for laryngectomised patients.

The data also show that, after 2 weeks of HME use, only a small proportion (10%) of all patients report to cough more. After 6 weeks, this number drops and after 12 weeks none of the patients report to cough more; almost 90% reports to cough less compared to the time when they did not use an HME. None of the patients reported that they coughed more. Our experience is that clinicians tend to tell patients that when they start using an HME, collected mucus in the airways might come loose and patients might experience a higher coughing frequency which will decrease in time. Our data suggest that this phenomenon exists, but only in a small proportion of patients. The vast majority of patients will experience a lower or equal coughing frequency from the beginning of HME use.

Based on our findings, it is recommendable that regular follow-ups by a speech language pathologist are scheduled in the first weeks after the start of HMEs as some patients report in the first weeks that they hear noise coming from the HME and a small proportion reports minor skin irritation. In a follow-up, the speech language pathologist should evaluate whether the patient needs another type of attachment (OptiDermTM adhesive or LaryTubeTM) if skin irritation occurs. Also, in the follow-up, the patients' technique of occluding the HME when speaking can be evaluated in order to reduce any concomitant noise coming from the HME when speaking. Also, our data show that patients in the first 2 weeks will have difficulty with the attachment of the adhesive to the skin. After 12 weeks, only one patient reported problems, showing that there is a learning curve for patients in the appliance of adhesives and from our clinical experience, support by a speech language pathologist could help the patient in learning how to attach an adhesive optimally.

The data from this study provide more insight in the way patients are experiencing the use of HMEs in the first weeks after commencing to use these products. These outcomes can contribute to a better knowledge of HME use by healthcare providers and help to provide better information to patients on what they might expect when they start using HMEs. Based on our findings, it is recommendable that patients that start using HMEs have regular follow-ups in the first weeks, as in the first weeks the patient might experience some problems (especially with attachment of adhesive to the skin, unnecessary replacement of HME because due to non-removal when coughing and in some cases minor problems with skin irritation).

Conclusion

When patients start using an HME, they may report in the first 2 weeks after start some difficulties with breathing resistance. However, after 6 weeks patients are generally accustomed to the breathing resistance and over 96% reports after 12 weeks of HME use that breathing is equal or less strenuous compared with breathing though an open stoma. A small proportion of patients (10%) experiences problems with more coughing when starting with an HME; in the weeks following the start of HME use, the coughing frequency will be lower than it used to be. Although over 80% used an adhesive as attachment, in the first weeks of HME use, patients tend also to use an intraluminal attachment. In the first weeks, patients can experience problems with attaching the adhesive to the skin; however, after 12 weeks of use, over 95% will not have any problems. Only a small proportion of the patients (4%) will experience skin irritation at any stage of adhesive use.

Keypoints

- When starting with HMEs only a small proportion of patients will experience breathing difficulties.
- After 6 weeks patients are accustomed to HME use.
- In the first two weeks patients might experience some problems with attachments and is supervision by a therapist recommended.

Acknowledgments

The authors acknowledge Atos Medical AB, Sweden, for providing the devices used in this study.

Conflict of interest

None declared.

Reference

- 1 Hilgers F.J., Dirven R., Wouters Y. *et al.* (2012) A multicenter, prospective, clinical trial evaluating a novel adhesive baseplate (Provox StabiliBase) for peristomal attachment of postlaryngectomy pulmonary and voice rehabilitation devices. *Laryngoscope* **11**, 2447–2453
- 2 Zuur J.K., Muller S.H., Vincent A. *et al.* (2009) The influence of a heat and moisture exchanger on tracheal climate in a cold environment. *Med. Eng. Phys.* **7**, 852–857
- 3 Scheenstra R.J., Muller S.H. & Hilgers F.J. (2011) Endotracheal temperature and humidity in laryngectomized patients in a warm and dry environment and the effect of a heat and moisture exchanger. *Head Neck* **9**, 1285–1293
- 4 Brook I., Bogaardt H. & van As-Brooks C. (2013) Long-term use of heat and moisture exchangers among laryngectomees: medical, social, and psychological patterns. *Ann. Otol. Rhinol. Laryngol.* **6**, 358–363
- 5 Scheenstra R.J., Muller S.H., Vincent A. *et al.* (2010) Influence of breathing resistance of heat and moisture exchangers on tracheal climate and breathing pattern in laryngectomized individuals. *Head Neck* 8, 1069–1078
- 6 Hilgers F.J., Ackerstaff A.H., Balm A.J. *et al.* (1996) A new heat and moisture exchanger with speech valve (Provox stomafilter). *Clin. Otolaryngol. Allied Sci.* **5**, 414–418
- 7 Barton D., DeSanto L., Pearson B.W. *et al.* (1988) An endostomal tracheostomy tube for leakproof retention of the Blom-Singer stomal valve. *Otolaryngol. Head Neck Surg.* **1**, 38–41
- 8 Hilgers F.J. & Ackerstaff A.H. (2006) Development and evaluation of a novel tracheostoma button and fixation system (Provox LaryButton and LaryClip adhesive) to facilitate hands-free tracheoesophageal speech. *Acta Otolaryngol.* **11**, 1218–1224
- 9 Ward E.C., Acton L.M. & Morton A.-L. (2007) Chapter 11. Stoma care and appliances. In *Head and Neck Cancer: Treatment, Rehabilitation, and Outcomes,* Ward E.C. & van As-Brooks C.J. (eds), pp. 289–311. Plural Publishing, San Diego

- 10 Pedemonte-Sarrias G., Villatoro-Sologaistoa J.C., Ale-Inostroza P. et al. (2013) Chronic adherence to heat and moisture exchanger use in laryngectomized patients. Acta Otorrinolaringol. Esp. 4, 247–252
- 11 van der Houwen E.B., van Kalkeren T.A., Post W.J. *et al.* (2011) Does the patch fit the stoma? A study on peristoma geometry and patch use in laryngectomized patients. *Clin. Otolaryngol.* **3**, 235–241
- 12 Bień S., Okła S., van As-Brooks C.J. *et al.* (2010) The effect of a Heat and Moisture Exchanger (Provox HME) on pulmonary protection after total laryngectomy: a randomized controlled study. *Eur. Arch. Otorhinolaryngol.* **3**, 429–435
- 13 Herranz J., Espiño M.A. & Morado C.O. (2013) Pulmonary rehabilitation after total laryngectomy: a randomized cross-over clinical trial comparing two different heat and moisture exchangers (HMEs). *Eur. Arch. Otorhinolaryngol.* **9**, 2479–2484
- 14 Zuur J.K., Muller S.H., de Jongh F.H. et al. (2006) The physiological rationale of heat and moisture exchangers in post-laryngectomy

pulmonary rehabilitation: a review. *Eur. Arch. Otorhinolaryngol.* 1, 1–8

- 15 Ackerstaff A.H., Hilgers F.J., Aaronson N.K. et al. (1993) Improvements in respiratory and psychosocial functioning following total laryngectomy by the use of a heat and moisture exchanger. Ann. Otol. Rhinol. Laryngol. 11, 878–883
- 16 Mérol J.C., Charpiot A., Langagne T. *et al.* (2012) Randomized controlled trial on postoperative pulmonary humidification after total laryngectomy: external humidifier versus heat and moisture exchanger. *Laryngoscope* 2, 275–281
- 17 Dassonville O., Mérol J.C., Bozec A. *et al.* (2011) Randomised, multi-centre study of the usefulness of the heat and moisture exchanger (Provox HME[®]) in laryngectomized patients. *Eur. Arch. Otorhinolaryngol.* 11, 1647–1654
- 18 Tavakol M. & Dennick R. (2011) Making sense of Cronbach's alpha. Int. J. Med. Educ. 2, 53–55