The use of tracheostoma humidification by people with total laryngectomy in the UK: a cross-sectional survey.

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Abstract

Objectives: To investigate the use of tracheostoma humidification by people with total laryngectomy (PTL) in the UK and explore influencing factors. Design: National cross-sectional survey and case note review. Setting: 26 UK National Health Service (NHS) centres providing care to PTL. Participants: PTL reviewed by speech and language therapy (SLT) between March and September 2020. Methods: Secondary analysis of data collected during a national multi-centre audit of PTL completed in response to the Covid-19 pandemic. Data were collected on type of humidification used by PTL and demographic information. Type of humidification was dichotomised as 'HME' (closed-system heat moisture exchanger) or 'non-HME' (alternative stoma cover or no stoma cover). Univariable analysis was performed to determine the association with several potential explanatory variables including gender, age, living circumstances, distance from treatment centre, communication method and time elapsed since laryngectomy. A backwards selection procedure was used to determine the final model for multiple regression analysis. Results: Data were obtained from 1216 PTL from 26 centres across the UK; information on type of tracheostoma humidification used was available for 1097 PTL. Most PTL (69%) used an HME. Following multiple regression analysis, time elapsed since laryngectomy (p=<0.001), living circumstances (p=0.002) and communication method (p=<0.001) were statistically significant factors in HME use. Conclusion: In the UK, most PTL follow recommendations to use a closed-system HME, though there is marked variability across centres. HME use is influenced by time elapsed since laryngectomy, living circumstances and communication method.

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Conclusion: In the UK, most PTL follow recommendations to use a closed-system HME, though there is marked variability across centres. HME use is influenced by time elapsed since laryngectomy, living circumstances and communication method.

Key words

total laryngectomy, humidification, neck-breathers, tracheostoma, stoma covers, HMEs

Key points

- PTL are advised to wear a closed-system heat moisture exchange system (HME) to optimise pulmonary health.
- Across the UK, 69% of PTL use a closed-system HME. This figure can be used as a benchmark for UK services.
- There is significant variability in HME use across treatment centres which may indicate inequity of service across regions.
- Factors influencing HME use include time elapsed since surgery, living circumstances and communication method.
- Findings may indicate a need for targeted education regarding pulmonary health for specific groups of PTL and their carers.

INTRODUCTION

People with total laryngectomy (PTL) have a permanent separation of the trachea and oesophagus and rely on a surgically created neck tracheostoma to breathe. This altered anatomy results in a loss of filtering and humidification capacity of the upper airways and consequent reduced respiratory resistance. The detrimental impact of this on pulmonary health is well-established, with increased bronchial secretions and reduced mucociliary clearance resulting in increased risk of chest infections, reduced respiratory capacity and negative effects on quality of life^{1,2}. Additionally, the permanent tracheostoma leaves PTL at risk of airway invasion by airborne particles or foreign bodies. PTL are advised to use a tracheostoma cover to protect the airway and to optimise pulmonary health.

A number of different tracheostoma covers are available: simple covers with no humidification properties (e.g. scarves); foam-based covers or bibs that offer some humidification³; closed-system heat moisture exchange (HME) devices comprising a filter cassette secured with an adhesive baseplate or laryngectomy tube (Figure 1). Closed-system HMEs have been available on prescription in the UK since the mid-1990s and are now considered the gold standard for humidification for PTL. UK guidelines recommend the use of HME as soon as possible post-surgery⁴ and initiation of HME use at day one post-surgery has been reported⁵.

While closed system HMEs are more expensive than alternative stoma covers³, the benefits are well recognised including reduced coughing, shortness of breath, mucous production, plug formation and chest infections^{5,6,7}. There is a correlation between duration of HME use and pulmonary benefit⁸. HME use has been found

to significantly enhance quality of life for PTL⁹, and can offer PTL with surgical voice restoration (SVR) improved digital occlusion for voicing and better speech intelligibility^{8,9}.

Despite evidence of efficacy, variable compliance rates with HME use have been reported, from 35% to $83\%^{10,5}$. Reported reasons for resistance to HME use include excessive mucus production, blockage of the filter and poor baseplate seal⁶. In some healthcare systems the financial burden of HME use may be a barrier³. Additional factors that could influence use of HME include patient age, time elapsed since surgery, neck contour, and the recommendations from different health services, clinicians and patient communities.

With the onset of the Covid-19 pandemic in March 2020, PTL were thought to be a high-risk group for contracting and transmitting Covid-19 infection through respiratory droplet formation and aerosolisation due to their altered airways^{11,13}. This paper reports on the use of tracheostoma covers as reported by patients and/or their clinicians during a UK-wide audit of PTL during the first UK national lockdown period. The audit was initiated in response to queries regarding the specific risks associated with Covid-19 for PTL. Data on shielding, hospital admission and mortality have been reported previously¹³. The objectives of the current paper are to report on the following:

The usage of tracheostoma covers by PTL in the UK, specifically use of a commercially available closedsystem HME (termed "HME" for this analysis) versus all alternatives (termed "non-HME" for this analysis).

The factors that may influence HME use by PTL in the UK.

Based on literature and clinical experience, we postulate the following factors may influence HME use in the UK: age, gender, time elapsed since surgery, distance from the treating centre, employment status, living circumstances and primary communication method.

METHODS

This paper has been prepared with reference to the STROBE checklist for cross-sectional studies.

2.1. Ethical considerations

The Health Research Authority decision tool (*http://www.hra-decisiontools.org.uk/research/*) identified the project as service evaluation, which was approved by the Applied Health in Cancer Governance Group at the lead NHS site. Individual sites sought local approval to share data. A data flowchart is attached as supplementary information.

2.2 Study design and setting

A national multi-centre audit of PTL was completed in response to the Covid-19 pandemic over a six-month period (March to September 2020). The background and development of the project has been described in detail previously¹³. This is a secondary analysis of data collected during the audit.

2.3 Participants

All PTL under the care of participating centres were eligible for inclusion. Data were collected during the six-month period on PTL who were reviewed by SLT either in person or via telehealth during the first national lockdown.

2.4 Data collection

Data were obtained via case note review and survey questions. A data capture worksheet (devised in Excel, password protected and encrypted) was used to collect data. Personal identifying information was minimised as advised by the information governance team. Verbal patient consent was obtained whenever possible.

Data were collected on the potential explanatory variables described above. The type of tracheostoma cover used was recorded at two time points: before the onset of the Covid-19 pandemic (time point 1) and during

the six-month period of data collection (time point 2). This paper reports on data collected from time point 1 to describe HME use among PTL in the UK before the onset of Covid-19. Data on incidence of Covid-19 infection, hospital admission and shielding advice were also collected and have been reported previously¹³. Detailed analysis of factors influencing primary communication method will be reported independently of this paper.

2.5 Data analysis

Analyses were carried out using SPSS for Windows. A univariable analysis was initially performed to evaluate the association between each potential explanatory variable and HME use, using Pearson's chi-square test for categorical variables and the two-sample t-test or Mann-Whitney U test for continuous variables. Logistic regression analysis was conducted to examine the association of selected variables with HME. A backwards selection procedure was used to determine the final model (criteria for entry p<0.05 and for removal p>0.1). The overall fit of the model was ascertained using the Hosmer and Lemeshow goodness of fit test.

RESULTS

3.1 Participants

Twenty-six centres across England and Wales submitted data for analysis. Data were collected on a total of 1216 PTL. Details of the participating centres and patient demographics are described in previous work¹³.

3.2 HME vs non-HME use

Data on type of tracheostoma cover were available for 1097 PTL. The majority (n= 835, 69%) used a closedsystem HME. A range of alternative tracheostoma covers was used by 17% (n=219). Only four percent (n=43) were recorded as not using a tracheostoma cover (Table 1). For subsequent analysis PTL were grouped into HME users (n= 835, 69%) or non-HME users (n=262, 21%). One hundred and nineteen (10%) PTL were excluded from further analysis due to missing data. Patient demographics are illustrated in Table 2.

There was marked variation in the number of cases submitted for analysis and the percentage of PTL using HME across centres (Figure 2). In two centres (centres 1 and 19) 95% of PTL used a closed-system HME. However, in four centres (3, 5, 13 and 26) less than 50% did so. The amount of missing data also varied across centres. Centre 1 submitted the largest number of cases (n=110) and also reported the highest HME use, while centre 26 submitted only 3 cases with only 1 patient (33%) using an HME. Centre 13 had the lowest HME use at 28% (n=12), but also had a large amount of missing data (n=16, 37%).

3.3 Factors associated with HME use

In univariable analysis, age (p=0.02), gender (p=0.01), time elapsed since surgery (p<0.0001), living circumstances (p=0.01) and communication method (p<0.0001) demonstrated significant differences between HME users and non-HME users. Distance from the treating centre (p=0.92) and employment status (p=0.19) were not significant factors.

Following multiple regression analysis, time elapsed since surgery (p<0.001), living circumstances (p=0.003) and communication method (p<0.001) remained statistically significant (Table 3). Time elapsed since surgery was longer for non-HME users than for HME users (median 108 months vs 59 months). Only 42% of PTL living in a care facility used an HME, compared with 77% of those living with someone or alone. SVR users were more likely to use an HME than non-SVR users (80% vs 65%).

DISCUSSION

This is a novel study exploring HME usage among PTL in the UK. It reports secondary analysis of data obtained in the UK national audit of PTL carried out during the first national Covid-19 lockdown. To our knowledge this is the largest audit of current practice in the management of PTL and provides an important opportunity for benchmarking. Our findings show that the majority of PTL (69%) included in the audit used a closed-system HME. While this is a lower proportion than has been quoted in previous studies⁵, HME

usage varied across centres from 28% to 95%. The centre with the largest number of cases also reported the highest HME use, while many of those centres with lower HME use also reported higher levels of missing data. This may reflect SLT capacity and resources at those centres, and such variability may indicate inequity of service across regions.

Although age was significant at univariable analysis, this was not retained following multivariable analysis indicating that older PTL are not disadvantaged in access to pulmonary rehabilitation. Similarly, although males demonstrated higher use of HME than females (78% vs 69%) this was not significant in multivariable analysis. Employment status and distance from the treating centre were not significant, suggesting that these factors do not impact on access to rehabilitation and advice or influence decision-making around humidification.

Factors found to be significantly associated with HME use in multivariable logistic regression were time elapsed since surgery, living circumstances and primary communication method.

4.1 Time elapsed since surgery

Average time post-surgery was 96 months, range 0-578 months. PTL who were longer post-surgery were less likely to use an HME. Adherence to HME use is improved with early introduction¹⁴, therefore PTL who had surgery since closed-system HMEs have been widely available on prescription are perhaps more likely to have commenced early use and be ongoing HME users than those who had surgery before this time. Average time elapsed since surgery for PTL with non-HME in our study was nine years, and as HMEs have been available on prescription since the mid-1990s it is clear that other factors are also involved.

4.2 Living circumstances

Although previous studies have looked at factors that might predict discharge destination following laryngectomy¹⁵, as far as we are aware no study has looked at the impact of living circumstances on HME use. We found that PTL living in a care facility were significantly less likely to use an HME which may relate to wider issues around the complexity of adherence to healthcare recommendations in care facilities¹⁶ and has important implications for the pulmonary health of this vulnerable group. Given HME use involves specialist intervention and ongoing use of specialist consumables, it may be that lower usage in care facilities indicates a need for training and therapeutic input in this setting. Further investigation is warranted.

4.3 Communication method

It is recognised that a closed-system HME supports improved digital occlusion for voicing and better speech intelligibility for SVR users^{8,9}, therefore it may be expected that PTL with SVR are more likely to use an HME. This is consistent with our findings. This highlights the importance of pulmonary rehabilitation for non-SVR users, who may receive less direct SLT intervention over time than those PTL receiving regular input for voice prosthesis management.

4.4 Limitations of the study

This study reports on a range of factors that may influence HME use, however there are additional factors that may account for the variability identified. In order to optimise participation in the audit a limited data set was selected, inevitably leading to a series of unknowns. For example, we did not collect data on duration of HME use. Full adherence is considered to be [?]20 hours per day¹⁷ and various factors could influence this. We did not collect data on barriers to HME use, whether HMEs are suitable for all PTL or on which MDT member takes responsibility for pulmonary rehabilitation at each centre. These factors could be explored in future work.

There was an amount of missing data in our study. It is not clear whether this was due to pressure on the services providing data, reduced contact with PTL due to the Covid-19 pandemic or other factors.

4.5 Future directions

Several professional organisations produced guidelines during the Covid-19 pandemic that may have influenced advice given to patients regarding humidification, including advice regarding the use of specialist viral filter HMEs^{11,12,18}. A survey of PTL in the USA¹⁹ found that more patients reported self-initiated changes to their HME use due to the pandemic than their clinicians had advised. We note however that the ability of closed-system HMEs to protect users against SARS-CoV-2 has not been demonstrated. The current study presents data on HME use in the UK pre-Covid-19 (time point 1). Future work could investigate behaviour change as a result of the pandemic. The impact of social factors that may outweigh clinician advice, such as the impact of marketing, social media and peer influence¹⁹, could also be explored.

For the purpose of current analysis, PTL were divided into those using a commercially available closed-system ("HME") and all others ("non-HME"). However, some researchers have found bibs to be superior to closed-system HMEs in terms of humidity and temperature³. Future work could explore factors associated with the use of non-HMEs.

Our study identified marked variability in HME use across the UK, with some centres reporting much higher HME use than others. The underlying reasons for variation in practice could be examined to support equity of access to pulmonary rehabilitation across centres.

Current findings suggest there may be education and training needs around pulmonary rehabilitation for PTL who are less likely to use an HME, such as those who are longer post-surgery, those living in care facilities, and non-SVR users. This paper supports the need to target education and training to ensure equity of access to pulmonary rehabilitation for all PTL.

CONCLUSIONS

Across the UK, most PTL follow advice to use a closed-system HME to maximise pulmonary health after surgical alteration to their upper airway. Use of HMEs varies across participating treatment centres but was found to be primarily impacted by certain factors: time elapsed since surgery (PTL with a shorter time since surgery were more likely to use an HME), living circumstances (PTL living in a care facility were less likely to use an HME than those living alone or with someone) and primary communication method (SVR users were more likely to use an HME than PTL without SVR). The national average of 69% of PTL using an HME serves as a benchmark for UK services. Education and training should be targeted to ensure equity of access to pulmonary rehabilitation for all PTL.

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Figure 1: Types of tracheostoma cover.

Figure 2: HME vs non-HME use by centre.

REFERENCES

- Maurizi M, Paludetti G, Almadori G, Ottaviani F, Todisco T. Mucociliary Clearance and Mucosal Surface Characteristics before and after Total Laryngectomy, Acta Oto-Laryngologica, 1986: 102 (1-2): 136-145
- 2. Guye C. On the Function of the Nose in Respiration. The Journal of Laryngology and Rhinology, 1887: 1(1), 41-43
- 3. Quail G, Fagan JJ, Raynham O, Krynauw H, John LR, Carrara H. Effect of cloth stoma covers on tracheal climate of laryngectomy patients. *Head & Neck*. 2016 Apr;38 Suppl 1:E480-7

- Clarke P, Radford K, Coffey M, Stewart M. Speech and swallow rehabilitation in head and neck cancer: United Kingdom National Multidisciplinary Guidelines. *The Journal of Laryngology & Otology*. 2016; 130:176-180
- 5. Ebersole B, Moran K, Gou J, Ridge J, Schiech L, Liu JC, Lango M. Heat and moisture exchanger cassettes: Results of a quality/safety initiative to reduce postoperative mucus plugging after total laryngectomy. *Head Neck*. 2020 Sep;42(9):2453-2459
- 6. Jones AS, Young PE, Hanafi ZB, Makura ZGG, Fenton JE, Hughes JP. A study of the effect of a resistive heat moisture exchanger (trachinaze) on pulmonary function and blood gas tensions in patients who have undergone a laryngectomy: a randomized control trial of 50 patients studied over a 6-month period. *Head & neck* 2003 May; 25(5):361–367.
- Scheenstra RJ, Muller SH, Vincent A, Ackerstaff AH, Jacobi I, Hilgers FJ. Short-term endotracheal climate changes and clinical effects of a heat and moisture exchanger with an integrated electrostatic virus and bacterial filter developed for laryngectomized individuals. *Acta Otolaryngol*. 2010 Jun;130(6):739-46
- 8. Ackerstaff AH, Hilgers FJM, Balm AJM, Bin Tan I. Long-term compliance of laryngectomzed patients with a specialized pulmonary rehabilitation device: Provox Stomafilter. *The Laryngoscope*. 1998 Feb; 108(2):257-260.
- Ackerstaff AH, Fuller D, Irvin M, Maccracken E, Gaziano J, Stachowiak L. Multicenter study assessing effects of heat and moisture exchanger use on respiratory symptoms and voice quality in laryngectomized individuals. *Otolaryngol Head Neck Surg*. 2003 Dec; 129(6):705-12
- Lorenz KJ, Maier H. Pulmonale Rehabilitation nach totaler Laryngektomie durch die Verwendung von HME (Heat Moisture Exchanger) [Pulmonary rehabilitation after total laryngectomy using a heat and moisture exchanger (HME)]. Laryngorhinootologie . 2009 Aug;88(8):513-22. German
- Kligerman MP, Vukkadala N, Tsang RKY, Sunwoo JB, Holsinger FC, Chan JYK, Damrose EJ, Kearney A, Starmer HM. Managing head and neck cancer patients with tracheostomy or laryngectomy during the COVID-19 pandemic. *Head Neck.* 2020 Jun;42(6):1209-1213
- Varghese JJ, Aithal VU, Rajashekhar B. Self-care and clinical management of persons with laryngectomy during COVID-19 pandemic: a narrative review. Support Care Cancer. 2021 Dec;29(12):7183-7194
- Govender R, Behenna K, Brady G, Coffey M, Babb M, Patterson JM. Shielding, hospital admission and mortality among 1216 people with total laryngectomy in the UK during the COVID-19 pandemic: A cross-sectional survey from the first national lockdown. Int J Lang Commun Disord. 2021 Aug 5;56(5):1064–73
- Pedemonte-Sarrias G, Villatoro-Sologaistoa JC, Ale-Inostroza P, Lopez-Vilas M, Leon-Vintro X, Qer-Agusti M. Chronic adherence to heat and moisture exchanger use in laryngectomized patients. Acta Otorrinolaringol Esp. 2013 Jul-Aug; 64(4):247-52
- Panwar A, Wang F, Lindau R, Militsakh O, Coughlin A, Smith R, et al. Prediction of discharge destination following laryngectomy. Otolaryngol Head Neck Surg. 2018 Dec, 159(6):1006-1011.
- 16. Hughes C. Compliance with medication in nursing homes for older people: Resident Enforcement or Residential Empowerment? *Drugs and Aging.* 2008, 25(6)
- Brook I, Bogaardt H, van As-Brook C. Long-term use of heat and moisture exchangers among laryngectomees: medical, social, and psychological patterns. Ann Otol Rhinol Laryngol, 2013 Jun;122(6):358-63.
- Parrinello G, Missale F, Sampieri C, Carobbio ALC, Peretti G. Safe management of laryngectomized patients during the COVID-19 pandemic. Oral Oncology. 2020 Aug; 107: 104742
- 19. Searl J, Kearney A, Genoa K, Doyle PC. Clinical Experiences of People With a Laryngectomy During the SARS COVID-19 Pandemic. Am J Speech Lang Pathol . 2021 Nov 4;30(6):2430-2445



Foam cover

Humidification bib

HME filter cassette with adhesive baseplate

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