PHYSICAL AND PSYCHOSOCIAL CONSEQUENCES OF TOTAL LARYNGECTOMY

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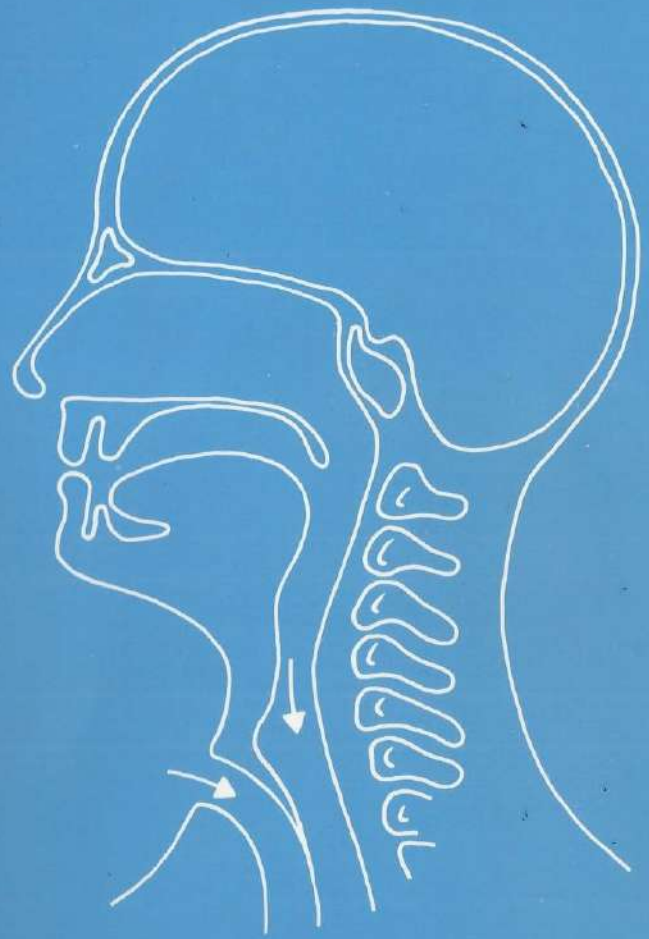

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Prof. Dr. Joh. Hoogstraten

Prof. Dr. J.J. Manni

Dr. A.J.M. Balm

Dr. N. van Zandwijk

to Esther and Miriam,

to my parents and

all my friends

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Contents

Preface

Total laryngectomy is one of the more frequently performed major oncological head and neck operation in the Netherlands. Approximately 250 of these surgical procedures are performed annually (Dutch Network & National Database for Pathology, PALGA).

The first laryngectomy for cancer of the larynx was performed by the Viennese surgeon Theodor Billroth on December 31, 1873.[1] Already in this first patient, voice rehabilitation was a major concern, and successful application of an artificial larynx could be achieved. However, surgical complications were frequent and serious in this early period. From this time onward, otolaryngologists were concerned primarily with postoperative recovery and the prospect for ultimate cure of cancer. In the 1950's, an increasing awareness developed not only for the need for postlaryngectomy speech, but also for the social, psychological and economic readjustment of the patients.[2] Until the 1970's most attention was given to voice rehabilitation, while during the last decades the focus of research has broadened to include the physical, psychological and social adjustment of the laryngectomized patient as well.

The aims of the investigations, described in this thesis were:

1. to document the various consequences of total laryngectomy, including not only the physical, but also the psychosocial implications, the voice and life style changes;
2. to investigate whether the use of Heat and Moisture Exchangers (HME) can influence positively the physical and psychosocial consequences of this mutilating surgical procedure;
3. to optimize pulmonary function testing in this category of patients;
4. to determine the possible changes of pulmonary function resulting from the use of an HME.
5. to investigate whether the use of an HME could prevent the development or reduce the severity of respiratory symptoms by initiating use of the device as soon as possible following total laryngectomy.

This thesis is divided into 7 chapters. Chapter I presents a general introduction, including an overview of various aspects of total laryngectomy, characteristics of the patient population studied, the content of the questionnaires and the methodological approach. The physical and psychosocial consequences, communication and life style changes are reported in chapters II and III. Chapter IV presents the results of the influence of an HME on respiratory and psychosocial functioning, while in chapter V the adjustments and techniques of pulmonary function testing are described. In chapter VI, the results of the

extended use of another HME on respiratory and psychosocial functioning, with emphasis on the implications for pulmonary function, are given. Finally, the results of the investigation whether the use of an HME in the period following total laryngectomy could prevent the development or diminish the respiratory symptoms, are presented in chapter VII.

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2. Martin H. Rehabilitation of the laryngectomee. Cancer 1963;16(7):823-841.

Chapter I.

General introduction

1. Introduction

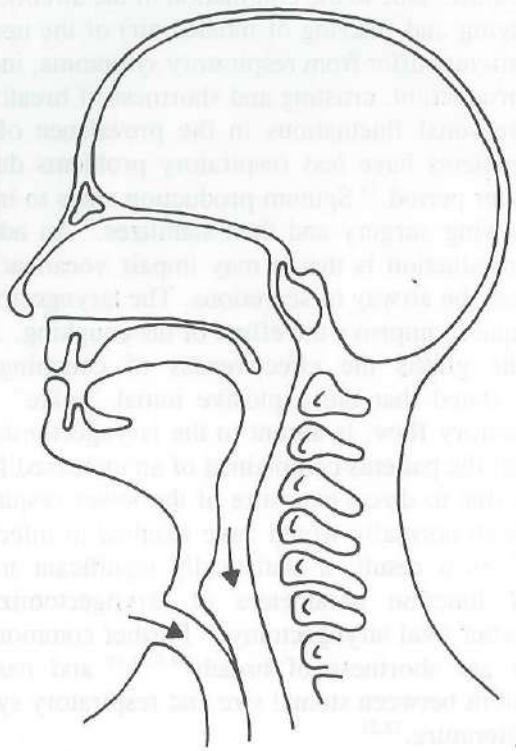
1.1. Total laryngectomy

Laryngeal carcinoma is the most frequent head and neck malignancy in the Netherlands. Approximately 700 new cases per year are detected.[1] Fortunately, most patients present with early disease and can still be treated by curative radiotherapy with preservation of all laryngeal functions, especially the voice. Only advanced cases with or without obstruction of the airway and recurrences after radiotherapy have to be treated with surgery. In most cases this means that a total laryngectomy has to be performed. Due to the removal of the entire larynx, the trachea has to be sutured to the skin in the base of the neck to form a tracheostoma.[2] The result is a permanent disconnection between the airway and the alimentary tract and between the upper (c.q. the nose) and lower airways. Figure 1 shows schematically the end result of this surgical procedure.

1.2. Etiology and symptoms

A significant etiological factor in the development of laryngeal cancer is tobacco use in the form of cigarettes, pipes or cigars.[3] Furthermore, there appears to be a synergistic effect between smoking and alcohol intake that increases the risk for supraglottic laryngeal cancer. The relative risk of developing laryngeal cancer is increased by 50% from what would be predicted by the simple additive effect when tobacco and alcohol abuse are combined. Although the incidence of laryngeal cancer has historically been much greater for males than females, the ratio has been changing as increased numbers of women are diagnosed with laryngeal cancer. The incidence rates by age increase beyond the age of 55 years. The most common symptom of laryngeal cancer is hoarseness, while for large tumors dyspnea and stridor may be present as well.[4,5] Laryngectomized patients have a relatively favourable prognosis, with a 5 year survival rate of 65%. Although, survival rates for patients with head and neck malignancy have changed little over the past 25 years, increased emphasis on rehabilitation has generated an important development of improvement of the quality of that survival.[6]

Figure 1. Schematic drawing of postlaryngectomy anatomy.



1.3. Physical and psychosocial consequences

Laryngectomy does not only result in the loss of the normal voice[7], but causes also a wide range of physical and psychosocial changes. The changes in the pulmonary physiology after laryngectomy have been given relatively little attention in the literature. Due to the elimination of the airconditioning functions (warming, humidifying and filtering of inhaled air) of the upper airway, many laryngectomized patients suffer from respiratory symptoms, including coughing, excessive sputum production, crusting and shortness of breath.[8-13] According to Natvig there are seasonal fluctuations in the prevalence of these problems. Laryngectomized patients have less respiratory problems during the summer than during the winter period.[14] Sputum production tends to increase during the first half year following surgery and then stabilizes.[8] An additional aspect of excessive sputum production is that it may impair vocalization.[15] Cough is a vital function to clear the airway of secretions. The laryngectomized patient has to acquire a technique to improve the effect of his coughing. Due to the loss of the function of the glottis the effectiveness of coughing is considerably decreased.[8] Murty stated that the explosive initial "spike", referred to as a supramaximal expiratory flow, is absent in the laryngectomized patient.[16] In a study of Jay, 54% of the patients complained of an increased frequency of chest infection, probably due to direct exposure of the lower respiratory tract to the infective agents which normally would have resulted in infection of the upper respiratory tract.[17] As a result, a statistically significant impairment of the overall pulmonary function parameters of laryngectomized patients was observed one year after total laryngectomy.[11] Further common complaints after total laryngectomy are shortness of breath [6,9,18,19] and nasal discharge.[17,20] Significant correlations between stomal size and respiratory symptoms have not been noted in the literature.[12,21]

Feelings of fatigue and malaise(6, 19, 22), problems with swallowing[6,12,17,19,22], and affected senses of smell (and taste), reflecting the inability to sniff postoperatively are also regularly reported.[6,17,20,23]

Speech related problems are frequently noted in the literature.[12,17-19,24] Natvig[12] stated that, for 40% of the 186 patients he interviewed, loss of the normal voice was the greatest problem, independent of their postoperative speech intelligibility. Sixty-seven percent of the patients noted that other people mistook them for deaf and consequently talked loudly or even shouted at them, or addressed their partners instead. He reported that 76 patients (40%) showed an increased tendency toward social isolation. Dhillon[24] found that 16 out of 35 laryngectomized patients studied, reported constant difficulty in making themselves understood, and that this difficulty caused some reduction in their social functioning. The same results were also observed by Jay[17], who reported

that about 50% of the patients he studied, found their social acceptability and social and outdoor activity decreased following laryngectomy.

It is estimated that 12 to 40 percent of cancer patients suffer from anxiety and/or depression.[25] Patients with head and neck malignancy may be at even greater risk, due to their often mutilating surgery.[26,27] While feelings of anxiety and depression are frequently reported, especially during the first 6 months after surgery, long-term chronic psychological symptoms are noted in a minority of approximately 15% of the patients.[18,24,28,29] Interestingly, not all head and neck procedures are comparable in this respect. In contrast to patients with oral cavity and oropharyngeal cancers, whose operative procedure consisted of a composite resection, laryngectomized patients had less difficulty in adjusting to the disease and their surgical treatment.[30]

Among all surgical patients, anxiety in anticipation of a major operation is common. Sometimes the anxiety is diminished by a discussion with a well adjusted patient. This has proved helpful, particularly among patients anticipating laryngectomy.[26] In the postoperative period high levels of anxiety are provoked by concerns about inability to speak, about appearance, socialization and adaptation to dysfunction.[26] In order to eliminate as many of the sources of anxiety as possible, the rehabilitation program itself should begin immediately after surgery, involving a multidisciplinary team (see 1.5).[31,32]

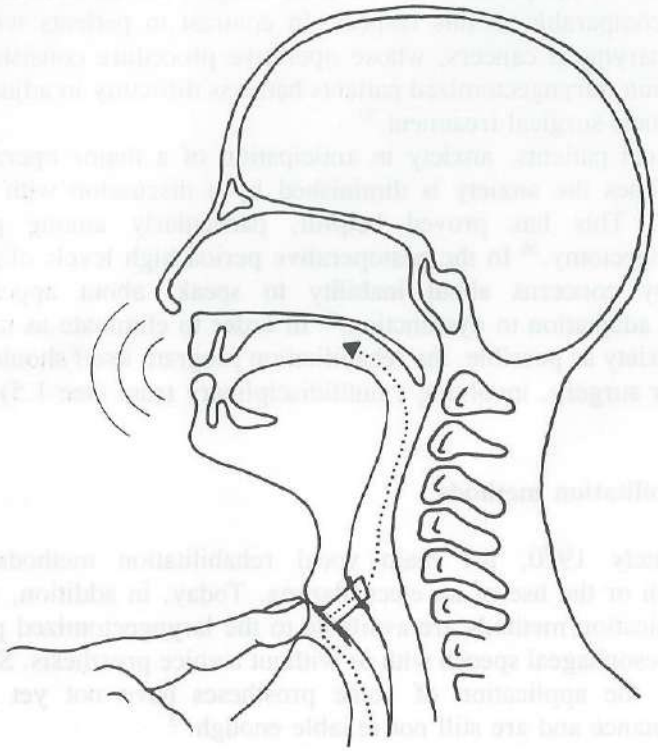
1.4. Voice rehabilitation methods

Until approximately 1970, the main vocal rehabilitation methods were esophageal speech or the use of an electrolarynx. Today, in addition, several surgical communication methods are available to the laryngectomized patient, including tracheoesophageal speech with or without a voice prosthesis. Surgical methods without the application of voice prostheses have not yet gained widespread acceptance and are still not reliable enough.[33]

- voice prosthesis

Tracheoesophageal fistulization/puncture is a minor surgical procedure in which a small puncture (fistula) is made through the tracheoesophageal party wall. This opening between trachea and oesophagus allows the insertion of a prosthesis which acts as a one way valve through which pulmonary air can be directed into the pharyngesophageal (PE) segment for voicing, and at the same time aspiration is prevented. (see Figure 2) This method was first introduced

Figure 2. Schematic drawing of postlaryngectomy anatomy with an indwelling Provox voice prosthesis in a TE-fistula and closure of the stoma with a finger to direct the pulmonary air into the pharynx in order to obtain speech.



by Singer and Blom in 1979.[34] In general, fair to good results were obtained with the Blom-Singer and other voice protheses, such as the Panje button, the Groningen voice prosthesis and, since 1988, with the indwelling, low resistance Provox voice prosthesis.[35-38]

When the surgical procedure for the insertion of the voice prosthesis is performed at the time of the laryngectomy, the patient will be able to speak within a few weeks. This may be advantageous to the patients psychological state.[39]

The latest development is the Blom-Singer adjustable tracheostoma valve with humidifier, designed to eliminate the need to manually close off the tracheostoma with a finger during speech.[40]

- esophageal speech

To produce conventional esophageal speech, air is injected from the mouth into the oesophagus and this column of air, passing upwards through the PE segment, produces the sound. Various studies of laryngectomized patients have shown that only about 25-50% of the patients is able to develop functional esophageal speech.[2,41-43] One factor, which causes the patients to discontinue attempts to talk, is the complaint of severe heartburn and epigastric pain on swallowing air.[44] Esophageal speech, when successful, provides most laryngectomized patients with a harsh voice of low pitch and loudness that is adequate for communication in small groups and quiet settings.[41,45] Motivation to practice and support from family or friends are important factors in the complicated process of acquiring esophageal speech.[46] According to Mjönes et al.[47], age was the only factor which correlated significantly with an intelligible esophageal speech, while Gilchrist[18] found no evidence of such an association. The results of the latter study suggest furthermore that females may be less successful in attaining a good esophageal voice than males. There is no apparent difference in the basic musculature of the male and the female pharynx to account for these findings. Psychologic elements were strong factors in women to deter from acquiring esophageal speech. Some women thought that they were less conspicuous with no voice at all, while others failed to develop a voice because of an over-sensitive aesthetic sense.[44] The low coarse tones of esophageal speech tend to be unattractive and embarrassing to many women.[18]

- electrolarynx

The electrolarynx is a hand-held, battery-powered device and uses a diaphragm acted upon by an electromechanical vibrator. When the diaphragms held tightly against the neck, its vibrations are transmitted through the tissue of the neck and emerge from the vocal tract where the user modulates them with his mouth

to create speech.[48] Speech produced with an electro-larynx sounds rather mechanical or robot-like; the perceived voice quality is monotone. For this reason the acceptance rate is rather low. This device is often used as the initial speech method in the immediate postoperative period, especially in the U.S.A..[43] In the Netherlands, this method has been avoided at the start of speech rehabilitation in order not to subvert the motivation to learn esophageal speech.

- whispering c.q. writing

When none of the above mentioned voice rehabilitation methods are successful, whispering or writing remain the only possible means of communication. It is reported in the literature that the percentage of non-speakers varies from 15-50% of the laryngectomized patients.[42,49]

In conclusion, the most consistently successful technique of voice rehabilitation today is the use of a prosthetic valve, with the possibility of achieving fluent speech in 80% to 90% of laryngectomized patients.[38] The acoustic and temporal characteristics of normal speech are more closely approximated by the prosthetic voice than by esophageal speech.[15] The main difference between the voice characteristics of prosthetic and esophageal speech are the maximum phonation time (10.05 and 1.76 seconds respectively) and the voice availability, i.e. the ability to vocalize immediately without lagtime.[50] In other studies phonation time of 16 seconds for prosthetic speakers has been reported.[15] The longer the maximum phonation time, the less a patient will have to interrupt his speech in order to take gasps of air. This, at least in theory, should make speech more intelligible.[50]

1.5. Counseling and social support

To prepare the patient for treatment and to ensure optimal long-term adjustment and rehabilitation, proper patient education and counseling about total laryngectomy (pre- and postoperatively) is essential.[31,32,39,49] Approximately one-quarter of the patients is not satisfied with the counseling they received, in particular with the pre-operative counseling.[18,22,23,32,51] There appears to be some uncertainties about the effects of pre-operative counseling in association with voice rehabilitation. On the one hand, Gilchrist and Pruyn [18,22] have suggested that pre-operative counseling is related to positive outcomes in voice rehabilitation and social functioning, while, on the other hand, Gates and Volin[43,52] report that pre-operative information is a non-relevant variable in speech reacquisition.

It is important that health care providers be aware of the importance placed on various physical and psychosocial consequences as experienced and reported by the patients themselves.[53] In a study of Mohide et al., laryngectomized patients ranked physical consequences and interference with social activities as the two most important issues, whereas health care professionals ranked communication impairment and self-image / self-esteem as the most important. Counseling should involve a multidisciplinary team, including the otolaryngologist, the speech therapist, the oncologic nurse and a recovered laryngectomized patient.[32,51] During the counseling the partner/family of the patient should be present.[31,32] Family involvement in pre-operative counseling helps family members to understand the changes that occur during laryngectomy. Berkowitz and Lucente suggest that it may be appropriate to also consider counseling family members separately from the patient, in order to allow them the opportunity to express their reactions about the patient openly and freely.[32] Printed materials and/or audiovisual programs may be useful, because many patients and their partners may not be able to retain information given in crisis circumstances or more information may be given in a single session than can be retained.[49,51] It is not uncommon for patients to say "I didn't hear a word the doctor said".[26]

Another factor contributing to the rehabilitation of the laryngectomized patient is the degree of social support available.[54,55] Patient satisfaction with his/her social support is seen to play a part in speech recovery, psychological state and quality of life. A laryngectomee's home environment may be a critical motivating factor for successful rehabilitation.[31,52] Gardner, a speech pathologist, stated that "success or failure often depends on the attitude of the wife toward her husband's handicap and his effort to talk".[56] Societies for Laryngectomized Patients are also a potential source of social support, providing concrete assistance and advice.[26]

2. Patients and Methods

2.1. Patients

In the period 1988 to 1993, a total of 167 patients participated in three prospective clinical trials (59 in the 1988 trial, 48 in the 1991 trial and 60 in the 1992/93 trial) investigating the physical and psychosocial consequences of total laryngectomy, and the influence of an HME on the respiratory problems. The patient sample consisted of 147 men and 20 women, with a mean age of 64 years (range 37-89 years). The time since total laryngectomy varied from 3 months to 24 years, with a median of 4.5 years. Seventy-nine (47%) patients underwent their surgery for recurrent disease after radiotherapy, 60 (36%) were irradiated post-operatively and 28 (17%) patients did not receive radiotherapy. The majority of the sample was married (76%), and 62% of the patients were retired. A detailed overview of the patient characteristics is shown in table 1.

Table 1. Patient characteristics (N=167)

		trial '88 % (n=59)	trial '91 % (n=48)	trial 93 % (n=60)	total % (n=167)
Sex:	men	90	88	87	88
	women	10	12	13	12
Age:	mean (yrs)	68	66	61	64
Follow-up:	median (yrs)	6.2	2.4	--	4.5
RT:	pre-operative	43	50	50	47
	post-operative	25	37	45	36
	none	32	13	5	17
Status:	single	8	4	13	9
(marital)	married	73	81	75	76
	widowed/ separated	19	15	12	15
Education:	element. school	66	48	48	54
	adv.elem.school	30	31	40	35
	college	2	15	9	8
	university	2	6	3	3
Employed:	yes	7	4	22	11
	no	22	31	28	27
	retired	71	65	50	62

More than half (54%) of these patients had only completed primary school. When you compare the education of the patient sample of the first (1988) with that of the second study (1991) a statistically significant higher education level could be detected in the latter sample ($p<.05$, Table 2).

Table 2. Comparison education level in first ('88) and second study ('91).

	first study (n=59) %	second study (n=48) %
Elementary school	66	48
Adv.elem. school	30	31
College	2	15
University	2	6

Chi-square 8.86, $p=.03$

Voice rehabilitation was achieved with an indwelling voice prosthesis in 75% of the cases, with esophageal speech in 14%, and an electrolarynx in 7%. Seven patients communicated by whispering c.q. writing. The choice of voice rehabilitation method showed some changes over time. In the first study, 59% of the patients were rehabilitated with a voice prosthesis, as compared with 77% in the second study. Use of esophageal speech (as the only means of communication) and the use of an electrolarynx was lower in the second study sample (Table 3). This indicates that, even within a period of three years, a trend ($p=.09$) towards more frequent use of prosthetic voice rehabilitation had occurred.

Table 3. Comparison voice rehabilitation method in first ('88) and second ('91) study.

	first study (n=59) %	second study (n=48) %
Voice prosthesis	59	77
Esophageal speech	25	17
Electro larynx	13	2
Whispering/no voice	3	4

Chi-square 6.38, $p=.09$

2.2. Methods

All patients were interviewed by means of a structured interview protocol. The first part of the interview evaluated the prevalence and severity of respiratory symptoms (sputum production, coughing, shortness of breath, wheezing, bronchial asthma, nasal discharge, pulmonary infections before and after laryngectomy, and forced expectoration), fatigue and sleep problems, smoking habits, perceived adequacy of voice rehabilitation, feelings of anxiety and inhibition in social interactions, social contacts, and levels of psychological distress. The interview was based primarily on existing items and scales, with some additional items developed especially for this specific patient group. Questions concerning respiratory symptoms were derived from the "bronchitis" questionnaires of the American Thoracic Society and the British Medical Research Council and a Dutch epidemiological study.[57,58] Questions concerning fatigue and malaise were taken from an EORTC quality of life questionnaire.[59] Questions on sleep problems were derived from J. Snel (personal communication, department of Psychology of the University of Amsterdam), while items tapping social contacts were derived from the Rand Health Insurance Study.[60] Perceived adequacy of voice rehabilitation was estimated according to the method proposed by Harwood and Rawlinson.[61] The Hospital Anxiety and Depression Scale (HADS) was used to assess psychological status.[62] This instrument has two subscales, anxiety (7 items) and depression (7 items). The second part of the interview, used in the studies evaluating the efficacy of a Heat and Moisture Exchanger (HME), included additional items on various practical aspects of the device such as the number of devices used per day, use during the night, skin irritation, problems with adhesion to the skin, fixation during coughing, and airway resistance. Finally, patients were asked to provide an overall rating of the usefulness of the HME, and to report whether they would use it in the future and whether they would recommend it to other patients. The same interview protocol was employed in the second HME study, with some minor alterations and additions. Fatigue was assessed with the 3-item subscale of the EORTC QLQ-C30, and feelings of anxiety and depression were measured with a four-item subscale of the same EORTC QLQ-C30.[63] Questions concerning sense of smell and taste, eructation, swallowing and diet, and some items on the practical aspects of the alterations in prosthetic voice rehabilitation were added (see appendix A).

The majority of the quality of life items was combined into a more limited set of multiple-item scales according to Likert's method of summated ratings.[64] For Likert scaling, item responses were first assigned numeric values: 1, "not at all"; 2, "a little bit"; 3, "quite a bit"; 4, "very much" (severity) or 1, "not at all"; 2, "1-2 days per week"; 3, "3-4 days per week"; 4, "5 or more days per week" (frequency). The reliability of the Likert scales was measured by Cronbach's alpha.[65] Internal consistency of a magnitude of 0.70 or greater is considered acceptable for group comparisons. The reliability of the Likert scales was as follows: fatigue and malaise 0.91, sleep problems 0.68, perceived voice quality 0.78, social anxiety 0.70, social contacts 0.68, and anxiety and depression 0.83 (subscales: anxiety 0.80 and depression 0.77).

2.3. Heat and Moisture Exchanger (HME)

The heat and moisture exchanger (HME) has been in clinical use for more than 30 years.[66] The principle on which it is based is the exchange of heat and moisture between a gas and a surface over which it flows. Expired gas may be assumed to be saturated with water vapour at the temperature at which it leaves the respiratory tract. If the humid gas then comes into contact with a surface at a lower temperature, the gas is cooled, the surface is warmed, and condensation of some of the vapour onto the surface occurs. The extent of deposition depends on the magnitude of the fall in gas temperature. After exhalation has ceased and inspiration begins once again, gas at ambient temperature comes into contact with the same surface and, being dry by comparison, is able to take up as vapour some of the water previously deposited. It is also warmed as it passes over the surface. Hence, a proportion of both the heat and water from the exhaled air has been transferred to the inspired gas, thereby reducing the extent to which water would otherwise be drawn from the mucosa of the respiratory tract. In this way, the tendency towards drying of the respiratory mucosa is reduced and in turn, because of the reduced need for vaporization at the mucosal surface, less heat is lost. The use of an HME also restores, to some extent, the airway resistance.[67]

To evaluate the effect and the influence of the use of an HME on the physical and psychosocial consequences of total laryngectomy, we used the "Stomvent"[1] Heat and Moisture Exchanger in our first study (chapter IV) and the "Freevent"[2] Heat and Moisture Exchanger in our second and third study (chapter VI and VII, respectively).

[1] Stomvent is manufactured and distributed by Gibeck Respiration, Sweden.

[2] Freevent is manufactured and distributed by Pharma Systems, Sweden.

2.4. Pulmonary function assessment

Pulmonary function tests were performed on all patients entering the second HME study (chapter IV) and 3 months thereafter, and included maximum vital capacity (VC Max), total lung capacity (TLC), forced expiratory volume in 1 second (FEV1), peak expiratory flow (PEF), maximum expiratory flow volume at 50% (MEF 50), and the same measurements for inspiratory flow/volume (FIV1, PIF, and MIF 50, respectively).
The validity of the standard method of pulmonary function testing with an intratracheal device (cuffed trachea cannula) was assessed in comparison with an extratracheal device. For the latter, the baseholder (the silicone housing placed in adhesive tape) of the Freevent HME was used to connect the patient to the standard lung function testing equipment (standard Masterlab Transfer, Erich Jaeger GmbH, Würzburg, Germany).

2.5. Data management

All data were entered into a specially developed database application in the database management system SIR (Scientific Information Retrieval), installed on an IBM personal computer. In the database, several internal checks were included to ensure correct data entry. After the data entry and a random data verification of 10% of the files, an SPSS data file was retrieved. For the descriptive statistics and the statistical analyses the SPSS/PC+ statistical package (versions 3.0 - 5.0) was used.

2.6. Statistical analyses

Statistical comparisons between groups were made by means of a repeated measures multivariate analysis of variance, the Mann-Whitney U test, Student's t-test and the Chi-square. Differences over time within groups were tested with paired Student's t-tests and the Wilcoxon nonparametric tests for paired observations. Statistical association was measured by Pearson's correlation coefficient. A two-tailed p-value below .05 was taken to indicate statistical significance.

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Chapter II

Physical and psychosocial consequences of total laryngectomy[3]

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[3]This chapter in combination with chapter IV was also published in a more extensive version under the title: 'Lichamelijke en psychosociale gevolgen van totale larynxextirpatie en het gebruik van een warmte- en vochtwisselaar'. Ned Tijdschr Geneesk 1990;134: 2438-42.

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Abstract

The incidence and severity of respiratory symptoms after total laryngectomy and their influence on daily living were studied in 59 laryngectomized patients. Daily sputum production was the principal complaint of these patients (98%), followed by coughing (64%) and the need for frequent forced expectoration (more than 5 times a day) in order to clear the airway (57%). Frequent stoma cleaning (i.e., more than 5 times a day) was required by 37% of the patients. Significant correlations were found between respiratory symptoms, voice rehabilitation and several aspects of daily living, including fatigue, sleep problems, social contacts and psychological distress. These findings indicate that respiratory symptoms after total laryngectomy are both frequent and troublesome. The development of effective methods for minimizing and/or preventing such respiratory problems would contribute significantly to improving the quality of life of laryngectomized patients.

Keywords total laryngectomy, respiratory symptoms, quality of life, voice rehabilitation

Introduction

Total laryngectomy has a profound impact on the life of a patient. The loss of the larynx creates significant communication problems which, in turn, can result in disruption of the patients normal pattern of social interaction.[1] It is for this reason that adaptation to the loss of normal speech has been the focus of research on the rehabilitation of laryngectomized patients.[2]

In contrast, relatively little attention has been paid to the respiratory symptoms following such an operation, and to the effect of such symptoms on daily living.[2] The available literature indicates that total laryngectomy can result in progressive bronchial obstruction and descending bacterial infection of the airways.[3] There is also considerable hypersecretion in the first months following surgery. While excess sputum production tends to stabilize after 6 months,[4] seasonal exacerbations of such symptoms are common.[5] Clearance of pulmonary secretions and care of the stoma remain bothersome and time-consuming activities.[5]

The principal aim of the current study was to establish the prevalence rates of respiratory symptoms among laryngectomized patients. Additionally, data were obtained regarding fatigue and sleep problems, perceived voice quality, problems related to social contacts, and level of psychological distress. The relationship among these variables is also reported.

Methods

All laryngectomized patients visiting the Netherlands Cancer Institute outpatient clinic during a two month period of 1988 were asked to participate in the study. All patients who were approached agreed to take part in the study. This resulted in a group of 59 patients. The large majority (90%) were male, with a mean age of 68 years (range of 48 to 89). Three-quarters of the patients had a partner. The time elapsed since total laryngectomy varied from 6 months to 19 years, with a median of 6.2 years. Two-thirds of the sample had received radiotherapy as part of the treatment. Only 2 patients were under the care of a pulmonologist for chronic respiratory problems already present before the operation.

Voice rehabilitation was achieved with a Groningen voice prosthesis[8] in 59% of the patients, with esophageal speech in 25% and with an electrolarynx in 13%. Only 2 patients had no other means of communication than whispering.

All patients were interviewed by the same investigator during a routine follow-up visit to the outpatient clinic. The interview required, on average, slightly over one hour to complete.

The interview was designed to evaluate the presence and severity of respiratory symptoms (cough, sputum production, breathlessness, wheezing, bronchial asthma, nasal discharge, pulmonary infections and forced expectoration), fatigue and sleep problems, perceived adequacy of voice rehabilitation, social contacts and anxiety and depression. The interview was based primarily on existing items and scales, with some additional items added specifically for this patient group. Questions concerning respiratory symptoms were derived from the "bronchitis" questionnaires of the American Thoracic Society and the British Medical Research Council[7] and a Dutch epidemiological study.[8] [4] Questions concerning fatigue were taken from an EORTC quality of life questionnaire.[9] Questions on sleep problems were derived from J.Snel (personal communication). Problems with social contacts were assessed by several specific behavioral and attitudinal items developed for this study. Perceived adequacy of voice rehabilitation was estimated according to Harwood and Rawlinson.[10] Anxiety and depression were assessed with the Hospital Anxiety and Depression Scale.[11]

Results

Pre-operative respiratory problems were rare, despite the fact that 96% of the patients had been smokers before laryngectomy. Bronchitis was present in 10% of the cases and occasional pneumonia in 15%.

In contrast to the pre-surgical period, respiratory symptoms after surgery were very prevalent. As shown in Table 1, 98% of the patients had daily complaints of excessive sputum production (mean of 11 times per day). Frequent daily coughing (mean of 12 times per day) and nasal discharge were reported by 64% and 42% of the patients, respectively. A significant correlation was found between these two symptoms (Kendall's Tau = 0.32, $p < 0.05$). More than half of the patients reported using forced expectoration to clear the bronchial airway more than 5 times a day, while approximately one-third reported the need to clean their stoma frequently (i.e., more than 5 times a day). While only a few patients suffered from bronchial asthma (4%), approximately one-third complained of breathlessness and 19% of wheezing. Approximately one-half of the patients reported seasonal effects on their respiratory symptoms, with exacerbations during the winter months. The remaining patients stated that their respiratory symptoms were continuous and often quite severe throughout the year. Radiotherapy did not appear to have an adverse effect on the respiratory problems in this patient group. Thirty percent of the patients reported being very fatigued and one-quarter experienced problems with sleep.

Table 1. Frequency distribution of daily respiratory symptoms, fatigue and sleeping problems after total laryngectomy

	Frequencies (%)
sputum production	98
cough	64
nasal discharge	42
forced expectoration	57*
stoma cleaning	37*
breathlessness	32
wheezing	19
bronchial asthma	4
fatigue	30
sleeping problems	24

* more than 5 times a day.

Table 2 shows the patients' ratings of the quality of their speech and social contacts. Approximately one-half of the patients reported satisfaction with their voice quality, including such dimensions as intelligibility, loudness, pitch, fluency and intelligibility over the telephone. However, a significant minority of patients stated that they had problems with one or more of these voice features. Contrary to expectations, no significant difference was found in perceived voice quality between patients using a voice prosthesis and those employing esophageal speech. Problems in social contact were surprisingly few. Less than 15% of the patients reported being anxious or inhibited in social situations.

[4] Objective evaluation of these symptoms would have been of possible interest. However, several problems mitigated such measurements. Repeatedly reliable measurements of pulmonary function and sputum production are difficult. Pulmonary function tests show a relatively wide variability, depending on the experience and the condition of the patient.[15] Further, there is the problem of diurnal variation in obstructive lung disease. Sputum volume measurements require optimal collection by the patient which is frequently hampered by psychologically adverse reactions. Study of the physical properties of the sputum i.e. viscosity measurements need elaborate laboratory testing.[16]

Table 2. Patients ratings of voice quality and problems with social contacts.

	Frequencies (%)			
Voice Quality	good	reasonable	fair	poor
intelligibility	38	32	21	9
loudness	2	58	38	2
pitch	2	41	48	9
fluency	19	39	37	5
telephone intelligibility	16	49	22	13

	Frequencies (%)			
Social Contacts	not at all	a little	quite a bit	very much
nervous about speaking	65	21	8	6
worried about others' opinion	83	13	2	2
anxiety speaking with others	74	18	3	3
inhibited with others	57	32	9	2
avoids strangers	83	7	2	8

Table 3. Correlations with respiratory symptoms and voice quality.

	Respiratory complaints			Voice Quality
	Cough	Sputum	Breath-lessness	
Voice quality	n.s.	-0.38[b]	-0.37[b]	----
Fatigue	0.42[b]	0.39[c]	0.47[c]	-0.41[b]
Sleeping problems	n.s.	0.36[a]	n.s.	n.s.
Anxiety	n.s.	n.s.	0.40[c]	n.s.
Depression	n.s.	0.36[b]	0.39[c]	-0.37[b]
Social contact	n.s.	n.s.	n.s.	0.40[b]

Pearsons's R: [a] $p < 0.05$; [b] $p < 0.01$; [c] $p < 0.001$; n.s. no statistically significant correlation found

Using a scale cut-point recommended by Zigmond and Snaith (scores above 11 on a scale ranging from 0 to 21), few patients exhibited clinically significant levels of anxiety or depression (5% and 7%, respectively).

Correlations between respiratory symptoms and voice rehabilitation, aspects of daily life and anxiety and depression are shown in Table 3. With regard to respiratory complaints, coughing was significantly related only to fatigue, whereas sputum production and breathlessness were found to be associated with a much wider range of physical and psychosocial problems. With regard to voice quality, there was a significant correlation with fatigue, depression and social contacts.

Importantly, a significant negative correlation was found between the time since laryngectomy and the severity of several respiratory symptoms and fatigue. Physical complaints tend to diminish with the passage of time.

Discussion

The results of this study indicate that respiratory problems among post-laryngectomized patients are much more prevalent than has been noted previously in the literature.[1,12] We found that 98% of the patients had complaints about daily sputum production. Coughing, nasal discharge, forced expectoration and stoma cleaning were also frequently reported. Interestingly, such symptoms were rarely noted in the patients' hospital charts. This suggests that physicians and/or patients may consider respiratory complaints to be such a natural consequence of laryngectomy that they are not considered worthy of special note.

The observed correlation between coughing and nasal discharge requires further attention. Laryngectomy leads to mucosal changes in the nose.[13] It is unclear, however, whether increase in nasal mucous production leads to coughing or whether coughing triggers nasal discharge.

Respiratory symptoms appear to decline with the passage of time. Patients laryngectomized less than 2 years before the study had more respiratory complaints than those who had been treated more than 2 years earlier. Whether this represents a real improvement or simply better adjustment by patients over time to such chronic symptoms remains unclear.

In accordance with earlier observations[5,14] we found that almost half of the patients experience seasonal fluctuations in respiratory symptoms, with increased symptoms during the winter months. Many patients also reported that a winter holiday in warmer climates improved significantly their pulmonary condition.

The most probable causal factor related to the high incidence of respiratory problems is the loss of the connection between the upper and the lower airway.

This leads to the inhalation of air which is not conditioned in the normal way. There is no filtration of small particles, or exchange of heat and moisture. This, in turn, leads to more irritation of the bronchial mucosa, coughing, excess sputum production and crusting.[4] Restoring the lost nasal functions may be an effective way to treat and prevent the respiratory problems of the laryngectomized patient.

The study results indicate that respiratory symptoms effect many areas of daily living. Most of the correlations noted between respiratory symptoms and aspects of daily life are self explanatory. Patients with excess sputum production tend also to be bothered by such symptoms during the night, resulting in sleep difficulties and fatigue. Some of these physical symptoms are also related to anxiety and depression.

Less expected was the finding that the voice quality was affected negatively by respiratory problems among both patients using prosthetic devices and esophageal speakers. This has important implications for future efforts to improve voice quality after total laryngectomy. Better voice rehabilitation can be expected when respiratory problems are effectively treated. This, in turn, could lead to improvement in social contacts and to a decrease in psychological distress.

The quality of life of head and neck cancer patients is an important issue deserving prospective study.[2] Such studies will provide more insight into the specific psychosocial needs of these patients. Particularly given the fact that, for many of these patients, the prognosis is good, improvement in the quality of life could yield substantial long-term benefits.

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Chapter III

Communication, functional disorders and life style changes after total laryngectomy

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Abstract

Functional changes after total laryngectomy, including voice quality, hyposmia and dysgeusia, nasal discharge, swallowing and smoking habits, were studied by means of a structured interview with 63 laryngectomized patients. Eighty percent of the patients reported being satisfied with their voice quality, including speaking on the telephone. Significant correlations were found between the quality of the voice and fatigue, frequency of making telephone calls and anxiety about speaking ($p < .01$). Vocal rehabilitation was achieved in the majority of patients (78%) with the indwelling Provox™ voice prosthesis. Forty-five percent of the patients complained about annoying eructation. Hyposmia was reported by 52% of the patients, while 15% experienced dysgeusia. A significant correlation was found between hyposmia and dysgeusia ($r = .43$, $p < .001$). All patients with a taste problem also reported a poor sense of smell. Daily nasal discharge was reported by 38% of the patients. Due to difficulties in swallowing solid food, about one quarter of the patients changed their diet. All but one patient had been heavy smokers preoperatively. Only 9% continued to smoke postoperatively.
These results along with the previously reported respiratory problems resulting from total laryngectomy, should be taken into account in counselling patients who are candidates for this surgical procedure.

Keywords: total laryngectomy, perceived quality of voice, voice rehabilitation methods, eructation, hyposmia, taste, nasal discharge, swallowing, dietary changes, smoking.

Introduction

Total laryngectomy is one of the more frequently performed major head and neck operations in the Netherlands. In 1990, 1991 and 1992, respectively 262, 252 and 241 of these surgical procedures were performed (Dutch Network & National Database for Pathology, PALGA). Between 12 and 16 percent of the patients were women. To prepare the patient for treatment and to ensure optimal long term adjustment and rehabilitation, proper patient education and counselling about total laryngectomy is essential.[1-4] Counselling of the patient and his family involves a multidisciplinary team composed of an otolaryngologist, a resident, a nurse, a speech therapist and a patient who has undergone laryngectomy.[3] Such counselling requires thorough knowledge of the full range of physical and psychosocial consequences of this operation. Besides the obvious implications for voice, the patient needs to be prepared for many other changes in his daily life, such as the development of respiratory complaints (coughing, sputum production, forced expectoration and shortness of breath), increased fatigue, sleep problems, psychological distress, and disruption of social interactions.[5]
In previous studies our focus has been on the prevalence of pulmonary problems and their possible improvement through the use of a heat and moisture exchanger (HME).[6,7] In the current study the focus is on the non-pulmonary consequences of total laryngectomy, including results and methods of vocal rehabilitation, eructation, hyposmia and dysgeusia, swallowing, and dietary changes. Smoking habits were also evaluated. Relationships between these variables and other aspects of daily life are also reported.

Patients and Methods

All laryngectomized patients who visited the Netherlands Cancer Institute outpatient clinic during a 4-month winter period were requested to participate in this study. Two patients declined participation, resulting in a group of 63 patients, 56 men and 7 women. The mean age was 66 years (range 46-84). The time since surgery varied from 3 months to 24 years, with a median of 2.8 years. The indication for total laryngectomy was a laryngeal carcinoma in 45 patients, a hypopharyngeal carcinoma in 15, and another malignancy in 3 patients. Twenty-seven patients underwent their surgery for recurrent disease after radiotherapy, 24 were irradiated postoperatively, and 12 did not have radiotherapy.
Vocal rehabilitation was achieved with a Provox™ voice prosthesis in 78% (n=49) of the patients, with esophageal speech in 14% (n=9), and an electrolarynx in 3% (n=2). One man and one woman patient communicated by

whispering and one woman had no means of speech, but communicated well in writing. These three patients were suffering from severe pharyngeal fibrosis after excessive surgery with flap reconstructions and radiotherapy, and had a gastrostomy for food intake. Twenty three of the 49 prosthetic speakers (47%) were able to use esophageal speech as well. The background characteristics of the sample are summarized in Table 1.

Table 1. Patient characteristics (N=63)

Sex:	Men	56
	Women	7
Age:	mean	66 years
	range	46-84 years
Follow-up:	mean	2.8 years
	range	3 mths-24 yrs
Primary tumour:	Laryngeal carcinoma	45
	Hypopharyngeal carcinoma	15
	Other malignancy	3
Radiotherapy:	pre-operative	27
	post-operative	24
	none	12
Vocal rehabilitation:	Provox™	49*
	Esophageal voice	9
	Electrolarynx	2
	Whisper	2
	No voice	1

* Twenty three of these patients (47%) also used esophageal speech.

All patients were interviewed by the same investigator during a routine follow-up visit to the outpatient clinic. The interview required, on average, one hour to complete. The contents of the interview have been described in detail elsewhere.[5] Briefly, the interview evaluated the presence and severity of respiratory symptoms, fatigue and sleep problems, quality of voice, eructation, senses of smell and taste, swallowing and diet, smoking habits, social contacts and levels of anxiety and depression. Student's t-tests were employed to evaluate differences between groups and statistical associations were measured

by Pearson's correlation coefficient. A two-tailed p value of ≤ 0.05 was employed to indicate statistical significance. Several quality of life items were combined into a more limited set of multiple-item scales according to Likert's method of summated ratings. Where appropriate, the reliability of the scale is reported (Cronbach's alpha).

Results

Quality of voice

Table 2 reports the patients' ratings of the quality of their speech, including the 2 whispering patients and the one patient without speech, who were categorized as "poor" in all voice features. The majority reported fair to good intelligibility, both in face-to-face conversation and in speaking on the telephone. Sixty percent of the patients were satisfied with the loudness and slightly more than half with the pitch of their voice. Two-thirds of the patients reported satisfaction with the fluency of their speech. Neither radiotherapy before or after surgery, nor age were associated with voice results.

Table 2. Patients' ratings of voice quality (N=63*)

	good(%)	fair(%)	moderate(%)	poor(%)
Intelligibility	52	25	14	9
Loudness	3	60	33	4
Pitch	0	51	44	5
Fluency	22	46	25	7
Telephone intelligibility	33	46	13	8

* The 2 whispering patients and the one non-speaking patient were categorized as "poor" in all voice features.

Differences between men and women were found only for loudness ($p < .001$) and pitch, with both being rated lower by the women. Of the various features of voice, only intelligibility was rated slightly lower by patients employing esophageal speech, compared with prosthetic speakers ($p = .08$). Patients who were less satisfied with their overall voice quality, (a summary scale of intelligibility, loudness, pitch, and fluency; Cronbach's alpha 0.78), reported making fewer telephone calls, being more anxious about speaking with other people ($p < .01$), and having fewer friends ($p < .001$).

A significant negative correlation was also found between the voice quality and feelings of fatigue ($p < .01$). Although statistical comparisons failed to detect significant differences between patients with ($n=51$) and without a partner ($n=12$), there was a clear trend toward increased social anxiety in the patient group without a partner ($p=.063$).

Vocal rehabilitation method

All 49 patients (78%) using a voice prosthesis employed the indwelling Provox™ prosthesis. Thirty one patients had experience with both this device and the formerly employed Groningen prosthesis. Seventy four percent (23/31) reported that their speech had improved substantially after introduction of the Provox™ prosthesis, while 16% (5/31) experienced no difference and 10% (3/31) preferred the former indwelling prosthesis. Some leakage of fluids through the Provox™ device was reported by slightly less than half of the patients (22/49). The time elapsed between placement of the prosthesis and the onset of leakage varied from 1 week to 1 year, with a median of 4 weeks. Fifteen of these 22 patients reported only occasional leakage, while the other 7 patients indicated that the leakage occurred more frequently. Leakage through the prosthesis was reported as the primary reason (68%) for replacing the device ($p < .05$). Increased airflow resistance was given as a reason for device replacement by only 6% of the patients.

Smell and taste

Almost all patients (95%) reported deteriorated sense of smell (hyposmia) and 44% reported a reduced sense of taste (dysgeusia) immediately following surgery. Long term problems with hyposmia and dysgeusia were reported by 52% and 15% of the sample, respectively. A strong correlation was observed between these two senses ($r=.43$, $p < .001$). All patients with a poor sense of taste also reported a poor sense of smell. Time since surgery, radiotherapy before or after surgery, or the type of voice rehabilitation (voice prosthesis or esophageal voice) showed no significant correlation with hyposmia and dysgeusia.

Nasal discharge

Daily nasal discharge was reported by 38% of the patients. A significant correlation was found between nasal discharge and feelings of fatigue ($r=.34$, $p<.01$) and social anxiety ($r=.37$, $p < .01$), while no statistically significant correlation was observed between hyposmia and dysgeusia, and nasal discharge.

Swallowing and diet

Approximately one-quarter of the patients reported changes in their diet and eating habits. More problems were reported in swallowing solid foods than liquids. Almost half of the patients reported no problems with solid food, whereas 27% experienced some and 25% significant or serious problems in this respect. Liquids caused no problems in 93% of the patients, minor problems in 3% and more serious problems in 4%. The main complaint was a feeling of "food sticking after swallowing". Some patients attempted to resolve this problem by taking smaller bites and chewing more thoroughly. Other patients avoided certain kinds of food, such as bread-crusts and solid meat. A significant correlation between dietary changes and swallowing problems was noted ($p < .01$), while the location of the primary tumour was not significant. No significant correlation between the different vocal rehabilitation methods and dietary changes was found, although 2 patients thought that their swallowing discomfort was caused by the voice prosthesis.

Eructation

This annoying problem was frequently reported by the patients. Minor problems were experienced by 13%, while 32% of the patients had serious complaints. Of the 7 patients who were able to use both prosthetic and esophageal speech, one had more problems when applying prosthetic speech, whereas four had more trouble when using esophageal speech. Two patients experienced no difference in these complaints in relation to either of both speech methods.

Smoking habits

With the exception of one woman who had surgery for a deeply invading recurrent thyroid carcinoma, all patients (98%) had been smokers before surgery (with a mean of 22 cigarettes per day). The majority started to smoke at the age of seventeen (range 10 - 40 years) and stopped smoking just prior to surgery. Six patients (9%) continued smoking following total laryngectomy. Three of these patients smoked cigars (1 - 5 per day) and three cigarettes (20 - 50 per day). The spouses of 4 of these 6 patients also were smokers. Twenty percent of all patients reported avoiding social gatherings because the passive inhalation of smoke triggered coughing and sputum production.

Discussion

To prepare the patient for total laryngectomy and to ensure optimal long term adjustment and rehabilitation, extensive pre-and postoperative information and counselling is essential. Previous studies have reported that about one-quarter of the patients are dissatisfied with the pre-operative counselling received.[1,3] In part, this may reflect differences between patients and their health care providers in the relative importance placed on various physical and psychosocial consequences of treatment. For example, in a study of Mohide et al.[8], laryngectomized patients ranked physical consequences and interference with social activities as the two most important issues, whereas health care professionals ranked communication impairment and self-image/self-esteem as the most important. This suggests the need to increase our knowledge of the full range of consequences of total laryngectomy as experienced and reported by the patients themselves.

In the Netherlands Cancer Institute vocal rehabilitation is generally accomplished with primary insertion of a voice prosthesis, with esophageal and electrolarynx speech held in reserve. Until 1988, the main voice prosthesis used was the indwelling Groningen prosthesis. A fair to good intelligibility during face-to-face contact and over the telephone was achieved in 70% and 65% of the patients respectively.[5]

From 1988 onwards, the indwelling low-resistance Provox™ voice prosthesis, developed in our institute, has been the device of choice.[9] Long term results of vocal rehabilitation with this prosthesis are favourable.[10] The results of the present study indicate that 77% of the patients are satisfied with their voice quality. Compared with the results of the previous study[5], this is a slight increase of 7%. The intelligibility over the telephone increased from 65% to 79%, which is a significant improvement (Student's t-test: $p < .001$).These improvements might be attributable to the fact that, in the first study, only 59% of the patients used a voice prosthesis compared with 78% in the current study. Another explanation could be that three-quarters of the patients in the current study (23/31) shifted from the standard Groningen voice prosthesis to the Provox™ voice prosthesis, which has a much lower airflow-resistance[11], resulting in a decreased tracheal pressure while speaking. The Provox™ device was considered more comfortable because less effort was needed to achieve adequate speech. It is noteworthy that immediately after replacement with the Provox™ voice prosthesis all patients told their physician that their speech had improved.[9] This difference (100% initial improvement vs 74% permanent improvement, 16% no difference and 10% preference for the former device) could be explained in two ways: (a) the interview took place some time after replacement, giving the patient more time to experience the new voice

prosthesis; (b) patients are perhaps more willing to report dissatisfaction with treatment results to a non-medical interviewer than to their physician.

Although there is a difference between women and men in both loudness and pitch, women report being less satisfied with their voice primarily because of the more obvious decrease in pitch. The normal pitch of a woman's voice cannot be acquired by any of the currently available rehabilitation methods.[2] This suggests that it may be useful to have women who have had laryngectomy available to counsel women due to undergo the procedure.

Approximately half of the patients (23/49) acquired esophageal speech in combination with a prosthetic voice. Variables which have been found to influence the learning of esophageal speech include age, motivation and support from family and friends.[4,12,13]

Patients who lack the encouragement of a partner may need special attention in their (voice) rehabilitation, since in the current study this group showed a tendency toward social withdrawal.

No significant differences were found in the rating of voice quality by the patients with a voice prosthesis versus those using esophageal speech. This finding is similar to that of a recently published study[14] in which no difference was found between these groups with regard to the "subjective" assessment of intelligibility, although "objectively" the intelligibility of with voice prostheses was significantly better than that of patients with esophageal voice or an artificial larynx.

Leakage of fluids was found to be the primary reason for replacing the voice prosthesis. It is important to instruct the patient properly about this problem and to explain the necessity of regular cleaning of the device. This can be done with a cotton swab or a specially developed cleaning brush.[10] It is striking that the appraisal of the severity of leakage seems to vary widely. Some patients may be concerned with the leakage of one drop of fluid, whereas others experience no obvious discomfort from more regular leakage. Again, proper counselling about this side effect of prosthetic voice rehabilitation is essential.

Hyposmia is a common side effect of total laryngectomy. The available literature indicates that about one-half of patients suffer from this problem.[1,15-18] The disconnection between the upper and lower airways results in the loss of the normal nasal function. Henkin et al.[19] have postulated that surgical interference with sensory nerves in the larynx at the time of laryngectomy alters olfactory acuity by some unknown, complex feedback mechanism and that anosmia is an inevitable consequence of laryngectomy. Some support for this hypothesis has been found recently in a canine model, showing more severe histological changes in the olfactory epithelium after denervation of the larynx compared to tracheotomy alone.[20] Moore-Gillon[21] found that the olfactory threshold is unchanged and that anosmia reported after laryngectomy is almost certainly due to failure of the olfactory stimulus to reach the olfactory mucosa.

About one half of our patient group suffered from hyposmia. Similar results have been reported in other studies.[15,18] One might have expected that patients with a voice prosthesis would experience less problems in this respect, due to the much higher airflow through the pharynx during speech production. However, no significant difference in the prevalence of hyposmia was found between prosthetic and non-prosthetic speakers. Approximately half of our patients mentioned a deficiency in sense of taste in the period immediately following surgery, while only 15% reported that the dysgeusia was still present at the time of the interview. Taste is mainly a function of the taste buds in the mouth, but it is common experience that olfaction also contribute strongly to taste perception.[22] Thus, it is not surprising that, in the current study, all patients with dysgeusia also suffered from hyposmia.

Slightly more than one-third of the patients in our study reported excessive daily nasal discharge. Toppazada and Gaafar[23] suggest the following two explanations for this problem: (a) few and poorly functioning mucous glands and (b) marked proliferation and activity in the cytoplasm of serous secreting cells, suggesting a continuous process of production and discharge. One-quarter of our patients reported problems with deglutition, especially with solid food. The incidence of dysphagia as reported in the literature varies between 10 to 58%.[12,15-17,24] The major functional change in the pharynx after total laryngectomy is increased pharyngeal resistance.[24] McConnel has stated that to overcome this resistance higher propulsive forces are needed for effective swallowing, and that laryngectomized patients produce higher amplitude pressures by the tongue during swallowing than non-laryngectomized individuals. Although there was a trend towards more swallowing problems in hypopharyngeal carcinoma patients, we found no significant differences ($p < .077$) in this respect between hypopharyngeal and laryngeal cancer patients. This was somewhat unexpected, as the extent of the resection is wider in hypopharyngeal cancer compared to laryngeal cancer. On the other hand, most patients have been treated with radiotherapy pre- or post operatively, which might explain the stronger tendency towards hypopharyngeal stenosis in the latter group.

Eructation was reported by approximately half of the patients. Although we found no significant difference between prosthetic and esophageal speakers, due to the small number of patients with this problem, employing both methods, we have the impression that this annoying symptom occurs more frequently in esophageal speakers. Some patients mentioned that this was an extra reason why they favoured the use of the voice prosthesis.

Epidemiological data have demonstrated a strong correlation between tobacco use and laryngeal (and hypopharyngeal) cancer[25]. This is also reflected in the current study, in which 98% of the patients were smokers prior to surgery. Fortunately, only 9% of the previous smokers continued to smoke following laryngectomy. This figure is similar to that reported in a recent study in

England.[15] Compared with a 1972 Dutch study, where 50% of the patients continued to smoke after surgery[18], the current results indicate a striking change in post-treatment smoking behaviour. The decrease in the percentage of smoking patients can probably be attributed to an increased awareness of the influence of continued smoking on the prognosis[26] and on the development of secondary malignancies[27], and consequently to an increased pressure by the physicians on patients to stop smoking.

In conclusion, the majority of patients in our study reported being satisfied with their voice quality, with the majority of patients using an indwelling voice prosthesis. Almost half of the patients had complaints of eructation. Hyposmia was reported by half of the patients, while for most patients a deficiency in gustatory sense appeared to be temporary. Excessive daily nasal discharge was reported by one-third of the patients. About one-quarter of our patients reported swallowing problems, resulting in dietary changes. Finally, 9% of the previous smokers continued to smoke following total laryngectomy.

These results, along with the previously reported data on respiratory problems resulting from total laryngectomy[5], should be taken into account in the counselling of patients who are candidates for this operation. Further improvements in the quality of life after this debilitating operation can only be achieved if the patient is fully informed about the full range of implications, including the alterations in communication, the resulting functional disorders and the possible life style changes. All mechanisms and procedures to reduce the side effects of total laryngectomy should be well understood, both by the patient and by the multidisciplinary treatment team.

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Chapter IV

The influence of a heat and moisture exchanger (HME) on the respiratory symptoms after total laryngectomy

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Abstract

The influence of a heat and moisture exchanger (HME) on the respiratory symptoms after total laryngectomy was studied in 42 patients. A significant reduction was found in the mean daily frequency of sputum production, forced expectoration in order to clean the airway and stoma cleaning after use of the HME for six weeks.
Symptoms of fatigue and malaise decreased significantly, while social contact improved. Patients using esophageal speech or an electrolarynx benefited more than patients using a voice prosthesis. The findings indicate that respiratory problems after total laryngectomy can be reduced significantly with the use of a device with heat and moisture exchanging properties. In turn, reduction of respiratory symptoms results in an improved quality of life.

Keywords: total laryngectomy, respiratory symptoms, heat and moisture exchanger, quality of life, voice rehabilitation

Introduction

Respiratory problems after total laryngectomy can have a profound impact on the life of the patient.[1] In a previous study[2] we found that excess sputum production was reported by 98% of the patients and coughing was a bothersome symptom for 64% of the patients. Frequent forced expectoration (more than 5 times per day) in order to clean the airways was reported by 57% of the patients. There were significant correlations between respiratory symptoms and several aspects of daily life such as social contact, voice quality, fatigue, sleep and psychological distress.
The most likely cause of the respiratory problems after total laryngectomy is the disconnection between the upper and lower airways, i.e., the loss of the nose with its cleaning, heating and moisturizing effect on inhaled air. Air inhaled after laryngectomy is not conditioned, probably leading to irritation of the bronchial mucosa, coughing, excess sputum production and crusting.[3] Although the respiratory problems tend to diminish somewhat in the first year after surgery, almost all patients continue to suffer from these symptoms. Frequently, there is an increase of respiratory symptoms in the winter period.[1,2]
Little is known about the possible value of employing special filters to exchange heat and moisture in the inspired air in laryngectomized patients. While many patients use covers for their stoma, these are seldom sufficient for this purpose.[4] Since 1978, many laryngectomized patients in Sweden have used a heat and moisture exchanger (HME; Stomvent)[1], which is fixed around the stoma with adhesive. It contains as a heat and moisture exchanging medium a rolled, corrugated microporous paper. With such a device it appears possible to reduce the diurnal loss of water through the exhaled air by 250-300 g.[5] In a retrospective study, it was found that the satisfaction of patients using the device was high.[6] Users of the Stomvent had fewer respiratory problems and pulmonary infections than non-users. Discomfort from respiratory symptoms was also diminished, leading to an improved quality of life. However, there is no information available on the efficacy of this device from prospective studies. The current study was undertaken to investigate in a prospective fashion the efficacy of this device in reducing respiratory symptoms after total laryngectomy.

Methods

All laryngectomized patients visiting the Netherlands Cancer Institute outpatient clinic during a 2-month period of 1988 were asked to participate in the study. Out of 45 patients, 42 agreed to participate. Of the three patients who refused, one claimed to have no respiratory problems, one considered the use of the HME too cumbersome, and a third patient did not want to replace her silver necklace, which had been specially designed to cover her stoma. The great majority of patients (90%) were male. The mean age of the sample was 68 years (range of 48 to 89) and the time since total laryngectomy varied from 6 months to 19 years, with a median of 6.2 years.

Each of the patients studied was provided with 160 HME's (Figure 1) and was instructed in how to fix the device to the skin around the stoma (Figure 2). Patients were informed of the likelihood of increased airway resistance and of the need to change the device whenever it became obstructed with secretions. They were also told that a reduction in the volume and frequency of mucus production could not be expected for one or two weeks.

Figure 1. Stomvent: details of microporous paper, housing and a complete device.

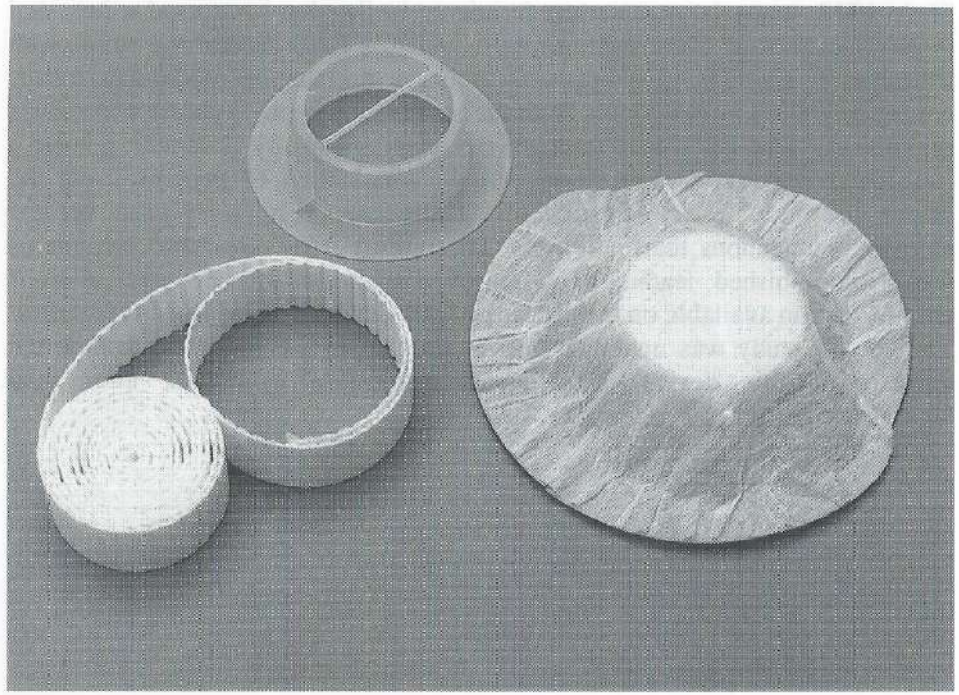
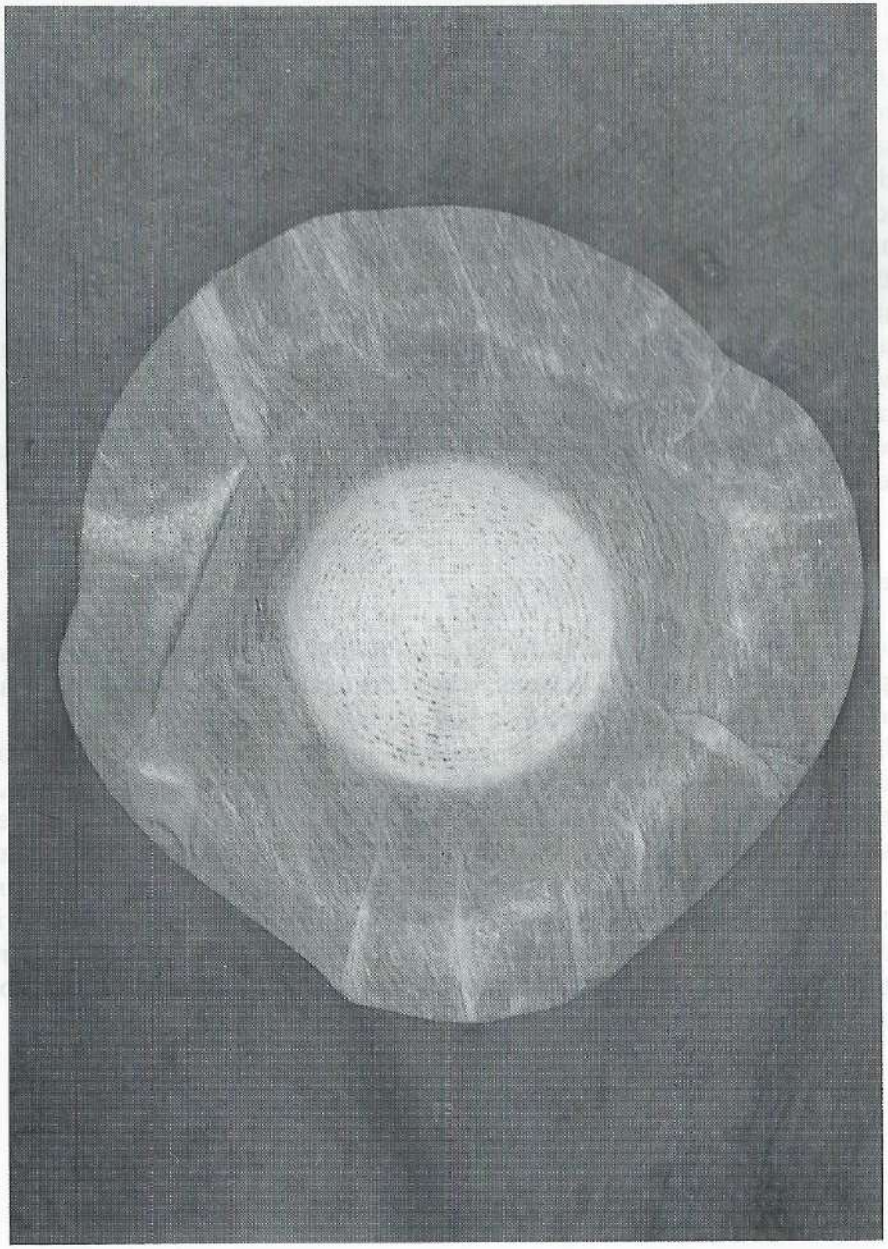


Figure 2. Stomvent glued around the stoma.



Patients were interviewed before starting to use the HME and after 6 weeks of use. All patients were interviewed by the same investigator during a routine follow-up visit to the outpatient clinic. Both interviews required, on average, slightly over 1 h to complete.

The first interview was designed to evaluate the presence and severity of respiratory symptoms (cough, sputum production, breathlessness, wheezing, bronchial asthma, nasal discharge, pulmonary infections and forced expectoration), fatigue and sleep problems, perceived adequacy of voice rehabilitation, social contacts and anxiety and depression.[2] The second interview included additional items on various practical aspects of the device such as the number used per day[5], use during the night, skin irritation, problems with adhesion to the skin, fixation during coughing and airway resistance. Finally, patients were asked to provide an overall rating of the usefulness of the usefulness of the HME and to report, whether they would use it in the future and whether they would recommend it to fellow patients. The size of the stoma was measured for all patients and photographs were taken to indicate the position of the stoma in relation to the border of the sternomastoid muscle and the upper border of the sternum.

Results

Twenty-nine of the 42 patients (69%) used the HME continuously, both day and night. Of the remaining 13 patients, 7 used the device frequently but irregularly and 6 discontinued use after only a few days.

All 42 patients complained at baseline measurement of excess sputum production. The use of the HME did not eliminate this problem. However, as noted in Table 1, a significant reduction in the mean daily frequency of several respiratory symptoms was found. Over the entire sample, both the frequency of daily sputum production and the incidence of stoma cleaning decreased significantly. Among the 29 patients who used the device continuously during the study period, the frequency of forced expectoration also declined significantly. Although the daily frequency of coughing decreased considerably, this difference was not statistically significant.

[5] Patients were asked to make note of the number of HME's they used in the first and in the last week of the test period.

Table 1. Mean daily frequency of respiratory symptoms before (pre) and after 6 weeks (post) use of an HME.

	All patients (n=42)		Regular users (n=29)	
	pre	post	pre	post
coughing	13.8	8.4	10.7	6.7
sputum production	12.6	8.2**	10.1	6.1***
forced expectoration	12.2	8.2	9.5	6.2*
stoma cleaning	9.0	4.5***	6.4	3.5*

(Wilcoxon test: * $p < 0.05$ / ** $p < 0.02$ / *** $p < 0.01$)

Symptoms of fatigue and malaise also improved significantly over time ($p < 0.01$). Social contacts (such as receiving visitors, making telephone calls and paying visits) improved as well ($p < 0.01$).

An important factor influencing the effectiveness of the HME appeared to be the method of vocal rehabilitation. Patients using esophageal speech or an electrolarynx (n=16) benefited more than did patients using a voice prosthesis (n=26). In the latter group, 56% of the patients had problems with the occlusion of the stoma which caused difficulty in speech production.

Other problems related to the use of the device are shown in Table 2. Frequent removal of the plaster was seldom painful. Skin irritation was infrequent and was never a reason for discontinuing use of the HME. More than half of the patients complained of loosening of the plaster by coughing, but with decreasing frequency of coughing after a few weeks this problem diminished considerably. A quarter of the patients felt that the adhesive properties of the plaster could be improved.

Table 2. Severity of problems in using the HME.

	Frequencies (%)			
	not at all	a little	quite a bit	very much
Removal painful	88	10	2	0
Skin irritation	79	14	7	0
Loosening by coughing	17	24	29	30
Inadequate adhesion	57	17	7	19

The number of HME's used decreased considerably during the 6 week study period. In the first week patients used an average of 32.3 devices and in the last week 23.1. Asked about this decrease, patients linked it with a reduction in the frequency of coughing and forced expectoration.
The increase in airway resistance appeared to be of relatively minor importance. Only 17% of the patients experienced a clear increase in resistance, and this was seldom a reason for abandoning the use of the HME. Most patients reported adjustment to this feeling after only a few days.
The size of the stoma, measured in two directions due to its usually oval shape, varied from 9 to 22 mm for the largest diameter and from 7 to 19 for the smallest diameter. The mean diameter was 15.4 mm and 12.7 resp. There was no significant correlation between the diameter of the stoma and the effectiveness of the HME. The actual position of the stoma in the neck (i.e. a deep or asymmetrically positioned stoma) made fixation of the device troublesome for 14% of the patients.
After six weeks of use, 63% of the patients reported that most of their respiratory symptoms were reduced by the HME, whereas 37% experienced no significant benefit. Of the patients who did benefit, more than 40% improved considerably. Asked about their advice to fellow patients, 20% would strongly recommend it, 78% would recommend at least a serious try out and only one patient would advise against the use of the device. Fifty-seven percent of the patients said that they would like to continue using the HME.

Discussion

The primary aim of this study was to assess prospectively the influence of a heat and moisture exchanger (HME) on the respiratory symptoms in laryngectomized patients. Also of interest was the influence of improvement of respiratory symptoms on other aspects of every day life.
Patients were asked to use the device for 6 weeks; a period assumed to be long enough to demonstrate its advantages and/or disadvantages. It was expected that most patients would need considerable time to adjust to the HME, but in practice most patients made this adjustment within a few days. Although all patients had their laryngectomy at least 6 month prior to participation in the study, and thus were accustomed to breathing with very little resistance, few complained of increased airway resistance. This problem was typically resolved within the first few days of use.
After a period of habituation and decrease of the respiratory symptoms, regular users needed about 3 devices per day. Some patients could remove the device when it became obstructed with secretions, clean it and use it again. Generally, however, patients tended to use a new device rather than re-use an old one.

Compliance with the use of the device was quite good. Approximately two-thirds of the patients used the device continuously. Some long term survivors who had long since adapted to their condition without a special stoma protector were resistant to using the HME.
Although a period of six weeks would seem to be relatively short to achieve any changes in the respiratory symptoms in laryngectomized patients, we observed several positive effects. A significant decrease in mean daily frequency of sputum production, forced expectoration and stoma cleaning was reported by the 29 patients who used the HME continuously.
Of equal importance is the observation that a decrease in respiratory problems had a significant impact on several aspects of daily life. Feelings of fatigue were diminished and social contacts improved. Many patients had reported that the need to frequently clean their stoma made them feel uncomfortable in social situations. By reducing the frequency of such hygienic activities, social contacts appeared to be facilitated.
Patients using esophageal speech or an electrolarynx benefited more from the HME than did patients using a voice prosthesis. This is primarily due to the problem of occlusion of the stoma in the latter group. In order to be able to use the voice prosthesis properly, the stoma has to be occluded air-tight. More than half of these patients had problems in achieving such occlusion with consequent speech difficulties. Confronted with the choice between maintaining voice quality or reducing respiratory symptoms, patients consistently choose the former.
One of the factors contributing to difficulties with the occlusion of the stoma might be the relatively high resistance of the voice prosthesis employed.[7] With the availability of a voice prosthesis with the same retaining properties as the Groningen voice prosthesis, but with a much lower resistance, this problem might be minimized.[8] Customizing the shape of the HME might also contribute to the resolution of this problem.
Generally, there were few side effects related to the use of the device. Frequent removal of the plaster was seldom painful and skin irritation was only a short-term problem though it should be noted that one patient who used the HME after the conclusion of this study experienced a severe allergic skin reaction which necessitated discontinuing use of the device. Loosening of the plaster by coughing diminished after a few weeks as the frequency of sputum production decreased.
The position of the stoma is an important factor affecting the use of the HME. Several patients reported problems with proper fitting of the device because of a deep or asymmetrical positioning of the stoma in the neck. One might expect that customization of the housing would resolve this problem.
In conclusion, the results of this study indicate that an HME can reduce respiratory symptoms after total laryngectomy. Sixty-three percent of the

patients experienced a significant reduction in sputum volume, frequency of forced expectoration and stoma cleaning. In about a quarter of the patients this reduction was quite dramatic (e.g. from almost 100 times per day to less than five times per day). With further reduction of the resistance of voice prostheses, and preferably customization of the housing of the device, one could expect that the large majority of patients would benefit from the use of an HME. Further research is needed to determine whether application of this device immediately after total laryngectomy could prevent the development of troublesome respiratory symptoms in this patient population.

It should be stressed that the HME is a medical device. Proper counseling in its use by the physician is needed to obtain optimal results, particularly in patients who have had a laryngectomy for some time.

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Chapter V

Improvements in the assessment of pulmonary function in laryngectomized patients

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Abstract

The validity of pulmonary function assessment after total laryngectomy was studied in eight patients by comparing the use of an extratracheal device, glued over the tracheostoma, with an intratracheal device, i.e. a cuffed trachea cannula, as a means to connect the patient to the spiro- or pneumotachometer. As extratracheal device, the baseholder of a Heat and Moisture exchanger (HME, Freevent) was used. The use of the HME baseholder did not create problems in any of the 8 patients. The device could easily be attached to the stoma and the spiro- or pneumotachometer in all patients. The use of the trachea cannula, however, did cause problems. All patients complained about tracheal irritation by the introduction of the cannula, and in two patients the assessment of the pulmonary function was hindered for several minutes by an unpleasant coughing-fit. Therefore, both the patients and the technician preferred the use of the HME baseholder. More importantly, the forced and peak expiratory flow/volume (FEV1 and PEF) and the forced, peak and maximum inspiratory flow/volume (FIV1, PIF and MIF50) appeared to be significantly higher ($p < 0.05$) when the HME baseholder was used.
The results of this study indicate that this HME baseholder as a means to connect a laryngectomized patient to a spiro- or pneumotachometer, is a simple and useful device to perform pulmonary function tests. The method is convenient for the patient and easy to apply for the lung function technician. Moreover, the test results assessed with the use of the HME baseholder give a more accurate representation of the actual lung function of these patients.

Keywords: total laryngectomy, heat and moisture exchanger (HME), pulmonary function analysis.

Introduction

Respiratory symptoms after total laryngectomy are both frequent and troublesome. The vast majority of laryngectomized patients is complaining of coughing, excessive sputum production and frequent need to clear the airway by forced expectoration.[1] Many of these patients also suffer from chronic obstructive lung disease (COLD).[2] In the literature, objective information on the respiratory condition in laryngectomees, as assessed in the pulmonary function laboratory, is scarce.[2-7] A reliable estimate of pulmonary function is mandatory, also in this category of patients, to avoid problems with surgical interventions and to assess the effects of (bronchodilator) therapy. Traditionally, the assessment of the pulmonary function in these patients has been performed by means of a cuffed trachea cannula, connected to a pulmonary function analyzer.[5,6] The use of a cannula, however, is troublesome for two reasons. First, its insertion is often an unpleasant experience for the patient and leads to uncomfortable coughing, sometimes lasting for several minutes. Spraying of a local anaesthetic does not completely solve this problem, as it is often initiates a coughing-fit. More importantly, the use of a cuffed cannula is considered a negative influence the results of forced expiration and inspiration tests by decreasing the actual diameter of the trachea.[2] To avoid this problem, extratracheal devices, such as specially constructed "mouthpieces", were used by some authors.[3,4,7] Also trachea masks, manually placed over the stoma, have been used for this reason.[2] A standardized, simple and accurate method for the assessment of pulmonary function in laryngectomized patients would undoubtedly be a step forward.
In a previous study, we have demonstrated that the regular use of a heat and moisture exchanger (HME) positively influences the subjective pulmonary problems of laryngectomees.[8] To obtain objective information on the pulmonary function of these patients before and after the use of an HME, a second study was designed. For this study, a recently developed HME(1), consisting of a baseholder (a silicone housing placed in adhesive tape) and a separate filter, was used. Its design enables its use as an extratracheal connecting device to a spiro- or pneumotachometer. The diameter of the baseholder of the HME is manufactured according to the standards for general use in breathing systems, set by the International Organization for Standardization (ISO).[9] This ensures easy connection to lung function testing and anaesthetic equipment through standard coupling parts. In this study, the effect of the new baseholder has been compared with that of a cuffed trachea cannula on the outcome of the pulmonary function tests in eight laryngectomized patients.

Patients and Methods

Eight laryngectomized patients, 7 men and 1 woman, visiting the Netherlands Cancer Institute outpatient clinic, participated in the study. Mean age was 59 years (range 47 - 70 years) and time elapsed since operation varied from 19 days to 11 years (mean 4.15 years, median 4.5 years).
The baseholder of the HME (Freevent, Pharma Systems, Sweden, (Figure 1) consists of a silicone housing with an internal diameter of 22 mm (ISO 5356), placed in adhesive tape, in which the separate filter can be inserted. This device is glued onto the skin around the stoma. The baseholder is available in five different shapes, enabling a proper fitting for every tracheal stoma, irrespective of form and size, even when deeply or asymmetrically situated in the neck. The standard Masterlab Transfer (Erich Jaeger GmbH, Würzberg, Germany) pneumotachometer was used. The trachea cannula used in all patients was a low-pressure cuffed tracheostomy tube no 8, manufactured by Shiley Inc. (USA).

Routine pulmonary function testing included measurements of vital capacity (VC), forced expiratory volume in 1 second (FEV1), peak expiratory flow (PEF), maximum expiratory flow-volume at 50% (MEF50) and the same measurements for the inspiratory flow (FIV1, PIF, and MIF50 respectively). Maximum expiratory and inspiratory flow-volume loops were also recorded. These measurements were performed sequentially with the HME baseholder and with the trachea cannula in every patient. The experimental set-up with the HME baseholder in situ over the stoma, connected to the pneumotachometer is shown in Figure 2.

Statistical analysis of the data, performed with the SPSS/PC+ package, included the Wilcoxon non-parametric tests for paired observations. A two-tailed p-value below 0.05 was considered significant.

Figure 1. Freevent heat and moisture exchanger: the 5 different shapes of the baseholder. Also shown are the cassette, containing the actual heat and moisture exchanging filter and the hook, which is used by the patient to remove the filter cassette.

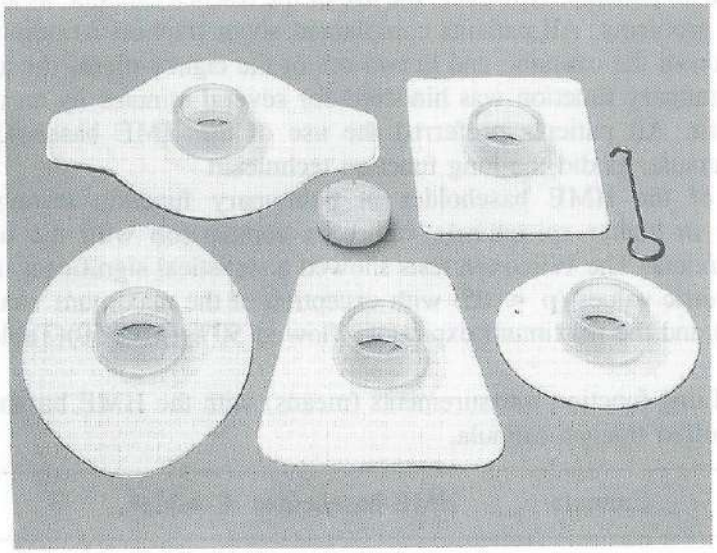
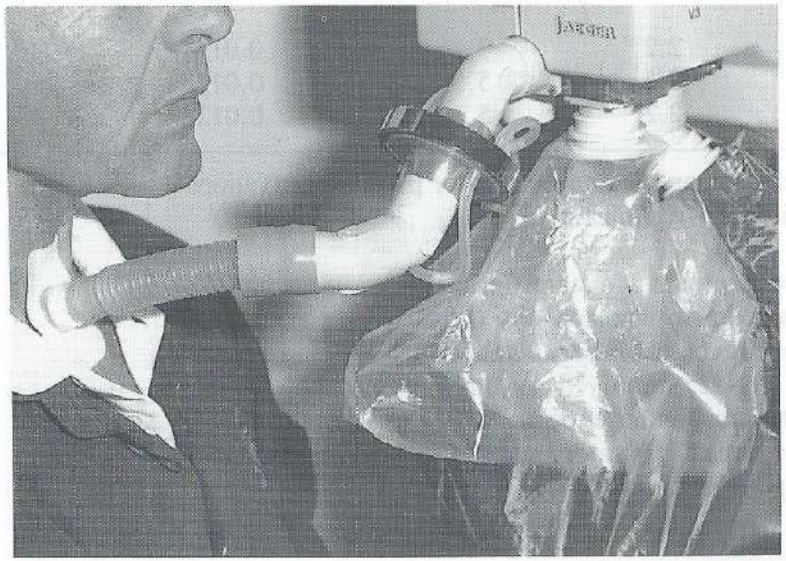


Figure 2. Patient connected with the HME baseholder to the standard lung function testing equipment.



Results

The use of the HME baseholder caused no problems in any of the 8 patients. The baseholder could easily be attached to the stoma and the lung function analyzer in all patients. However, the use of the trachea cannula, as anticipated, did cause problems. All patients complained about tracheal irritation after the introduction of the cannula, and in two out of the eight patients the assessment of the pulmonary function was hindered for several minutes by an unpleasant coughing-fit. All patients preferred the use of the HME baseholder to the trachea cannula, as did the lung function technician.

The use of the HME baseholder in pulmonary function testing resulted invariably in higher spirometric values in comparison with the use of the trachea cannula. The Wilcoxon tests showed a statistical significant increase in all spirometric values ($p < .05$) with exception of the maximum vital capacity (VC Max) and the maximum expiratory flow at 50% (MEF50)(Table 1).

Table 1. Lung function measurements (means) with the HME baseholder and with the cuffed trachea cannula.

	Cannula	HME baseholder	P-value*
VC	3.1	3.3	0.063
FEV1	2.2	2.4	0.012**
PEF	4.8	7.1	0.012**
MEF50	2.2	2.5	0.484
FIV1	2.2	3.1	0.012**
PIF	2.5	5.5	0.012**
MIF50	2.2	5.1	0.012**

* Wilcoxon non-parametric test for paired observations
** Statistically significant

HME = Heat and Moisture Exchanger.
VC = maximum vital capacity (litres/sec.)
FEV1 = forced expiratory volume in 1 second (litres/sec.)
PEF = peak expiratory flow (litres/sec.)
MEF50 = maximum expiratory flow at 50% (litres/sec.)
FIV1 = forced inspiratory volume in 1 second (litres/sec.)
PIF = peak inspiratory flow (litres/sec.)
MIF50 = maximum inspiratory flow at 50% (litres/sec.)

This increase is most prominent in inspiratory tests. In some instances, the values obtained with a cannula showed a more than 50% drop compared with the figures for the HME baseholder.(Table 2)

Table 2. Differences (range %, standard deviation and mean %) between pulmonary function tests with the HME baseholder and with the cuffed trachea cannula.

	RANGE (%) *	SD	Mean (%)
VC	1.9 to -25.6	9.8	-7.9
FEV1	-1.6 to -21.4	6.5	-9.3
PEF	-16.6 to -46.4	11.1	-32.2
MEF50	65.0 to -49.6	39.6	1.6
FIV1	-15.6 to -57.8	14.0	-28.2
PIF	-44.5 to -67.4	6.7	-54.3
MIF50	-41.9 to -72.0	9.3	-56.2

* Difference between HME baseholder and cannula = (cannula - HME) * 100% / HME

To illustrate the obvious difference between the use of an HME baseholder and a cuffed trachea cannula, the flow-volume loops of two patients are shown in Figure 3. In both patients, the curve obtained with the cannula lies almost entirely inside the area, plotted for the HME baseholder. In patient A, mainly the inspiratory values are decreased with the cannula. In patient B, however, both the inspiratory and expiratory values are decreased significantly with the cannula.

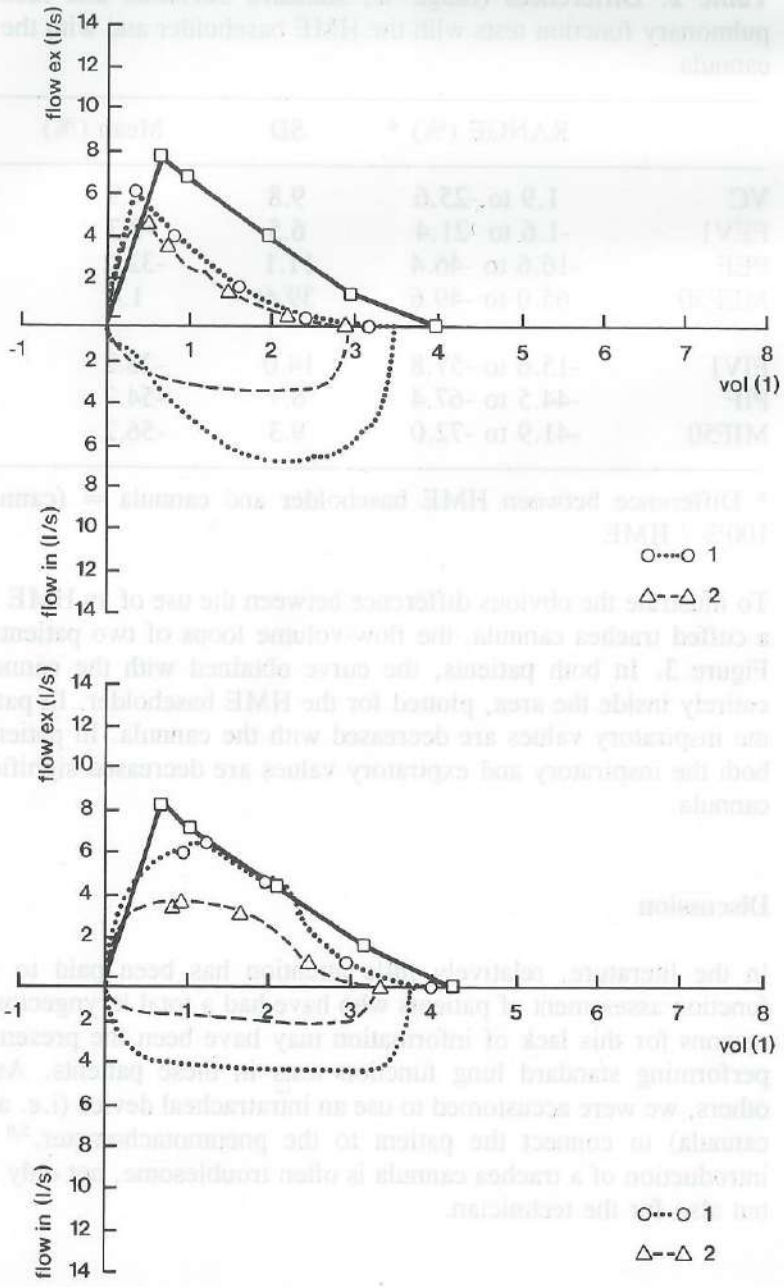
Discussion

In the literature, relatively little attention has been paid to the pulmonary function assessment of patients who have had a total laryngectomy. One of the reasons for this lack of information may have been the present difficulties in performing standard lung function tests in these patients. As described by others, we were accustomed to use an intratracheal device (i.e. a cuffed trachea cannula) to connect the patient to the pneumotachometer.[5,6] However, the introduction of a trachea cannula is often troublesome, not only for the patient, but also for the technician.

Figure 3. Flow-volume curve with the HME baseholder (1) and with the cuffed trachea cannula (2). The solid line with open squares represents the standard expiratory flow/volume loop, predicted for this patient, based on age, sex, weight, length, and race. (No standard inspiratory values are available in the Netherlands.)

I. Patient A.

II. Patient B.



To avoid this problem, some authors describe the use of an extratracheal device, consisting of a special "mouthpiece", constructed with a plastic tube and a latex balloon cuff, to obtain an air-tight seal.[3] Others, remove the lugs of a normal standard mouthpiece, and connect this to the stoma with air-tight sticking plaster,[4,10] or place a trachea mask manually over the stoma.[2,7] These methods are still uncomfortable for the patient as well as inconvenient for the technician. In contrast, the here described application of an extratracheal device glued over the stoma, i.e this HME baseholder, is easy to perform, both for the patient and the lung function technician. In addition, coughing-fits caused by the insertion of a cannula are avoided by using the HME baseholder. Because of the availability of 5 differently shaped plasters, it can be sealed air-tight around every type of tracheal stoma, even when this is situated deeply or asymmetrically in the neck.

Besides the convenience of the HME baseholder, our data show unequivocally that the values of the lung volumes and functions, determined with the use of this extratracheal device, are more reliable. Similar results were reported by Togawa et al.,[2] who compared the results obtained with a small mask, directly placed on the tracheostoma, with those obtained with a cuffed trachea cannula. Our experiments indicate that an intratracheal device, like a cuffed trachea cannula, negatively influences all pneumotachographic values, in particular the inspiratory flow values. The test results obtained with a cannula are for the peak and maximum inspiratory flows even more than 50% lower. The peaks of the expiratory and inspiratory loops of all patients are lopped off, which is most probably caused by the increased airway resistance of the cannula.[2]

In conclusion, the results of this study indicate that this HME baseholder, used for the extratracheal connection of a laryngectomized patient to a spiro- or pneumotachometer, is a simple and useful device for routine pulmonary function testing. The method is more convenient for the patient and easier to apply for the lung function technician than other methods, commonly used. Moreover, the values obtained with the HME baseholder give a more valid assessment of the actual lung function of laryngectomized patients.

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Chapter VI

Improvements in respiratory and psychosocial functioning following total laryngectomy by the use of a Heat and Moisture Exchanger (HME)

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Abstract

A prospective, clinical study in 61 patients was undertaken to investigate the subjective and objective influence of a heat and moisture exchanger (HME, Freevent) on the respiratory and psychosocial problems following total laryngectomy. Although statistical comparisons failed to detect significant differences between the experimental and the control group, there was a clear trend towards improvements in respiratory and psychosocial functioning in the experimental group. Analyses of differences over time within the HME user group showed significant reductions in the incidence of coughing, the mean daily frequency of sputum production, forced expectoration and stoma cleaning. Significant reductions were also found in shortness of breath, fatigue and malaise, sleep problems, levels of anxiety and depression and in perceived voice quality. Pulmonary function tests showed significant improvements in the inspiratory flow/volume values (FIV1, PIF and MIF50) following use of the HME. This objective improvement in inspiratory pulmonary function reflects the decrease in sputum production reported by the patients.

Keywords: heat and moisture exchanger, laryngectomy, pulmonary function, quality of life, voice restoration.

Introduction

After total laryngectomy patients frequently experience a range of respiratory problems, including excessive sputum production, coughing, forced expectoration to clear the airway and stoma cleaning.[1] These problems can have a serious impact on many aspects of daily life, including increased fatigue and sleeping problems, compromised voice quality, disrupted social contacts and heightened psychological distress.[1]

The most likely cause of the respiratory problems after total laryngectomy is the disconnection between the upper and lower airways, that is, the loss of the nose with its cleaning, heating and moisturizing effect on inhaled air. Air inhaled after laryngectomy is not conditioned, and this can result in irritation of the bronchial mucosa, coughing, increased sputum production and crusting.[2] Moreover, the pulmonary physiology may be negatively influenced by the decrease in airway resistance of the stoma. Although respiratory problems tend to diminish somewhat in the first year after surgery, almost all patients continue to suffer from these symptoms. Frequently, there is an increase of respiratory symptoms during the winter.[3]

In an attempt to restore some of the lost "nose" functions we previously investigated the influence of a Heat and Moisture Exchanger (HME) on respiratory symptoms after total laryngectomy.[4] Use of a similar device has been demonstrated to reduce the diurnal loss of water through the exhaled air by approximately 60% (250-300ml).[5] The filter also increases airway resistance. Moreover, the results of this study significantly reduce many respiratory symptoms after total laryngectomy, including the frequency of daily sputum production and the incidence of stoma cleaning, even after a relatively short period of use (6 weeks).[4] Symptoms of fatigue and malaise and social contacts improved significantly over time as well. However, the combination of a voice prosthesis and this HME created some difficulties. Some patients had problems creating an air-tight seal around the stoma in order to speak properly. One of the factors contributing to these problems might be the relatively high resistance of the voice prosthesis then employed.[6] Other contributing factors were the rigidity of the HME and the difficult fixation, in case of a deep or asymmetrical situated stoma.

Although the results of this earlier study were encouraging, the absence of an appropriate control group, the relatively short follow-up period and the absence of objective measures of lung function suggested the need for further research. Moreover, certain technical advances achieved since the first study held promise for resolving the problems observed in using an HME. First, a new voice prosthesis (Provox™), developed in our institute, became available.[7] Its low airflow resistance could make the occlusion of the stoma to obtain speech less critical. Second, a new type of HME became available which is more flexible

and comes in various shapes, thus facilitating tailoring to the anatomical characteristics of individual patients.

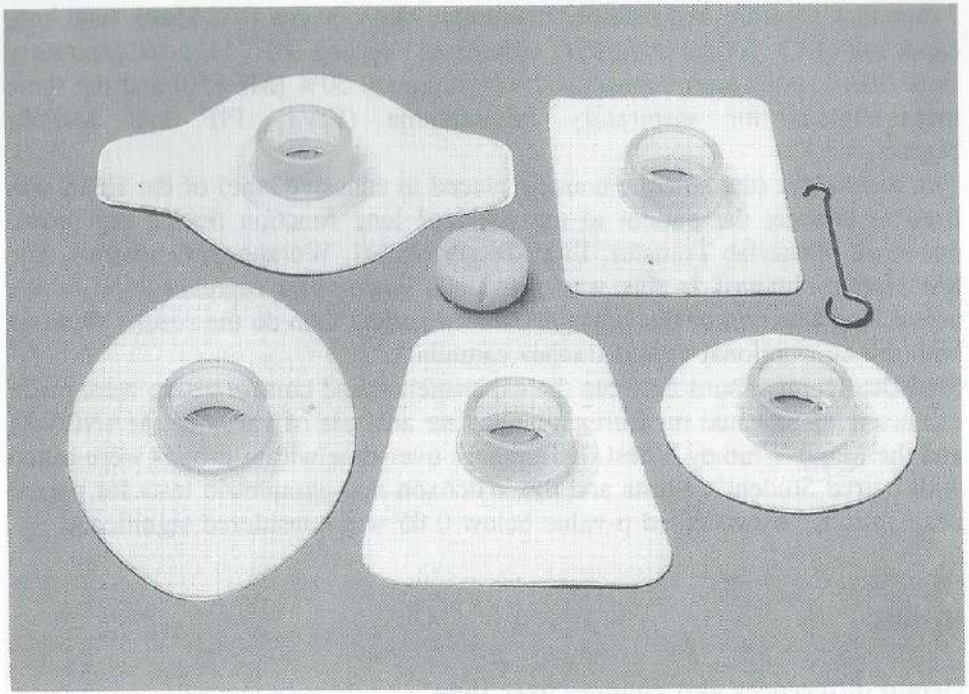
The current clinical study was undertaken to: (1) investigate the influence of this new type of HME on physical and psychosocial consequences of total laryngectomy; (2) determine if subjective improvements in pulmonary function could be confirmed with objective lung function measures; (3) determine whether the new HME could successfully resolve the problems concerning fixation; and (4) investigate whether the combination of the new HME and voice prosthesis could resolve the previously observed speech problems.

Patients and Methods

All laryngectomized patients without prior experience with an HME who visited the Netherlands Cancer Institute outpatient clinic during a 4-month winter period of 1990/1991 were requested to participate in the study. Two elderly patients refused to participate. The 48 patients who gave their consent were randomized either to the experimental group to test the HME (n=24), or to a no-treatment control group (n=24). An additional group comprising of 15 patients who participated in our earlier HME study[4], was included in order to compare their experience with the previous device and the new device. The majority of patients (89%) was male. The mean age of the sample was 66 years (range 46-84). The time since total laryngectomy varied from 3 months to 24 years, with a median of 2.8 years.

The patients randomized to the HME group and the group from our previous study were provided with HME's for a 3-month period. The HME (Freevent) used in this study consists of a silicone housing (with a diameter of 22 mm), placed in adhesive tape, and a removable filter, consisting of a non-woven, monofilament polymer (polypropene/polythene). This device is glued to the skin around the stoma as well. When the filter becomes obstructed with secretions it is not necessary to replace the complete device, but only the filter. The tape is available in 5 different shapes (Figure 1). The best possible fitting plaster was prescribed for each patient. Patients were instructed in how to fix the device to the skin around the stoma and how to replace the filter when it became obstructed with secretions. The patients were instructed to use the HME, if possible, both day and night.

Figure 1. Freevent Heat and Moisture Exchanger: 5 different shapes of the baseholder, the cassette containing the heat and moisture exchanging filter and a hook, which is used by the patient to remove the filter cassette.



All patients were interviewed by the same investigator at the start of the study and again after 3 months during a routine follow-up visit to the outpatient clinic. Both interviews required, on average, one hour to complete.

The content of the interview has been described in detail elsewhere.[1] Briefly, the first interview evaluated the presence and severity of respiratory symptoms (cough, sputum production, shortness of breath, wheezing, bronchial asthma, nasal discharge, pulmonary infections and forced expectoration), fatigue and sleep problems, perceived adequacy of voice rehabilitation, social contacts and anxiety and depression. The second interview included additional items on various practical aspects of the device, such as the number of filters and plasters

used per day[6], use during the night, skin irritation, problems with adhesion to the skin, fixation during coughing, problems with replacing the filter, and airway resistance. Finally, patients were asked to provide an overall rating of the usefulness of the HME and to report whether they intended to use it in the future and whether they would recommend its use to fellow patients.

Pulmonary function tests were performed on all patients entering on study and 3 months thereafter, and included maximum vital capacity (VC Max), total lung capacity (TLC), forced expiratory volume at 1 second (FEV1), peak expiratory flow (PEF), maximum expiratory flow-volume at 50% (MEF50) and the same measurements for inspiratory flow/volume (FIV1, PIF and MIF50, respectively).

The baseholder (the silicone housing placed in adhesive tape) of the HME was used to connect the patient to the standard lung function testing equipment (standard Masterlab Transfer, Erich Jaeger GmbH, Würzberg, Germany). The test results obtained in this way provide a more valid representation of the actual lung function of the laryngectomized patient than do the results obtained with the conventional cuffed trachea cannula.[8]

Statistical comparisons between the experimental and control group were made by means of repeated measures multivariate analysis of variance (MANOVA) and the Mann-Whitney U test. Differences over time within groups were tested with paired Student's t-tests and the Wilcoxon non-parametric tests for paired observations. A two-tailed p-value below 0.05 was considered significant.

Results

Group differences and changes over time

Statistical comparisons failed to detect any significant differences between the experimental and the control group in respiratory and other physical symptoms, voice rehabilitation, or psychological and social functioning. In part, the failure to detect statistically significant group differences can be attributed to the small sample size and the resulting restriction in statistical power. Nevertheless, the results suggested a trend toward diminished respiratory problems, a reduction in levels of fatigue and malaise, improved lung function and improved voice quality among the HME user group. Additional analyses were carried out to examine differences over time within the group of HME users (the experimental group and the 15 experienced patients, combined) and within the control group.

[6] Patients were asked to report the number of HME's they used during the first and last week of the 3-month trial period.

These within-group analyses do not require as large a sample size as do the between-group multivariate analyses.

Of the 24 patients randomized to the HME group, one patient died during the observation period due to intercurrent disease and another patient suffered from severe, prolonged bronchitis which prevented him from using the HME. Combined with the 15 patients, this resulted in a group of 37 patients that used the HME. Of these 37 patients 19 (51%) used the HME continuously, 7 (19%) used the device frequently, but irregularly, and 11 (30%) patients discontinued use after a period of between 3 and 42 days. The mean number of filters employed by those patients who used the HME continuously decreased significant from 20.9 to 16.4 filters per week ($p < .05$) . The mean number of baseholders used did not change significantly over time (from 10.2 to 8.6 baseholders per week).

Table 1. Weekly incidence of coughing before and after the 3-month study period.

	HME group (N=37)*		Control Group (N=24)	
	before	after	before	after
not at all	12	20	12	11
1 à 2 days per week	2	-	1	-
3 à 4 days per week	2	-	1	1
5 or > days per week	21	17	10	12

* $p < .05$

The number of patients who do not cough at all increased from 12 to 20 patients (Table 1), and the mean daily frequency of sputum production, forced expectoration and stoma cleaning decreased significantly among the HME users.(Table 2).

Significant improvements were also observed within the HME group over time in shortness of breath ($p < .01$), feelings of fatigue and malaise ($p < .01$), sleep problems ($p < .01$), symptoms of anxiety and depression ($p < .01$), and perceived voice quality ($p < .001$).

Table 2. Mean daily frequency of respiratory symptoms before and after the 3-month study period.

	HME Group (N=37)		Control Group (N=24)	
	before	after	before	after
Coughing	9.5	7.2	7.4	8.3
Sputum production	10.4	7.2*	11.6	9.9
Forced expectoration	10.2	6.9*	11.7	9.8
Stoma cleaning	4.7	3.2**	5.1	5.0

* $p < .005$ ** $p < .01$

Within the control group (n=24) a slight, statistically non-significant decrease in the mean frequency of sputum production and forced expectoration was noted. A significant reduction in sleep problems ($p<.05$) and symptoms of anxiety and depression ($p<.05$) was also found. In part, these observed changes in the control group can be attributed to those patients (n=7) for whom the time since surgery was less than 1 year. That is, during the first post-operative year respiratory problems tend to diminish spontaneously. With the exclusion of these 7 patients the decrease in sleeping problems and levels of anxiety and depression was no longer statistically significant. In the HME group there were also 5 patients who had been laryngectomized less than a year ago. When these 5 patients were excluded, the improvements in the HME group remained statistically significant.

HME users' experience

Increase in airway resistance due to the filter was never given as a reason for discontinuing the use of the HME. Only a few patients (n=5) reported that they sometimes removed the filter during the first days of the study period.
Half of the patients with a voice prosthesis (n=31) reported problems with the occlusion of the HME in order to speak. Interestingly, a few patients (n=3) mentioned that the HME facilitated speaking, while their intelligibility also improved. Other problems relating to the use of the HME are shown in Table 3. The removal of the plaster was seldom painful and replacement of the filter did not present any problems. A few patients (n=3) were troubled by skin irritation. One third of the patients complained about loosening of the plaster by coughing although, in general, patients were satisfied with the adhesive properties of the plaster.

Table 3. Severity of problems after using HME* (N=37).

	Frequency (%)			
	None	Slight	Moderate	Great
Removal painful	69	25	6	0
Skin irritation	64	25	8	3
Loosening by coughing	47	20	2	11
Inadequate adhesion	81	8	8	3
Replacement filter	97	3	0	0

* HME - heat and moisture exchanger

After 3 months of HME use 61% of the patients reported that their respiratory symptoms had diminished, with the remaining 39% experiencing no significant benefit. Fifty-eight percent of the patients stated that they intended to continue using the HME. All patients reported that they would recommend that fellow patients try the HME, with 25% stating that they would strongly recommend its use. Fourteen of the fifteen patients who participated in the previous HME study expressed a preference for the Freevent HME over the Stom-Vent HME. The main reasons for this preference were that it facilitated speech (n=4) and had better adhesive properties (n=5).

Pulmonary functioning

Pulmonary function tests were available for 30 of the 37 HME users. In 2 cases, one of the two pulmonary function tests was not available. In 5 cases the test results could not be used because the first lung function test had been performed with a trachea cannula instead of the HME baseholder. Earlier research has demonstrated that these 2 methods produce significantly different test results.[8]
The results of the pulmonary function tests indicated that the HME was more effective on the inspiratory flow/volume than on the expiratory flow/volume. Within the HME group, a significant improvement over time was found in the forced inspiratory volume in 1 second (FIV1, $p<.05$) and in the maximum and peak inspiratory flow (MIF50 and PIF, $p<.005$)(Table 4). No such improvements in pulmonary functioning were found for the control group.

Table 4. Pulmonary function before and after the 3-month study period (N = 30).

	Before	After
VC max	3.5	3.6
FEV1	2.3	2.4
PEF	6.1	6.5
MEF50	2.1	2.4
FIV1	2.9	3.1*
PIF	4.2	5.0**
MIF50	3.7	4.6**

* $p < .05$ ** $p < .005$

Discussion

The principal aim of this prospective clinical study was to determine whether the use of an HME diminishes respiratory symptoms in laryngectomized patients and therefore improve the quality of their lives, and to determine if subjective improvements in pulmonary function could be confirmed by pulmonary function tests. In this study a new type of HME was tested whose design was intended to resolve previously observed problems associated with the combined use of an HME and a voice prosthesis and with fixation problems due to a deep and/or asymmetrically positioned stoma.

Given the fact that approximately half of all laryngectomized patients report an increase in respiratory problems during the winter season[1,3], all patients needed to be interviewed and subjected to pulmonary tests during the same season. The restricted period of patient accrual resulted in a relatively small sample size, thus limiting the power of the current study to detect significant differences between the experimental and control group. However, among the HME users group a clear trend was noted toward diminished respiratory problems and fatigue, and toward improved pulmonary function and voice quality.

Additional analyses of within-group changes over time confirmed that, for the HME user group, there was a significant reduction in respiratory problems and in the need to clean the stoma over the 3-month study period. As a consequence, among the HME users a positive change was noted over time in several aspects of daily life, including decreased fatigue and sleep problems, decreased psychological distress and improved voice quality. These findings are, in general, in accordance with our previous HME study, where a

significant reduction was observed in sputum production, stoma cleaning, and fatigue and a significant improvement was noted in social contacts.[4]

Half of the patients using a voice prosthesis continued to have difficulties with the occlusion of the stoma in order to speak. For some patients the diameter of the HME filter (22 mm) was too large to be easily closed air-tight with a finger. The use of a special adaptor ring (with a smaller diameter) can minimize this problem.

A proper fitting and fixation of the HME for irregular or deep and/or asymmetrically situated stoma's was possible given the availability of 5 different HME plaster shapes. The anatomical shaped plaster was particularly effective in this regard. The adhesive properties of the HME used in the current study were better than those of the earlier model. An important practical advantage of the Freevent HME is that the plaster does not need to be removed when replacing a filter obstructed by secretions. However, some experience and skill is required to clean the stoma while the baseholder is still glued over the stoma. The patient may require some assistance (for example, from a spouse) in performing this task. As was noted in our previous study, irritation caused by an allergic skin reaction to the HME led a few patients (n=3) to discontinue use of the device. Loosening by coughing diminished with the drop in sputum production. Some patients also mentioned that transpiration sometimes resulted in loosening of the plaster. Cleaning the skin with alcohol contributes to the resolution of this problem. Patients who had experience with the previous HME preferred the current model, mainly because of the improved adhesive properties. While patients also reported that it was easier to speak with the Freevent HME, this is most likely the result of the lower resistance of the Provox™ voice prosthesis used in this study.

The results of the pulmonary function tests indicated improved function over time, particularly in inspiratory flow/volume values. This objective improvement in inspiratory pulmonary function reflects the decrease in sputum production reported by the patients. These objective and subjective results are indicative of a recovery of the upper airway mucosa. This improved lung function is all the more noteworthy given the relatively short period of HME use (only 3 months). Other lung function values such as the maximum vital capacity and the total lung capacity did not change significantly over time. As the median time elapsed since surgery was 2.8 years it is probable that continuous exposure of bronchial mucosa to "unmodified" air resulted in increased irritation, coughing, excess sputum production and crusting. It is not likely that these problems can be resolved completely in 3 months time. Further improvement in pulmonary function might be expected with the prolonged use of the HME. Additional support for the beneficial effect of an HME on pulmonary function has recently been reported in a study of patients with exercise-induced asthma.[9] The use of a mask containing an HME was found to

be as effective as conventional medication in the prevention of this form of obstructive lung disease. This suggests that besides water loss, also heat loss, both thought to be the main causes of this form of asthma[10], plays a causative role in the pulmonary problems of laryngectomized patients.

In conclusion, both the objective and subjective results of this prospective study suggest that the use of an HME can effectively reduce the physical and psychosocial problems following total laryngectomy. Due to the small sample size, it is not possible to attribute all of the observed improvements to the use of an HME. Nevertheless, the results of the within-group analyses of change over time fully support the results of our previous study concerning the positive effect of an HME. The pulmonary function tests, indicating an increase in the inspiratory flow/volume values for HME users, support the beneficial effect of the HME on upper airway mucosa recovery.

It should be emphasized that the HME is a medical device. Counseling by a physician is needed to ensure proper use of the device and to obtain optimal results. Further research to investigate whether use of an HME immediately following total laryngectomy can prevent the development of respiratory symptoms is in progress.

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Chapter VII

Heat and moisture exchangers as a treatment option in the postoperative rehabilitation of laryngectomized patients

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Abstract

A multi-institutional, prospective clinical study was undertaken to investigate whether the use of a heat and moisture exchanger (HME) in the period following total laryngectomy could prevent the development or reduce the severity of respiratory symptoms. Fifty-nine patients from 3 hospitals were provided with HME's either immediately post-surgery or, in the case of post-surgical radiotherapy, upon completion of the radiotherapy. Patients were interviewed at 3 months and 6 months post-laryngectomy. Additionally, lung function tests were available for 39 patients. Patients reported the same range of respiratory symptoms 6 months post-laryngectomy as was previously observed in patients with longer follow-up. However, these symptoms were less frequent and less severe. For the total sample (N=59) statistically significant improvements over time (between 3 and 6 months) could be found in forced expectoration ($p < .05$), in the perceived voice quality ($p < .001$), social anxiety ($p < .001$), social interactions ($p < .001$) and in feelings of anxiety and depression ($p < .05$).

A clear trend was observed in respiratory symptoms over time, with regular HME users reporting a decline in symptoms, as compared with non(regular) HME users (patients who discontinued using the HME or did not use the HME at all), who reported a slight increase in these symptoms. Repeated measures analysis of variance indicated statistically significant group differences over time in forced expectoration and stoma cleaning ($p < .05$), and marginally significant differences in sputum production ($p < .10$).

No statistically significant differences over time were noted between the regular and non(regular) HME user groups in voice quality or in various aspects of daily living. This suggests that the postoperative improvements in psychosocial functioning reported by the total sample may reflect primarily the normal process of adjusting to and coping with the sequelae of total laryngectomy.

The results of this study lend partial support to the potential value of an HME in preventing and/or resolving respiratory problems during the first 6 months following total laryngectomy. Positive effects of HME use were noted primarily in terms of reduced respiratory complaints.

Keywords: total laryngectomy, pulmonary problems, HME

Introduction

Total laryngectomy results in a wide range of physical and psychosocial sequelae, including voice and life style changes for the patient.[1,2] Due to the disconnection of the upper and lower airways, the conditioning - warming, humidifying and filtering - of inhaled air is no longer possible.[3-7] Consequently, many laryngectomized patients suffer from respiratory problems, including coughing, excessive sputum production and shortness of breath. These symptoms develop c.q. increase during the first 6 months postoperatively, and than tend to stabilize.[4] An objective impairment of the pulmonary function of the laryngectomized patient can also be expected.[8] According to Natvig[9], and confirmed by our previous studies[1], there are seasonal fluctuations in symptoms, with patients reporting fewer respiratory problems during the summer than during the winter period.

In two previous studies, in an attempt to restore some of the lost 'nose' functions, we investigated the influence of two different types of heat and moisture exchangers (HME) on respiratory symptoms after total laryngectomy.[10,11] With such a device it is possible to reduce the diurnal loss of water through the exhaled air by approximately 60% (250-300 ml in 24 hours).[12] The filter also increases the expiratory pressure, shifting the equal pressure point back up again and increasing the pulmonary flow/volume.[13] The results of both previous studies indicated that the use of an HME can lead to a significant reduction in the respiratory and the related psychosocial problems of laryngectomized patients.[10,11] The positive influence of an HME could also be established objectively. The second HME study included a pulmonary function assessment at the start of the study and again after 3 months. A significant improvement over time in the inspiratory flow-volume values was observed.[11]

The current, multi-institutional, prospective clinical study was undertaken to investigate whether the use of an HME could prevent the development or reduce the severity of respiratory symptoms by initiating use of the device as soon as possible following the total laryngectomy.

Patients and Methods

Over a period of approximately 14 months, 60 laryngectomized patients were accrued onto the study by the 3 participating centres (19 from the Netherlands Cancer Institute, 23 patients from the Dr. Daniel den Hoed Cancer Centre, and 18 patients from the University Hospital Rotterdam 'Dijkzigt'). One patient died before the follow-up interview could be completed, resulting in a study group of 59 patients. During the study accrual period, several additional patients were laryngectomized (n= 23), but were not eligible for the study for the following

reasons: (1) lost to follow-up due to return to their native country; (2) early tumour relapse; (3) postoperative complications; and (4) patient refusal. The large majority of the patient sample was male (87%), with a mean age of 61 years (range 37 - 81 years). Voice rehabilitation was achieved with a Provox^{R} voice prosthesis[14] in 53 of the 59 patients (90%). The remaining 6 patients were rehabilitated with an electrolarynx (3) or had no other means of communication but whispering. Thirty patients underwent surgery for recurrent disease after radiotherapy, 27 were irradiated post-operatively, and 3 patients did not receive radiotherapy.

All patients who participated in the study were interviewed 3 and 6 months after surgery. Pulmonary function tests were performed pre-operatively, and 2 weeks, 3 months and 6 months postoperatively.

Patients typically began using the HME after completion of wound healing (i.e., approximately 2 weeks post-laryngectomy), unless postoperative radiotherapy was necessary. Instructions on how to fix the device to the skin around the stoma and how to replace the filter when it becomes obstructed with secretions were given several days before release from the hospital. The patients were advised to apply the device, if possible, both day and night. From earlier experience it was known that adverse skin reactions were frequently encountered with simultaneous HME use and irradiation. Therefore, in case of postoperative radiotherapy, patients were instructed to start using the device some weeks after finishing their radiation treatment. The patients were provided with a 2 week supply of HME's, and with prescriptions for the remaining period.

The HME (Freevent) used in this study consists of a silicone housing (with a diameter of 22 mm) placed in adhesive tape, and a removable filter consisting of a nonwoven, monofilament polymer (polypropylene and polyethylene). The tape is available in 5 different shapes. A typical example is shown in Figure 1 and 2.

The interviews (3 and 6 months postoperatively) took place in the outpatient clinic during a routine follow-up visit. Both interviews required, on average, one hour to complete. The content of the structured interview has been described in detail elsewhere.[1] Briefly, the first part of the interview (after 3 months) evaluated the presence and severity of respiratory symptoms (cough, sputum production, shortness of breath, wheezing, bronchial asthma, nasal discharge, pulmonary infections and forced expectoration), fatigue and sleep problems, perceived adequacy of voice rehabilitation, social contacts, and anxiety and depression. The second part of the interview included items on various practical aspects of the device, such as the number of filters and plasters used per day, use during the night, skin irritation, problems with adhesion to

Figure 1. Baseholder of the HME glued to the skin around the stoma. The tracheostoma with a Provox^{TM} voice prosthesis in situ is still visible.

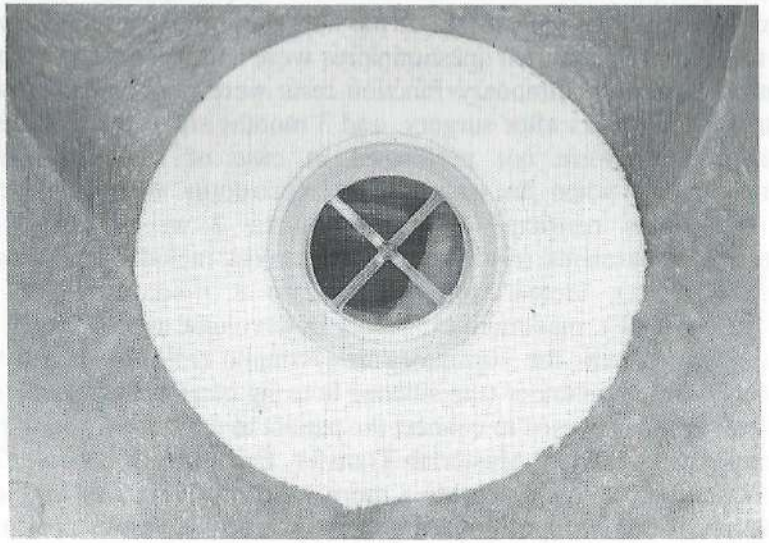
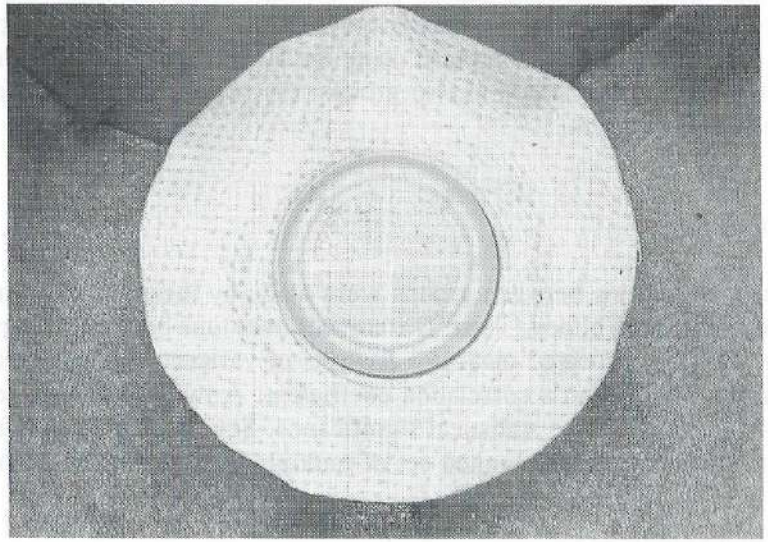


Figure 2. Baseholder of the HME with the stoma filter in situ.



the skin, fixation during coughing, problems with replacing the filter, and airway resistance. Patients were also asked to provide an overall rating of the usefulness of the HME, and to report whether they intended to use it in the future and whether they would recommend its use to fellow patients. Patients who had to postpone the use of the HME due to postoperative radiotherapy were excluded from the second part of the interview. For the second interview (after 6 months) the same two questionnaires were administered to all patients. As mentioned above, pulmonary function tests were performed, if possible, before surgery, 2 weeks after surgery, and 3 months and 6 months thereafter. Preoperative tests were not performed in case of severely obstructive malignancy and/or when an emergency tracheostomy was necessary. The current analysis is restricted to data from the 2 weeks and 6 months postoperative assessments (n=39). The assessment included maximum vital capacity (VC Max), forced expiratory volume at 1 second (FEV1), peak expiratory flow (PEF), maximum expiratory flow-volume at 50% (MEF 50) and the same measurements for inspiratory flow/volume (FIV1, PIF and MIF50, respectively). The baseholder (the silicone housing placed in adhesive tape) of the Freevent HME was used to connect the patient to the standard lung function testing equipment (standard Masterlab Transfer, Erich Jaeger GmbH). The test results obtained in this way provide a more valid representation of the actual lung function of the laryngectomized patient than do the results obtained with the conventional cuffed trachea cannula.[15]

Accrual of a patient sample large enough for randomization to an experimental and a control group was deemed unrealistic given the limited time-frame of the study. From earlier studies we knew that approximately one-third of the patients discontinued using the HME due to adverse skin reactions (glue allergy or radiotherapy irritation) or lack of dexterity. Consequently, we used the patients in the current study who discontinued using the HME or did not use it at all as a control group. This resulted in two groups: (1) regular HME users and (2) non(regular) HME users.

Statistics

Statistical comparisons between groups were made by means of the Student's t-test and the Mann-Whitney U test. Differences over time between groups were tested by means of repeated measures analysis of variance. Associations were measured by the Pearson's correlation coefficient. A two-tailed p-value of < 0.05 was taken to indicate statistical significance. Several quality of life items were combined into a more limited set of multiple-item scales according to

Likert's method of summated ratings. Where appropriate, the reliability of the scales is reported (Cronbach's alpha).

Results

The total sample at 3 and 6 months

The respiratory problems after 3 and 6 months following total laryngectomy are shown in Table 1 . The main complaint, as reported by all patients, was sputum production (with a mean of 12 times per day), followed by forced expectoration to clear the bronchial airway. Daily, involuntary coughing was reported by 18% of the patients, while nasal discharge was reported by 65% and 56% of the patients at 3 months and 6 months, respectively. Other reported problems included shortness of breath, the need to frequently clean the stoma (more than 5 times a day) and wheezing. Respiratory symptoms tended to either remain stable or to decline in prevalence over time. The only symptom for which a statistically significant decline over time was observed was forced expectoration (70% versus 56% at 3 and 6 months, respectively, $p < .05$).

Table 1. Frequency of daily respiratory symptoms after total laryngectomy (N=59).

	3 months	6 months
	%	%
Sputum production	100	98
Forced expectoration	70*	56*+
Nasal discharge	65	56
Stoma cleaning	26*	22*
Cough	18	18
Shortness of breath	20	7
Wheezing	7	5

* more than 5 times a day

\+ $p < .05$

Statistically significant improvements over time (between 3 and 6 months) were also observed for voice quality ($p < .001$), social anxiety ($p < .001$), social interactions ($p < .001$) and feelings of anxiety and depression ($p < .05$). These

4 quality of life aspects were all assessed with multiple-item scales with the following reliability coefficients (Cronbach's alpha): voice quality 0.87, social anxiety 0.87, social interactions 0.71, and anxiety and depression 0.73.

Composition of the groups

Due to postoperative radiotherapy treatment, 27 patients could not use the HME during the first three months of the study. Additionally, 2 patients were so preoccupied with the acute sequelae of total laryngectomy that they preferred delaying the use of the HME, and 2 patients did not receive the HME in the postoperative period due to logistical problems. Of the remaining 28 patients, 13 used the HME regularly during the first 3 months after surgery, 2 reported using the HME irregularly during this period, and 13 patients reported that they discontinued use of the HME after a period of initial use (ranging from 3 to 42 days).

In the second period (3 to 6 months postoperatively) 29 patients used the HME regularly (regular HME users). Of the remaining 30 patients, 18 patients discontinued use after 1 to 28 days, and 12 did not use the HME at all (non(regular) HME users). Statistical comparisons between the regular (N=29) and non(regular) HME users (N=30) showed no significant differences with respect to sociodemographic characteristics (age, sex, marital status, or education) or radiation treatment. Of the 27 patients who underwent radiation therapy during the first 3 months, 13 subsequently became regular HME users and 14 non(regular) HME users (table 2).

Table 2. Composition of the groups.

	HME use postoperatively (n=59)		
	0 - 3 months	3 - 6 months	
		regular use	no (regular) use
Regular use	n=13:	n=11	n= 2
No (regular) use	n=19:	n= 5	n=14
No use (radiotherapy)	n=27:	n=13	n=14
Total	n=59:	n=29	n=30

Group differences over time

Table 3 displays the mean daily frequencies of respiratory symptoms for regular and non(regular) HME users at the 3 and 6 month assessments. A clear trend can be observed, with regular HME users reporting a decline in respiratory symptoms over time, as compared with non(regular) HME users who reported a slight increase in these symptoms. Repeated measures analysis of variance indicated statistically significant group differences over time in forced expectoration and stoma cleaning ($p < .05$), and marginally significant differences in sputum production ($p < .10$).

No statistically significant differences were observed over time between the regular and non(regular) HME users with respect to psychosocial functioning; both groups reported improvements over time.

Table 3. Mean daily frequencies of respiratory symptoms after 3 and 6 months+

	regular HME users (N=29)		non(regular) HME users (N=30)	
Symptoms	3 mth	6 mth	3 mth	6 mth
cough	9.5	3.0	9.7	11.7
sputum production*	11.2	6.2	14.5	15.5
forced expectoration**	11.7	5.6	14.3	16.4
stoma cleaning**	7.1	3.4	7.2	9.4

+ Analysis based on repeated measures analysis of variance. Statistical tests for group x time interaction with two groups (regular and non(regular) HME users) and two assessment points (3 and 6 months postoperatively).

* $p < .10$ ** $p < .05$

Pulmonary functioning

Pulmonary function tests (2 weeks postoperatively and 6 months postoperatively) were available for 39 patients. For the total sample, all pulmonary values, with the exception of maximum expiratory flow at 50% (MEF 50), remained stable or improved over time (Table 4). A trend toward an improvement in the peak and maximum inspiratory flow (PIF and MIF50, respectively) was also observed. However, no significant differences over time in pulmonary function were observed between the regular and non(regular) HME user groups.

More detailed results of the pulmonary function tests (pre-operatively, 2 weeks, and 3 and 6 months postoperatively) will be reported in a subsequent paper.

Table 4. Pulmonary function 2 weeks and 6 months postoperatively (N=39)

	2 weeks	6 months	P
VC max	4.1	4.2	ns
FEV	2.8	2.8	ns
PEF	7.7	8.0	ns
MEF50*	2.7	2.3	.025
FIV	3.5	3.8	.002
PIF	6.0	6.4	.071
MIF50	5.3	5.7	.072

* MEF50 decreased

Experience with the HME

The regular HME user group reported, on average, using 9.6 baseholders and 14.6 filters per week.

Patients' experiences with the use of the HME (assessed for the total sample) were mixed. Ten patients reported difficulties in achieving airtight occlusion of the filter in order to speak. Conversely, 15 patients reported that the HME facilitated their speech and improved their intelligibility. Thirteen patients reported that the HME caused skin irritation. Such skin irritation was not related significantly to pre- or postoperative radiotherapy. While the majority of the patients were satisfied with the adhesive properties of the HME, 17 patients experienced loosening of the plaster due to involuntary coughing or forced expectoration to clear the bronchial airway. While an increase in airway resistance was experienced by 15 patients, only two patients reported that this lead to discontinuation of the use of the HME.

Discussion

The aim of the current study was to investigate whether the use of an HME in the period following total laryngectomy could prevent the development or reduce the severity of respiratory sequelae normally associated with the anatomic changes due to this surgical procedure. The results indicated that the same type of respiratory symptoms existed after 6 months of HME use as in our previous studies[1,10,11], but these symptoms were less frequent and less severe. Coughing and wheezing were reported by 18 and 5 percent of the patients, respectively, while in our previous study[10] with a median follow-up time of 6.2

years, 64% and 19% of the patients complained of these symptoms. Problems with shortness of breath were reported by 20% of the patients after 3 months and by 7% of the patients after 6 months. In our previous study[10], 32% of the patients experienced shortness of breath. This suggests that respiratory problems tend to increase well beyond the 6 months postoperative period.

Compliance with the use of the device was moderate in the present patient group. Due to HME-related problems, such as skin irritation, speaking problems and loosening of the plaster by coughing c.q. forced expectoration to clear the airway, approximately half of the patients discontinued using the device. It should be stressed that proper patient education about the use of the HME by the otolaryngologist and other health care providers, such as the speech therapist, is of utmost importance to enhance the compliance of the patient.

For the total patient sample, significant improvements over time were observed in forced expectoration, and in several aspects of daily life, including perceived voice quality, social anxiety, social interactions, and feelings of anxiety and depression. Due to practical considerations, it was not possible to employ randomization procedures in the current study. As an alternative, a comparison was made between patients who reported regular use of the HME with those who used the HME irregularly or discontinued its use altogether. These two groups were comparable in terms of sociodemographic characteristics, time elapsed since laryngectomy, and frequency of postoperative radiotherapy. Statistically significant group differences over time (between 3 and 6 months post-laryngectomy) were observed in the frequency of daily sputum production, forced expectoration, and stoma cleaning. These results are similar to those obtained in our previous studies in which patients initiated use of an HME many months or even years after having undergone a laryngectomy.[10,11]

No statistically significant differences over time were noted between the regular and non(regular) HME user groups in voice quality or in various aspects of daily living. This suggests that the post-operative improvements in psychosocial functioning reported by the total sample may reflect the normal process of adjusting to and coping with the sequelae of total laryngectomy[1], rather than any specific beneficial effect of HME use.

The results of the pulmonary function tests indicated a stabilization or slight improvement of the inspiratory values for the total patient sample. However, statistical comparisons failed to detect significant differences between the regular and the non(regular) HME users.

In conclusion, the results of this study lend partial support to the potential value of an HME in preventing and/or resolving respiratory problems during the first 6 months following total laryngectomy. Positive effects of HME use were noted primarily in terms of reduced respiratory complaints. Postoperative HME use

does not appear to have any measurable effect on the psychosocial sequelae of total laryngectomy.

It should be noted that the availability of several models of HME, differing in the type of adhesive tape used and in other technical features, allows one to tailor the choice of HME to each individual patient. This may resolve some of the problems that result in discontinued use of an HME (e.g., loosening of the plaster). Further technical improvements in the design of HME's are needed to optimize their use in combination with a voice prosthesis. Airtight closure of the stoma in order to speak is of utmost importance for these patients. The Blom-Singer adjustable tracheostoma valve which incorporates an HME facilitates such airtight closure. Hopefully, future models will increase the ease with which such valve-HME's can be used.

In the recent past, the main attention of otolaryngologist working with laryngectomized patients has been given to the problem of voice rehabilitation. Since satisfactory longterm results of this rehabilitation by using prosthetic devices, such as the Provox^{R} voice prosthesis, can now be achieved in the vast majority of patients,[16] time might have come to focus more on the pulmonary rehabilitation of this patient category. Finally, it should be emphasized, that an HME is a medical device. Optimal results can be achieved only by combining state-of-the-art HME technology with appropriate patient education and supervision by the physician and ancillary health care personnel.

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Summary and Conclusions

Samenvatting en Conclusies

Summary and Conclusions

The specific aims of the studies described in this thesis, were:

1. to document the various consequences of total laryngectomy, including not only the physical, but also the psychosocial implications, the voice and life style changes;
2. to investigate whether the use of Heat and Moisture Exchangers (HME) can influence positively the physical and psychosocial consequences of this mutilating surgical procedure;
3. to optimize pulmonary function testing in this category of patients;
4. to determine the possible changes of pulmonary function resulting from the use of an HME.
5. to investigate whether the use of an HME could prevent the development or reduce the severity of respiratory symptoms by initiating use of the HME as soon as possible following total laryngectomy.

Chapter I presents a review of the literature, pertinent to the various aspects of total laryngectomy and its impact on the daily life of the patient are described. Furthermore, the methodological approach, including the data collection by means of structured interviews, the data entry and the statistical analyses, and the technical background of heat and moisture exchangers, are presented.

Chapter II provides the results of the first study of the prevalence rates of respiratory problems after total laryngectomy. Sputum production (98%), coughing (64%), the need for frequent expectoration (> 5 times a day; 57%) and stoma cleaning (> 5 times a day; 37%) were the most common complaints. Significant correlations were found between respiratory symptoms and various aspects of daily living, including fatigue, sleep problems, voice rehabilitation, social contacts and psychological distress. It is noteworthy that only a few patients in this study exhibited clinically significant levels of anxiety or depression (5 and 7 percent, respectively).

Chapter III describes a study of other consequences of total laryngectomy, including communication, functional disorders and lifestyle changes. Vocal rehabilitation was achieved with a voice prosthesis in 78% of the patients, with esophageal speech in 14%, and with electrolarynx in 3%. Five percent of the patients had no other means of communication than whispering c.q. writing. The majority of patients reported being satisfied with their voice quality, including speaking on the telephone. Almost half of the patients had complaints

of eructation. Hyposmia was reported by 52% of the patients, while for most patients a deficiency in gustatory sense appeared to be temporary. Excessive nasal discharge was reported by one-third of the patients and about one-quarter of the patients reported swallowing problems, resulting in dietary changes. Finally, 9% of the previous smokers continued to smoke following total laryngectomy.

Chapter IV: The influence of the use of a heat and moisture exchanger (HME, Stomvent) during 6 weeks on the respiratory symptoms after total laryngectomy was studied. Sixty-three percent of the patients experienced a significant reduction in sputum volume, frequency of forced expectoration and stoma cleaning. These reductions resulted in diminished feelings of fatigue and malaise and in an improvement in social contacts. Patients using esophageal speech or an electrolarynx benefited more from the HME than patients using a voice prosthesis. The latter group experienced some problems with the occlusion of the HME in order to speak. Few other side effects related to the use of the device were reported. These reductions in pulmonary problems were correlated significantly with an improved quality of life.

Chapter V: In order to verify the validity of pulmonary function testing a comparison was made between the effect of an extratracheal device and an intratracheal cuffed cannula on the outcome of the pulmonary function tests. These devices are used as a means to connect the patient to the spiro- or pneumotachometer. Besides the convenience of the HME baseholder (for both the patient and the lung function technician), the use of the HME baseholder resulted in consistently higher spirometric values in comparison with the trachea cannula. With this simple device, a more valid assessment of the actual lung function of laryngectomized patients can be obtained.

Chapter VI: Although the results of the first HME study were encouraging, the absence of an appropriate control group, the relatively short trial period and the absence of objective measures of lung function suggested the need for this second HME study. The subjective and objective effects of a different type of HME (Freevent) on the respiratory and psychosocial problems following total laryngectomy was investigated during a 3 months trial period. The participating patients were randomized either to the experimental group to test the HME, or to a no-treatment control group. As in the first study, the incidence of coughing, the mean daily frequency of sputum production, forced expectoration and stoma cleaning decreased with the use of an HME. Significant reductions were also observed in shortness of breath, fatigue and malaise, sleep problems, psychological distress, and the perceived voice quality improved among the HME user group. No such improvements could be found for the control group.

Importantly, these subjective indications of the efficacy of the HME were confirmed by objective improvements in pulmonary functioning. Pulmonary function tests showed an increase in the inspiratory flow/volume values for the HME users. This is in accordance with the reduction of sputum production as reported by the patients and supports the beneficial effect of the HME on upper airway mucosa recovery.

Chapter VII presents a multi-institutional, prospective clinical study that was undertaken to investigate whether the use of a heat and moisture exchanger (HME) in the period following total laryngectomy could prevent the development or reduce the severity of respiratory symptoms. Patients reported the same range of respiratory symptoms 6 months post-laryngectomy as was previously observed in patients with longer follow-up. However, these symptoms were less frequent and less severe. For the total sample ($N=59$) statistically significant improvements over time (between 3 and 6 months) could be found in forced expectoration ($p < .05$), in the perceived voice quality ($p < .001$), social anxiety ($p < .001$), social interactions ($p < .001$) and in feelings of anxiety and depression ($p < .05$).
A clear trend was observed in respiratory symptoms over time, with regular HME users reporting a decline in symptoms, as compared with non(regular) HME users (patients who discontinued using the HME or did not use the HME at all) who reported a slight increase in these symptoms. Repeated measures analysis of variance indicated statistically significant group differences over time in forced expectoration and stoma cleaning ($p < .05$), and marginally significant differences in sputum production ($p < .10$).
No statistically significant differences over time were noted between the regular and non(regular) HME user groups in voice quality or in various aspects of daily living. This suggests that the postoperative improvements in psychosocial functioning reported by the total sample may reflect primarily the normal process of adjusting to and coping with the sequelae of total laryngectomy.
The results of this study lend partial support to the potential value of an HME in preventing and/or resolving respiratory problems during the first 6 months following total laryngectomy. Positive effects of HME use were noted primarily in terms of reduced respiratory complaints.

Conclusions

The results of the studies described in this thesis indicate that the sequelae of total laryngectomy are considerable. The disconnection of the upper and lower airways does not only lead to the loss of the normal voice, but also to extensive respiratory symptoms, fatigue and sleep problems, hyposmia and dysgeusia, swallowing difficulties, disrupted social contacts, and psychological distress. This thesis clearly shows that these respiratory symptoms can be positively influenced by the regular use of a stomafilter with heat and moisture exchanging capacities (HME). Both HME's tested had a positive influence on the physical and psychosocial problems following this debilitating surgical procedure. The decline of several respiratory symptoms resulted in a decrease of fatigue, sleeping problems and feelings of anxiety and depression. Moreover, an improvement of the perceived quality of voice was observed. The pulmonary function appeared to improve objectively as well following the regular use of these HME's, as could be demonstrated through pre- and posttreatment pulmonary function tests. Especially an increase in the inspiratory values, indicating an improvement of the mucosa of the tracheo-bronchial tract, was noticeable. The results also lend partial support to the potential value of an HME in preventing and/or resolving respiratory problems during the first 6 months following total laryngectomy. Positive effects of HME use in this period were noted primarily in terms of reduced respiratory complaints.
The rehabilitation after total laryngectomy must be a multidisciplinary team effort, which should not only be directed towards restoration of the obvious communication problems of the patient, but, as shown in these studies, ample attention should be given to the treatment and possible prevention of respiratory problems resulting from this operation. This will ultimately lead to an improved well being and quality of life of the patient.

Samenvatting

De specifieke studie doeleinden, zoals in dit proefschrift beschreven, waren:

1. het inventariseren van de verschillende gevolgen van een larynxextirpatie, niet alleen de fysieke maar ook de psychosociale implicaties, de veranderingen in stem en levensstijl;
2. te onderzoeken of het gebruik van een warmte- en vocht wisselaar (Heat and Moisture Exchanger, HME) de fysieke en psychosociale gevolgen van deze mutilerende operatie gunstig kan beïnvloeden;
3. het optimaliseren van het testen van de longfunctie in deze patiënten populatie;
4. het vaststellen van de mogelijke veranderingen van de longfunctie na gebruik van een HME.
5. te bestuderen of luchtwegsymptomen voorkomen of verminderd kunnen worden door zo snel mogelijk na de larynxextirpatie met het gebruik van een HME te beginnen.

In **hoofdstuk I** wordt, aan de hand van de literatuur, nader ingegaan op de verschillende aspecten van een larynxextirpatie en op de gevolgen hiervan voor het dagelijks leven van de patiënt. Verder worden de methodologische aanpak, waaronder de dataverzameling door middel van gestructureerde interviews en dataverwerking, en het werkingsmechanisme van de warmte- en vochtwisselaar beschreven.

In **Hoofdstuk II** worden de resultaten van de eerste studie, waarin een overzicht is opgenomen van de prevalentie van luchtwegproblemen na larynxextirpatie, beschreven. Sputumproduktie (98%), hoesten (64%), actief ophoesten om de luchtweg schoon te maken (> 5 x per dag; 57%) en het schoonmaken van het stoma (> 5 x per dag; 37%) waren de meest voorkomende klachten. Er werden significante correlaties gevonden tussen de luchtwegproblemen en verschillende aspecten van het dagelijks leven, waaronder vermoeidheid, slaapproblemen, stemrevalidatie, sociale contacten en gevoelens van angst en depressie. Het is opmerkelijk dat bij deze patientengroep klinisch significante gevoelens van angst en depressie sporadisch voorkwamen (resp. 5% en 7%).

In **hoofdstuk III** wordt nader ingegaan op de communicatie, functionele problemen en veranderingen in leefwijze na larynxextirpatie. De stem was in 78% van de patiënten gerevalideerd met behulp van een stemprothese, bij 14% door middel van slokdarmspraak en bij 3% door gebruik making van een electrolarynx. Vijf procent van de patiënten bediende zich uitsluitend van een

fluisterstem of schriftelijk. De meerderheid van de patiënten geeft aan tevreden te zijn met zijn stemkwaliteit, ook aan de telefoon.
Ongeveer de helft van de patiënten had last van hinderlijke oprispingen. Hyposmie kwam bij 52% van de patiënten voor, terwijl voor de meeste patiënten een gestoorde smaak slechts van tijdelijke aard bleek te zijn. Een loopneus werd door 1/3 van de patiënten genoemd. Omdat het slikken van voornamelijk vast voedsel problemen gaf, werden er veranderingen in het dieet gemeld door 1/4 van de patiënten. Vóór de operatie rookte 98% en dit werd door 9% van de patiënten gecontinueerd na de operatie.

In **hoofdstuk IV** wordt de invloed van het gebruik van een warmte- en vochtwisselaar (Stomvent HME) gedurende 6 weken op de luchtwegproblemen na larynxextirpatie bestudeerd. Drie en zestig procent van de patiënten ervaarde een significante vermindering in sputumproduktie, actief ophoesten en in het schoonmaken van het stoma. Door deze vermindering nam de vermoeidheid af en namen sociale contacten toe. Patiënten, die de slokdarmspraak gebruiken of die met behulp van een electrolarynx spreken, hadden meer baat van de warmte- en vocht wisselaar dan patiënten met een stemprothese. De laatste groep had soms moeite de HME adequaat af te sluiten om te kunnen praten. De verminderingen in luchtwegproblemen lieten een duidelijk verband met een verbeterde kwaliteit van leven zien.

Hoofdstuk V: om de validiteit van het testen van de longfunctie te verifiëren, werden de resultaten van een longfunctietest, eerst gemeten met behulp van een extratracheaal gefixeerde filterhouder en daarna met behulp van een intratracheale gecuffte canule, met elkaar vergeleken. Als hulpstuk om de patiënt aan de spiro- of pneumotachometer aan te sluiten, bleek de filterhouder zeer geschikt. Naast het gemak voor zowel de patiënt als voor de longfunctietechnicus, bleken ook de longfunctiewaarden hoger te liggen, wanneer de filterhouder werd gebruikt dan bij gebruik van de trachea canule. Met deze eenvoudige vinding kan een meer valide meting van de werkelijke longfunctie van de gelaryngectomeerde patiënt verkregen worden.

Hoofdstuk VI: het ontbreken van een controlegroep, de relatief korte testperiode en het ontbreken van objectieve longfunctiematen waren de aanleiding voor een tweede HME studie. Hierin werd de subjectieve en objectieve invloed van het gebruik gedurende 3 maanden van een andere warmte- en vochtwisselaar (Freevent HME) op de respiratoire- en psychosociale problemen na larynxextirpatie bestudeerd. De patiënten, die aan deze studie deelnamen, werden gerandomiseerd in twee groepen t.w. de experimentele (het testen van de HME) groep of de controle groep. Ook in deze studie, nam onder de HME gebruikers de incidentie wat hoesten betreft af en verminderde de

dagelijkse frequentie van sputumproductie, actief ophoesten en het schoonmaken van het stoma. Er werden ook significante afnames gevonden in kortademigheid, vermoeidheid, slaapproblemen en gevoelens van angst en depressie. Ook werd een verbeterde stemkwaliteit geconstateerd. Dergelijke verbeteringen werden niet in de controlegroep gevonden. Het verminderde klachtenpatroon kon ook door een verbeterde longfunctie worden geobjectiveerd. De longfunctiemetingen gaven bij de HME gebruikers een toename in de inspiratoire stroom/volume waarden aan. Dit is in overeenstemming met de vermindering in sputumproductie, zoals door de patiënten zelf wordt aangegeven en ondersteunt het gunstige effect van een warmte- en vocht wisselaar op het herstel van de mucosa in het bovenste gedeelte van de luchtweg.

In **hoofdstuk VII** wordt een prospectieve studie in samenwerking met nog 2 andere centra beschreven, die erop gericht was om te onderzoeken of het gebruik van een HME zo spoedig mogelijk na de larynxextirpatie de ontwikkeling van de luchtwegproblemen kon voorkómen of verminderen. Patiënten rapporteerden dezelfde soort luchtwegproblemen 6 maanden postoperatief als ook eerder werd waargenomen bij patiënten met een langere follow-up periode. De symptomen waren echter minder frequent en minder ernstig. Voor de gehele patiëntengroep (n=59) werden er tussen 3 en 6 maanden significante verbeteringen gevonden in luchtwegklaring ($p < .05$), stemkwaliteit ($p < .001$), sociale angst ($p < .001$), sociale interactie ($p < .001$) en in gevoelens van angst en depressie ($p < .05$).
Er werd een duidelijke positieve trend in de longklachten waargenomen in de periode van 3 tot 6 maanden. De groep, die de HME regelmatig gebruikte, gaf aan dat er een afname in symptomen was, terwijl de groep, die de HME slechts kort of helemaal niet gebruikte, aangaf dat er een lichte stijging in de luchtwegsymptomen was. Variantie-analyse voor herhaalde metingen liet statistisch significante groepsverschillen tussen 3 en 6 maanden zien in actief ophoesten, het schoonmaken van het stoma ($p < .05$) en marginaal significante verschillen wat sputumproductie betreft ($p < .10$).
Tussen de regelmatige en niet regelmatige HME gebruikers werden er geen significante verschillen gevonden met betrekking tot de stemkwaliteit en andere aspecten van het dagelijks leven. Dit veronderstelt dat de postoperatieve verbeteringen in het psychosociale functioneren, die door de totale patientengroep werd gerapporteerd, voornamelijk veroorzaakt worden door de gewoonlijk optredende aanpassing aan en het leren omgaan met de gevolgen van een larynxextirpatie.
De resultaten ondersteunen gedeeltelijk ook de potentiële preventieve werking van een HME in het voorkómen en/of reduceren van de luchtwegproblemen gedurende de eerste 6 maanden na een larynxextirpatie. De positieve effecten

van het gebruik van een HME gedurende deze periode zijn duidelijk terug te vinden in een vermindering van de longklachten.

Conclusies

De resultaten, zoals die in dit proefschrift beschreven worden, geven aan dat de gevolgen van een larynxextirpatie aanzienlijk zijn. Het verbreken van de verbinding tussen de bovenste en de onderste luchtweg leidt niet alleen tot het verlies van de normale stem, maar ook tot uitgebreide klachten van de luchtwegen, vermoeidheid en slaapproblemen, hyposmie en dysgeusie, slikklachten, verminderde sociale contacten en een verslechtering van de psychische gesteldheid. Dit proefschrift laat duidelijk zien dat deze luchtwegproblemen positief beïnvloed kunnen worden door het regelmatig gebruik van een stomafilter met warmte- en vochtwisselende eigenschappen (HME). Beide in dit onderzoek geteste HME's hadden een gunstig effect op de fysieke en psychosociale problemen na larynxextirpatie. De vermindering van de longklachten leidde tot een afname van vermoeidheid, slaapproblemen en gevoelens van angst en depressie. Bovendien werd er een verbetering in de stemkwaliteit geconstateerd. Ook de longfunctie bleek door het regelmatig gebruik van deze HME's te verbeteren, zoals door middel van longfunctie-onderzoeken, voor en na de behandeling, aangetoond kon worden. Er werd vooral een toename waargenomen van de inspiratoire waarden, hetgeen wijst op een verbetering van de conditie van de tracheo-bronchiale mucosa. De resultaten ondersteunen gedeeltelijk ook de potentiëel preventieve werking van een HME in het voorkómen en/of reduceren van de luchtwegproblemen gedurende de eerste 6 maanden na een larynxextirpatie. De positieve effecten van het gebruik van een HME gedurende deze periode zijn duidelijk terug te vinden in een vermindering van de longklachten.
De revalidatie na een totale larynxextirpatie vereist een multidisciplinaire teamaanpak, waarbij de aandacht niet alleen op het herstel van de voor de hand liggende communicatieproblemen van de patiënt gericht is, maar waarbij ook nadrukkelijk aandacht wordt besteed aan de behandeling en het mogelijk voorkómen van de luchtwegproblemen ten gevolge van deze operatie. Uiteindelijk zal dit tot een beter welbevinden en een betere kwaliteit van leven van de patiënt kunnen leiden.

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Curriculum vitae

Annemieke Henriëtte Ackerstaff was born in October 1943 in Ede, The Netherlands. After graduating from Gymnasium alpha of the Marnix College in Ede, she started to study English at the University of Amsterdam. Since this study was not what she expected, she accepted a job at the modelagency 'Modelplanning' (owned by Corine Spier-Rottschaefer) in 1965. At this agency she was responsible for the home and abroad bookings (photo sessions, tv commercials and fashion shows) of the female models. She was employed till the birth of her first daughter, Esther, in 1972. For almost 10 years she stayed at home to look after and care for her daughter Esther and her second daughter, Miriam, born in 1974. In 1982, she started with the study Psychology, also at the University of Amsterdam, and graduated in 1988. In 1987 (as part of the graduation program), she started the series of clinical trials, described in this thesis, on the physical and psychosocial sequelae of total laryngectomy, in the Netherlands Cancer Institute.
At this moment she continues to serve as a researcher at the departments of Otolaryngology-Head&Neck Surgery and Psychosocial Research and Epidemiology in the Netherlands Cancer Institute. The research is focused mainly on the further improvements of the treatment options for the respiratory problems and the prosthetic voice rehabilitation of laryngectomized patients.

Appendix A

Vragenlijst.

Appendix A. Vragenlijst gebruikt bij onderzoek beschreven in hoofdstuk VII

A. Algemeen:

1. Statusnummer:

   1a. Interview:
   1= alleen
   2= met begeleider

   1b. datum interview dag maand jaar

2. Geboortedatum: dag maand jaar

3. Geslacht:
   1= vrouw
   2= man

4. Wat is uw burgerlijke staat?
   1= alleenstaand, nooit getrouwd
   2= getrouwd
   3= gescheiden of apart wonend
   4= weduwnaar, weduwe

5. Wat was de aanname datum in het ziekenhuis?
   dag maand jaar

6. Wanneer was de operatiedatum?
   dag maand jaar

7. Heeft u radiotherapie gehad?
   1= nee
   2= vóór operatie
   3= na operatie

8. Heeft u een halsklieroperatie gehad?
   1= nee
   2= 1 kant
   3= 2 kanten
   4= weet niet

9. Hoe vaak bent u afgelopen jaar naar de huisarts geweest?
   aantal:

10. Hoe vaak bent u afgelopen jaar naar de longarts geweest?
    aantal:

11. Hoe is uw woonsituatie?
    1= alleenwonend.
    2= wonend met echtgenote of partner
    3= wonend met kind(eren)
    4= wonend met andere familie
    5= wonend met anderen die geen familie zijn
    6= bejaardenhuis

12. Wat is uw hoogst bereikte opleidingsniveau?
    1= lagere school
    2= ulo, mulo
    3= HBS of gymnasium
    4= Universiteit

13. Werkt u?
    1= heeft een baan
    2= is werkeloos
    3= WAO c.q. afgekeurd
    4= is gepensioneerd

B. Ziekte van de luchtwegen - preoperatief.

1. Heeft u ooit voor de operatie bronchitis gehad?
   1= ja
   2= nee; ga door naar vraag 2

   1a. Hoe vaak heeft u bronchitis gehad?
   aantal:

2. Heeft u ooit voor de operatie longontsteking gehad?
   1= ja
   2= nee; ga door naar vraag 3

   2a. Hoe vaak heeft u longontsteking gehad? aantal:

3. Komt er in de directe familie (ouders, broers, zusters) bronchitis voor?
   1= Ja
   2= Nee

C. Huidige klachten.

I. Hoest.

1. Hoeveel dagen in de week hoest u?
   1= nooit
   2= 1 à 2 dagen per week; ga door naar vraag 2
   3= 3 à 4 dagen per week; ga door naar vraag 2
   4= 5 of meer dagen per week; ga door naar vraag 2

   1a. Klopt het dat u nooit bij het opstaan, overdag of 's nachts hoest?
   1= ja; ga door naar vraag 9
   2= nee

   1b. Hoeveel dagen in de week hoest u?
   2= 1 à 2 dagen per week
   3= 3 à 4 dagen per week
   4= 5 of meer dagen per week

2. Hoe vaak hoest u gemiddeld per dag? aantal:

3. Hoeveel dagen in de week hoest u bij het opstaan?
   1= nooit
   2= 1 à 2 dagen p.w.
   3= 3 à 4 dagen p.w.
   4= 5 of meer dagen p.w.

4. Hoeveel dagen in de week hoest u in bed voor het inslapen?
   1= nooit
   2= 1 à 2 dagen p.w.
   3= 3 à 4 dagen p.w.
   4= 5 of meer dagen p.w.

5. Hoeveel nachten in de week hoest u?
   1= nooit; ga door naar vraag 8
   2= 1 à 2 nachten p.w.
   3= 3 à 4 nachten p.w.
   4= 5 of meer nachten p.w.

   5a. Hoe vaak hoest u gemiddeld per nacht?
   aantal:

8. Hoeveel jaar hoest u al?
   aantal:

   8a. Gebruikt u geneesmiddelen tegen het hoesten?
   1= ja
   2= nee

   8b. Hoe vaak gebruikt u geneesmiddelen tegen het hoesten?
   aantal weken per jaar:

II. Sputum.

9. Hoeveel dagen in de week heeft u last van slijm?
   1= nooit
   2= 1 à 2 dagen p.w.; ga door naar vraag 10
   3= 3 à 4 dagen p.w.; ga door naar vraag 10
   4= 5 of meer dagen p.w.; ga door naar vraag 10

   9a. Klopt het dat u bij het opstaan, overdag of 's nachts nooit last heeft van slijm?
   1= ja; ga door naar vraag 18
   2= nee

   9b. Hoeveel dagen in de week heeft u last van slijm?
   2= 1 à 2 dagen per week
   3= 3 à 4 dagen per week
   4= 5 of meer dagen per week

10. Hoe vaak gemiddeld per dag geeft u slijm op?
    aantal:

11. Hoeveel dagen in de week geeft u slijm op bij het opstaan?
    1= nooit
    2= 1 à 2 dagen p.w.
    3= 3 à 4 dagen p.w.
    4= 5 of meer dagen p.w.

12. Hoeveel nachten in de week geeft u slijm op?
    1= nooit; ga door naar vraag 15
    2= 1 à 2 nachten p.w.
    3= 3 à 4 nachten p.w.
    4= 5 of meer nachten p.w.

    12a. Hoe vaak geeft u gemiddeld per nacht slijm op?
    aantal:

15. Hoeveel jaar geeft u al slijm op?
    aantal:

16. Gebruikt u geneesmiddelen tegen slijm?
    1= ja
    2= nee; ga door naar vraag 18

17. Hoe vaak gebruikt u geneesmiddelen tegen slijm?
    aantal weken per jaar:

III. Kortademigheid.

18. Bent u kortademig als u een trap oploopt (c.q. bij inspanning)?
1= helemaal niet
2= een beetje
3= nogal
4= heel erg

19. Bent u kortademig wanneer u gewoon loopt?
1= helemaal niet
2= een beetje
3= nogal
4= heel erg

20. Als u rustig zit, bent u dan kortademig?
1= helemaal niet
2= een beetje
3= nogal
4= heel erg

Indien vraag 18,19,20 beantwoord zijn met "helemaal niet" dan door naar vraag 23.

22. Hoe lang bent u al kortademig?
aantal maanden:

IV. Piepende ademhaling.

23. Heeft u last van piepen op de borst?
1= helemaal niet; ga door naar vraag 27
2= een beetje
3= nogal
4= heel erg

24. Heeft u alleen last van piepen op de borst als u kou heeft gevat?
1= ja
2= nee

26. Hoe lang heeft u last van piepen op de borst?
aantal maanden:

V. Astma.

27. Heeft u astma-aanvallen?
1= ja
2= nee, ga door naar vraag 30

28. Op welke leeftijd is de astma begonnen?
leeftijd:

29. Wanneer was de laatste astma-aanval?
maanden geleden:

29a. Komt er in de directe familie (ouders, broers, zusters) astma voor?
1= ja
2= nee

VI. Neusklachten

30. Hoeveel dagen in de week heeft u last van een loopneus?
1= nooit; ga door naar vraag 32
2= 1 à 2 dagen p.w.
3= 3 à 4 dagen p.w.
4= 5 of meer dagen p.w.

31. Heeft u alleen last van een loopneus, als u kou heeft gevat?
1= ja
2= nee

32. Heeft u hooikoorts?
1= ja
2= nee

33. Hoe is uw reuk?
1= slecht
2= matig
3= goed
4= uitstekend

34. Is uw reuk sinds de operatie anders?
1= veel slechter
2= iets slechter
3= gelijk
4= iets beter
5= veel beter

35. Hoe is uw smaak?
1= slecht
2= matig
3= goed
4= uitstekend

36. Is uw smaak sinds de operatie anders?
1= veel slechter
2= iets slechter
3= gelijk
4= iets beter
5= veel beter

VII. Slikken

37. Is uw dieet na de operatie veranderd?
1=ja
2=nee; ga door naar vraag 38

37a. Kunt u ook zeggen hoe?

38. Heeft u problemen bij het slikken van vast voedsel?
1= helemaal niet
2= een beetje
3= nogal
4= heel erg

39. Heeft u problemen bij het slikken van vloeibaar voedsel?
1= helemaal niet
2= een beetje
3= nogal
4= heel erg

Indien vraag 38 en 39 beantwoord zijn met "helemaal niet" dan door naar vraag 41.

40. Wat is volgens u de oorzaak van de slikproblemen?
1= nauwe slokdarm
2= stemprothese
3= beide
4= geen van beide
5= weet niet

VIII. Longziekten.

41. Heeft u na de operatie bronchitis gehad?
1= ja
2= nee; ga door naar vraag 42

41a. Hoe vaak heeft u na de operatie bronchitis gehad?
aantal:

42. Heeft u na de operatie longontsteking gehad?
1= ja
2= nee; ga door naar vraag 43

42a. Hoe vaak heeft u na de operatie longontsteking gehad?
aantal:

IX. Luchtwegklaring.

43. Hoe vaak gemiddeld per dag maakt u de longen schoon door middel van ophoesten van slijm?
aantal:

44. Hoe vaak gemiddeld per dag maakt u het stoma schoon?
aantal:

45. Bedekt u overdag uw stoma?
1= nooit
2= soms
3= vaak
4= altijd

46. Gaat het stoma wel eens stuk?
1= ja
2= nee

47. Hoe lang moet u een canule moet dragen om te voorkomen dat het stoma nauwer wordt?
1= nooit
2= een paar uur per dag
3= 's nachts
4= dagelijks

48. Heeft u last van piepende ademhaling omdat het stoma nogal nauw is?
1= ja
2= nee; ga door naar vraag 49

48a. Hoe vaak heeft u last van piepende ademhaling omdat het stoma nogal nauw is?
1= nooit
2= minder dan 1 x per week
3= vaker dan 1 x per week
4= dagelijks

X. Vermoeidheid.

Gedurende de laatste week.

49. Had u behoefte om te rusten?
1= helemaal niet
2= een beetje
3= nogal
4= heel erg

50. Heeft u zich slap gevoeld?
1= helemaal niet
2= een beetje
3= nogal
4= heel erg

51. Was u moe?
1= helemaal niet
2= een beetje
3= nogal
4= heel erg

XI. Slaap.

52. Hoe vaak is het voor u een probleem in slaap te komen?
1= nooit
2= 1 à 2 dagen p.w.
3= 3 à 4 dagen p.w.
4= 5 of meer dagen p.w.

53. Hoe vaak wordt u 's nachts wakker?
1= nooit; ga door naar vraag 54
2= 1 à 2 keer per nacht
3= 3 à 4 keer per nacht
4= 5 of meer keer per nacht

53a. Als u 's nachts wakker wordt, heeft u dan problemen weer in slaap te komen?
1= helemaal niet
2= een beetje
3= nogal
4= heel erg

54. Hoe vindt u dat u de afgelopen maand geslapen heeft?
1= slecht
2= matig
3= redelijk
4= goed

55. Hoe vaak heeft u tijdens u dagelijkse bezigheden last van slaperigheid?
1= nooit
2= 1 à 2 dagen p.w.
3= 3 à 4 dagen p.w.
4= 5 of meer dagen p.w.

56. Gebruikt u slaapmiddelen?
1= ja
2= nee; ga door naar vraag 57

56a. Hoe vaak gebruikt u slaapmiddelen?
2= 1 à 2 dagen p.w.
3= 3 à 4 dagen p.w.
4= 5 of meer dagen p.w.

56b. Welk slaapmiddel gebruikt u?

XII. Roken.

57. Rookt u?
1= ja; ga door naar vraag 58, 59, 60, 64 en 65
2= nee, ga door naar vraag 61

58. Wat rookt u?
1= sigaretten
2= sigaren
3= pijp

59. Hoeveel per dag? aantal:

60. Op welke leeftijd bent u met roken begonnen?
leeftijd:

61. Heeft u ooit gerookt?
1= ja
2= nee; ga door naar vraag 64

62. Wat rookte u?
1= sigaretten
2= sigaren
3= pijp

62a. Hoeveel rookte u per dag?
aantal:

63. Op welke leeftijd bent u met roken begonnen?
jaar:

64. Wanneer bent u met roken gestopt?
jaar:

65. Rookt uw partner (en/of huisgenoten)?
1= ja; ga door naar vraag 65
2= nee

66. Verbiedt u uw huisgenoten of bezoek te roken?
1= ja
2= nee

67. Vermijdt u feestjes of bijeenkomsten, omdat u last van de rook heeft?
1= ja
2= nee

XIII. Spraak.

68. Welke van de volgende spreekmogelijkheden heeft u?

68a. Heeft u een stemprothese?
1= ja
2= nee

68b. Heeft u een slokdarmspraak?
1= ja
2= nee

68c. Heeft u een servox?
1= ja
2= nee

68d. Heeft u een fluisterspraak c.q. geen spraak
1= ja
2= nee

68e. Welke spraak gebruikt u het meest?
1= stemprothese
2= slokdarmspraak
3= servox
4= fluisterspraak
5= n.v.t.

69. Welke stemprothese gebruikt u nu?
1= Provox
2= Groninger stemprothese
3= geen/ander

70. Hoe vaak is de stemprothese verwisseld?
aantal:

71. Lekt de stemprothese bij het drinken?
1= ja
2= nee; ga door naar vraag 75

72. Hoe lang na prothesewisseling begint het lekken?
weken:

73. Hoe vaak lekt de stemprothese bij het drinken?
2= soms
3= vaak
4= altijd

74. Hoe hinderlijk vindt u het lekken?
1= helemaal niet
2= een beetje
3= nogal
4= heel erg

75. Wat is de belangrijkste reden voor wisseling van de prothese?
1= lekkage
2= verhoging van de weerstand bij het spreken
3= andere reden:

76. Heeft u last van lucht in de maag?
1= helemaal niet; ga door naar vraag 78
2= een beetje
3= nogal
4= heel erg

Stel vraag 77 alleen als 66a en b met ja zijn beantwoord.

77. Heeft u meer last van lucht in de maag bij het gebruik van de stemprothese dan bij de slokdarmspraak?
1= meer last bij gebruik stemprothese
2= meer last bij slokdarmspraak
3= gelijk

78. Hoe vindt u dat u te verstaan bent?
1= slecht
2= matig
3= redelijk
4= goed

79. Hoe is het volume van uw stem?
1= geen volume
2= zacht
3= gewoon
4= hard

80. Hoe is de toonhoogte van uw stem?
1= heel laag
2= laag
3= gewoon
4= hoog

81. Hoe is het tempo van uw manier van spreken?
1= heel laag
2= redelijk
3= gewoon
4= vlot

81a. Hoe vindt u uw stem?

82. Bent u aan de telefoon te verstaan?
1= helemaal niet
2= een beetje
3= redelijk
4= goed

83. Bent u soms zenuwachtig wanneer u in een groep mensen iets moet vertellen?
1= helemaal niet
2= een beetje
3= nogal
4= heel erg

84. Maakt u zich er zorgen over wat andere mensen van uw manier van spreken denken?
1= helemaal niet
2= een beetje
3= nogal
4= heel erg

85. Hebben vrienden en kennissen geduld om naar u te luisteren?
1= helemaal niet
2= een beetje
3= nogal
4= heel erg

Stel vraag 86 alleen aan patiënten met partner.

86. Heeft uw partner geduld om naar u te luisteren?
1= helemaal niet
2= een beetje
3= nogal
4= heel erg

87. Ziet u er tegenop om met een vreemde te praten?
1= helemaal niet
2= een beetje
3= nogal
4= heel erg

XIV. Sociale contacten.

Gedurende de laatste maand.

88. Hoe vaak bent u de afgelopen maand bij familie of vrienden op bezoek geweest?
1= iedere dag
2= een paar keer per week
3= 1 keer in de week
4= 2 of 3 keer deze maand
5= 1 keer deze maand
6= helemaal niet.

89. Hoe vaak zijn familie of vrienden bij u op bezoek geweest?
1= iedere dag
2= een paar keer per week
3= 1 keer in de week
4= 2 of 3 keer deze maand
5= 1 keer deze maand
6= helemaal niet

90. Hoe vaak heeft u de laatste maand met vrienden of familie getelefoneerd?
1= iedere dag
2= een paar keer per week
3= 1 keer in de week
4= 2 of 3 keer per maand
5= 1 keer per maand
6= helemaal niet

91. Hoe vaak heeft u een familielid of een vriend de afgelopen maand een brief geschreven?
aantal:

92. Hoe is de laatste tijd het contact met andere mensen?
1= slecht
2= matig
3= redelijk
4= goed

93. Bent u lid van de Tweede Stem?
1= ja
2= nee; ga door naar vraag 95

94. Hoe actief bent u daar?
1= zeer actief
2= tamelijk actief
3= niet actief, ga bijna nooit

94a. Gaat u naar de kringbijeenkomsten?
1= ja
2= nee

94b. Gaat u naar de jaarbijeenkomst?
1= ja
2= nee

95. Voelt u zich in uw omgang met andere mensen geremd?
1= helemaal niet
2= een beetje
3= nogal
4= heel erg

96. Mijdt u vreemde mensen?
1= nooit
2= soms
3= vaak
4= altijd

97. Is ten gevolge van de operatie uw kennissenkring groter of kleiner geworden of gelijk gebleven?
1= veel kleiner
2= iets kleiner
3= gelijk; ga door naar vraag 99
4= iets groter
5= veel groter

98. Kunt u in uw eigen woorden zeggen hoe dat komt?

XV. AD vragen.

Gedurende de afgelopen week.

99. Voelt u zich gespannen?
1= helemaal niet
2= een beetje
3= nogal
4= heel erg

100. Maakt u zich zorgen?
1= helemaal niet
2= een beetje
3= nogal
4= heel erg

101. Voelt u zich prikkelbaar?
1= helemaal niet
2= een beetje
3= nogal
4= heel erg

102. Voelt u zich neerslachtig?
1= helemaal niet
2= een beetje
3= nogal
4= heel erg

Longfunctietest:
1= ja
2= nee

FOLLOW-UP VRAGENLIJST HME onderzoek NKI, 1992/93.

"Klachten" na 6 maanden gebruik van de stomafilter (FreeVent). Tenzij anders aangegeven, "klachten" in de laatste maand.

A. Algemeen:

1. Statusnummer:

1a. Interview:
1= alleen
2= met begeleider

1b. datum interview dag maand jaar

C. Huidige klachten.

I. Hoest.

1. Hoeveel dagen in de week hoest u?
1= nooit
2= 1 à 2 dagen per week; ga door naar vraag 2
3= 3 à 4 dagen per week; ga door naar vraag 2
4= 5 of meer dagen per week; ga door naar vraag 2

1a. Klopt het dat u nooit bij het opstaan, overdag of 's nachts hoest?
1= ja; ga door naar vraag 7
2= nee

1b. Hoeveel dagen in de week hoest u?
2= 1 à 2 dagen per week
3= 3 à 4 dagen per week
4= 5 of meer dagen per week

2. Hoe vaak hoest u gemiddeld per dag?
aantal:

3. Hoeveel dagen in de week hoest u bij het opstaan?
1= nooit
2= 1 à 2 dagen p.w.
3= 3 à 4 dagen p.w.
4= 5 of meer dagen p.w.

4. Hoeveel dagen in de week hoest u in bed voor het inslapen?
1= nooit
2= 1 à 2 dagen p.w.
3= 3 à 4 dagen p.w.
4= 5 of meer dagen p.w.

5. Hoeveel nachten in de week hoest u?
1= nooit; ga door naar vraag 6
2= 1 à 2 nachten p.w.
3= 3 à 4 nachten p.w.
4= 5 of meer nachten p.w.

5a. Hoe vaak hoest u gemiddeld per nacht?
aantal:

6. Gebruikt u geneesmiddelen tegen het hoesten?
1= ja
2= nee; ga door naar vraag 7

6a. Hoe vaak gebruikt u geneesmiddelen tegen het hoesten?
aantal weken per jaar:

II. Sputum.

7. Hoeveel dagen in de week heeft u last van slijm?
1= nooit
2= 1 à 2 dagen p.w.; ga door naar vraag 8
3= 3 à 4 dagen p.w.; ga door naar vraag 8
4= 5 of meer dagen p.w.; ga door naar vraag 8

7a. Klopt het dat u bij het opstaan, overdag of 's nachts nooit last heeft van slijm?
1= ja; ga door naar vraag 12
2= nee

7b. Hoeveel dagen in de week heeft u last van slijm?
2= 1 à 2 dagen per week
3= 3 à 4 dagen per week
4= 5 of meer dagen per week

8. Hoe vaak gemiddeld per dag geeft u slijm op?
aantal:

9. Hoeveel dagen in de week geeft u slijm op bij het opstaan?
1= nooit
2= 1 à 2 dagen p.w.
3= 3 à 4 dagen p.w.
4= 5 of meer dagen p.w.

10. Hoeveel nachten in de week geeft u slijm op?
1= nooit; ga door naar vraag 11
2= 1 à 2 nachten p.w.
3= 3 à 4 nachten p.w.
4= 5 of meer nachten p.w.

10a. Hoe vaak geeft u gemiddeld per nacht slijm op? aantal:

11. Gebruikt u geneesmiddelen tegen slijm?
1= ja
2= nee; ga door naar vraag 12

11a. Hoe vaak gebruikt u geneesmiddelen tegen slijm? aantal weken per jaar:

III. Kortademigheid.

12. Bent u kortademig als u een trap oploopt (c.q. bij inspanning)?
1= helemaal niet
2= een beetje
3= nogal
4= heel erg

13. Bent u kortademig wanneer u gewoon loopt?
1= helemaal niet
2= een beetje
3= nogal
4= heel erg

14. Bent u in rust kortademig?
1= helemaal niet
2= een beetje
3= nogal
4= heel erg

IV. Piepende ademhaling.

15. Heeft u last van piepen op de borst?
1= helemaal niet; ga door naar vraag 17
2= een beetje
3= nogal
4= heel erg

16. Heeft u alleen last van piepen op de borst als u kou heeft gevat?
1= ja
2= nee

V. Astma.

17. Heeft u astma-aanvallen?
1= ja
2= nee, ga door naar vraag 19

18. Wanneer was de laatste astma-aanval?
weken geleden:

VI. Neusklachten.

19. Hoeveel dagen in de week heeft u last van een loopneus?
1= nooit;
2= 1 à 2 dagen p.w.
3= 3 à 4 dagen p.w.
4= 5 of meer dagen p.w.

VII. Longziekten.

20. Heeft u in de afgelopen 3 maanden bronchitis gehad?
1= ja
2= nee; ga door naar vraag 22

21. Hoe vaak heeft u in de afgelopen 3 maanden bronchitis gehad?
aantal:

22. Heeft u in de afgelopen 3 maanden longontsteking gehad?
1= ja
2= nee; ga door naar vraag 24

23. Hoe vaak heeft u in de afgelopen 3 maanden longontsteking gehad? aantal:

VIII. Luchtwegklaring.

24. Hoe vaak gemiddeld per dag maakt u de longen schoon door middel van ophoesten van slijm?
aantal:

25. Hoe vaak gemiddeld per dag maakt u het stoma schoon?
aantal:

IX. Vermoeidheid.

Gedurende de laatste week.

26. Had u behoefte om te rusten?
1= helemaal niet
2= een beetje
3= nogal
4= heel erg

27. Heeft u zich slap gevoeld?
1= helemaal niet
2= een beetje
3= nogal
4= heel erg

28. Was u moe?
1= helemaal niet
2= een beetje
3= nogal
4= heel erg

X. Slaap.

29. Hoe vaak is het voor u een probleem in slaap te komen?
1= nooit
2= 1 à 2 dagen p.w.
3= 3 à 4 dagen p.w.
4= 5 of meer dagen p.w.

30. Hoe vaak wordt u 's nachts wakker
1= nooit; ga door naar vraag 32
2= 1 à 2 keer per nacht
3= 3 à 4 keer per nacht
4= 5 of meer keer per nacht

31. Als u 's nachts wakker wordt, heeft u dan problemen weer in slaap te komen?
1= helemaal niet
2= een beetje
3= nogal
4= heel erg

32. Hoe vindt u dat u de afgelopen maand geslapen heeft?
1= slecht
2= matig
3= redelijk
4= goed

33. Hoe vaak heeft u tijdens uw dagelijkse bezigheden last van slaperigheid?
1= nooit
2= 1 à 2 dagen p.w.
3= 3 à 4 dagen p.w.
4= 5 of meer dagen p.w.

34. Gebruikt u slaapmiddelen?
1= ja
2= nee; ga door naar vraag 35

34a. Hoe vaak gebruikt u slaapmiddelen?
2= 1 à 2 dagen p.w.
3= 3 à 4 dagen p.w.
4= 5 of meer dagen p.w.

34b. Welk slaapmiddel gebruikt u?

XI. Spraak.

35. Welke van de volgende spreek mogelijkheden heeft u?

35a. Heeft u een stemprothese?
1= ja
2= nee

35b. Heeft u een slokdarmspraak?
1= ja
2= nee

35c. Heeft u een servox?
1= ja
2= nee

35d. Heeft u een fluisterspraak c.q. geen spraak
1= ja
2= nee

35e. Welke spraak gebruikt u het meest?
1= stemprothese
2= slokdarmspraak
3= servox
4= fluisterspraak
5= n.v.t.

36. Hoe vindt u dat u te verstaan bent?
1= slecht
2= matig
3= redelijk
4= goed

37. Hoe is het volume van uw stem?
1= geen volume
2= zacht
3= gewoon
4= hard

38. Hoe is de toonhoogte van uw stem?
1= heel laag
2= laag
3= gewoon
4= hoog

39. Hoe is het tempo van uw manier van spreken?
1= heel laag
2= redelijk
3= gewoon
4= vlot

40. Bent u aan de telefoon te verstaan?
1= helemaal niet
2= een beetje
3= redelijk
4= goed

41. Bent u soms zenuwachtig wanneer u in een groep mensen iets moet vertellen?
1= helemaal niet
2= een beetje
3= nogal
4= heel erg

42. Maakt u zich er zorgen over wat andere mensen van uw manier van spreken denken?
1= helemaal niet
2= een beetje
3= nogal
4= heel erg

43. Hebben vrienden en kennissen geduld om naar u te luisteren?
1= helemaal niet
2= een beetje
3= nogal
4= heel erg

Stel vraag 44 alleen aan patiënten met een partner.

44. Heeft uw partner geduld om naar u te luisteren?
1= helemaal niet
2= een beetje
3= nogal
4= heel erg

45. Ziet u er tegenop om met een vreemde te praten?
1= helemaal niet
2= een beetje
3= nogal
4= heel erg

XII. Sociale contacten.

Gedurende de laatste maand.

46. Hoe vaak bent u de afgelopen maand bij familie of vrienden op bezoek geweest?
1= iedere dag
2= een paar keer per week
3= 1 keer in de week
4= 2 of 3 keer deze maand
5= 1 keer deze maand
6= helemaal niet.

47. Hoe vaak zijn familie of vrienden bij u op bezoek geweest?
1= iedere dag
2= een paar keer per week
3= 1 keer in de week
4= 2 of 3 keer deze maand
5= 1 keer deze maand
6= helemaal niet

48. Hoe vaak heeft u de laatste maand met vrienden of familie getelefoneerd?
1= iedere dag
2= een paar keer per week
3= 1 keer in de week
4= 2 of 3 keer per maand
5= 1 keer per maand
6= helemaal niet

49. Hoe vaak heeft u een familielid of een vriend de afgelopen maand een brief geschreven?
aantal:

50. Hoe is de laatste tijd het contact met andere mensen?
1= slecht
2= matig
3= redelijk
4= goed

51. Mijdt u vreemde mensen?
1= nooit
2= soms
3= vaak
4= altijd

52. Voelt u zich in uw omgang met andere mensen geremd?
1= helemaal niet
2= een beetje
3= nogal
4= heel erg

XIII. AD vragen.

Gedurende de afgelopen week.

53. Voelt u zich gespannen?
1= helemaal niet
2= een beetje
3= nogal
4= heel erg

54. Maakt u zich zorgen?
1= helemaal niet
2= een beetje
3= nogal
4= heel erg

55. Voelt u zich prikkelbaar?
1= helemaal niet
2= een beetje
3= nogal
4= heel erg

56. Voelt u zich neerslachtig?
1= helemaal niet
2= een beetje
3= nogal
4= heel erg

XIV. HME vragen:

Alleen voor personen die een stomafilter gebruikt hebben.

1. Heeft u de stomafilter 3 maanden lang gebruikt?
1= ja
2= nee; ga door naar vraag 1b

1a. Klopt het dat u de stomafilter regelmatig 3 maanden lang gebruikt heeft?
1= ja; ga door naar vraag 2
2= nee

1b. Na hoeveel dagen bent u met het gebruik van de stomafilter gestopt?
aantal:

1c. Bent u later weer begonnen met het gebruik van de stomafilter?
1= ja
2= nee; ga door naar vraag 1e

1d. Na hoeveel dagen bent u weer begonnen met het gebruik van de stomafilter?
aantal:

1e. Waarom bent u gestopt?

2. Hoeveel dagen in de week heeft u de stomafilter gebruikt?
1= nooit
2= 1 à 2 dagen per week
3= 3 à 4 dagen per week
4= 5 à 6 dagen per week
5= iedere dag

2a. Heeft u de stomafilter overdag gebruikt?
1= nooit
2= soms
3= vaak
4= altijd

2b. Heeft u de stomafilter 's nachts gebruikt?
1= nooit
2= soms
3= vaak
4= altijd

3a. Aantal gebruikte filters gedurende de eerste week?
aantal:

3b. Aantal gebruikte pleisters gedurende de eerste week?
aantal:

4a. Aantal gebruikte filters gedurende de laatste week?
aantal:

4b. Aantal gebruikte pleisters gedurende de laatste week?
aantal:

5. Vond u het moeilijk of makkelijk er aan te denken de stomafilter te gebruiken?
1= heel moeilijk
2= vrij moeilijk
3= niet moeilijk, niet makkelijk
4= vrij makkelijk
5= heel makkelijk

6. Vond u het moeilijk of makkelijk er aan te denken de stomafilter te verwisselen?
1= heel moeilijk
2= vrij moeilijk
3= niet moeilijk niet makkelijk
4= vrij makkelijk
5= heel makkelijk

7. Hebt u door het gebruik van de stomafilter meer of minder gehoest?
1= veel meer; ga naar vraag 8
2= iets meer; ga naar vraag 8
3= gelijk; ga naar vraag 10
4= iets minder; ga naar vraag 9
5= veel minder; ga naar vraag 9

8. Als u meer hoestte, verwijderde u dan de filter?
1= nooit
2= soms
3= vaak
4= altijd

9. Als u minder hoestte, verwijderde u dan de filter?
1= nooit
2= soms
3= vaak
4= altijd

10. Hebt u door het gebruik van de stomafilter meer of minder last van slijm gehad?
1= veel meer; ga naar vraag 11
2= iets meer; ga naar vraag 11
3= gelijk; ga naar vraag 13
4= iets minder; ga naar vraag 12
5= veel minder; ga naar vraag 12

11. Als u meer last van slijm had, verwijderde u dan de filter?
1= nooit
2= soms
3= vaak
4= altijd

12. Als u minder last van slijm had, verwijderde u dan de filter?
1= nooit
2= soms
3= vaak
4= altijd

13. Is de ademhaling door het gebruik van de stomafilter moeilijker of makkelijker gegaan?
1= veel moeilijker
2= iets moeilijker
3= gelijk; ga naar vraag 15
4= iets makkelijker; ga naar vraag 15
5= veel makkelijker; ga naar vraag 15

14. Als de ademhaling moeilijker ging, verwijderde u dan de filter?
1= nooit
2= soms
3= vaak
4= altijd

15. Hebt u door het gebruik van de stomafilter de longen meer of minder vaak schoon hoeven maken?
1= veel meer
2= iets meer
3= niet meer, niet minder
4= iets minder
5= veel minder

16. Hebt u door het gebruik van de stomafilter meer of minder vaak het stoma schoon hoeven maken?
1= veel vaker
2= iets vaker
3= niet vaker, niet minder vaak
4= iets minder vaak
5= veel minder vaak

17. Hebt u door gebruik van de stomafilter slechter of beter geslapen?
1= veel slechter
2= iets slechter
3= niet slechter, niet beter; ga naar vraag 19
4= iets beter; ga naar vraag 19
5= veel beter; ga naar vraag 19

18. Als het slapen slechter ging, verwijderde u dan de filter?
1= nooit
2= soms
3= vaak
4= altijd

19. Vond u het onprettig of prettig het stoma af te dekken door middel van deze stomafilter?
1= zeer onprettig; ga naar vraag 19a
2= enigszins onprettig; ga naar vraag 19a
3= niet onprettig, niet prettig
4= enigszins prettig; ga naar vraag 19b
5= zeer prettig; ga naar vraag 19b

19a. Waarom vond u het onprettig?

19b. Waarom vond u het prettig?

20. Was het spreken moeilijker of makkelijker door gebruik van de stomafilter?
1= veel moeilijker
2= iets moeilijker
3= niet moeilijker, niet makkelijker; ga naar vraag 22
4= iets makkelijker; ga naar vraag 22
5= veel makkelijker; ga naar vraag 22

21. Als het spreken moeilijker ging, verwijderde u dan de stomafilter?
1= nooit
2= soms
3= vaak
4= altijd

22. Vond u dat u slechter of beter te verstaan was door gebruik van de stomafilter?
1= veel slechter
2= iets slechter
3= niet slechter, niet beter; ga naar vraag 24
4= iets beter; ga naar vraag 24
5= veel beter; ga naar vraag 24

23. Als u slechter te verstaan was, verwijderde u dan de stomafilter?
1= nooit
2= soms
3= vaak
4= altijd

Stel vraag 24 alleen aan patiënten met een stemprothese.

24. Kunt u de filter d.m.v. vinger(s) of duim afsluiten om te spreken?
1= helemaal niet
2= een beetje
3= nogal
4= heel goed

24a. Als u de filter afsluit om te praten, heeft u dan last van valse lucht via de pleister?
1= nooit
2= soms
3= vaak
4= altijd

25. Was het pijnlijk de pleister van het stoma te verwijderen?
1= helemaal niet
2= een beetje
3= nogal
4= heel erg

26. Had u last van irritatie van de huid door gebruik van de pleister?
1= helemaal niet
2= een beetje
3= nogal
4= heel erg

27. Liet de pleister van de stomafilter los wanneer u moest hoesten?
1= helemaal niet
2= een beetje
3= nogal
4= heel erg

28. Plakte de pleister van de stomafilter goed op de huid?
1= helemaal niet
2= een beetje
3= nogal
4= heel erg; ga naar vraag 29

28a. Indien de pleister niet (goed) plakte, lag dit dan aan het diep liggen van het stoma.
1= ja
2= nee

29. Welke vorm pleister gebruikt u nu?
1= rond
2= rechthoekig
3= wigvormig
4= elliptisch
5= anatomisch

29a. Bevalt deze vorm pleister u?
1= helemaal niet
2= een beetje
3= nogal; ga naar vraag 30
4= goed; ga naar vraag 30
5= heel goed; ga naar vraag 30

29b. Waarom bevalt deze vorm pleister niet zo goed?

30. Gebruikte u tijdens de onderzoeksperiode eerst een andere vorm pleister?
1= ja
2= nee; ga door naar vraag 31

30a. Welke vorm?
1= rond
2= rechthoekig
3= wigvormig
4= elliptisch
5= anatomisch

31. Heeft u problemen met het indrukken van de filter in de houder, voordat u de pleister opplakt?
1= helemaal niet
2= een beetje
3= nogal
4= heel erg

32. Heeft u problemen met het indrukken van de filter in de houder, als de pleister voor het stoma zit?
1= helemaal niet
2= een beetje
3= nogal
4= heel erg

33. Heeft u problemen met het verwijderen van de filter uit de houder, als de pleister voor het stoma zit?
1= helemaal niet
2= een beetje
3= nogal
4= heel erg

34. Na hoeveel dagen was u aan de stomafilter gewend?
aantal:

35. Had u baat bij de stomafilter?
1= nee, helemaal niet
2= ja, een beetje
3= ja, redelijk veel;ga naar vraag 35b
4= heel veel; ga naar vraag 35b

35a. Waarom had u geen/een beetje baat?

35b. Na hoeveel dagen had u baat bij de stomafilter?
aantal:

36. Wat waren in het begin de problemen met de stomafilter?

37. Hoe is nu uw indruk over de stomafilter?

38. Bent u van plan de stomafilter te gebruiken indien hij wordt voorgeschreven?
1= ja, zeker wel; ga naar vraag 39
2= waarschijnlijk wel; ga naar vraag 39
3= waarschijnlijk niet
4= zeker niet

38a. Kunt u aangeven waarom niet?

39. Wat zou u andere gelaryngectomeerden adviseren over het al of niet gebruiken van de stomafilter.
1= beslist aanraden
2= in elk geval proberen
3= niet aan- of afraden
4= afraden
5= weet niet

Longfunctietest:
1= ja
2= nee

Appendix B

Tables

Appendix B.

As this thesis is based on a series of peer-reviewed papers, published in several different journals, the style used to present tables and information varies from chapter to chapter. In the interest of clarity and consistency, this appendix provides a number of revised tables with more complete information than may be available in the original tables.

Table 1 (chapter IV; p.61).Mean daily frequency of respiratory symptoms before (pre) and after (post) 6 week use of an HME.

	All patients N=42		Continue users N=29	
	pre	post	pre	post
coughing	13.8	8.4	10.7	6.7
(SD)	(18.9)	(6.8)	(11.6)	(6.6)
Z=		-.99		-1.19
sputumproduction	12.6	8.2*	10.1	6.1**
(SD)	(15.8)	(6.6)	(8.3)	(5.9)
Z =		-2.13		-2.60
forced expectoration	12.2	8.2	9.5	6.2*
(SD)	(16.8)	(6.6)	(10.4)	(5.9)
Z=		-1.55		-1.94
stoma cleaning	9.0	4.5**	6.4	3.5*
(SD)	(15.8)	(4.5)	(7.4)	(2.6)
Z=		-2.35		-1.74

(Wilcoxon non-parametric test for paired observations: * $p < 0.05$ / ** $p < 0,01$)
SD = standard deviation

Table 1 (chapter V; p.72). Lung function measurements (means) with the HME baseholder and with the cuffed trachea cannula.

	Cannula (SD)	HME baseholder (SD)	Z	P-value*
VC	3.1 (.87)	3.3 (.75)	-1.86	0.063
FEV1	2.2 (.90)	2.4 (.94)	-2.52	0.012**
PEF	4.8 (1.4)	7.1 (2.0)	-2.52	0.012**
MEF50	2.2 (1.3)	2.5 (1.7)	-.70	0.484
FIV1	2.2 (.59)	3.1 (.74)	-2.52	0.012**
PIF	2.5 (.57)	5.5 (.87)	-2.52	0.012**
MIF50	2.2 (.64)	5.1 (.91)	-2.52	0.012**

* Wilcoxon non-parametric test for paired observations
** Statistically significant

HME = Heat and Moisture Exchanger.
VC = maximum vital capacity (litres/sec.)
FEV1 = forced expiratory volume in 1 second (litres/sec.)
PEF = peak expiratory flow (litres/sec.)
MEF50 = maximum expiratory flow at 50% (litres/sec.)
FIV1 = forced inspiratory volume in 1 second (litres/sec.)
PIF = peak inspiratory flow (litres/sec.)
MIF50 = maximum inspiratory flow at 50% (litres/sec.)

Additional table (chapter VI; p.83) Improvements in quality of life aspect after the 3-month study period (N=37)

	Before mean (SD)	After mean (SD)	t-value	P-value
Shortness of breath	4.5 (1.3)	4.0 (1.0)	2.70	.010
Fatigue and malaise	5.0 (2.4)	4.2 (1.8)	2.72	.010
Sleep	5.3 (2.4)	4.5 (1.7)	3.32	.002
Anxiety and depression	5.5 (1.4)	5.2 (1.4)	2.78	.009
Voice quality	14.8 (2.3)	16.2 (2.1)	-4.12	.000

Student's t-test for paired observations

Table 2 (chapter VI; p.84). Mean daily frequency of respiratory symptoms before and after the 3-month study period.

	HME Group (N=37)		Control Group (N=24)	
	before	after	before	after
Coughing	9.5	7.2	7.4	8.3
SD	(7.7)	(4.2)	(6.3)	(5.4)
t-value		1.32		-.50
Sputum production	10.4	7.2*	11.6	9.9
SD	(6.6)	(4.7)	(10.8)	(6.4)
t-value		2.90		1.03
Forced expectoration	10.2	6.9*	11.7	9.8
SD	(6.3)	(4.7)	(10.7)	(6.4)
t-value	3.27		1.13	
Stoma cleaning	4.7	3.2**	5.1	5.0
SD	(5.3)	(2.4)	(5.4)	(4.4)
t-value		2.04		.04

Student's t-test for paired observations * $p < .005$ ** $p < .01$

Table 3 (chapter VI; p.86). Pulmonary function before and after the 3-month study period (N = 30).

	Before (SD)	After (SD)	t-value	P-value
VC max	3.5 (.89)	3.6 (.83)	-1.30	.204
FEV1	2.3 (.82)	2.4 (.85)*	-2.13	.041
PEF	6.1 (2.5)	6.5 (2.5)	-1.69	.102
MEF50	2.1 (1.2)	2.4 (1.5)	-1.43	.162
FIV1	2.9 (.84)	3.1 (.90)*	-2.57	.016
PIF	4.2 (1.4)	5.0 (1.8)**	-4.01	.000
MIF50	3.7 (1.3)	4.6 (1.8)**	-3.85	.001

Students t-test for paired observations * $p < .05$ ** $p < .005$

Additional table (chapter VII; p.97). Improvements in 4 quality of life aspects (N=59)

	3 months Mean (SD)	6 months Mean (SD)	t-value	P
Voice quality	13.7 (3.3)	14.8 (2.8)*	-3.50	.001
Social anxiety	7.6 (2.9)	5.8 (1.6)*	4.67	.000
Social interactions	6.4 (2.1)	5.3 (1.5)*	4.50	.000
Anxiety and depression	6.0 (1.9)	5.4 (1.8)**	2.58	.012

Student's t-test for paired observations * $p < .001$ ** $p < .05$

Table 3 (chapter VII; p.99). Mean daily frequencies of respiratory symptoms after 3 and 6 months+

	regular HME users (N=29)		non(regular) HME users (N=30)	
Symptoms	3 mth	6 mth	3mth	6mth
cough	9.5	3.0	9.7	11.7
SD	(4.9)	(2.0)	(8.3)	(11.1)
sputum production*	11.2	6.2	14.5	15.5
SD	(12.8)	(6.1)	(8.6)	(12.3)
forced expectoration**	11.7	5.6	14.3	16.4
SD	(13.1)	(5.6)	(8.5)	(12.1)
stoma cleaning**	7.1	3.4	7.2	9.4
SD	(10.7)	(5.4)	(8.4)	(12.9)

+ Analysis based on repeated measures analysis of variance. Statistical tests for group x time interaction with two groups (regular and non(regular) HME users) and two assessment points (3 and 6 months postoperatively).

sputum production*	F=3.08 (df=1)	p=.085
forced expectoration**	F=6.10 (df=1)	p=.017
stoma cleaning**	F=4.54 (df=1)	p=.038

Table 4 (chapter VII; p. 100). Pulmonary function 2 weeks and 6 months postoperatively (N=39)

	2 weeks	6 months	P-value	t-value
VC max (SD)	4.1 (.87)	4.2 (.99)	ns	- .97
FEV (SD)	2.8 (.83)	2.8 (.91)	ns	.97
PEF (SD)	7.7 (2.5)	8.0 (2.6)	ns	-1.04
MEF50* (SD)	2.7 (1.7)	2.3 (1.3)	.025	2.33
FIV (SD)	3.5 (1.0)	3.8 (1.0)	.002	-3.29
PIF (SD)	6.0 (1.9)	6.4 (2.0)	.071	-1.86
MIF50 (SD)	5.3 (2.0)	5.7 (1.9)	.072	-1.85

* MEF50 decreased