Pulmonary rehabilitation in patients with total laryngectomy

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Abstract. Introduction. As a result of total laryngectomy, the air is not anymore passing through the nasal cavity and therefore the warming, humidifying and filtering are not realized, resulting in an „unconditional” air, thereby leading to an increase in the mucus production and excessive coughing, causing frequent infections of the respiratory tract. At the moment, the best treatment option for the loss of superior respiratory tract function is the use of heat and moisture exchangers (HME). Material and method. We conducted a prospective study based on 11 patients with total laryngectomy, for larynx cancer, at ENT Clinic of Cluj County Hospital, during the period June 2018 – April 2019. The patients were pulmonary rehabilitated with the help of HME filters, during one month. The respiratory function was evaluated before the beginning of pulmonary rehabilitation and after. Results. The result of the respiratory function tests (Spirometry) of the patients have shown lower values than those predicted: value of PEF index (3.19 ± 1.58) patients with total laryngectomy compared to predictive value (7.54 ± 1.16), the difference between the two values being statistically significant (p=0.00). The value of the variable PEF (2.47 ± 1.42), at the patients after the use of the filters, was lower compared with the value of those before the use of the filters (2.86 ± 1.39). At 90% patients the adaptation with filters was satisfactory. All the patients have declared the reduction in the number of cough/day and in the expectoration. Conclusion. HME filter can not totally restore the functions of the superior respiratory tract, but it plays a major role in the pulmonary rehabilitation for the patients with total laryngectomy.

Key Words: total laryngectomy, heat and moisture exchangers, pulmonary rehabilitation.

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Introduction
Following a total laryngectomy, the heating, humidifying and air filtration functions of the nose and upper airways are lost, and this can cause cough and excessive mucus production. Even from the first days after laryngectomy, a significant increase in mucus production was observed, which requires special care (Kai 2013). Further in time after laryngectomy, changes in pulmonary function, total lung capacity and forced expiratory volume were observed (Todisco et al. 1984). The heating and humidification of inspired air may alleviate some of those symptoms (Hilgers et al 1991). It is necessary that the inspired air to have close characteristics to the air that passed naturally through the upper airways, in order to avoid respiratory complications (Dassonville et al 2011). Pulmonary protection, through an adequate air conditioning, can be obtained by a filter which heats and humidifies the air (HME), which is placed in the cannula or it is sealed to the stoma (Brook et al 2013). HME filter displays characteristics close to a normal nasal function, being nicknamed “artificial nose”. It assures a superior air flux and a good air humidification. The HME filter is a single-use device, which contains a foamed sponge, treated with CaCl2, and is incorporated in a plastic case. The superior lid can be pushed down using a finger during speech, in order to achieve a sealed case (Cindy van den Boer et al 2014). Many studies have demonstrated that patients with total laryngectomy, suffers from pulmonary respiratory problems like cough, excessive bronchial secretions, dyspnea, that are caused by the discontinuity between upper and lower airways and by the lack of air conditioning (Ackerstaff et al 1993; Ackerstaff 1998; Hilgers et al 2003).

Clinical studies have showed that most of patients with laryngectomy, that use a HME filter 24 hours, even during sleep, displayed a decrease in mucus secretion and fewer cough episodes (Dassonville et al 2011).

The aim of the study is to characterize the pulmonary functional status in patients with laryngectomy and the presence of functional respiratory alterations, as well as to evaluate the efficacy of filters.

Material and methods
This study included 11 patients diagnosed with laryngeal cancer that underwent total laryngectomy at least 6 months from
the inclusion moment. The study took place in ENT Clinic of Cluj County Hospital between June 2018 and April 2019. The patients have used the HMEs filters for a period of one month. Pulmonary respiratory function was evaluated before the use of the filters and one month after that. All the patients were interviewed before the use of the filters and after it. The exclusion criteria were: acute respiratory disease in the previous month, patients with recurrence disease and patients that could not do the tests.

The study was approved by the Ethics Committee of “Iuliu Hatieganu” University of Medicine and Pharmacy, Cluj-Napoca (registration no. 306 / 26.07.2018). All study participants signed the informed consent. The patients have used the HMEs filters for a period of one month. Pulmonary respiratory function was evaluated before the use of the filters and one month after that. All the patients were interviewed before the use of the filters and after it. The filters are attached directly to the cannula or to some special adhesives. HME extra moisture filter has capabilities closer to normal nasal function. The filters are attached directly at the cannula level or at the level of some special adhesives. The extra moisture filter HME has capacities which are more similar to the normal nasal function and the best properties of humidification from all other filter types. Pulmonary function tests show the functional lung status, allow measurements of lung’s volumes, of capacities and flux. The spirometry was employed in order to evaluate the pulmonary function. The device used was a BTL-08 Spiro PRO plus, which is a portable compact spirometer, designed for non-invasive evaluation of lung capacity. The patients were in a sitting position and were connected to the spirometer by placing the mouth piece to the tracheostomy orifice, due to the fact that the patients underwent laryngectomy. The parameters evaluated by spirometry were: forced expiratory volume during the first second (FEV1), forced vital capacity (FVC), peak expiratory flow (PEF) - the maximal flow that can be exhaled; mid expiratory flow 25, 50, 70 – maximal flows obtained when in the lung remains 25%, 50% or 75% from FVC; FEV1/FVC (Tiffneau index). The tests were repeated twice. The tests results, as well as the results selection followed the criteria established by the pulmonary function test guideline. The selected values for pulmonary function indexes were expressed as percentage from the normal values, calculated according to European Society of Lung Diseases. Using the tests results we calculated pulmonary volumes. All patients were interviewed after a month, in order to investigate the compliance to filters. The tests were interpreted by a specialist in spirometry and classified as: obstructive airways disorders, restrictive disorders and mixt disorders. The results were expressed as percentage from the predicted values, in accordance to the age, gender and height of the patient. The statistical analysis was performed using the MedCalc Statistical Software version 19.0.4 (MedCalc Software bvba, Ostend, Belgium; https://www.medcalc.org; 2019). Continuous variables were expressed by mean and standard deviation. Differences between measurements were assessed with ANOVA test for repeated measures. A p value <0.05 was considered statistically significant.

Results

We included in the study 11 patients with a mean age of 55.7±15.4. Eight (72.7%) patients were males and three (27.3%) females. Seven (63.3%) were from urban areas and four (36.4%) from rural areas. Three (27.3%) had an early TNM stage (T1-2), and eight (72.7%) had an advanced TNM stage (T3-4). Seven (63.6%) patients followed radiotherapy and two (18.2%) patients followed neo-adjuvant chemotherapy. Five (45.5%) patients were smokers and two (18.2%) consumed alcohol. One (9.1) patient followed treatment for bronchial asthma. About 90.9% patients followed vocal rehabilitation: 81.8% with vocal prosthesis, and 9.9% by esophageal voice. Most of the patients, 54.5%, were one year after the surgery, 27.3% were at two years after the surgery and one (9.1%) patient was at 5 years after the surgery. Most of the patients retired after the total laryngectomy, but 27.3% patients still worked. The results of the predicted values and the first and second measurements can be found in table 1. The results of pulmonary functional tests (spirometry) in patients with laryngectomy showed: the PEF value was reduced in patients with laryngectomy as compared with the predicted value (p<0.001). The mean value of measured FEV1 was lower than of predicted FEV1, but the difference was near the threshold of statistical significance (p=0.09). The mean value of predicted CFV was higher than the one of the patients with laryngectomy, without a statistical significance. The value of measured FEV1/CFV was lower than of predicted FEV1/CFV, but the difference was not statistically significant. The value of MEF75 is reduced in patients with total laryngectomy, as compared with the predicted values, and the difference is statistically significant (p<0.001). The mean value of MEF50 was lower than the predicted value (p=0.006). Values of measured MMEF did not differ than the predicted ones. As well, the was not a significant difference between the measured MEF25 and the predicted MEF25.

The value of spirometry parameters before the use of the filters did not differ significantly from those after the use. Approximately 63.6% patients had modified values of pulmonary function: 5 (45.5%) patients had mix respiratory disorder, 1 (9.1%) patient had obstructive airways disorder, and 1 (9.1%) had restrictive disorder. After 1 month of filter use, 72% patients had modified values, as follows: 4 (36.4%) patients had mix respiratory disorder, 2 (18.2%) patients had obstructive airways disorder, and 2 (18.2%) had restrictive disorder. Four (36.4%) patients had normal values before filter use and after a month, only 3 (27.3%) had normal values.

Table 1. Pulmonary function - reference normal predicted values, first and second measurement. Test 1-the value before using the filter; Test 2-the value after using the filter

<table>
<thead>
<tr>
<th>Variables</th>
<th>Predicted values</th>
<th>Test 1</th>
<th>Test 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>FEV1</td>
<td>3.1 ± 0.5</td>
<td>2.1 ± 1.2</td>
<td>1.5 ± 0.6</td>
</tr>
<tr>
<td>CVF</td>
<td>3.8 ± 0.7</td>
<td>2.9 ± 1.3</td>
<td>2.6 ± 1.4</td>
</tr>
<tr>
<td>FEV1/CVF</td>
<td>77.7 ± 3.1</td>
<td>75.8 ± 21</td>
<td>68.3 ± 25.6</td>
</tr>
<tr>
<td>PEF</td>
<td>7.5 ± 1.1</td>
<td>3.1 ± 1.5</td>
<td>2.4 ± 1.4</td>
</tr>
<tr>
<td>MEF75</td>
<td>6.6 ± 1.0</td>
<td>2.5 ± 1.4</td>
<td>1.8 ± 0.9</td>
</tr>
<tr>
<td>MEF50</td>
<td>4.1 ± 0.5</td>
<td>2.4 ± 1.3</td>
<td>1.6 ± 0.5</td>
</tr>
<tr>
<td>MEF25</td>
<td>1.5 ± 0.9</td>
<td>1.4 ± 1.0</td>
<td>1.0 ± 0.6</td>
</tr>
<tr>
<td>MMEF</td>
<td>2.9 ± 1.3</td>
<td>2.4 ± 1.2</td>
<td>1.3 ± 0.4</td>
</tr>
</tbody>
</table>
After using the filter for a month, 90% patients declared that the adaptation was satisfactory. We addressed the patients the following questions, in order to evaluate the changes perceived by them: If they sensed an improvement after using the filters – 90% responded affirmatively. All patients reported a decrease in number coughing episodes/day (from 9-10 to 4-5) and expressed their satisfaction towards the valve used for digital occlusion of the stoma.

**Discussions**

The larynx removal has negative effects, not only the loss of voice, but it leads to chronic pulmonary disorders. In order to compensate the functional loss of upper airways, it was demonstrated that the HME filters reduce the secondary pulmonary symptoms that derives from total laryngectomy and they improve the quality of life (Parrilla et al 2015; Ackerstaff et al 1995). The humidification and heating of the inspired air in patients with laryngectomy is important (Lorenz 2009), however the HME filters are too expensive in the context of the medical assistance in Romania. Most patients do not use the filters or they use the same filter for a long period of time.

The results of the study show an improvement of subjective respiratory symptoms and prosthetic voice after only one month of using the Provox HME® filters, without an objective change of pulmonary function. On contrary the results after filter use were lower than before.

The use of HME filters reduced significantly the number of coughing and forced expectorations per day. The mucus production and the tiredness decreased a lot during filter use, which lead to an increase in patient’s satisfaction with an improvement of quality of life.

The results of pulmonary function tests in our study on patients with laryngectomy are similar to those in the medical literature (Ackerstaff et al 1993; Castro et al 2018; Hess et al 1999) and they show lower than predicted values. Similarly, to the study made by Arkerstaff et al the results of our study revealed a clear worsening of pulmonary function parameters after total laryngectomy, as compared to the preoperative values (Ackerstaff et al 1993; Ackerstaff 1995). The results of measured values of pulmonary function indexes were compared to the references values individually adjusted (estimated values). The results showed that all ventilatory indexes were decreased, however the difference between predicted and measured value was not statistically significant for most of them. Statistical significance was observed only for PEF, and for FEV1 the statistical threshold was barely passed.

The result interpretation showed changes in functional parameters that correspond to obstructive, restrictive and mixt airway disorders. The pulmonary ventilatory disorders are classified as obstructive, restrictive and mixt. When FEV1, Tiffeneau index are decreased and FVC is normal, we are talking about an obstructive airway disorder. In the restrictive syndrome, FVC is reduced, FEV1 is normal and Tiffeneau index is normal or elevated. The mixt airway disorders is characterized by a decreased FEV1 and FVC, and a normal Tiffeneau index (Ackerstaff et al 1993). The obstructive disorders after total laryngectomy may be caused by inflammatory changes at the lower airways, as a lacking of conditioning of the inspired air (Renske et al 2011).

It is interesting that although the subjective evaluation of pulmonary function shows the improvement of respiratory symptoms, the objective evaluation after filter use, revealed the worsening of pulmonary function indexes: FVC, FEV1, FEV1/FVC, PEF, MMEF, MEF75, 50, 25, but the difference between the values was not statistically significant. It is not surprising the fact that the valued of pulmonary function parameters in patients with laryngectomy, before the filter use, are significantly lower than the predicted ones, due to the pulmonary physiological changes (Hilgers et al 2000). It is interesting though that we did not manage to demonstrate the objective efficacy of the HME filter, due to the fact that the values recorder after the use of HME were lower.

The direct improvement of objective spirometry function parameters with the use of HME was not demonstrated by any study (Ackerstaff et al 1993). A slight improvement of inspiratory function parameters (FEV1, PEF, and MIV50) was observed after three months of use (Ackerstaff et al 1993; Rajan et al 2011). It was demonstrated that the filters raise significantly the water content of the inspired air at the endotracheal level, they reduce considerably the pulmonary respiratory problems and increase the quality of life (Zuur et al 2008; Scheenstra et al 2010). However, they do not solve totally the pulmonary problems. This is due to the fact the filters only condition partially the inspired air, that suggests that the HME capacity of heat and humidify the inspired air is lower than that of the upper airways (Scheenstra et al 2010).

This study has its limitations. The patient group is relatively small (11 patients). In order to make a definitive conclusion regarding the changes of objective pulmonary function parameters, a larger group of patients is needed and a longer period of filter use.

**Conclusions**

Although HME cannot completely reestablish the upper airways function, it plays a major role in pulmonary rehabilitation in patients with total laryngectomy, by reducing the physical and psychosocial problems. Even though, in this study, the objective evaluation showed a worsening in respiratory function indexes results, there was a subjective significant difference in decrease of coughing episodes, expectoration and an improvement of quality of life. For obtaining an optimal effect of pulmonary rehabilitation, it is necessary a continuous use of HME filters.

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