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Laryngectomy Clinical Summaries

Optimizing Pulmonary Outcomes After Total Laryngectomy: Crossover Study on New Heat and Moisture Exchangers (HMEs)

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Background

- The physical consequences of a total laryngectomy (TL) include increased mucus production and frequent coughing, which often translate into socio-emotional problems such as chronic fatigue, sleep disorders, anxiety, and depression.
- Addressing these difficulties inspired the development of a new generation of medical devices: Provox® Life™.
- Provox® Life™ HMEs are designed to provide different levels of humidification, breathing resistance and filtration. Provox® Life™ Adhesives are designed to suit various skin types and to fit individual stoma shapes.

Objective

To evaluate the effect of the use of new generation devices (Provox® Life™) on pulmonary symptoms, subject adherence to HME use, quality of life, dermatological symptoms, and patient satisfaction.

Design and methods

- The clinical study was designed as a randomized prospective crossover study and took place in Italy from December 2020 to April 2021.
- A total of 40 laryngectomized patients (the majority using tracheoesophageal speech by means of a voice prosthesis) were randomized into two groups: Group A, starting with Provox® Life™ (PL), followed by Usual Care (UC) (n=20) and Group B, starting with UC, followed by PL (n=20).
- All patients had routinely used HMEs and adhesives prior to the study.
- Each study period had a duration of 6 weeks, and all participants were asked to keep a diary during the last two weeks of each period.
- During the last week of each study period, they were also asked to record their daily number of coughs on a tally sheet for 3 days. Data was collected at baseline and after 3 months.
- At baseline and after each study period, the patients were additionally asked to complete structured interviews on usage rates of HMEs and adhesives, shortness of breath, frequency of stoma cleaning, sleep disturbances, skin irritation, and comparative questionnaires with EQ-5D[1] and CASA-Q[2].

AT A GLANCE

Study Design

- Randomized prospective crossover study.
- 40 laryngectomized patients with an HME and attachment routine.
- Average age: 68 years old.
- Average time since surgery: 5 years.
- Evaluation period: 6 weeks each.
- Randomized into Group A, Provox Life followed by Usual Care (n=20) and Group B, Usual Care followed by Provox Life (n=20).
- Patient Reported outcomes (PROs) collected at baseline and after each 6-week period by means of tally sheets, diaries, study-specific questionnaires, and validated questionnaires (EQ-5D, CASA-Q).

Patient Experience with Provox Life HMEs

- 75% of patients preferred Provox Life over their usual care.
- 95% of patients were moderately, quite a bit, or very much satisfied with Provox Life.
- The main advantages reported were greater skin-compatibility of adhesives and the better breathability of Provox Life HMEs.

Key Points

- Provox Life optimized pulmonary rehabilitation in laryngectomized patients who were already highly adherent to HME use.
- These improvements can be linked to high humidification HME use throughout the day, enabled by reduced shortness of breath and reduced skin irritation.
- This demonstrates the clinical importance of using better performing HMEs to further compensate for the humidification deficit in laryngectomized patients as well as to reduce the impact of pulmonary complaints on daily life.

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Results

Pulmonary Health Outcomes and Quality of Life

After 6 weeks of use of Provox® Life™, there was a significant reduction in the average daily forced mucus expectorations and dry coughs compared to UC (see Fig. 1) and a significant improvement in all four domains of the CASA-Q (see Fig. 2). In addition, a significant reduction in shortness of breath when going up the stairs (p=0.046) and when walking on level ground (p=0.005) with Provox® Life™ compared to UC was observed. A statistically significant overall reduction in the number of nights during which sleep medication was used for Provox Life compared to UC was observed (108 nights during the PL period, compared to 219 nights during the UC period, p=0.044).

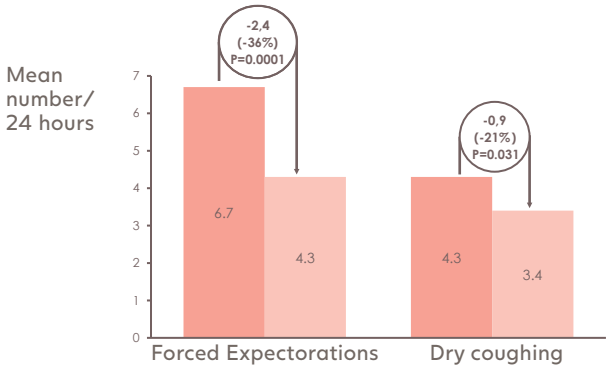

Figure 1 Average daily forced expectorations and dry coughing frequencies
The graph shows the average daily forced expectorations and dry coughing frequencies as reported by patients for Usual Care and Provox Life, including the reduction for each parameter and group, respectively. A significant reduction in both average daily forced expectorations and dry coughing frequencies were found after 6 weeks of Provox Life use.

Usual Care
Provox Life

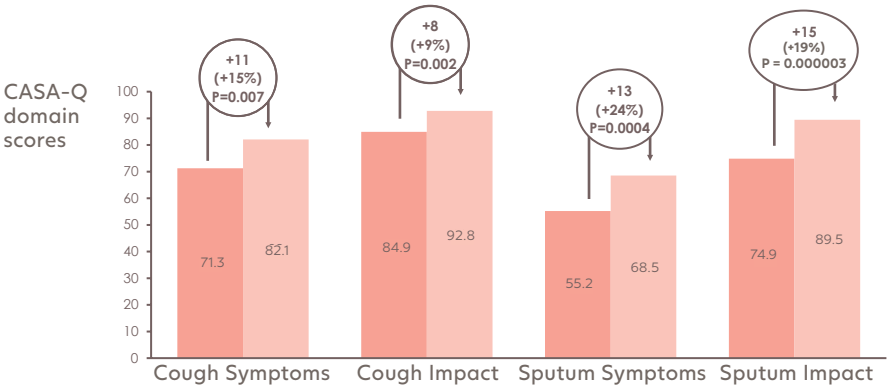

Figure 2 CASA-Q scores
The graph shows CASA-Q domain scores (from left to right: Cough Symptoms, Cough Impact, Sputum Symptoms, and Sputum Impact) as reported by patients for Usual Care and Provox Life, including the increase in scores for each domain and group. Each domain receives a score between 0-100, with lower scores indicating higher symptoms/impact levels. A significant improvement in all four domains of the CASA-Q was found after 6 weeks of Provox Life use.

Usual Care
Provox Life

This data was confirmed by the diary, in which subjects reported skin irritation on 4.3 days during the last 2 weeks of the UC period and on 2.6 days during the last two weeks of using PL products (31% vs. 19% of the days, p=0.013) (Fig. 3).

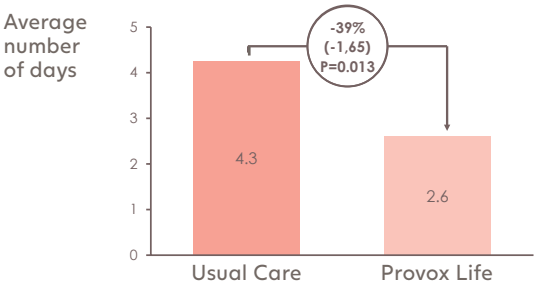

Figure 3 Skin irritation
The figure shows the average number of days within 14 days for which adhesive users reported skin irritation during Usual Care (UC), and during Provox Life (PL) period, respectively. During the UC period, patients reported to have skin irritation for 31% of the days, compared to 19% with PL, a significant reduction of 39%.

Usual Care
Provox Life

[1] European Quality of Life 5 Dimensions, used to self-assess QoL by recording scores on five health care dimensions (mobility, self-care, daily activities, pain/discomfort, and anguish/depression).
[2] Cough and Sputum Assessment Questionnaire. A 20-item questionnaire, used to assess the frequency and severity of cough and sputum and their impact on daily activity (validated for Chronic Obstructive Pulmonary Disease-COPD).