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Laryngectomy Clinical Summaries

Optimizing Pulmonary Outcomes After Total Laryngectomy: Crossover Study on New Heat and Moisture Exchangers.

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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.
- The humidification deficit in laryngectomized patients is primarily addressed using heat-and-moisture exchangers (HMEs).
- Despite clinically proven benefits, currently available HMEs are not equally as effective as breathing through the nose.
- In addition, patients experience problems with peristomal adhesives, and struggle to cope with the added breathing resistance of HMEs, which contributes to the variance seen amongst patients in adherence to HME use 24/7.
- 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.

Objective

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

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 the humidification deficit in laryngectomized patients as well as to reduce the impact of pulmonary complaints on daily life.

Study design

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

Outcome parameters

- Pulmonary health (forced expectorations i.e., coughs with mucus, involuntary dry coughs and their impact on daily life, and other pulmonary symptoms).
- Quality of life.
- Patient experience and satisfaction.

Reference

Longobardi Y, Galli J, Di Cesare T, D'Alatri L, Settimi S, Mele D, Bussu F, Parrilla C. Optimizing Pulmonary Outcomes after Total Laryngectomy: Crossover study on new Heat and Moisture Exchangeers. Otolaryngol Head Neck Surg. 2022. https://doi.org/10.1177/01945998221086200

- Each 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].

Results

Adherence to HME use and Pulmonary Health

- All 40 enrolled patients completed the study and thereby 6 weeks of Provox Life use.
- An average of 2.0 HMEs were used daily during the Provox Life period, compared to 1.7 HMEs during UC, a significant increase (p=0.025).
- Similarly, in terms of adherence to HME use 24/7, the average increased significantly from 22.6 hours to 23.9 hours with Provox Life (p=0.011).
- The percentage of patients using an HME during the night increased from 87.5% to 100% with Provox 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 ground level (p=0.005) with Provox Life compared to UC was observed.

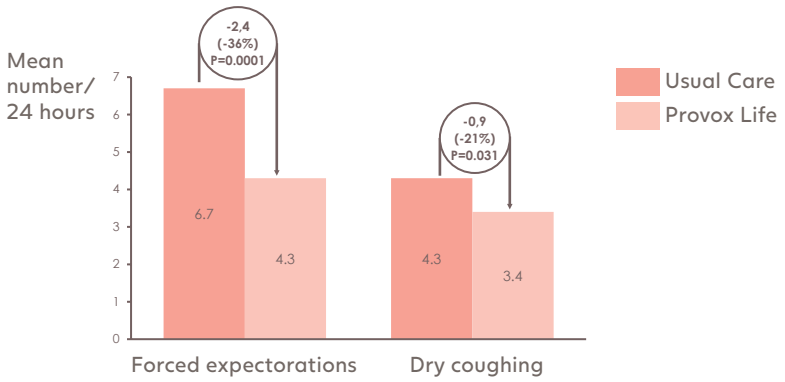

Figure 1 Average daily forced expectorations and dry coughing frequencies
The graph shows the average daily forced expectorations and dry coughing frequencies as reported by patients for Usual Care and Provox Life, including the reduction for each parameter and group, respectively. A significant reduction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

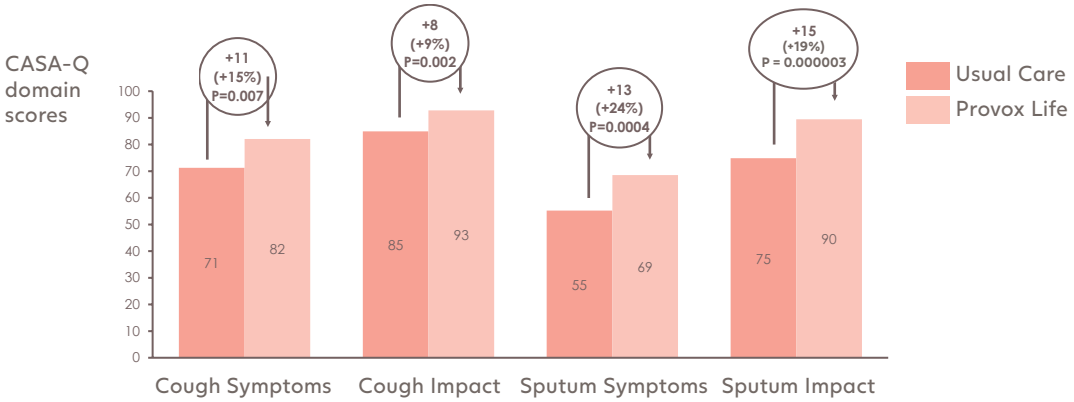

Figure 2 CASA-Q scores
The graph shows CASA-Q domain scores (from left to right: Cough Symptoms, Cough Impact, Sputum Symptoms, and Sputum Impact) as reported by patients for Usual Care and Provox Life, including the increase in scores for each domain and group. Each domain receives a score between 0-100, 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.

[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).

Quality of life aspects

- EQ-5D scores were better for the Provox Life period compared to UC, however overall, no significant difference was observed. One exception was the anxiety/depression domain, where scores were significantly better for Provox Life compared to UC (70% compared to 55% reported “no problems”, respectively, p=0.035).
- 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).

Attachments and dermatological symptoms

- The average hours of use per adhesive was similar between the Provox Life period and UC (19.3 hours on average during the Provox Life period, compared to 20.3 during the UC period).
- During UC, 65% of adhesive users indicated to have skin irritation, compared to 58% in the Provox Life period.
- When taking the frequency of skin irritation into account, patients had skin irritation significantly less often during the Provox Life period.
- 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).

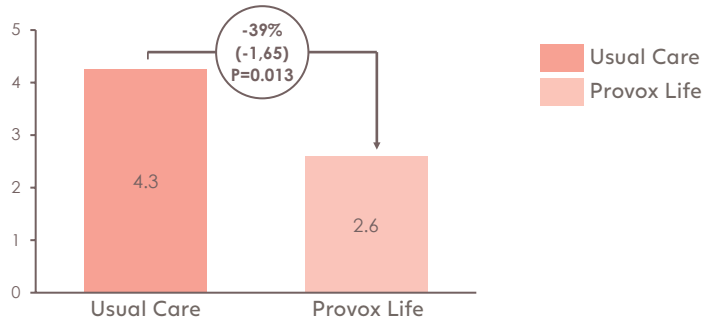

Figure 3 Skin irritation
The figure shows the average number of days within 14 days for which adhesive users reported skin irritation during Usual Care (UC), and during Provox Life (PL) period, respectively. During the UC period, patients reported to have skin irritation for 31% of the days, compared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

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Patients’ experience with HME use

- **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 concerned the greater skin-compatibility of adhesives and the better breathability of Provox Life HMEs.**

Conclusions

- 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 the humidification deficit in laryngectomized patients as well as to reduce the impact of pulmonary complaints on daily life.