Effectiveness of Olfactory Rehabilitation With the Nasal Airflow-Inducing Maneuver After Total Laryngectomy

One-Year Follow-up Study

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Objective: To assess the long-term results of the nasal airflow-inducing maneuver in olfaction rehabilitation in patients who had undergone laryngectomy.

Design: Prospective interventional study.

Setting: University hospital.

Patients: Twenty-four patients who had undergone laryngectomy (21 men and 3 women; mean age, 68 years) who received olfactory rehabilitation with the nasal airflow-inducing maneuver were reevaluated 6 and 12 months after primary treatment.

Main Outcome Measure: Olfactory function was tested by means of a semistructured interview; the Questionnaire on Olfaction, Taste and Appetite; and the Scandinavian Odor-Identification Test. Quality of life was measured with the European Organization for Research and Treatment of Cancer QLQ-C30 and QLQ-H&N35 questionnaires. Patients were categorized as smellers or non-smellers based on results of the Scandinavian Odor-Identification Test.

Results: Before treatment, 10 of 24 patients (42%) were smellers and 14 (58%) were nonsmellers. At 6-month follow-up, 20 of 23 patients (87%) were smellers, whereas after 12 months, 21 of 24 patients (88%) were smellers. Long-term olfaction rehabilitation was achieved in 11 of 14 patients (79%) with anosmia, and 15 of all 24 patients (63%) could be classified as having normal olfactory capacity at the end of the study.

Conclusion: The nasal airflow-inducing maneuver is a patient-friendly, inexpensive, and effective method for restoring the sense of smell in patients after laryngectomy, and the results persist in the long term.
SUBJECTS

Twenty-four patients (21 men and 3 women, with a mean age of 68 years [age range, 53-83 years] who had undergone total laryngectomy on average 7 years (range, 0.4-29 years) previously were included in the study. All patients reported having functional sense of smell before laryngectomy and none had a head trauma or severe respiratory infection resulting in olfactory deterioration. More detailed sociodemographic and clinical data have been published elsewhere.1 The study was conducted in accord with the Declaration of Helsinki and was approved by the ethical committee of the Sahlgrenska University Hospital, Göteborg, Sweden.

All 24 patients received olfactory rehabilitation training with NAIM during the interval between September 1, 2002, and May 31, 2004, and were followed up at 6 and 12 months after the initial intervention. One patient was examined only once (at 12 months) after the primary rehabilitation because of concomitant disease. Another patient, categorized as a smellers, had swallowing difficulties requiring feeding via a nasogastric tube at both the prelaryngectomy and the present periods. Questions were categorized into the following 5 scales1: subjective feelings of present taste perception (8 items);4 present smell perception compared with past smell perception (3 items); and5 appetite (6 items)3; subjective feelings of present taste perception, or odor perception (Present Odor Perception Scale; 3 items)2; appetite (6 items)3; and daily feelings of hunger (9 items). A low score indicates poor function or that these functions have deteriorated compared with the pretreatment score. Conversely, a high score indicates good function or improvement in these functions.

METHODS

STATISTICAL ANALYSIS

Pearson correlation coefficients were calculated for descriptive purposes. Changes with time were analyzed using the Fisher nonparametric permutation test for matched pairs. All tests were 2-tailed, and statistical significance was attained at P<.05.

Olfaction

The 30-item European Organization for Research and Treatment of Cancer (EORTC) QLQ-C30 (Core Quality of Life Questionnaire) was used to assess patient quality of life (QOL), general physical and psychosocial functioning, and symptoms.6,7 To address additional symptoms associated specifically with head and neck cancer and its treatment, we used the complementary 35-item EORTC Quality of Life Head and Neck Module (QLQ-H&N35).8 Calculated scores range from 0 to 100, with 100 indicating maximum functioning (functioning scales and global QOL) or worst symptoms (symptom scales and items).9 In general, score differences with time of at least 10 points could be interpreted as indicating clinically important changes.

The study protocol was conducted in the following order: semistructured interview; Questionnaire on Olfaction, Taste, and Appetite; EORTC QOL questionnaires; and SOIT administration. The intervention outcome was then measured using the patient’s self-estimation of smell and taste; the Questionnaire on Olfaction, Taste, and Appetite; EORTC QOL questionnaires; and SOIT scores. In addition, the patients were, whenever possible, videotaped during each treatment session and at follow-up visits and the recordings were used for biofeedback. The results of these recordings are reported elsewhere (B.R.-B., R.Y.M., and C.F., unpublished data, 2002-2004). The execution of the NAIM was repeated with all patients at the 6-month follow-up visit. The total examination time was approximately 90 minutes.

EXAMINATION AT FOLLOW-UP VISITS

At follow-up visits 6 and 12 months after the primary intervention, semistructured interviews (including questions on olfaction and taste at the time of the interview) were conducted by speech-language pathologists (including B.R.-B.). Calculated scale scores ranged from 0 to 100, with 0 indicating “very bad” and 100 indicating “very good.”

Olfactory acuity was tested with the Scandinavian Odor Identification Test (SOIT).4 This test has age- and gender-related cutoff scores and categorizes the sense of smell in 3 categories: normosmia, hyposmia, or anosmia. The cutoff scores used in this study for age groups 55 to 74 years were 11 to 16 for normosmia, 8 to 10 for hyposmia, and 7 or lower for anosmia. On the basis of performance on the SOIT, patients were categorized as smellers or nonsmellers. Smellers were patients having a diagnosis of functional hyposmia or normosmia and nonsmellers were patients with anosmia.

The Questionnaire on Olfaction, Taste, and Appetite was used,3 which consists of multiple-choice questions addressing both the prelaryngectomy and the present periods. Questions were categorized into the following 5 scales: subjective feelings of present smell perception, or odor perception (Present Odor Perception Scale; 3 items)2; appetite (6 items)3; subjective feelings of present taste perception (8 items)5; present smell perception compared with past smell perception (3 items); and daily feelings of hunger (9 items). A low score indicates poor function or that these functions have deteriorated compared with the pretreatment score. Conversely, a high score indicates good function or improvement in these functions.

STATISTICAL ANALYSIS

Before treatment, 10 of 24 patients (42%) were smellers, that is, categorized as having normosmia (n=6) or functional hyposmia (n=4) according to the SOIT, and 14 patients (58%) were nonsmellers, that is, they had anosmia. After treatment, 4 of 24 patients (17%) remained nonsmellers and 20 patients (83%) were classified as smellers; 13 of 20 patients (65%) had normosmia and 7 (35%) had hyposmia.3

The results before and after treatment and at 6- and 12-month follow-up visits for smellers and nonsmellers are summarized in the Table. The variation in olfactory categories across time for smellers and nonsmellers is shown in the Figure. At the 6-month follow-up, 4 of 23 patients (17%) were nonsmellers and 19 patients (83%) were smellers; 7 of the 19 patients had normosmia and 12 had hyposmia. One patient was unavailable for examination at the 6-month follow-up because of concomitant disease. Both the nonsmellers and smellers had significantly better sense of smell at the 6-month follow-up (P<.001 and P=.004, respectively) compared with before intervention, based on their own estimation. However, olfactory acuity at the 6-month follow-up on the basis of the SOIT scores was significantly better only for the nonsmellers (P=.004).

At the 12-month follow-up, the results were improved. Of 24 patients, 3 (12%) were nonsmellers and 21 (88%) were smellers; 15 of the 21 patients had normo-
Table. Score Changes From Pretreatment to 12 Months After Treatment in Smellers and Nonsmellers

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Smellers (n = 10)</th>
<th>Nonsmellers (n = 14)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Before Treatment</td>
<td>At 6 mo</td>
</tr>
<tr>
<td>SOIT score</td>
<td>11.1 (10 to 12)</td>
<td>11.3 (10 to 13)</td>
</tr>
<tr>
<td>Patient self-estimation</td>
<td>30.0 (6 to 54)</td>
<td>60.0 (41 to 79)</td>
</tr>
<tr>
<td>Present olfaction</td>
<td>58.3 (30 to 87)</td>
<td>58.3 (40 to 76)</td>
</tr>
<tr>
<td>Present gustation</td>
<td>8.0 (5 to 11)</td>
<td>9.8 (8 to 11)</td>
</tr>
<tr>
<td>QOTA a</td>
<td>22.2 (19 to 25)</td>
<td>23.2 (21 to 26)</td>
</tr>
<tr>
<td>Appetite b</td>
<td>40.0 (7 to 73)</td>
<td>40.0 (13 to 67)</td>
</tr>
<tr>
<td>Taste b</td>
<td>30.0 (2 to 59)</td>
<td>33.3 (4 to 63)</td>
</tr>
<tr>
<td>Senses (smell plus taste)</td>
<td>35.0 (5 to 65)</td>
<td>36.7 (10 to 64)</td>
</tr>
</tbody>
</table>

Abbreviations: CI, confidence interval; EORTC, 30-item European Organization for Research and Treatment of Cancer (EORTC) QLQ-C30, quality of life; QLQ-C30, 30-item Core Quality of Life Questionnaire (general physical and psychosocial functioning and symptoms questionnaire for patients with cancer); QLQ-H&N35, 35-item EORTC Quality of Life Head and Neck Module (complementary 35-item questionnaire addressing symptoms specific to patients with head and neck cancer and its treatment); QOTA, Questionnaire on Olfaction, Taste, and Appetite; SOIT, Scandinavian Odor-Identification Test.

a Data are given as mean (95% CI).
b Three-category score range: anosmia, 7 or lower; hyposmia, 8 to 10; and normosmia, 11 to 16.
c P < .05 for comparison with pretreatment within the group.
d P < .004 for comparison with pretreatment within the group.
e 100-Point scale, with 100 indicating best function.
f P < .001 for comparison with pretreatment within the group.
g P < .003 for comparison with pretreatment within the group.
h SOIT, Scandinavian Odor-Identification Test.
i In general, score differences with time of at least 10 points could be interpreted as clinically important change.

In general, the score values were stable among smellers across all time points except for senses scale (ie, smell and taste), for which an improvement (Δ, −11) was noted. A deterioration of clinical significance (ie, Δ > 10) in nonsmellers from preintervention to the 6-month follow-up visit was seen in 4 scales and 3 single items, as follows: global QOL scale (Δ, −13), role-functioning scale (Δ, −29), pain scale (Δ, 12), and senses scale (Δ, 17) and in the symptoms of diarrhea (Δ, 17), opening mouth (Δ, 17), and sticky saliva (Δ, 17). In addition, from preintervention to the 12-month follow-up visit, deterioration was detected in nonsmellers on the following scales: global QOL (Δ, −19), taste (Δ, 26), senses (Δ, 22), social eating (Δ, 31), and in the single items of teeth problems (Δ, 11), dry mouth (Δ, 22), and coughing (Δ, 22).

**USE OF THE NAIM**

At the 12-month follow-up visit, 21 of 24 patients (88%) were active users of the NAIM. Eight patients used it on a daily basis, 7 used it frequently but not every day, and 6 used it sometimes. The 3 patients who had not used the NAIM at all at the 12-month follow-up were all nonsmellers. Many patients reported considerably improved QOL with their newly gained ability to smell. Examples of important scents patients regained were those associated with nature (eg, flowers, grass, and forest), food and cooking (eg, bread, fruit, and garlic), and personal hygiene (eg, perfume, soap, and toothpaste).
At 12 mo

follow-up period. As long as 1 year after primary rehabilitation, 11 of 14 patients with preintervention anosmia (79%) had become smellers and 15 of all 24 patients (63%) could be classified as having normal olfactory capacity. In addition, the results after primary rehabilitation seem to be prognostic for the outcome in the long term.

Olfactory impairment has been overlooked as a problem in patients after laryngectomy because it has not been considered critical to life. Consequently, available treatment options and development of new therapies have remained limited. One of the few recent rehabilitation studies included 20 patients who underwent the most common treatment, larynx bypass, to reestablish the sense of smell. Goktas et al. concluded that, even if patients experienced better olfactory acuity, the larynx bypass procedure was cumbersome and did not seem to be well suited for routine use. The new rehabilitation technique, NAIM, was introduced by Hilgers et al. in 2000 and has shown encouraging results. Despite the potential to become a part of regular rehabilitation in patients after laryngectomy, systematic long-term results have been few. This study extends our present knowledge about outcome during a longer follow-up period and confirms that the NAIM is effective and easy to learn. Consequently, we recommend that the NAIM be included in standard treatment of patients undergoing laryngectomy in the future.

One striking finding was that the results after treatment seem to be predictive of the long-term outcome. After the primary rehabilitation, 20 of 24 patients (83%) were smellers and 4 patients (17%) still had anosmia. One year after treatment, the rehabilitation results resembled those directly after treatment. Only 3 patients remained nonsmellers and 21 of 24 patients (88%) of the studied population were smellers. These results are similar to those published by Hilgers et al. Even if the follow-up period varied and the olfaction acuity testing and duration of intervention differed from ours, in their study, too, the percentage of smellers after treatment (57%) was similar to that 18 to 24 months later (54%). These results give rise to questions about the rehabilitation of those patients who still had anosmia after the intervention. Miani et al. recently described various degrees of degeneration and atrophy in olfactory epithelium in patients after laryngectomy compared with healthy control subjects. These changes may give rise to olfactory impairment that is impossible to treat. Our patients with anosmia were not studied in that respect. Future studies may show whether extended rehabilitation with the NAIM with consequent intensified follow-up for those with anosmia after ordinary training will result in additional improvement.

During follow-up, however, there was fluctuation in the level of the sense of smell. Six months after primary rehabilitation, the percentage of smellers and nonsmellers, on the whole, was unchanged (data for 1 patient is missing). Yet, the number of patients with normosmia was halved, compared with the postintervention assessment, whereas most smellers were categorized as having hyposmia. This observation may indicate some problems in the implementation of the technique. Hilgers et al. suggested earlier that the correct execution of the NAIM was prerequisite for the ability to smell. It is plausible that the follow-up period of 6 months was rather long compared with a short but intensive training episode. Without regular clinical controls, the patients perhaps had not used the NAIM optimally and, therefore, it had not developed to an automatic behavior. Another reason for this fluctuation might be that the movements (lowering of the floor of the mouth and the jaw) were not effective enough to result in sufficient air flow through the nose. The improvement at the 12-month follow-up visit may, consequently, depend on repetition of the NAIM performed after measurements at the 6-month visit. It can be speculated that it is easier for patients to focus on details in performing the NAIM when they have been accustomed to the technique itself. It is recognized that behavioral changes must be repeated often to achieve results.

Figure. Changes in olfactory capacity in preintervention smellers (A) and nonsmellers (B) across time based on Scandinavian Odor-Identification Test (SOIT) scores. Anosmia indicates SOIT score of 0; hyposmia, SOIT score of 1 to 5; and normosmia, SOIT score of 6 to 10.
Recent studies have suggested that QOL is severely altered in most patients with olfactory disorders.\textsuperscript{12,13} Despite the homogeneous population in the present study, we could not confirm an association between olfaction and QOL when measured with the EORTC questionnaires. This discrepancy may have several explanations. Our cohort size was small and included only patients who had undergone laryngectomy, whereas the study published by Miwa et al\textsuperscript{13} included a large number of patients (n=420) and most of them had nasal or sinus disease. In addition, the questionnaires used in the present study and in that of Miwa and colleagues differed from each other. We used the EORTC QLQ-C30 questionnaire,\textsuperscript{6} one of the most popular instruments for QOL assessment in patients with cancer, because of its high specificity, reliability, and validity, whereas Miwa et al\textsuperscript{13} asked patients to rate their global satisfaction with life using 5 alternatives. One additional explanation for the different results may be the well-known coping abilities of cancer patients and their adaptation to living with the disease with time.\textsuperscript{14,15} Our observations suggest that QOL is a complex concept and depends on factors other than olfaction.

We are aware of potential limitations of our study. The small number of patients who had undergone laryngectomy living in our catchment area did not allow for a control group. In addition, the number of patients included in the study is limited and did not allow comparisons within the groups of smellers and nonsmellers during follow-up period. An additional weakness is that the patients were not objectively tested before laryngectomy. However, none had expressed complaints or sought medical help because of deterioration in sense of smell before the operation. Thus, the patients’ own reports should suffice.

The NAIM is a patient-friendly, easy, inexpensive, and effective method for restoring the sense of smell in patients after laryngectomy. Moreover, our findings indicate that the results persist in the long-term.

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Author Contributions: Drs Risberg-Berlin, Ylitalo Moller, and Finizia had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. Study concept and design: Finizia. Acquisition of data: Risberg-Berlin and Finizia. Analysis and interpretation of data: Risberg-Berlin, Ylitalo Moller, and Finizia. Drafting of the manuscript: Risberg-Berlin, Ylitalo Moller, and Finizia. Critical revision of the manuscript for important intellectual content: Risberg-Berlin, Ylitalo Moller, and Finizia. Statistical analysis: Risberg-Berlin, Ylitalo Moller, and Finizia. Obtained funding: Finizia. Administrative, technical, and material support: Risberg-Berlin, Ylitalo Moller, and Finizia. Study supervision: Ylitalo Moller and Finizia.

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REFERENCES


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