Effect of Turbinate Surgery in Rhinoseptoplasty on Quality-of-Life and Acoustic Rhinometry Outcomes: A Randomized Clinical Trial

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Objectives/Hypothesis: To evaluate the role of inferior turbinate reduction during rhinoseptoplasty in quality-of-life outcomes and nasal airway cross-sectional area.

Study Design: Randomized clinical trial.

Methods: Individuals over 16 years with nasal obstruction, candidates to functional and aesthetics primary rhinoseptoplasty, were evaluated from December 2010 though January 2012 at a tertiary University Hospital, Brazil. Eligible participants were randomly allocated to rhinoseptoplasty with or inferior turbinate reduction through submucosal diathermy. Outcomes: Relative changes ([postop–preop]/preop score) in specific (Nasal Obstruction Symptom Evaluation; NOSE) and general quality-of-life instruments (WHOQOL-bref), nasal obstruction visual analogue scale (NO-VAS) and nasal area measurements in acoustic rhinometry. Outcomes were blindly assessed 3 months postoperatively. Protocol was registered at ClinicalTrials.gov (NCT01457638).

Results: 50 patients were included, mainly Caucasians with moderate/severe allergic rhinitis symptoms. Mean age was 32 ± 12 yr and 58% were female. Rhinoseptoplasty improved specific and general quality-of-life scores irrespective of turbinate intervention (P < 0.001). There was no difference between subjects submitted or not to inferior turbinate reduction in NOSE score (−75% vs. −73%; P = 0.893); all WHOQOL-bref score domains (P > 0.05), NO-VAS (−86% vs. −81%; P = 0.89) and acoustic rhinometry recordings (P > 0.05). During follow-up less patients in the rhinoplasty with inferior turbinate resection group were using topical corticosteroids (6[24%] vs. 13[54%]; P = 0.03). Multivariable analyses, adjusting for postoperative topical corticosteroid use and previous nasal fracture, had no effect on these results.

Conclusions: Turbinate reduction through submucosal diathermy during primary rhinoseptoplasty did not improve short-term general and specific quality-of-life outcomes and acoustic rhinometry recordings. The role of turbinate reduction in sparing chronic corticosteroid use should be confirmed in long-term follow-up studies.

Key Words: Rhinoplasty, turbinate surgery, quality of life, acoustic rhinometry, randomized clinical trial.

Level of Evidence: 1b.

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INTRODUCTION

Rhinoplasty remains one of the most commonly performed aesthetic surgical procedures in plastic surgery. Interest in functional and quality-of-life outcomes has increased as a method of validation of surgery results, and is a growing focus among otolaryngologists and facial plastic surgeons.

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Inferior turbinates are the main regulator of nasal airflow, playing an important role in normal respiratory function. They are also part of nasal valve area, frequently reduced in rhinoplasty surgeries. It seems reasonable to consider that turbinate reduction during rhinoseptoplasty would improve postoperative nasal airflow and, consequently, quality-of-life outcomes. However, no randomized clinical trial has evaluated whether turbinate reduction during rhinoseptoplasty impacts on clinical outcomes. Considering the paucity of evidence on inferior turbinate surgery efficacy, recent systematic reviews reaffirmed the need of prospective controlled studies with both objective and subjective validated outcomes measures.

The aim of this trial was to evaluate the clinical effect of turbinate reduction during primary rhinoseptoplasty upon quality-of-life outcomes and nasal airway cross-sectional area among patients with functional and aesthetic nasal complaints.

MATERIALS AND METHODS

Trial Design

This was a pragmatic double-blind, single-center, randomized [1:1] and parallel-group clinical trial comparing quality-of-
life outcomes (general and specific to nasal obstruction) and acoustic rhinometry recordings of primary rhinoseptoplasty with versus without inferior turbinate reduction.

**Settings and Participants**

The study was undertaken at the Facial Plastic Surgery Clinic of Otolaryngology Department of the Hospital de Clinicas de Porto Alegre, a tertiary care, university hospital in southern Brazil.

Eligible participants were adults aged ≥16 years old with symptoms of nasal obstruction, and candidates to functional and aesthetic primary rhinoseptoplasty. Besides nasal obstruction complaints, eligible individuals should present an anatomic abnormality, such as septal deviation, insufficient nasal tip support or rotation, nasal valve collapse, or crooked nose.

Exclusion criteria were: 1) previous nasal surgery; 2) turbinate hypertrophy as the unique reason to explain nasal obstruction; and/or 3) additional concomitant procedures, as functional endoscopic sinus surgery, adenoidectomy, blepharoplasty or otoplasty.

Written informed consent was obtained from each patient before study enrollment. The protocol was registered at Clinical-Trials.gov (http://clinicaltrials.gov) as NCT01457638. The research protocol was approved by the Ethics and Research Committee of Hospital de Clinicas de Porto Alegre (registered #10-420).

**Randomization**

Randomization sequence was created using Randomization.com statistical software with a 1:1 allocation and random block sizes of 4 and 6. The computer-generated random number list was prepared by an investigator not related to this trial. The allocation sequence was concealed from those involved in enrolling and assessing participants.

**Data Collection**

At study enrollment, each subject completed a brief questionnaire to provide demographic and baseline characteristics.

**Interventions**

All patients underwent primary rhinoseptoplasty. During anesthetic induction, patients were randomly allocated to rhinoseptoplasty with or without inferior turbinate reduction. Surgeries were performed by a single surgeon (MLW) with the assistance of medical residents. All procedures were performed using an endonasal rhinoplasty technique. Septoplasty, nasal tip refinement, appropriate dorsal profile alignment, and lateral and medial osteotomies were performed in all procedures. No other techniques which would affect nasal airway, such as spreader grafts, batten grafts or flaring sutures, were performed.

**Rhinoseptoplasty with Inferior Turbinate Reduction (ITR)**

Patients allocated to this group had turbinate reduction through submucosal diathermy. The procedure was done by inserting a 22-Gauge spinal anesthesia needle into the anterior end of the inferior turbinate and advancing it until the posterior end was reached.6 This procedure was performed at least twice on each inferior turbinate, until maximal coagulation and shrinkage of mucosal and submucosal structures was achieved without charring. The electrosurgical unit was set in coagulation mode at 30 Watts. Intervention was carried out by the same surgeon (MLW) in all cases.

**Rhinoseptoplasty without Inferior Turbinate Reduction (ITR)**

Patients in this group underwent primary rhinoseptoplasty as described above, without any intervention in inferior turbinates.

**Primary Outcome**

Primary outcome was the relative change in a disease-specific quality-of-life questionnaire for assessing outcomes in nasal obstruction in trials, the Nasal Obstruction Symptom Evaluation in the Portuguese language (NOSE-p), published elsewhere.7-8 A score of “ 0” means no problems with nasal obstruction, and a score of “ 100” means the most severe problem possible with nasal obstruction.

**Secondary Outcomes**

**WHOQOL-bref.** WHOQOL-bref is a generic quality-of-life instrument, a cross-culturally and valid assessment of well-being developed by the World Health Organization.9-13 It is composed of 26 questions, two of them measuring overall and general health. The other 24 questions are divided into four domains: physical, psychological, social relationships, and environment. The score varies between 0 and 100, with 0 being the least favorable quality of life and 100 being the most favorable one.

**Rhinoplasty Outcome Evaluation (ROE).** The Rhinoplasty Outcome Evaluation (ROE)12,13 scale is a quality-of-life questionnaire validated for rhinoplasty patients. It is composed of six questions that capture three quality-of-life domains: physical, mental/emotional, and social. According to this scale, highest level means “total satisfaction” and 0 “major dissatisfaction.”

**Nasal Obstruction Visual Analogue Scales (NO-VAS).** Subjects were asked to grade their present nasal obstruction and annoyance with the symptom on a scale with anchor 0 indicating no symptoms (“fully open” and “not annoyed at all”) and anchor 100 indicating maximum symptoms (“totally obstructed” and “severely annoyed”).

**Acoustic Rhinometry (AR).** AR noninvasively measures nasal airway cross-sectional area as a function of longitudinal distance along the nasal passageway following the path of an acoustic pulse.14 An impulse acoustic rhinometer (RhinoMetrics SRE2100, Rhinocan version 2.5, built 3.2.5.0; Interacoustics, Minneapolis, MN) was handled by the same experienced physician blinded to intervention throughout the study (HLC). Recordings were performed in accordance to published protocols.15 The following measures were recorded: minimum cross-sectional area (MCA) in cm² between 0 to 2.2 cm (MCA1) and between 2.2 to 5.4 cm (MCA2); and, nasal cavity volumes (NCV) in cm³ between 0 to 2.2 cm (NCV1) and between 2.2 to 5.4 cm (NCV2). To account for variations of nasal cavities dimensions due to the nasal cycle, an average value from the left and right side were calculated.15

**Follow-Up**

Outcomes were blindly assessed, preoperatively and at 3 months postoperatively, by trained investigators. Patients were clinically evaluated weekly in the first month and then monthly. In all medical appointments patients were asked about allergic rhinitis symptoms and were classified as presenting 1) intermittent or persistent and 2) mild or moderate/severe allergic rhinitis symptoms, according to Allergic Rhinitis and its Impact

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on Asthma (ARIA) guidelines. Patients with mild intermittent symptoms were advised to use oral H1-antihistamines as needed. From the 30th day postoperative visit on, topical corticosteroids (Budesonide 100 mcg, twice a day) were prescribed to patients presenting mild persistent or moderate/severe intermittent or persistent symptoms, according to ARIA guidelines. If patients were still presenting mild persistent, or moderate/severe intermittent or persistent symptoms, on day 60 reevaluation visit, high-dose topical corticosteroids were prescribed (Budesonide 200 mcg, twice a day). All patients were oriented to use oral H1-antihistamines as needed. In each medical visit patients answered a standardized questionnaire about medications used for allergic rhinitis.

Sample Size
Sample size was calculated to detect a reduction of 20 points in NOSE-p score, using the results reported by Stewart et al. as reference. A two-sided 5% significance level and a power of 80% were used to calculate a total sample size of 42 patients divided in two groups. In order to account for a dropout rate of 10% and to apply multivariate analysis, 50 patients were recruited.

Statistical Methods
Statistical analyses were carried out using the SPSS version 18.0. Data were reported as mean ± standard deviation or median, 25th and 75th percentiles, or percent, as appropriate. The analyses adhered to the intention-to-treat principle and a 2-tailed P value of less than 0.05 indicates statistical significance.

For intragroup comparisons of pre- and postoperative data, a paired 2-tailed t test for normally distributed variables and Mann-Whitney U test for of asymmetric variables were used.

Outcomes were described as delta relative change (postoperative score-preoperative score)/preoperative score) in percent. Interaction of postoperative corticosteroid use and intervention group was tested, and a composite variable (postoperative topical corticosteroid use *intervention group) was created and included into the multivariable model.

Analysis of variance was conducted to compare differences in outcomes across intervention groups, controlling for baseline history of nasal fracture, postoperative corticosteroids use, and the composite interaction variable. Spearman coefficient was used to assess the WHOQOL-bref domains, NOSE-p, and NO-VAS scores correlation.

RESULTS
From December 2010 through October 2011, potentially eligible patients were screened. The first 50 subjects who fulfilled the entry criteria and consented to participate in the protocol were included (Fig. 1). Previous nasal surgery and aesthetic complaints only (without nasal obstruction symptoms), were the main reasons for noneligibility. After randomization, one patient did not complete the 90-day follow-up visit and one other patient did not perform the acoustic rhinometry follow-up. Both patients had been randomized were assigned to “rhinoseptoplasty without ITR” group.

The study population included predominantly Caucasian subjects with moderate/severe allergic rhinitis symptoms. Mean age was 32 ± 12 years and 58% were female. Except for previous nasal trauma, more prevalent in the “rhinoseptoplasty without ITR” group, all other baseline clinical characteristics were similar between groups (Table I).

Previous self-reported nasal trauma, postoperative use of topical corticosteroids, and the composite variable (postoperative corticosteroid use *intervention group) were not independently associated to general and disease-specific quality-of-life scores, but were maintained in the multivariate model for clinical reasons.

There was a negative and regular correlation between the 3-months postoperative psychological and environment WHOQOL-bref domains with NOSE-p scores. Postoperative NO-VAS was strongly correlated with NOSE-p scores, and inversely correlated with physical and psychological WHOQOL-bref domains (Table II).

At the third month follow-up visit (mean 99 ± 12 days), fewer patients in the “rhinoseptoplasty with ITR” group were using topical corticosteroids (6(24%) vs. 13(54%), P = 0.03).

NOSE-p score
NOSE-p mean scores were significantly lower postoperatively in both groups (71 ± 23 vs. 24 ± 24 in ITR group [P < 0.001]; 76 ± 19 vs. 25 ± 20 in control group [P < 0.001]), but no difference was observed in postoperative NOSE-p and Δ relative change of NOSE-p scores between intervention groups (Table III).

WHOQOL-bref
Both groups presented higher postoperative WHOQOL-bref scores when compared to preoperative scores in all domains (P < 0.05). However, no difference was observed in all WHOQOL-bref domains scores between intervention groups (Table III).

Rhinoplasty Outcome Evaluation (ROE) scale
ROE scale scores were significantly higher postoperatively in both groups (27.5 vs. 78.1 in ITR group [P < 0.001] and 31.8 vs. 74.5 in control group [P < 0.001]). No significant difference was observed in Δ relative change score between patients allocated to rhinoseptoplasty with or without ITR (200% vs. 175%, respectively; P = 0.111) (Table III).

Nasal Obstruction Visual Analogue Scales (NO-VAS)
Degree of nasal obstruction (61.8 vs. 19.6 in ITR group [P < 0.001], and 63.6 vs. 22.3 in control group [P < 0.001]) and annoyance with nasal obstruction (58.4 vs. 18.6 in ITR group [P < 0.001], and 71.7 vs. 23.2 in control group [P < 0.001]) were significantly lower in 3 months postoperative evaluation in both groups. No significant difference was observed between groups (Table III).

Acoustic Rhinometry (AR)
Minimal cross-sectional area and volume of the nasal cavity anterior segment (MCA1 and NCV1) recordings were reduced after rhinoseptoplasty with and without ITR (Table IV). The same did not occur in other posterior
AR recordings. No difference was observed in AR recordings between both groups (Table IV).

**DISCUSSION**

The theory that turbinate reduction could be particularly effective in rhinoseptoplasty patients as an adjunctive maneuver to avoid postoperative nasal valve area narrowing is advocated by some authors, but this intervention is based on case reports and expert opinion. This was the first randomized clinical trial designed to evaluate the role of turbinate reduction in rhinoseptoplasty.

Our results did not demonstrate short-term benefit associated to turbinate reduction in primary rhinoseptoplasty upon general and specific quality-of-life outcomes as well as in acoustic rhinometry recordings.

The only difference detected between groups was the postoperative need of topical corticosteroid. In the 3-month follow-up visit, significantly more patients from the control group were using topical corticosteroid. In multivariable analysis, the effect of turbinate surgery over the studied outcomes was controlled for that potential confounding factor, but no relevant differences were seen between crude and adjusted analysis (data not shown). However, avoidance of chronic topical corticosteroid use may be advocated as a justification for surgical inferior turbinate reduction in rhinoseptoplasty patients with preoperative nasal obstruction symptoms, particularly if this finding persists in longer follow-up.

Nasal obstruction is a subjective complaint involving mucosal, structural, and even psychological factors. It is a symptom with great variability during the day, and can present differently during the same
Correlations Between 3-months Postoperative WHOQOL-bref Domains, NOSE-p scores and NO-VAS (Spearman coefficient) in 49 Patients.

<table>
<thead>
<tr>
<th>NOSE-p WHOQOL-bref domains</th>
<th>NO-VAS</th>
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</thead>
<tbody>
<tr>
<td><strong>NOSE-p</strong></td>
<td><strong>WHOQOL-bref domains</strong></td>
</tr>
<tr>
<td>Physical</td>
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<tr>
<td></td>
<td>-0.232</td>
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<tr>
<td>Psychological</td>
<td>-0.313</td>
</tr>
<tr>
<td>Social</td>
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<tr>
<td>Environment</td>
<td>-0.355</td>
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<tr>
<td>NO-VAS</td>
<td>0.789</td>
</tr>
</tbody>
</table>

NOSE-p = Nasal Obstruction Symptom Evaluation in the Portuguese language; NO-VAS = Nasal obstruction visual analogue scale (degree of nasal obstruction).

*Correlation is significant at 0.05 level (2-tailed).

†Correlation is significant at 0.01 level (2-tailed).
TABLE III.
Quality-of-Life Outcomes and Visual Analogue Scales Scores Between Individuals Who Underwent Rhinoseptoplasty with and without Inferior Turbinate Reduction.

<table>
<thead>
<tr>
<th></th>
<th>Rhinoseptoplasty with Inferior Turbinate Reduction (n = 25)</th>
<th>Rhinoseptoplasty without Inferior Turbinate Reduction (n = 24)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Preop Mean (SD) Median (P25;P75)</td>
<td>3 mo Postop Mean (SD) Median (P25;P75)</td>
</tr>
<tr>
<td>NOSE-p</td>
<td>70.8 (23.2) 24.2 (24.4)</td>
<td>77.2 (18.9) 25.2 (19.7)</td>
</tr>
<tr>
<td>ROE</td>
<td>27.5 (16.0) 78.2 (126;490)</td>
<td>31.8 (17.3) 74.3 (15.8)</td>
</tr>
<tr>
<td>NO-VAS degree of nasal obstruction</td>
<td>61.7 (27.7) 19.7 (26.9)</td>
<td>63.6 (28.0) 22.4 (24.9)</td>
</tr>
<tr>
<td>NO-VAS annoyance with nasal obstruction</td>
<td>58.5 (28.8) 18.6 (26.7)</td>
<td>71.8 (22.2) 23.2 (27.9)</td>
</tr>
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<thead>
<tr>
<th>WHOQOL-bref domains</th>
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<th>Rhinoseptoplasty without Inferior Turbinate Reduction (n = 24)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Preop Median (P25;P75)</td>
<td>3 month Postop Median (P25;P75)</td>
</tr>
<tr>
<td>Physical</td>
<td>53.6 (50.0;60.7) 60.7 (54.4;66.9)</td>
<td>53.6 (50.0;60.7) 57.1 (50.0;67.8)</td>
</tr>
<tr>
<td>Psychological</td>
<td>58.4 (45.8;70.8) 66.6 (55.2;75.0)</td>
<td>62.5 (56.2;70.8) 66.7 (58.4;77.0)</td>
</tr>
<tr>
<td>Social</td>
<td>75.0 (52.0;83.3) 75.0 (66.8;88.5)</td>
<td>75.0 (66.7;83.4) 75.0 (75.0;97.9)</td>
</tr>
<tr>
<td>Environment</td>
<td>60.9 (50.0;68.7) 67.2 (53.9;74.2)</td>
<td>65.6 (54.6;70.3) 68.7 (58.3;77.3)</td>
</tr>
</tbody>
</table>

*P value = Analysis of variance adjusted for postoperative corticosteroid use, group * postoperative topical corticosteroid use and previous nasal fracture; Dependent variables = Δ Relative Change score = (postop - preop) / preop score; # P > 0.05 for preoperative characteristics among both groups: Independent Samples T-Test for normal distributed variables; Independent Samples Mann-Whitney U Test for non-normally distributed variables (WHOQOL-bref domains).

P25 = 25th Percentile; P75 = 75th Percentile; NO-VAS = Nasal Obstruction Visual Analogue Scale; NO = Nasal Obstruction.
Coronary artery disease. These findings reinforce the interpretation. WHOQOL-bref questionnaire, a cross-culturally valid assessment of well-being, was applied in rhinoseptoplasty patients for the first time in our study. Baseline scores found in our sample were worse than those from general Brazilian population normative data, and comparable to scores of patients with coronary artery disease. These findings reinforce the idea that dissatisfaction with nasal appearance associated to nasal obstruction symptoms can impact negatively general health quality-of-life outcomes. Significant correlation between postoperative psychological and environment WHOQOL-bref domains and NOSE-p scores suggests that both instruments are able to capture postoperative quality of life.

The use of the acoustic reflection technique in the nasal cavity was first described in 1989. Since then, it is described in several articles evaluating nasal cavity dimensions, some of them evaluating rhinoplasty patients. Our AR results were comparable to literature findings, demonstrating nasal cavity area and volume reduction, especially in anterior segments. But, contrary to expectations, turbinate reduction patients did not present larger nasal valve area dimensions in short-term follow-up, even after adjusting for postoperative topical corticosteroid use.

One of limitations of our study is the short-term follow-up. However, considering that one of the main critics to submucous diathermy technique is its uncertain long-term effectiveness, the absence of positive effects in 3 months makes unlikely that long-term benefits would be significant.

Also, the choice of submucous diathermy technique could be discussed, since other modern and technological approaches are available. But, there is no gold standard approach and no consensus about superiority among techniques. Therefore, we choose submucous diathermy technique since it is commonly used, in addition to being fast and not expensive.

Concerning the sample size, the study was not powered to detect small differences in secondary outcomes, leading to a potential beta error. However, the results were very similar between groups, and even though larger samples may detect statistically significant differences, they would be doubtfully of clinical relevance. For the primary outcome, the sample size calculation previous assumed was achieved.

CONCLUSION

Our study demonstrated that inferior turbinate reduction through submucosal diathermy during primary rhinoseptoplasty did not improve short-term general and specific quality-of-life outcomes and acoustic rhinometry recordings. The role of turbinate reduction in sparing chronic corticosteroid use should be confirmed in long-term follow-up studies.

BIBLIOGRAPHY


