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The submucosal approach influences long-term outcomes of refractory obstructive rhinitis: A prospective study and a STROBE analysis

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ABSTRACT

Objective: The surgical approach to refractory hypertrophy of the inferior turbinates is the main therapeutic choice in the management of its symptoms. Although submucosal approaches have demonstrated efficacy, long-term results are debated in the literature and show variable stability. Therefore, we compared the long-term outcomes of three submucosal turbinoplasty methods with regard to the efficacy and stability managing the respiratory disorders.

Design: Multicenter prospective controlled study. A computer-generated table was used to allocate participants to the treatment.

Setting: Two teaching and university medical centers.

Methods: We used the EQUATOR network for guidelines describing design, conduct, and reporting of studies and searched the references of these guidelines to identify further relevant publications reporting adequate study protocols.

Patients with persistent bilateral nasal obstruction due to lower turbinate hypertrophy were prospectively recruited from our ENT units. Participants were randomly assigned to each treatment and then underwent symptom assessment by visual analog scales, endoscopic assessment at baseline and 12, 24 and 36 months after treatment.

Results: Of the 189 patients with bilateral persistent nasal obstruction initially assessed, 105 met the study requirements; 35 were located in the MAT group, 35 in the CAT group and 35 in the RAT group. Nasal discomfort was significantly reduced after 12 months with all the methods. The MAT group presented better outcomes for all VAS scores at the 1-year follow-up, greater stability at the 3-year follow-up for VAS results ($p < 0.001$ in all cases) and lower disease recurrence (5/35; 14.28 %). At the 3-year follow-up intergroup analysis, a statistically significant difference was confirmed except for RAA scores ($H = 2.88$; $p = 0.236$). Rhinorrhea ($r = -0.400$; $p < 0.001$) was demonstrated as a predictive factor of 3-year recurrence, while sneezing ($r = -0.25$; $p = 0.011$), and operative time needed ($r = -0.23$; $p = 0.016$) did not reach statistical significance.

Conclusions: Long-term symptomatic stability varies depending on the turbinoplasty method used. MAT demonstrated greater efficacy in controlling nasal symptoms, presenting better stability in reducing turbinate size and nasal symptoms. In contrast, radiofrequency techniques presented a higher rate of disease recurrence both symptomatically and endoscopically.

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1. Introduction

Chronic hypertrophy of the lower turbinates is a frequent condition in the general population, often related to comorbidities such as atopy and vasomotor hyperactivity of the nasal mucosa [1,2]. Different treatments, both medical and surgical, have been reported in the literature with variable outcomes. Indeed, patients are often refractory to topical nasal corticosteroid or decongestant therapies, with little resolution of reported symptoms or rhinomanometric parameters [3–6]. In contrast, turbinate surgery may offer long-lasting results, with increased short-term outcomes compared with medical therapy. Among the most widely used submucosal methods are radiofrequency assisted turbinoplasty (RAT), coblation turbinoplasty (CAT) and microdebrider-assisted submucosal turbinoplasty (MAT) [7–10]. Submucosal approaches propose less aggressive surgery, respecting mucociliary clearance. However, patients often report adverse effects such as perioperative pain, bleeding, and crusting [11–14].

The new high radiofrequency procedures allow rapid symptomatic improvement with minimal adverse events through molecular bond breaking without heat dissipation [15]. However, long-term results remain mixed, with possible recurrence of nasal obstruction and lower quality of life for the patient [16,17].

In contrast, MAT provides a greater volumetric reduction with concomitant removal of submucosal erectile tissue and bony turbinate [18–20]. However, several authors have reported more postoperative pain and bleeding [21–23].

However, to the best of our knowledge, the long-term evidence on the efficacy of submucosal turbinoplasty is scarce, and disease recurrence of the different approaches has not yet been compared.

The main objective of this study was to define long-term symptom control and disease recurrence for each of the three different submucosal approaches performed.

A secondary objective was to evaluate the role of different clinical factors, such as surgical success variables at long-term follow-ups.

2. Methods

2.1. Study design and patients

We retrieved studies describing design, conduct, and reporting of randomized clinical studies from the EQUATOR network (https://www.equator-network.org/). Further research of the guidelines' references was performed to identify relevant publications. We then selected and adhered to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) checklist [24].

A prospective multicentre, randomized surgical study was conducted

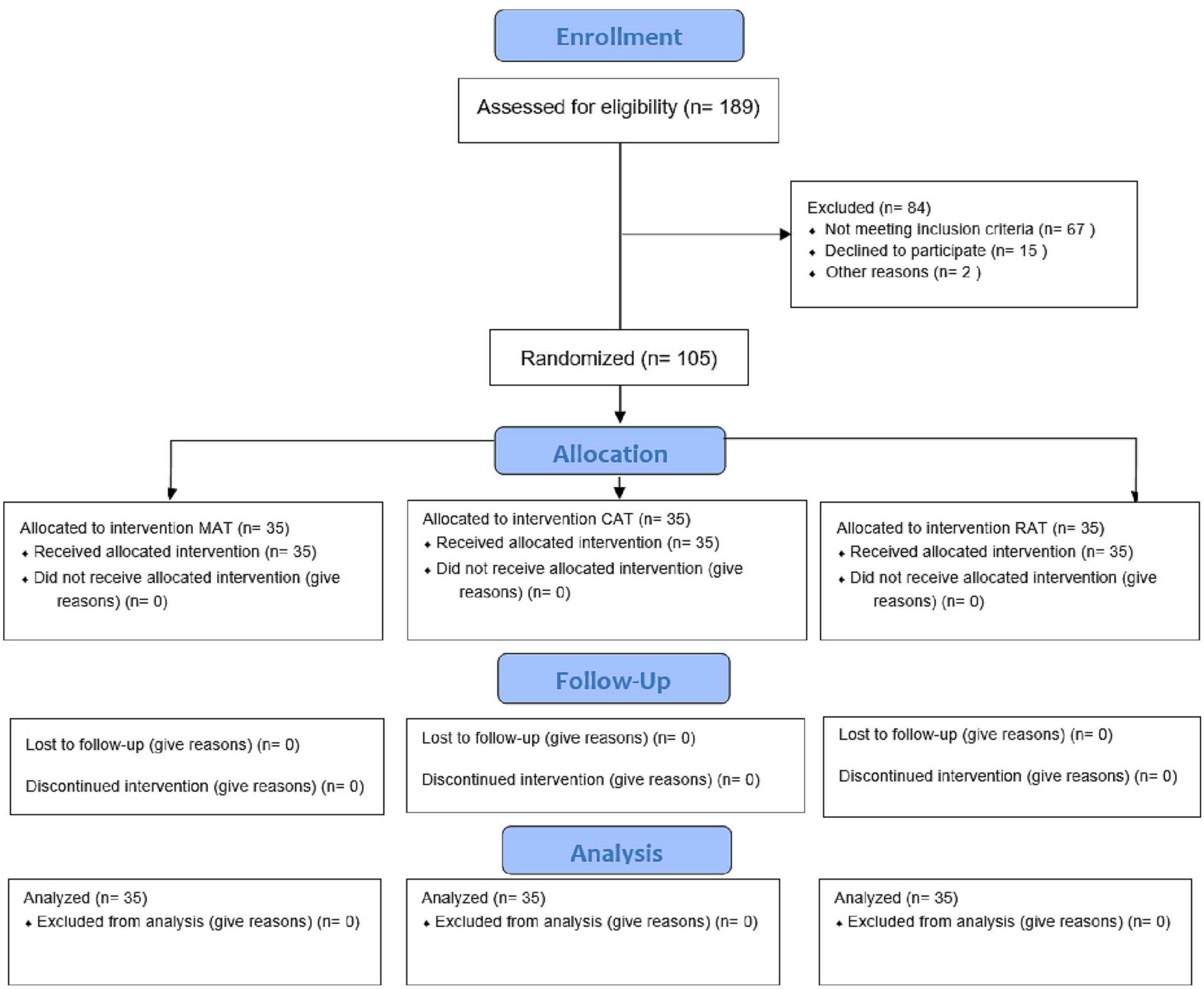


Fig. 1. Consort flow-diagram. Study protocol and patients' randomization.

from 1 January 2018 to 1 August 2022. We compared the efficacy and safety of two different radiofrequency techniques, RAT and CAT, with the MAT approach. We included patients aged 18 to 45 who underwent turbinoplasty for medically refractory nasal obstruction due to inferior turbinate hypertrophy [25]. Medical therapy consisting of intranasal steroid monotherapy (INS) was performed according to recent guidelines [26]. The study protocol is summarized in Fig. 1. The protocol was approved by the University's Human Medical Research and Ethics Committee and was conducted in accordance with the Declaration of Helsinki.

The randomization was performed using the web-based statistical program (www.graphpad.com/quickcalcs).

The list of random numbers was computer generated by a researcher unrelated to this study. Patients were then randomly assigned 33.33 % to Group A (MAT), 33.33 % to Group B (CAT), and 33.33 % to Group C (RAT) (Fig. 1).

Patients with the following conditions were excluded: other sinonasal anatomical disorders, e.g. deviated nasal septum, concha bullosa, sinusitis, septal spur, nasal valve collapse, nasal polyps or neoplasms; history of turbinate or sinus surgery; overall follow-up ≥36 months after turbinoplasty.

In all enrolled patients, a clinical and endoscopic nasal evaluation was performed to assess the hypertrophy of the inferior turbinates by the same three physicians [27]. Active anterior rhinomanometry (RAA), performed according to the recommendations of the International Committee for the Standardisation of Rhinomanometry (Rhinomanometer Labat Srl, Venice, Italy), was used to confirm nasal obstruction [28]. The RAA was performed in a room with constant humidity and temperature controlled by a thermostat after 30 min of acclimatization.

Nasal cytology was used to assess the nasal health through cytofunctional changes. The middle turbinate was scraped with a Rhino-Probe and the sample obtained was placed on a slide (Arlington Scientific Inc., Springfield, MA, USA). The samples were fixed with 2 % glutaraldehyde, stained with 2 % osmium tetroxide, dehydrated in alcohol and then observed with a Hitachi 100 keV H-600 electron microscope (Hitachi Ltd., Chiyoda, Japan). We evaluated the cellular distribution, the different cytotypes and the various intracellular components according to the modified grading of Gelardi et al. [29].

2.2. Patient assessment

Patients were evaluated at baseline and after the surgical procedure at 1, 2 and 3 years. Symptom scoring was performed based on the visual analogue scale (VAS), with 0 representing the absence of symptoms and 10 the most severe ones, for nasal obstruction, postoperative pain, rhinorrhea, blood crusting and synechiae formation. Three qualified specialists endoscopically assessed the size of the inferior turbinate and used the grading of Camacho et al. to classify the size of the inferior turbinate into 4 grades [27]. The RAA examination to study nasal resistance and cytological analysis were repeated at each follow-up.

2.3. Operational technique

Local anesthesia (1 % lidocaine with epinephrine 1:100,000) was applied by injecting 2–3 ml of solution onto the lower and medial edges of both inferior turbinate until whitening and waiting 10 min before starting the procedure.

In group A (MAT) we performed turbinoplasty using the integrated power console (Medtronics, Minneapolis, MN, USA) with a Straightshot M4 microdebrider blade in oscillating mode at 5000 rpm. All surgical procedures were performed by the same senior surgeon. Nasal surgery was performed under endoscopic guidance (0° nasal endoscope, 4 mm in diameter, Karl Storz, Germany), allowing visualization of the different portions of the inferior turbinate. In MAT group, patients underwent turbinoplasty after incision of the antero-inferior turbinate.

Table I
Preoperative main features. RAA expressed as Pa/cm^3/s. Nasal ostruction, Rhinorrhea and Sneezing expressed as VAS scale. Abbreviation: y, years; MAT, microdebrider-assisted turbinoplasty; CAT, coblation-assisted turbinoplasty; RAT, radiofrequency-assisted turbinoplasty.

Features	MAT (n = 35)	CAT (n = 35)	RAT (n = 35)
Age (y)	33.05 ± 8.1	33.47 ± 8.45	30.60 ± 5.21
Gender	21M; 14F	18M; 17F	16M; 19F
Nasal obstruction	8.85 ± 0.77	8.74 ± 0.81	8.51 ± 0.70
Rhinorrhea	6.80 ± 0.71	6.68 ± 0.75	6.51 ± 0.61
Sneezing	7.40 ± 0.81	7.51 ± 0.88	7.42 ± 0.81
Headache	6.05 ± 1.10	6.28 ± 1.10	6.62 ± 0.80
Inferior turbinate size	3.60 ± 0.49	3.51 ± 0.50	3.57 ± 0.50
RAA (Pa/cm^3/s)	0.96 ± 0.07	0.93 ± 0.08	0.92 ± 0.07

2.4. Statistical analysis

We used standard descriptive statistics, reporting mean and standard deviation for continuous variables and percentages for categorical variables. The normal distribution of the data was checked with the Kolmogorov-Smirnov test.

The sample size needed for the study was calculated assuming a 95 % confidence interval, a p value <0.005, a power of 0.8 and a mean difference set at 2.0. Therefore, at least 30 patients per group were identified and, accordingly, a 30 % drop-out rate was added to the sample. The independent t-test was performed for normally distributed values, while the Mann-Whitney U test was performed for non-normally distributed values. The chi-square test was performed to test the difference between the observed and expected data. Pearson's correlation coefficients were determined with r- and p-values reported for normally distributed variables, while the Spearman's correlation was used when variables did not follow a normal distribution.

The Kruskal Wallis test was used for continuous variables when comparing the results of three treatment groups (in the case of non-normal distribution).

Disease recurrence at 3 years was compared between groups using Kaplan-Meier function analysis and the log-rank test. In the multiple linear regression model, we included all clinical factors as potential predictor variables for success. According to the evolution for better science advocated by the European Annals of Otolaryngology and Head and Neck Diseases, a p value <0.005 was considered statistically significant. All analyses were performed using the Statistical Program for the Social Sciences (IBM SPSS Statistics for Windows, IBM Corp. Released 2017, Version 25.0 Armonk, NY: IBM Corp).

3. Results

3.1. Setting and patients

A total of 105 participants were enrolled, of which 35 patients in group A (MAT), 35 in group B (CAT) and 35 in in group B (RAT). The clinical features are summarized in Table I.

The mean age in the MAT group was 33.05 ± 8.1, 30.60 ± 5.21 in the RAT group, 33.47 ± 8.45 in the CAT group. No statistical difference in gender ratio was observed (p > 0.005 for the three groups). The most severe disorder reported among preoperative symptoms was nasal obstruction, which had the highest VAS score in all groups (MAT = 8.85 ± 0.77; CAT = 8.74 ± 0.81; RAT = 8.51 ± 0.70). Inferior turbinate hypertrophy was confirmed in all groups by endoscopy, with a grade from 3 to 4 and according to RAA data (Pa S/cm^3) (MAT = 0,96 ± 0,07; CAT = 0.93 ± 0.08; RAT = 0.92 ± 0.07). No statistical difference was found in the remaining preoperative outcomes of the three groups (p > 0.005 for all) (Table I).

Table II
Postoperative outcomes of each surgical approach up to 3-years follow-up. RAA expressed as Pa/cm^3/s. Nasal ostruction, Rhinorrhea and Sneezing expressed as VAS scale. Abbreviation: MAT, microdebrider-assisted turbinoplasty; CAT, coblation-assisted turbinoplasty; RAT, radiofrequency-assisted turbinoplasty.

	MAT			CAT			RAT		
	1 year	2 year	3 year	1 year	2 year	3 year	1 year	2 year	3 year
RAA	0.27 ± 0.07	0.33 ± 0.05	0.38 ± 0.06	0.31 ± 0.07	0.49 ± 0.15	0.53 ± 0.18	0.42 ± 0.11	0.54 ± 0.14	0.59 ± 0.19
Nasal obstruction	2.22 ± 0.53	2.45 ± 0.95	3.05 ± 1.08	2.77 ± 0.80	3.77 ± 1.37	4.31 ± 2.08	2.8 ± 0.75	4.11 ± 1.36	5.22 ± 1.92
Rhinorrhea	1.85 ± 1.68	2.51 ± 1.29	2.8 ± 1.18	2.6 ± 0.73	3.71 ± 1.2	4.2 ± 1.64	3.45 ± 0.98	3.97 ± 1.27	4.79 ± 1.58
Sneezing	1.88 ± 0.47	1.91 ± 0.37	2.17 ± 0.85	3.02 ± 0.70	3.57 ± 0.97	4.37 ± 1.33	3.68 ± 1.05	4.25 ± 1.17	4.82 ± 1.40
Headache	1.37 ± 0.49	1.68 ± 0.63	1.82 ± 0.51	2.48 ± 0.56	3.22 ± 1.01	4.22 ± 1.61	3.25 ± 1,12	4.02 ± 1.46	4.94 ± 1.81
Inferior turbinate size	1.45 ± 0.49	2.05 ± 0.59	2.14 ± 0.65	1.77 ± 0.8	2.28 ± 0.92	2.31 ± 0.96	2.22 ± 0.64	2.77 ± 0.91	2.88 ± 0.93

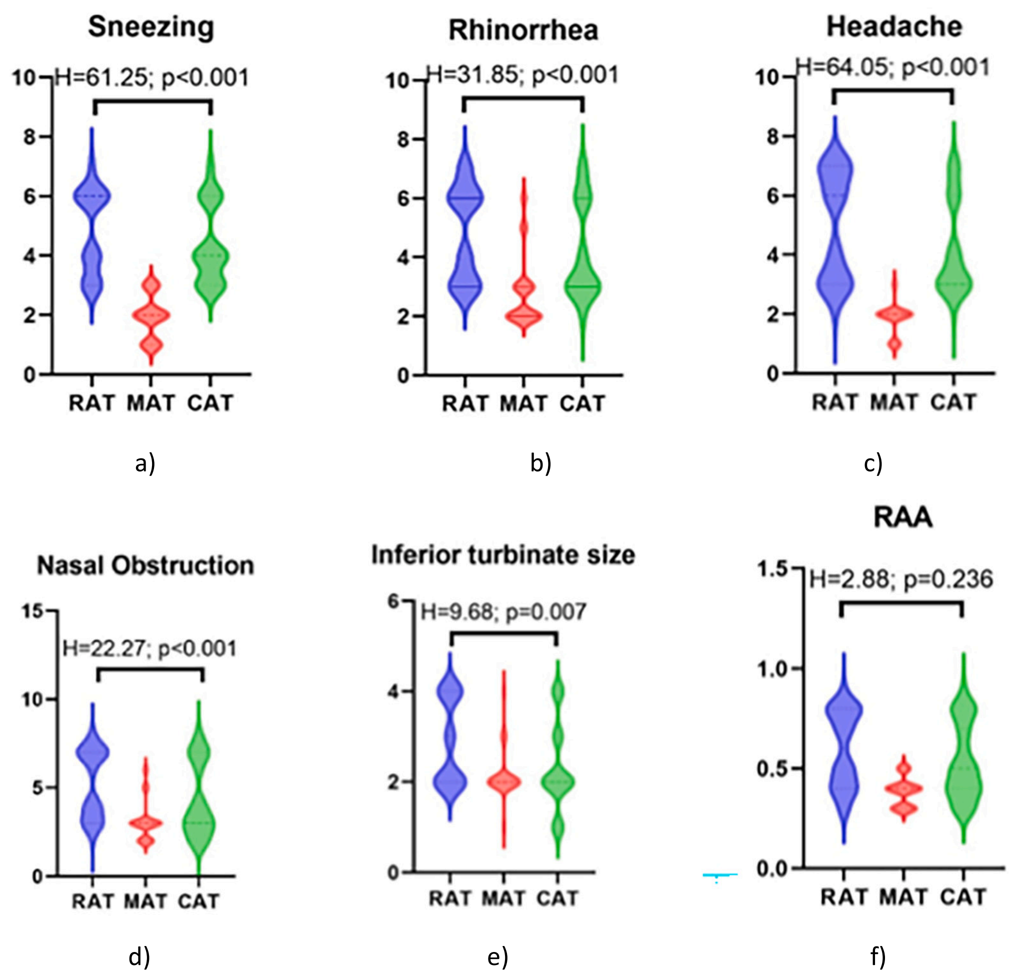


Fig. 2. 3-years VAS outcomes comparison represented by Violin Plot. Abbreviations: RAT, radiofrequency assisted turbinoplasty; MAT, microdebrider-assisted turbinoplasty; CAT, coblation-assisted turbinoplasty. Kruscall-Wallis was adopted to assess intergroup differences.

3.2. Postoperative outcomes and treatment efficacy

All the surgical treatments demonstrated improved outcome with a statistically significant decrease in all VAS scores from 1-year follow-up (Table II).

The MAT group had better outcomes for all the VAS scores already at the 1-year follow-up.

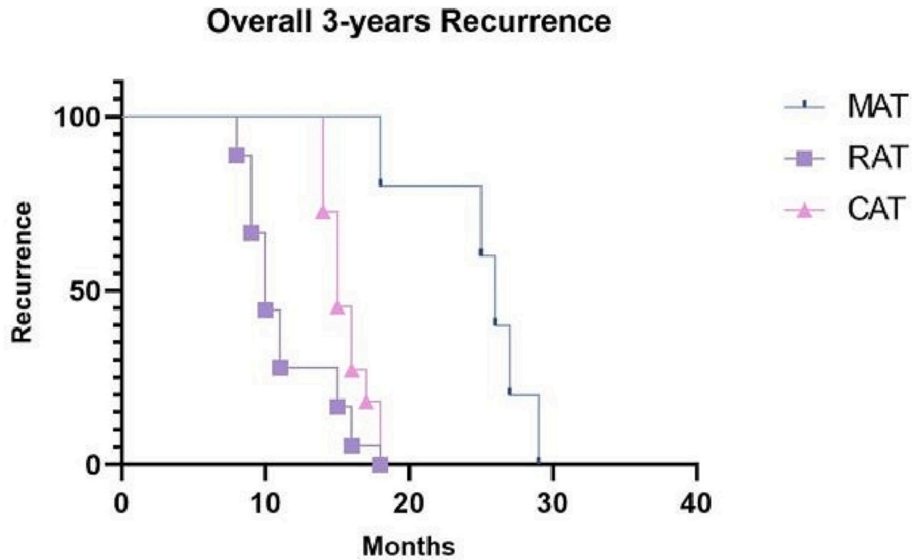
When comparing VAS outcomes at 3-year follow-up, MAT demonstrated better control for all six outcomes evaluated ($p < 0.001$ in all cases) (Table II). Moreover, at the 3-year Kruscall-Wallis test, a statistically significant difference was confirmed (Fig. 2a, b, c, d, e), except for RAA scores (H = 2.88; $p = 0.236$) (Fig. 2f).

The analysis of disease recurrence at 12 months reported a rate of 25.71 % (9/35) for RAT patients, reaching the 45.71 % (16/35) at 36 months (Fig. 3). In contrast, patients in the CAT group presented a recurrence rate of 31.42 % (11/35 cases), all occurred 12 months after treatment. The MAT technique reported a better stability of symptoms of 2.85 % (1/35) at 24 months and 14.28 % (5/35) at 36 months.

At Pearson's analysis for the 3-years recurrence, a significant anticorrelation was found for rhinorrhea ($r = -0.400$; $p < 0.001$); in contrast, sneezing ($r = -0.25$; $p = 0.011$) and RAA severity ($r = -0.16$; $p = 0.093$) were not significant (Fig. 4). Among variables, the operative time needed was also anticorrelated with disease recurrence but did not reach statistical significance ($r = -0.23$; $p = 0.016$).

Although a positive correlation was found for cytologic grade ($r = -0.08$, $p = 0.419$) and VAS headache ($r = -0.12$, $p = 0.228$), statistical significance was not found.

At logistic regression we found an R-squared of 0.336, and AUC of



Months			
	12m	*24m*	*36m*
MAT	0	1	4
CAT	0	11	0
RAT	9	7	0

Fig. 3. 3 years disease recurrence according to treatment subtype.

0.86 (95 % CI = [0.77, 0.94]).

4. Discussion

When lower turbinate hypertrophy is refractory to medical therapy, surgical treatment is the main therapeutic option to reduce symptoms such as nasal obstruction and rhinorrhea [30–32]. Although submucosal methods are the most widely used because of their minimal invasiveness, postoperative pain and preservation of physiological nasal clearance, they present variable results in the literature [33,34].

Singh et al. demonstrated the promising effects of decongestion with MAT on nasal obstruction, headache, turbinate size and sneezing, with a significant reduction from the first month [18].

However, few comparative studies in the literature compared different surgical techniques in the long term, especially with prospective protocols [19]. Long-term efficacy is also much debated in the literature, especially with regard to radiofrequency-related outcomes beyond 2 years [22,23,33].

Cingi et al. in a study with a larger cohort of 268 patients compared the postoperative outcomes of MAT turbinoplasty versus radiofrequency, reporting significant results at 3 months for both study groups [33]. However, the authors reported a decrease in patient satisfaction levels, which was more evident in the radiofrequency group at 12 months after surgery compared to the microdebrider technique ($p < 0.005$).

Liu et al., in a comparative study on subjective and objective results of radiofrequency techniques, reported recurrence at 1-year follow-up compared to baseline; in contrast, MAT results showed stability up to 3 years [35].

Our study demonstrated, at the Kruskall test of VAS results at 3 years, a significant difference for all subjective parameters analyzed between RT and MAT methods, except for RAA (H = 2.88, $p = 0.236$). However, at the intergroup analysis, MAT demonstrated a significant improvement both vs. CAT (0.38 ± 0.06 vs. 0.53 ± 0.18; $p < 0.001$) and RAT (0.38 ± 0.06 vs. 0.59 ± 0.19; p < 0.001).

Chen et al. confirmed the long-term efficacy of MAT in 80 patients with perennial allergic rhinitis, reporting not only an improvement in subjective complaints at 1, 2, and 3 years after surgery, but also in saccharin transit time ($p < 0.005$ for all) [23].

Our analysis of disease recurrence at 12 months reported a higher rate of 25.71 % (9/35) for patients undergoing RAT, reaching 47.71 % (16/35) at 36 months. In contrast, patients in the CAT group had a recurrence rate of 31.42 % (11/35 cases), all occurring at 12 months after treatment.

Finally, the MAT group reported better stability of symptomatology, with lower recurrence rates both at 24 months (1/35, 2.85 %) and 36 months (5/35; 14.28 %).

We have previously shown how a predictive model based on patient-reported symptoms can be useful in therapeutic indications [20].

Our study evaluating the 3 years-predictive factors of recurrence showed a negative correlation for cytologic grading ($r = -0.08$, $p = 0.419$), VAS headache ($r = -0.12$, $p = 0.228$) and RAA severity ($r = -0.16$; $p = 0.093$); however, no statistical significance was found. In contrast, a significant anticorrelation was found for rhinorrhea ($r = -0.400$; $p < 0.001$). Instead, operative time ($r = -0.25$; $p = 0.011$) and sneezing ($r = -0.23$; $p = 0.016$) although anti-correlated with disease recurrence did not reach a statistical significance.

Our study, however, have some structural limitations. First, although the sample size was achieved, the enrolled sample consisted of a low number of patients, which did not allow further subgroup analysis of the outcomes. Furthermore, the study design did not include a blinded clinical protocol, which may have conditioned the examiner's evaluation of long-term outcomes. The same analysis of the subjective parameters, although related to the patient's perception of surgical results, does not provide such a reliable parameter like rhinomanometry.

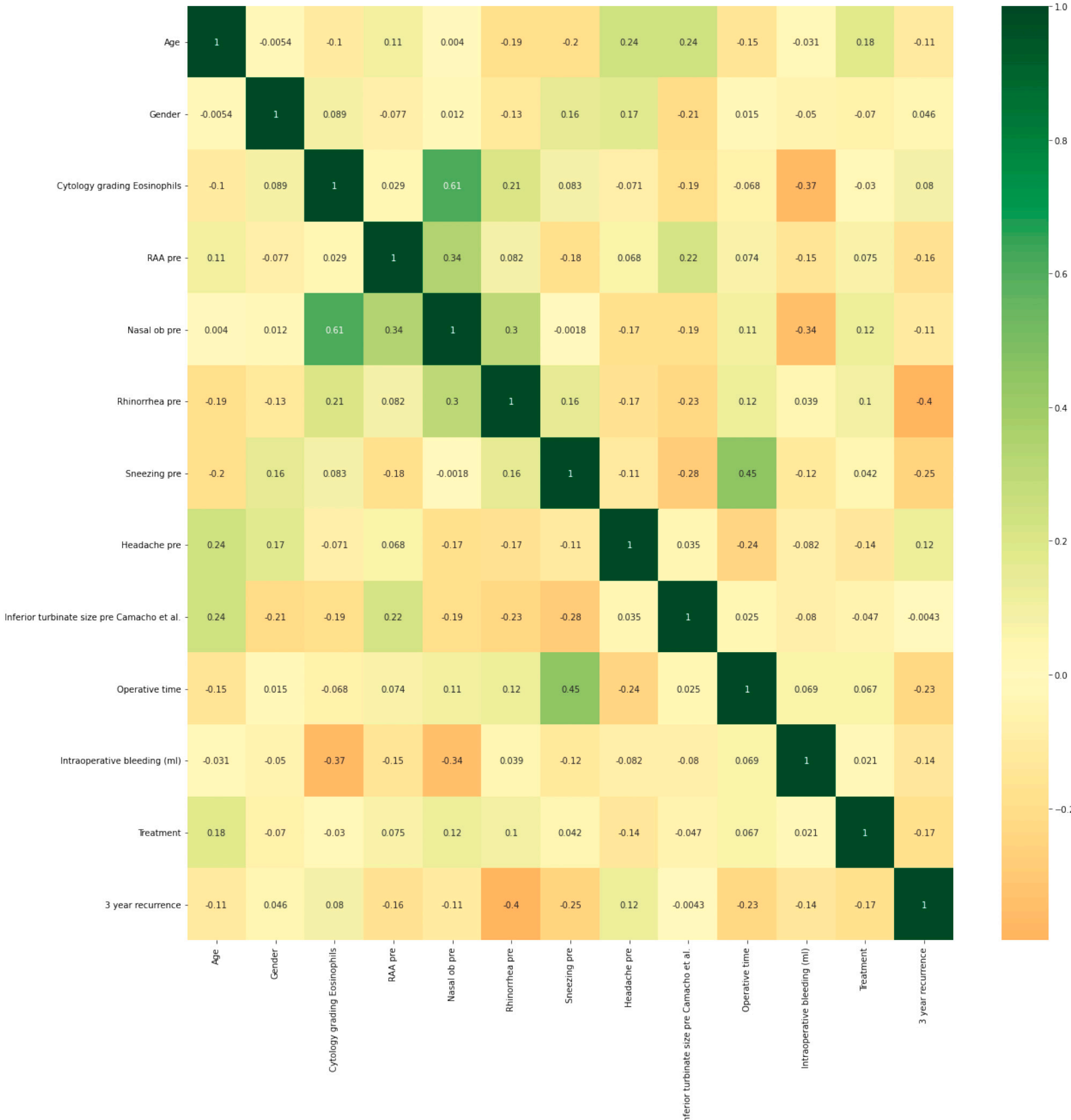


Fig. 4. Multiple linear regression assessing predictors of surgical success. The heatmap legend identify as green the positive correlation while orange as anti-correlation one. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

5. Conclusions

Radiofrequency techniques might have higher disease recurrence rates than turbinoplasty with the microdebrider technique. The latter, even in cases of recurrence, could result in a more stable therapeutic effect. Among the preoperative predictive factors of treatment, rhinorrhea and sneezing could correlate with better long-term results, influencing the choice of treatment.

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