



Effectiveness of submucosal turbinoplasty in refractory obstructive rhinitis: a prospective comparative trial

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Received: 11 December 2021 / Accepted: 10 January 2022 / Published online: 25 January 2022
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Abstract

Objective Refractory inferior turbinate hypertrophy requires a surgical approach to address symptomatic complaints. Submucosal approaches demonstrated their efficacy in restoring respiratory function and respecting the nasal mucosa. Microdebrider-assisted turbinoplasty (MAT) tools effectively reduces the soft tissue, exploiting a very different principle from the kinetic energy of radiofrequency. Thus, we aimed to compare the microdebrider-assisted turbinoplasty and the quantum molecular resonance (QMR) to assess patients' perspectives and respiratory outcomes.

Methods Subjects with persistent bilateral nasal blockage due to inferior turbinates hypertrophy were prospectively recruited from the University Medical Center. We randomly assigned the patients to each treatment and performed symptom evaluation via the visual analog score and endoscopic assessment at baseline and 30-, 90-, and 180-day post-treatment.

Results Seventy participants completed the evaluations, 35 in MAT and 35 in the QMR group. Nasal complaints were significantly reduced after 1 month using both methods. Although the MAT group reported higher postoperative bleeding and edema than QMR group, similar significant reductions were seen for turbinate size at long-term follow-up. Conversely, the MAT group reported greater VAS outcomes than QMR from the first postoperative month. In addition, MAT showed a longer operating time, although this difference was not statistically significant ($p < 0.05$).

Conclusion MAT allows effective control of nasal symptoms by reducing the size of turbinates in patients with lower turbinate hypertrophy. Although QMR may cause fewer postoperative complications, functional results are comparable to long-term follow-up.

Keywords Inferior turbinate hypertrophy · Microdebrider assisted turbinoplasty · Radiofrequency assisted turbinoplasty · Refractory rhinitis · Turbinate surgery

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Introduction

Turbinate hypertrophy and consequent chronic nasal obstruction are very common conditions in the general population, associated with disorders, such as allergic rhinitis and mucosal vasomotor hyperactivity [1, 2]. Despite the various medical therapies available, the patient with chronic obstruction often demonstrates refractoriness to topical corticosteroids or decongestants, with poor symptom control and consequently reduced related quality of life [3–6].

On the other hand, the adverse effects of aggressive endonasal surgery such as pain, bleeding, scabs, and synechiae of the inferior turbinates have led to the search for less invasive and easy-to-use techniques [7–9].

Aiming to balance efficacy and invasiveness among available surgical approaches for turbinal decongestion, submucosal techniques showed greater efficacy in reducing nasal obstruction and associated symptoms while respecting mucociliary clearance [10, 11]. Radiofrequency methods, electrocautery, and microdebrider-assisted submucosal turbinoplasty are currently considered the best options available in this regard [12–14].

Novel high radiofrequency procedures, as the QMR, allow the separation of tissues due to the effect of "resonance" at the cellular level by breaking the molecular bonds inside the cell, not producing kinetic energy and heat [15, 16]. High frequencies thus maintaining minimal heat emissions, are a widely used methods with proven benefits in immediate symptom amelioration at the expense of very limited side effects. However, this technique has shown conflicting results at long-term follow-up, and it yields worse control of posterior turbinate hypertrophy, a possible cause of persistent nasal obstruction [17, 18].

Conversely, endoscopy-assisted intratubal microshaver (MAT) allows greater precision with concomitant removal of the submucosal erectile tissue and the bony turbinate [19]. Therefore, this technique would allow the selective removal of the non-functional obstructive part, sparing the medial portion useful in heating and air humidification [20, 21]. However, this method presents debated postoperative pain and bleeding as often described in the literature [22, 23].

To systematically define outcomes and complications related to these two common techniques, we designed a prospective evaluation of the middle and long-term results of the two submucosal turbinoplasty methods, MAT and QMR, reporting their efficacy in symptom control and adverse event rates.

Methods

Study design and patients

The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines were followed [24].

A prospective, randomized, comparative surgical trial was conducted at the ear, nose, and throat (ENT) Unit of the University Hospital from January 1, 2020, to October 1, 2021. It compares the efficacy and safety of MAT vs. molecular quantum resonance (QMR). Patients between 18 and 45 years performing turbinoplasty surgery for medical refractory nasal blockage due to inferior turbinate hypertrophy were included [25]. In particular, lower turbinate reduction has been offered by clinicians in patients with nasal airway obstruction and enlarged lower turbinates who have failed prior medical management consisting of Intra-Nasal steroid (INS) monotherapy and inadequate control of symptoms.

Medical treatment was applied according to the latest guidelines [26]. The study design is summarized in Fig. 1. Informed consent from all the enrolled participants was obtained. The study protocol was approved by the Human Medical Research and Ethics Committee of the University and was performed in adherence with the Declaration of Helsinki. We performed randomization utilizing statistical computing web programming (www.graphpad.com/quickcalcs). An investigator not related to this study prepared the random number list computer-generated. We consequently carried out a random patients' allocation patients into 50% Group A (microdebrider-assisted turbinoplasty) and 50% Group B (radiofrequency-assisted turbinoplasty) (Fig. 1). Patients with the following features were excluded from the study:

- turbinate hypertrophy associated with other sinonasal anatomic anomalies or disorders including but not limited to the deviated nasal septum, septal spur, concha bullosa, sinusitis, nasal valve collapse, nasal polyps, or tumors;
- history of prior turbinate or sinonasal surgeries;
- ongoing or planned pregnancy;
- overall follow-up time < 6 months after turbinoplasty.

All patients initially considered in the study were subjected to clinical and endoscopic nasal evaluation to assess inferior turbinate hypertrophy [27]. Nasal obstruction was confirmed through active rhinomanometric examination (RAA), while nasal health was assessed via cyto-functional changes. The recommendations of the International Committee on Standardization of Rhinomanometry were

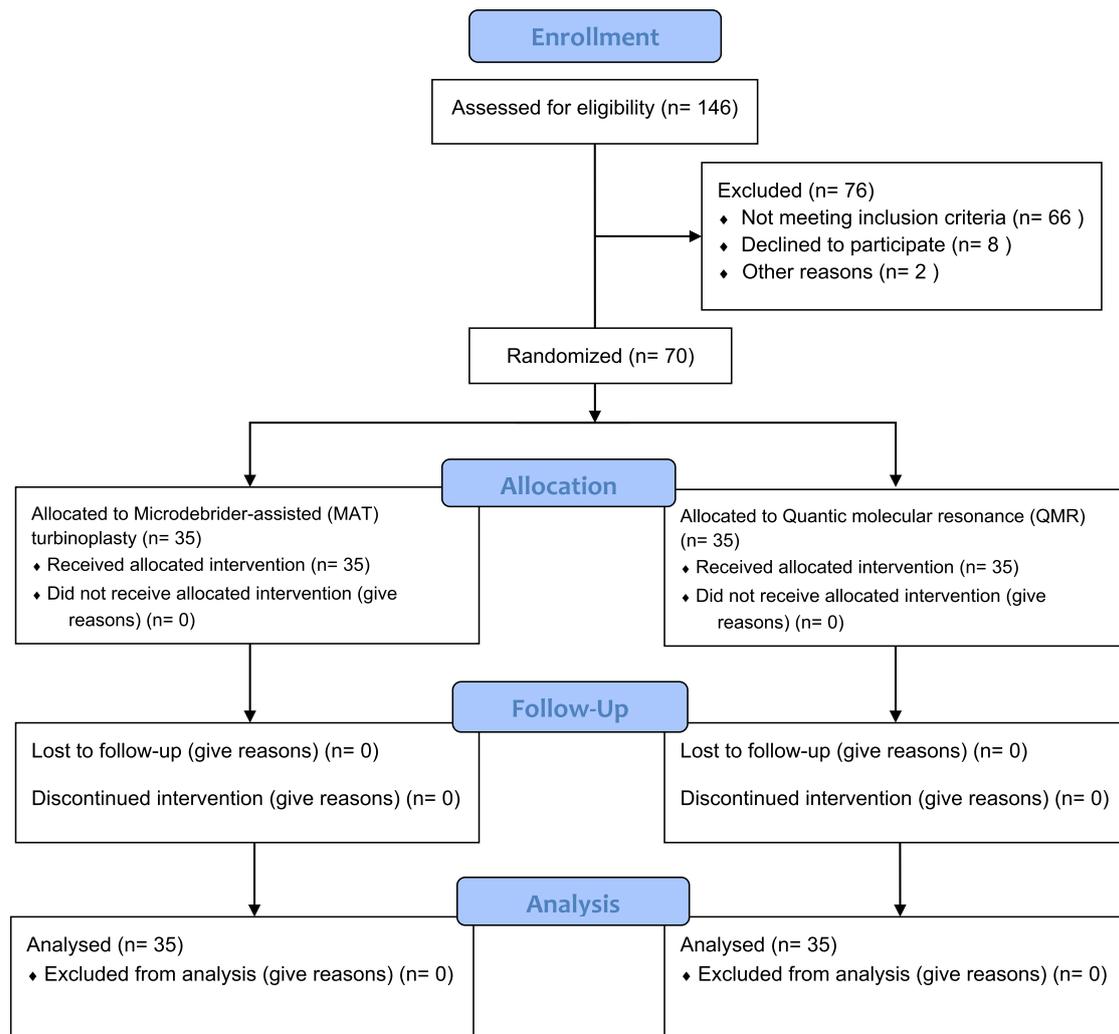


Fig. 1 CONSORT 2010 flow diagram

followed [28]. After 30 min of acclimatization, Rhinomanometry was performed in a room with constant humidity and temperature-controlled with a thermostat.

Patient assessment

Patients were evaluated at baseline and after the surgical procedure at 1, 3, and 6 months. Symptom scoring was based on the visual analog scale (VAS), with 0 representing no symptoms and 10 the most severe symptoms, to document nasal obstruction, postoperative pain, and rhinorrhea. Nasal endoscopic assessment of the inferior turbinate's size was based on Camacho et al. classification, which classifies inferior turbinate's size as 4 grades based on its position in the total nasal airway space [27]. Two trained specialists documented turbinate size, postoperative pain, bleeding crusting, and synechiae formation. At

all-timepoints, we performed an active rhinomanometric examination to study the nasal resistance (Rhinomanometer Labat Srl, Venice, Italy). At the same timepoints, each patient underwent sampling for cytological analysis. The sample was obtained by scraping the middle inferior turbinate part via a Rhino-Probe and placed on a slide (Arlington Scientific Inc., Springfield, MA, US). The samples were fixed with 2% glutaraldehyde, stained with 2% osmium tetroxide, dehydrated with alcohol, and then observed with a Hitachi 100 keV H-600 electron microscope (Hitachi Ltd, Chiyoda, Japan). Therefore, the cell distribution, different cytotypes, and various intracellular components were described. We assessed the integrity of ciliated cells, detecting the percentage of patients with cellular changes. Cytological analysis was scored according to Gelardi et al. modified grading (Table 1) [29].

Table 1 Modified Gelardi cytological classification

Description	Quantitative	Grading
Epithelial ciliated cells		
Normal	–	N
Abnormal	–	A (CCP/MN)
Mucinous cells		
None	0	0
Occasional	1–24%	1+
Moderate number	25–49%	2+
Large number	50–74%	3+
Covering the entire field	75–100%	4+
Neutrophils and eosinophils		
None	0	0
Occasional	0.1–1%	1/2+
Few scattered cells, small clumps	1.1–5%	1+
Moderate number, large clumps	5–15%	2+
Large clumps not covering the field	15–20%	3+
Clumps covering entire field	> 20%	4+
Basophilic (mast cells)		
None	0	0
Occasional	0.1–0.3	1/2+
Few scattered cells, small clumps	0.4–1	1+
Moderate number, large clumps	1.1–3	2+
Large clumps not covering the field	3.1–6	3+
Up to 25 per an X100 field	> 6	4+
Eosinophil/mast cell degranulation		
None observed	Present/absent	0
Occasional granules		1+
Moderate number of granules		2+
Many granules easily seen		3+
Massive degranulation, entire field		4+
Bacteria and spores		
None observed	None standardized	0
Occasional clumps		1+
Moderate number		2+
Many cells easily seen		3+
Bacteria/spores over the entire field		4+

CCP ciliocytophthoria, MN multinucleation

Operative technique

Turbinoplasty was performed in group A using the integrated power console (Medtronic, Minneapolis, MN, US) with a Straightshot M4 microdebrider blade in oscillating mode at 5000 rpm or group B using the quantum molecular resonance turbinoplasty (Vesalius Quantum surgical system). All surgical procedures were performed by the same senior surgeon (CS). Nasal surgery was performed under endoscopic guidance

using a 0° 4 mm diameter nasal endoscope (Karl Storz, Germany), viewing the different portions of the inferior turbinate during the procedure. Local anesthesia (1% lidocaine with 1:100,000 epinephrine) was applied by injecting 2–3 ml of the solution to the inferior and medial border of both inferior turbinates until whitening. Ten minutes after the injection, the surgical procedure was performed. In group A, patients underwent MAT after incision of the anteroinferior portion of the inferior turbinate and subsequent intratubinal debridement. The procedure was performed in an anteroposterior direction to remove the entire lateral aspect of the inferior turbinate mucosa and soft tissue in an anteroposterior direction.

In group B, patients underwent QMR (Vesalius system). After incision and formation of the inferior anterior window, the radiofrequency needle was introduced up to the posterior portion of the turbinate, removing the entire lateral part of the soft tissues in the posterior–anterior direction [30]. We delivered radiofrequency energy for 10 s on each anterior, middle, and posterior turbinate portion, placing the needle submucosal during all the procedures. We used the coagulation mode setting the power level on grade three. Any bleeding was cauterized with dedicated hemostasis bipolar forceps.

Statistical analysis

Standard descriptive statistics were used, reporting mean and standard deviation for continuous variables and percentages for categorical ones. The sample size required for the study was calculated assuming a 95% confidence, p value < 0.05, a power of 0.8, and a mean difference set to 2.0. Therefore, at least 25 patients per group were identified, and subsequently, the drop-out rate of 30% was added to the sample. The independent t test was performed for the normally distributed values, while the Mann–Whitney U test was performed for the not normally distributed values. The chi-square test was performed to test the observed and expected data difference. Pearson correlation coefficients were determined with r and p values reported for normally distributed variables, while Spearman correlation was used when variables did not follow a normal distribution. In the multiple linear regression model, we included all clinical factors as potentially predictive success variables. A value of $p < 0.05$ was deemed to be statistically significant. All analyses were performed using the Social Sciences Statistical Program (IBM SPSS Statistics for Windows, IBM Corp. Released 2017, Version 25.0 Armonk, NY: IBM Corp).

Results

Setting and patients

A total of 70 participants were enrolled, 35 patients in group A (MAT) and 35 in group B (QMR). Clinical features are

Table 2 Preoperative features

n°/symptoms	n°/VAS score		<i>p</i>
	MAT	QMR	
Age	33.05 ± 8.07	31.54 ± 8.07	0.436
Gender	21M vs. 14F	16M vs. 19F	0.231
Nasal obstruction	8.74 ± 0.81	8.54 ± 0.88	0.326
Rhinorrhea	6.67 ± 0.84	6.91 ± 0.81	0.227
Sneezing	7.51 ± 0.88	7.25 ± 0.84	0.210
Headache	6.29 ± 1.07	6.54 ± 1.29	0.380
Inferior turbinate size	3.51 ± 0.5	3.37 ± 0.49	0.240
RAA (Pa/cm ³ /s)	0.94 ± 0.08	0.96 ± 0.06	0.236

Inferior turbinate size according to Camacho et al.

MAT microdebrider-assisted turbinoplasty, QMR quantic molecular resonance, M male, F female

summarized in Table 2. The mean age in the MAT group was 33.05 ± 8.07 while 31.54 ± 8.07 in QMR ($p=0.436$). No statistical difference in gender ratio was observed ($p=0.231$). Among preoperative symptoms reported, the most severe complaint was represented by nasal obstruction, with a severe mean VAS score both for MAT and QMR group (8.74 ± 0.81 vs. 8.54 ± 0.88; $p=0.326$).

Endoscopic findings confirmed Inferior turbinate hypertrophy in both groups, ranging from grade 3 to 4 ($p=0.240$) and RAA data (Pa S/cm³) (MAT = 0.94 ± 0.08 vs. QMR = 0.96 ± 0.06; $p=0.236$).

Furthermore, no statistical difference was detected in the remaining preoperative outcomes of the two groups ($p>0.05$ for all) (Table 2).

Postoperative outcomes and treatment efficacy

Both surgical treatments demonstrated symptomatic improvement with a statistically significant decrease in all VAS scores starting from the first-month follow-up (Fig. 2a, b). Although both methods achieved significant improvements from the first month, the MAT showed better outcomes except for rhinorrhea ($p=0.681$) (Fig. 2c).

At the same time, the outcomes obtained demonstrated stability at the subsequent 3-month (Fig. 2d) and 6-month (Fig. 2e) follow-up for both groups, confirming the efficacy of both techniques (Fig. 2).

Intergroup analysis of VAS outcomes MAT group demonstrated better control of nasal obstruction ($p<0.001$), sneezing ($p<0.001$), and headache ($p<0.001$) (Table 3). The objective outcomes of Inferior turbinate size (1.45 ± 0.5 vs. 1.91 ± 0.7; $p=0.002$) and RAA (0.28 ± 0.06 vs. 0.36 ± 0.05; $p<0.001$) were better in the MAT group than in the QMR, and they remained significant up to 6-month follow-up. In each group, no crusting or synechiae were reported at follow-up.

Perioperative bleeding was poor, and therefore, both techniques did not require any nasal tamponade at pre or postoperative controls. Although the VAS pain score postoperative at 6 h was considered tolerable in both groups, the MAT demonstrated a statistically higher average pain score than QMR (5.14 ± 0.68 vs. 4.37 ± 0.68; $p<0.001$). Similarly, the former reported a statistically higher difference for surgery duration when compared to QMR ($p=0.001$) and intraoperative bleeding than QMR (56.85 ± 6.15 vs. 48.71 ± 4.37; $p<0.001$).

At multiple linear regression for independent predictive factors, preoperative rhinorrhea and sneezing demonstrated positive correlation and statistical significance with surgical success assessed via VAS and RAA scores (0.405, $p=0.007$; 0.355, $p=0.016$, respectively) (Table 4). We reported an *R*-squared of the linear regression model of 0.211, while the adjusted value was 0.05. According to cytologic classification, moderate to severe preoperatively scores were found in 25/35 MAT patients and 32/35 QMR subjects ($p=0.68$). At 6-month follow-up, both groups presented a significant reduction of pathological cell findings, particularly in QMR patients than MAT ($p<0.001$ vs. $p=0.01$).

Discussion

Surgical treatment of refractory hypertrophy of the inferior turbinates represents the main therapeutic option in reducing nasal obstruction and related symptoms [3, 4, 31].

MAT and QMR are widely used among the different surgical techniques available, presenting advantages, such as minimal invasiveness, postoperative pain, and preservation of physiological nasal clearance [32]. Furthermore, it is preferred to associate turbinal decongestion with endoscopic monitoring, ensuring the reduction of all portions of the lower turbinates [33, 34].

Recently Singh et al. reported the effects of decongestion with MAT on nasal obstruction, headache, turbinate size, and sneezing, demonstrating a significant reduction evaluated from the first month [19]. On the other hand, QMR treatment efficacy analyzed by Di Rienzo et al. demonstrated greater efficacy than a control medical group ($p<0.05$), especially on nasal symptoms and rhinoendoscopy clinical score [35]. Nevertheless, few comparative studies in the literature compare the two methods [36–38].

Cingi et al. assessed objective and subjective outcome measures comparing microdebrider-assisted and radiofrequency-inferior turbinoplasty in a prospective study on 268 patients [36]. Subjective outcomes evaluation reported a significantly better nasal obstruction severity in the microdebrider group still to the third month than the radiofrequency group ($p<0.05$). Moreover, the rhinomanometric scores of

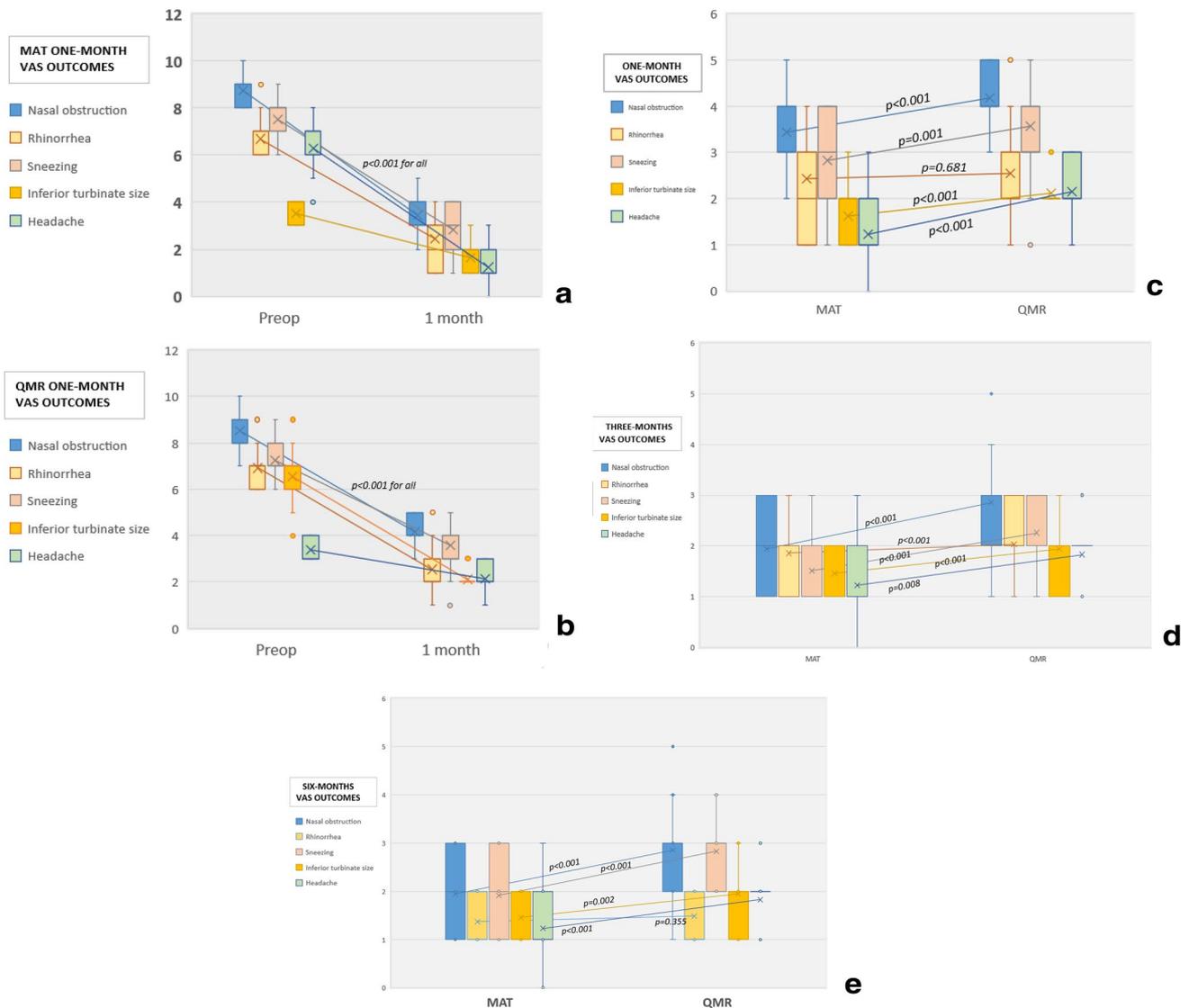


Fig. 2 a MAT preoperative vs. 1 month; b QMR preoperative vs. 1-month, c 1-month, d 3-month; e 6-month follow-up. Box plot according to MAT and QMR VAS scores at each follow-up

the QMR were significantly higher than the microdebrider group at 3 months ($p < 0.05$).

Our study demonstrated at intergroup analysis of VAS outcomes better control of nasal obstruction ($p < 0.001$), sneezing ($p < 0.001$), and headache ($p < 0.001$) in the MAT group. These results were also confirmed at objective assessment through RAA (0.28 ± 0.06 vs. 0.36 ± 0.05 ; $p < 0.001$).

Harju et al. instead evaluated in a randomized trial the effect of the surgical procedures on the ciliated epithelium, reporting greater cilia score in the radiofrequency ablation ($p = 0.03$) than the MAT group ($p = 0.03$ vs. $p = 0.04$) [37].

The long-term efficacy of postoperative results is highly debated in the literature, especially for radiofrequency-related outcomes beyond 2 years [23, 39–41]. In a comparative study by Liu et al., radiofrequency's subjective

and objective outcomes were inverted to baseline at 1-year follow-up, while MAT outcomes demonstrated stability up to 3 years [39].

Our intragroup-analysis of the QMR outcomes confirmed the stability of the outcomes obtained at the following 3 months (Fig. 2d) and 6 months (Fig. 2e) while demonstrating results below the MAT for nasal obstruction and sneezing at 6-month follow-up ($p < 0.001$ for both).

Chen et al. confirmed the long-term efficacy of MAT in 80 patients with perennial allergic rhinitis, reporting not only improvement in subjective complaints at 1, 2, and 3 years after surgery but also in saccharin transit time ($p < 0.05$ for all) [23].

The management of postoperative pain, on the other hand, predicts more favorable results for the QMR [40].

Table 3 Intergroup analysis of postoperative surgical outcomes

Symptoms	Follow-up	VAS score		<i>p</i>
		MAT (<i>n</i> = 35)	QMR (<i>n</i> = 35)	
Nasal obstruction	1st month	3.42 ± 1.01	4.17 ± 0.78	< 0.001
	3rd months	1.68 ± 0.71	2.28 ± 0.75	< 0.001
	6rd months	1.94 ± 0.83	2.85 ± 0.87	< 0.001
Rhinorrhea	1st month	2.43 ± 1.11	2.54 ± 1.12	0.681
	3rd months	1.85 ± 0.69	2.02 ± 0.7	0.309
	6rd months	1.37 ± 0.49	1.48 ± 0.5	0.355
Sneezing	1st month	2.82 ± 0.85	3.57 ± 1.03	0.001
	3rd months	1.51 ± 0.61	2.25 ± 0.7	< 0.001
	6rd months	1.91 ± 0.78	2.82 ± 0.61	< 0.001
Headache	1st month	1.62 ± 0.64	2.14 ± 0.69	< 0.001
	3rd months	1.02 ± 0.78	1.51 ± 0.74	0.008
	6rd months	1.21 ± 0.67	1.82 ± 0.45	< 0.001
Inferior turbinate size	1st month	1.74 ± 0.45	2.11 ± 0.32	< 0.001
	3rd months	1.22 ± 0.41	1.71 ± 0.45	< 0.001
	6rd months	1.45 ± 0.5	1.91 ± 0.7	0.002
RAA	1st month	0.41 ± 0.07	0.47 ± 0.08	0.001
	3rd months	0.34 ± 0.06	0.39 ± 0.08	0.018
	6rd months	0.28 ± 0.06	0.36 ± 0.05	< 0.001
Operative time (min)	–	17.94 ± 1.08	16.57 ± 1.54	< 0.001
Intraoperative bleeding (ml)	–	56.85 ± 6.15	48.71 ± 4.37	< 0.001
Postoperative VAS pain (6 h)	–	5.14 ± 0.68	4.37 ± 0.68	< 0.001

Table 4 Multiple linear regression of independent predictive factors

	6-month nasal obstruction		6-month turbinate size	
	Pearson correlation	Sig. (1-tailed)	Pearson correlation	Sig. (1-tailed)
Preoperative				
Age	– 0.154	0.181	– 0.137	0.210
Nasal obstruction	0.178	0.147	– 0.089	0.301
Rhinorrea	0.405	0.007	0.111	0.256
Sneezing	0.135	0.213	0.355	0.016
RAA	– 0.004	0.490	– 0.129	0.224
Headache	– 0.034	0.420	– 0.156	0.178
Turbinate size	0.041	0.404	– 0.129	0.223
Cytologic grading	– 0.072	0.340	0.228	0.094

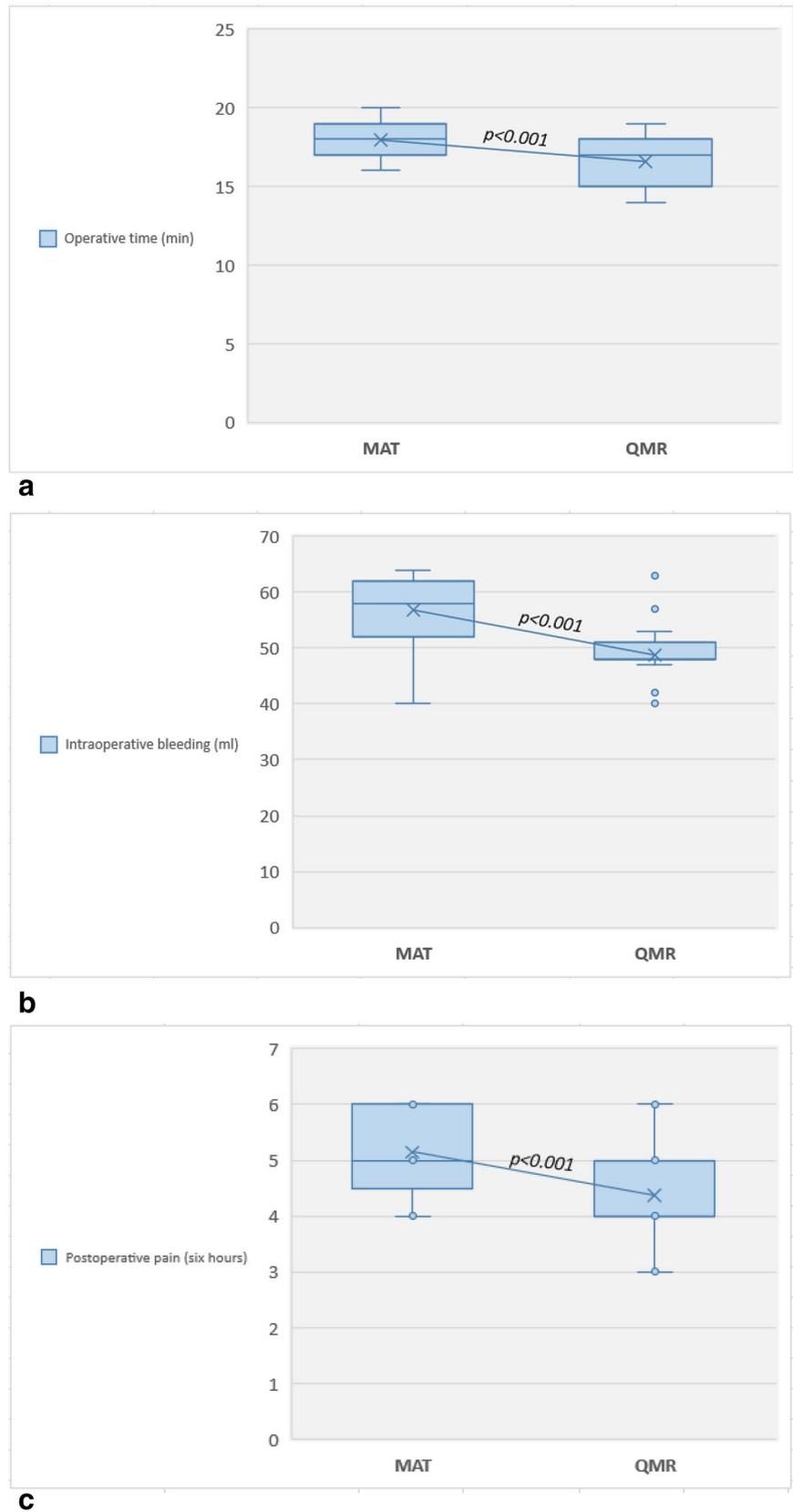
Preoperative rhinorrea and sneezing demonstrated positive correlation and statistical significance. The *R*-squared of our linear regression model was 0.211 while the adjusted 0.05

These assumptions are probably due to the fibrosis caused by radiofrequency and the reduction of the vascular component of the turbinate and the volume as a whole. Our study reported a significantly lower postoperative pain in the QMR group, with higher tolerability of the method (4.37 ± 0.68 vs. 5.14 ± 0.68 ; $p < 0.001$) (Fig. 3c).

Several authors in the literature affirm that symptomatic severity is useful in the therapeutic indication of the patient, suggesting excellent results in the case of refractory to medical therapy [35, 37, 38, 42]. However, no studies have evaluated predictive models based on

patient-reported subjective symptoms to our knowledge. In this regard, our study performed a multiple linear regression of preoperative independent predictive factors, demonstrating a positive correlation and statistical significance of preoperative rhinorrea and sneezing with surgical success assessed via VAS scores (0.405, $p = 0.007$ and 0.355, $p = 0.016$). Conversely, Cytologic grading did not reach a statistically significant correlation (0.228, $p = 0.094$). Moreover, our linear regression model demonstrated an *R*-squared of 0.211, thus adjusted at 0.05.

Fig. 3 Box Plot of mean operative time (min) (a), bleeding (ml) (b), and postoperative pain (VAS) (c) among the two different techniques



However, from the intragroup analysis carried out in our study according to cytologic classification both QMR and MAT groups found at 6-month follow-up a significant improvement of pathological cell findings, with better outcomes for QMR patients than MAT ($p < 0.001$ vs. $p = 0.01$). Our results comply with what is expressed in the literature, demonstrating how submucosal reduction can restore nasal function by improving both mucociliary clearance and cytological nasal health [43–45].

Luka et al. in a histopathological study evaluated the restoration of epithelial integrity in patients with turbinate hypertrophy treated with endoscopic reduction of the submucosa, reporting a significant epithelial denudation decrease ($p < 0.001$), basement membrane thickening reversal ($p < 0.001$) and increase in cilia density ($p < 0.001$) [44]. More recently, Pecorari et al. stated that submucosal reduction of the surgical turbinate is not responsible for a worsening of inflammatory infiltrate of the nasal mucosa, reporting a significant nasal cytology improvement after treatment in 29.2% of cases.

Conclusion

MAT seems to be effective in controlling nasal symptoms by reducing the size of turbinates in patients with lower turbinate hypertrophy. Although QMR may cause fewer postoperative complications, functional results of MAT and QMR approaches are comparable in the long-term follow-up.

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