ORIGINAL RESEARCH

Investigative Otolaryngology

Does nasal surgery improve multilevel surgical outcome in obstructive sleep apnea: A multicenter study on 735 patients

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Abstract

Objective: Does nasal surgery affect multilevel surgical success outcome.

Methods: Prospective eight country nonrandomized trial of 735 obstructive sleep apnea (OSA) patients, who had multilevel palate and/or tongue surgery, divided into two groups, with or without nose surgery.

Results: There were 575 patients in nose group, 160 patients in no nose group. The mean age for nose group 44.6 ± 11.4, no nose group 44.2 ± 11.8. Mean preoperative BMI for nose group 27.5 ± 3.6, no nose group 27.5 ± 4.1, mean postoperative BMI nose group 26.3 \pm 3.7, no nose group 27.1 \pm 3.8 (P = .006). Mean preoperative AHI nose group 32.7 \pm 19.4, no nose group 34.3 \pm 25.0 (P = .377); and mean postoperative AHI nose group 13.5 \pm 10.2, no nose group 17.1 \pm 16.0 (P = .001). Mean preoperative ESS nose group was 11.3 ± 4.7 , no nose group was 10.4 ± 5.4 (P = .051); and

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mean postoperative ESS nose group was 5.3 ± 3.2 , no nose group was 6.7 ± 2.8 (P = .001). The nose group had higher percentage change (adjusted for age, gender, BMI) in AHI (33.7%, 95% CI 14% to 53.5%) compared to the no nose group (P = .001); the nose group also had more percentage change in ESS (37%, 95% CI 23.6% to 50.3%) compared to the no nose group (P < .001). Change in BMI did not affect AHI nor ESS change (Cohen effect 0.03 and 0.14, respectively). AHI change in both groups were also statistically significant in the mild OSA (P = .008) and the severe OSA (P = .001). Success rate of surgery for the nose group 68.2%, while the no nose group 55.0% (P = .002).

Conclusion: Combining nose surgery in multilevel surgery improves surgical success.

Level of evidence: IIC.

KEYWORDS

multilevel surgery, obstructive sleep apnea, success rate

1 | INTRODUCTION

Snoring is usually due to the vibration of soft tissues in the oral cavity, namely the soft palate, uvula, tonsillar arches, tonsils, tongue base, supraglottis, and lateral pharyngeal walls. Vibration of these oropharyngeal structures may be due to a secondary effect arising from turbulent airflow caused by the turbulent air flowing through the nasal passages (due to nasal obstruction); and this vibration leads to snoring which may be a symptom of obstructive sleep apnea (OSA).

OSA is due to the collapse of the upper airway due to muscle tone relaxation during sleep. The narrowest part of the upper airway is the nasal valve; the upper airway extends from the nose to the hypopharynx. It is well accepted that the upper airway accounts for two-thirds of the entire airway (which extends down to the small alveoli). Intuitively, nasal surgery would significantly reduce the upper resistance and hence, decrease the inspiratory negative pressure (in the lungs/pleural space) during sleep and contribute to improvement of OSA. It is well accepted that the nasal valve area has the highest nasal resistance and careful examination of the nostrils, soft tissue and skeletal aperture, inferior sinus turbinates and nasal septal deviation, is crucial. Adenoid hypertrophy may also contribute to nasal obstruction in children.

Understanding the pathophysiology of airflow and respiratory dynamics in the nasal passages and the upper airway is crucial. The active phase of breathing is inspiration, in order to inhale air from the atmosphere, the intraplueral space creates a negative pressure (eg, negative 8cmH2O) to draw air into the alveoli for gaseous exchange. As there is this negative pressure exerting on the entire upper airway (including the hypopharyngeal, retroglossal, and retropalatal space) the hypopharyngeal may collapse. Hence, if there was nasal blockage (eg, a deviated nasal septum, enlarged swollen turbinates, nasal polyps, etc), the lungs would need to create a "more negative pressure" (eg, negative 30cmH2O) to inhale air from the atmosphere; this might result in a greater negative pressure on the

hypopharyngeal, retroglossal and retropalatal area, leading to collapse of the hypopharyngeal upper airway.² With nasal blockage, there would be turbulent airflow created, causing vibration of the soft palate (the first contact area from the turbulent nasal airflow). Therefore, it is plausible to conclude that nose surgery alone might not cure OSA, but it may decrease the negative pressure within the upper airway, thereby relieving any further secondary collapse.

Many scientific papers have showed that nasal surgery alone, as a single site procedure would likely not impact nor improve the sleep apnea results but may help reduce snoring intensity, moreover, the patient may subjectively breathe better.³⁻⁸ The pertinent question is whether incorporating nasal surgery as part of multilevel surgery in OSA would improve surgical outcomes. We investigate the surgical outcomes with the addition of nasal surgery into multilevel OSA surgery.

2 | MATERIALS AND METHODS

This study was a nonrandomized multicenter clinical trial of consecutive patients seen in the ENT office and diagnosed with OSA. All patients met the selection criteria and proceeded for either palate and/or tongue surgery of the upper airway, with or without nose surgery included. In one group, all patients had nose surgery included (nose group); while the other group no nose surgery was performed (no nose group). Patients were recruited from nine tertiary clinical centers from eight countries, including Singapore, Italy, Canada, India, Spain, Poland, Israel, and South Korea.

All patients had a thorough clinical assessment including a physical examination, flexible awake naso-endoscopy, and an overnight polysomnography (PSG) before and after surgery. Apnea was defined as a >90% continuous airflow reduction for >10 seconds; hypopnea was defined as a more than 30% decrease in airflow amplitude relative to the baseline and associated with >3% desaturation of oxygen

or arousal >10secs. Data was collated for duration of oxygen saturation below 90%, AHI, sleep latency and lowest oxygen saturation (LSAT). Patients completed the Epworth sleepiness scale (ESS) and a visual analogue scale (VAS) for snoring (bed partner had to fill this) before and after surgery. The preoperative sleep test and postoperative sleep test were done at the same respective hospital/center.

Physical examination included height, weight, neck circumference, body-mass index (BMI), and blood pressure (systolic and diastolic); a flexible endoscopic assessment of the nasal cavity, posterior nasal space, oropharyngeal area, soft palatal redundancy, uvula size and thickness, tonsillar size, and modified Mallampati grade. Flexible nasoendoscopic Mueller's maneuver was graded for the soft palate, lateral pharyngeal walls, and base of tongue.

Inclusion criteria for the patients were (a) adult patients (>18 years old), (b) AHI > 5, (c) all Friedman stage, (d) all modified Mallampati grades, (e) single or multilevel collapse, (f) all BMI, and (g) nose, palate and/or tongue surgery. All patients enrolled were counseled about CPAP, and those patients who tolerated and preferred the CPAP option were subsequently excluded from the study (as this was a surgical study, the CPAP patients were excluded). Patients who had previous upper airway surgery (including nasal surgery) and/or had any pillar implants or hypoglossal nerve implant inserted previously or currently (as this procedure is not offered in all centers and cost is also a consideration for patients) were excluded. Patients who refused surgery were also excluded. Patients who had allergic rhinitis were all given 4 to 6 months of antihistamines and corticosteroids nasal sprays: those who had deemed to have failed conservative medical therapy were offered surgery. Not all centers performed DISE (drug induced sleep endoscopy); DISE was not mandatory, depending on the surgeon and tertiary center's protocol and clinical expertise.

DISE in the operating room (OR) in the presence of an anesthesiologist. Full anesthetic monitoring was rendered. Topical anesthesia and local vasoconstrictors of the nose were not used. Intravenous target-controlled infusion (TCI) of Propofol was used as sedation, as described by the European position paper, only one center had used intravenous dexmedetomidine. Upper airway collapse was evaluated once the patients started to snore and bispectral index (BIS) monitor showed between 70 and 50. The Esmarch jaw thrust maneuver was performed as a last step during the DISE; the retroglossal area advancement was noted. VOTE classification system was used to score the DISE findings.¹⁰ The VOTE classification is based on the velum obstruction, the oropharynx, tongue base and/or epiglottis. Velopharyngeal collapse might indicate palate surgery might be needed, lateral wall oropharyngeal collapse might require lateral pharyngeal wall surgery, while tongue base collapse might indicate tongue base surgery is needed.

The selection criteria for nose surgery was based on the individual surgeon's and the country's/institution's surgery protocol and algorithm; in general, patients who had nasal symptoms of either allergic rhinitis and/or sinusitis, with/without nasal septal deviation, and/or turbinate hypertrophy were offered some form of nasal procedure. Nasal procedures included septoplasty (Septo), radiofrequency

turbinate reduction (RFIT), turbinoplasty (RFTurb), and functional endoscopic sinus surgery (FESS). Functional endoscopic sinus surgery was done only for patients with clinical evidence of gross nasal polyps that was causing nasal airway obstruction. The various palate surgeries were based on previously described techniques. The expansion sphincter pharyngoplasty (ESP) as described by Pang et al, 11 functional expansion pharyngoplasty (FEP) as described by Sorrenti et al, 12 barbed reposition pharyngoplasty (BRP) introduced by Vicini et al,¹³ modified uvulopalatopharyngoplasty (mUPPP) (uvular preservation or recreation surgically) as described by Li et al,14 uvulopalatal flap (UVPF) as proposed by Neruntarat, 15 suspension palatoplasty (SP) described by Li et al, 16 relocation pharyngoplasty (RP) as introduced by Li et al. 17 Z-palatoplasty (ZPP) as described by Friedman et al, 18 and anterior palatoplasty (AP) as described by Pang et al. 19,20 Tongue procedures were mainly the midline glossectomy (M.Gloss), genioglossus advancement mandibulotomy (GAM), and the radiofrequency tongue base reduction (RFBOT) technique. As this article was not to investigate the role of nasal surgery in snoring reduction. the primary objectives were adhered to. None of the postsurgery patients subsequently went on to use CPAP therapy.

The study protocol and methodology were reviewed and approved by the respective hospital Ethics Committee/Institutional Review Board (IRB).

3 | STATISTICAL METHODS

Analyses were carried out using SPSS 25.0 with statistical significance set at P < .05. Descriptive statistics for numerical variables were presented as mean (SD) and n (%) for categorical variables. The preoperative and postoperative change were analyzed using paired t test. General linear model adjusting for age and sex was performed to compare the differences in the numerical parameters between the nose group and the no nose group.

4 | RESULTS

There was a total of 735 patients collected from the nine tertiary clinical centers and eight countries. There were 620 males and 115 females, mean age of 44.4 \pm 11.5 years, mean BMI 27.5 \pm 3.8. The mean follow-up time for the postoperative polysomnogram was 10.9 months. There were 575 patients in nose group, and 160 patients in no nose group. The mean age for the nose group was 44.6 \pm 11.4, while no nose group was 44.2 \pm 11.8. The mean preoperative BMI for nose group was 27.5 \pm 4.1, while the mean postoperative BMI for nose group was 26.3 \pm 3.7, while no nose group was 27.1 \pm 3.8.

As a whole group, there was a total of 2045 surgical procedures performed, 183 (8.9%) BRP, 342 (16.7%) ESP, 136 (6.7%) AP, 20 UVPF, 66 (3.2%) mUPPP, 26 (1.3%) ZPP, 16 (0.8%) FEP, 21 (1.0%) SP, 27 (1.3%) RP, 525 (25.7%) Septo, 425 (20.8%) RFIT, 150 (7.3%) RFTurb, 24 (1.2%) FESS, 54 (2.6%) RFBOT, 17 (0.8%) M.Gloss, and

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13 (0.63%) GAM. Table 1 shows the above breakdown by surgery and nonsurgery groups. There was a total of 130 mild OSA (98 nose group, 32 no nose group), 258 moderate OSA (215 nose group, 53 no nose group), and 337 severe OSA (262 nose group and 75 no nose group). The within mean change in AHI showed significant improvement (P < .001) for all the OSA categories for both nose and no nose groups, see Table 2. In the nose group, the mild OSA patients AHI improved from 9.0 to 6.3, the moderate OSA patients AHI improved from 43.9 to 17.9. In the no nose group, the mild OSA patients AHI worsened from 9.6 to 10.2, the moderate

OSA patients AHI improved from 20.9 to 12.3, and the severe OSA patients AHI improved from 54.3 to 23.5.

When comparing the AHI preoperative and postoperative change (adjusting for age and sex) between the surgery vs nonsurgery, differences were observed only in the mild (P = .012) and severe (P = .005) OSA categories.

Based on the two broad groups, the mean preoperative and postoperative AHI, BMI, and ESS for both nose group and no nose group were shown in Table 3.

The nose group had a significant preoperative and postoperative change in all three parameters compared to the no nose group

TABLE 1 Different types of surgical procedures performed

	Nose group (n = 575)	No nose group (n = 160)	P-value
BRP	153 (26.6)	30 (18.8)	.042
ESP	282 (49.0)	60 (37.5)	.010
AP	111 (19.3)	25 (15.6)	.289
UVPF	16 (2.8)	4 (2.5)	.846
mUPPP	50 (8.7)	16 (10.0)	.610
ZPP	21 (3.6)	5 (3.1)	.750
SP	17 (3.0)	4 (2.5)	.759
RP	15 (2.6)	12 (7.5)	.004
FEP	11 (1.9)	5 (3.1)	.001
RFBOT	41 (7.1)	13 (8.1)	.670
M.Gloss	15 (2.6)	2 (1.3)	.312
GAM	10 (1.7)	3 (1.9)	.908
Septo	525 (91.3)	-	
RFIT	425 (73.9)	-	
RFTurb	150 (26.1)	-	
FESS	24 (4.2)	-	

Notes: Values are n (%).

Abbreviations: AP, anterior palatoplasty; BRP, barbed reposition pharyngoplasty; ESP, expansion sphincter pharyngoplasty; FEP, functional expansion pharyngoplasty; FESS, functional endoscopic sinus surgery; GAM, genioglossus advancement mandibulotomy; M.Gloss, midline glossectomy; mUPPP, modified uvulopalatopharyngoplasty; RFBOT, the radiofrequency tongue base reduction technique; RFIT, radiofrequency turbinate reduction; RFTurb, turbinoplasty; RP, relocation pharyngoplasty; Septo, septoplasty; SP, suspension palatoplasty; UVPF, uvulopalatal flap; ZPP, Z-palatoplasty.

TABLE 2 Respective OSA severity, preop and postop AHI values (% change)

	Mild		Moderate		Severe	
AHI	Preop	Postop	Preop	Postop	Preop	Postop
Nose group (575)	9.0 (3.8)	6.3 (5.0)	23.2 (4.0)	11.4 (7.2)	43.9 (15.7)	17.9 (11.6)
No nose group (160)	9.6 (4.1)	10.2 (12.7)	20.9 (4.1)	12.3 (8.1)	54.3 (23.0)	23.5 (18.9)
Unadjusted difference between groups at postop	-3.9 95% CI (-6 P = .013	.9 to −0.82)	-0.94 95% CI (-3.2 P = .407	2 to 1.3)	-5.6 95% CI (-9.1 P = .002	to -2.1)
Adjusted ^a difference between groups at postop	-3.9 95% CI (-6 P = .012	.9 to -0.86)	-1.7 95% CI (-3.9 P = .147	9 to 0.59)	-4.8 95% CI (-8.2 P = .005	to –1.5)

Notes: Values are mean (SD).

^aAdjusted for preop, age, and gender.

 TABLE 3
 Respective preop and postop BMI, AHI, ESS (numeric change)

	вмі		AHI		ESS	
	Preop	Postop	Preop	Postop	Preop	Postop
Nose group (575)	27.5 (4.0)	26.3 (3.6)	32.7 (19.4)	13.5 (10.2)	11.3 (4.7)	5.3(3.2)
No nose group (160)	27.6 (4.1)	27.2 (3.8)	34.3 (25.0)	17.2 (16.0)	10.4 (5.5)	6.8 (2.8)
Unadjusted difference between groups at postop	-0.9 95% CI (-1.5 P < .001	to -0.26)	-3.6 95% CI (-5.7 P = .001	to -1.6)	–1.5 95% CI (–2.0 P < .001	to -0.92)
Adjusted ^a difference between groups at postop	-0.82 95% CI (-1.1 P < .001	to -0.52)	-2.4 95% CI (-4.5 P = .024	to -0.32)	-1.6 95% CI (-2.1 P < .001	to -1.1)

Notes: Values are mean (SD).

 TABLE 4
 Distribution of severity of OSA in both groups and success rates

АНІ	Mild	Moderate	Severe	Success rate	Unadjusted OR 95% CI P-value	Adjusted ^a OR 95% CI <i>P</i> -value
Nose group (n = 575)	98 (17.0)	215 (37.4)	262 (45.6)	392 (68.2)	1.7 (1.2-2.5) P = .002	1.8 (1.3-2.7) P = .001
No nose group (n = 160)	32 (20.0)	53 (33.1)	75 (46.9)	88 (55.0)		

Notes: Values are n (%).

TABLE 5 Distribution of level of obstruction between the groups (overlap would exist)

Level obstruction	Nose group	No nose group
Nose	575	0
Palate (ant-posterior)	198	40
Palate (lateral wall)	488	111
Tongue base	66	18

Notes: Palate (ant-posterior)—Anterior and posterior velopharyngeal collapse. Palate (lateral wall)—Lateral pharyngeal wall collapse.

(age and gender adjusted). For the preoperative and postoperative BMI, the change was -0.82 (95% CI -1.1 to -0.52), P < .001; for AHI, 2.4 (95% CI -4.5 to -0.32), P = .024 and for ESS, -1.6 (95% CI -2.1 to -1.1), P < .001.

The change in BMI did not have an effect on the AHI nor ESS (Cohen effect 0.03 and 0.14, respectively), the change in BMI was not a cofounding factor. Of interest, we noted that the success rate (based on reduction of AHI by 50% and below AHI <20) of surgery for the nose group was 68.2%, while the no nose group was 55.0% (P = .002) (Table 4).

Based on the preoperative assessment, in the nose group there were 686 palatal level obstructions (198 anterior-posterior collapse and 488 lateral wall collapse) and 66 base of tongue obstructions;

while the no nose group had 151 palatal level obstructions (40 anterior-posterior collapse and 111 lateral wall collapse) and 18 base of tongue obstructions (Table 5).

5 | DISCUSSION

Nasal surgery is generally part of the surgical armamentarium used to treat sleep apnea, as part of a multilevel surgical plan. Nasal surgery also may facilitate other treatments for sleep disordered breathing, rather than being a treatment modality on its own (eg, it helps reduce pressure requirements for a patient on CPAP).^{4,21} However, in some instances, a significant treatment effect may be achieved in the reduction of snoring, improvement in daytime symptoms, and/or even reduction (may not be significant) in markers of OSA severity (eg, AHI).^{3,7}

Most authors would concur that the nasal surgery, as a single site procedure would not significantly improve OSA severity but may have a significant effect on snoring, and some patients may reveal that they breathe subjectively better when awake.³⁻⁸ Verse et al showed through a meta-analysis of nine studies with 102 patients with OSA that the success rate of nasal surgery alone for these OSA patients are at best 20%.⁵ Li et al had similar findings in their meta-analysis of 13 articles from 1999 to 2009,⁶ two studies provided control groups and 11 articles (84.6%) consisted of prospective noncontrolled clinical

^aAdjusted for preop, age, and gender.

^aAdjusted for preop AHI, age, and gender.

trials (level II in evidence strength). The weighted mean apnea/ hypopnea index measured by polysomnography in nine studies decreased from 35.2 \pm 22.6 to 33.5 \pm 23.8 events/hour after nasal surgery (overall, P = .69).⁶ The pooled success rate of nasal surgery alone in treating OSA was only 16.7%. Epworth sleepiness scale scores in eight studies decreased from 10.6 \pm 3.9 to 7.1 \pm 3.7 (P < .001). However, nasal surgery for snoring assessed by individual questionnaires and visual analog scale as reported by the bed partner had significant improvement in snoring volume reduction (P < .05). In addition, the effects of single level nasal surgery on OSA patients' sleep parameters are noted to be unpredictable and unreliable.⁷

Interestingly, Friedman et al studied 49 OSA patients and demonstrated worsening of RDI in patients with mild OSA undergoing nasal surgery alone.8 This study showed that subjective nasal breathing improved in 49 (98%) patients, and snoring decreased or disappeared in 17 (34%) patients, while the remaining 33 (66%) patients did not notice any significant change in their snoring. Daytime energy levels increased in 39 (78%) patients and remained unchanged or worsened in 11 (22%). Friedman et al reviewed the polysomnographic data and found that there was no significant changes in respiratory disturbance index (RDI) or lowest oxygen saturation levels (LSaO₂). Patients who were on continuous positive airway pressure (CPAP) had their mean pressure requirements decreased after nasal surgery (P < .01). However, patients with mild OSA showed significant worsening in RDI (P < .05), whereas LSaO₂ levels were improved in the group with moderate OSA (P < .05). In patients with severe OSA neither the RDI levels nor the LSaO₂ changed, but CPAP levels required to alleviate the obstruction after surgery were reduced significantly (P < .01).

Intuitively, as the upper airway originates in the nose, the patency of the nasal air space is very crucial; any form of nasal blockage would increase resistance and lead to further negative pressure in the lower part of the upper airway (retropalatal and retroglossal area). Hence, it would make sound scientific sense to reduce the nasal resistance by opening the nasal patency for better airflow from the external environment to the nose, and into the lungs. This study's objective was to evaluate the effect of nasal surgery on multilevel surgery in OSA patients, matched for age, gender and BMI. It was shown that the nose group (in the group where nose surgery was included as part of the multilevel surgery) had better improvements in ESS and greater reductions in AHI compared to the no nose group (the group where no nose surgery was performed), in all categories of AHI severity with statistical significance. The surgical success rates of the nose group were also better compared to the no nose group (success rate of surgery for the nose group was 68.2%, while the no nose group was 55.0% [P = .002]). Similarly, El-Anwar et al demonstrated in 40 patients (one group with nose surgery in multilevel surgery and another group with no nose surgery in multilevel surgery), that the group with nose surgery had better postoperative results compared to the group who did not have nose surgery included (although the p value in their study was not statistically significant).²² We evaluated that the change in BMI did not have an effect on the AHI nor ESS, as the Cohen effect of BMI was 0.03 and 0.14, respectively, indicating that the change in BMI was not a cofounding factor and did not significantly affect the outcome nor results.

Theoretically, it is plausible that patients with severe nasal obstruction might have more severe upper airway obstruction and more negative hypopharyngeal pressures leading to more airway collapse, hence, correcting the nasal blockage would relieve the hypopharyngeal collapse. This might explain the better overall outcome in the nose group compared to the no nose group. It is also noted that in the upper airway of OSA patients, the collapsing anatomical structure is not always the primary site of flow limitation.^{23,24}

We recognize that with all clinical research data, there will be shortcomings. The shortcomings of this article are:

- 1. All the 735 patients were recruited from nine tertiary clinical centers, the choice of DISE is based on the tertiary center protocol, attending physician, clinical findings and clinical judgment, hence, some heterogenicity exists (especially in the DISE procedures and observations)
- 2. Although the presence of nasal symptoms of either allergic rhinitis and/or sinusitis, with/without nasal septal deviation, with/without nose polyps, and/or turbinate hypertrophy might be deemed as obvious and precise, the judgment decision is still based on the individual attending physician.
- 3. As this is a multicenter study, different surgeons are involved and hence, surgical procedures used for the individual patients may not be identical.
- 4. It is also prudent to recognize that the two groups are fairly heterogenous and confounding factors have been matched as far as possible.
- 5. It is acceptable to assume that patients with larger 3+/4+ tonsils, might have better surgical success rates, this might be a potential confounding factor, if there are more of these patients in any one group. However, raw data showed the percentage of large tonsil size 3+/4+ in the nose group was 15.2%, while in the no nose group was 12.7% (the difference was not statistically significant).
- 6. We are aware that these two groups of patients may be guite different, as patients with more severe nasal disease and/or nasal obstruction might have more severe OSA (although there are no scientific studies reported that have found any correlation between nasal obstruction to OSA severity); performing nose surgery itself might have a greater dramatic effect on the secondary collapse and the negative pressure in the hypopharyngeal (retroglossal) area, hence, better improvements in AHI and ESS parameters.
- 7. Inherent in all multicenter surgery trials, there would be variations in surgical protocols, surgical procedures and surgical decisions; however, it is assumed that every surgeon would aim for the best outcome results for every patient.

CONCLUSION

Consistent with the upper airway theory that a significant amount of airway resistance is due to nasal obstruction, it might be prudent to consider including nasal surgery as part of the multilevel OSA surgery for patients with OSA. Notwithstanding the fact that medical evidence shows that nose surgery alone for treatment of OSA is not efficacious, it is pertinent to note that "nose surgery is pivotal, but not primary" in the treatment of OSA.

DISCLOSURE OF INTERESTS

There are no financial disclosures and no conflict of interest for all the above authors.

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