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Effectiveness of drug-induced sleep endoscopy in improving outcomes of barbed pharyngoplasty for obstructive sleep apnea surgery: a prospective randomized trial

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Abstract

Purpose To observe the effectiveness of preoperative drug-induced sleep endoscopy in improving surgical results of patients undergoing single-level barbed pharyngoplasty surgery for OSA, using a prospective randomized model.

Methods A single-center randomized controlled trial with two prospective arms was carried out to compare functional results in patients treated with barbed reposition pharyngoplasty (BRP) surgery without a preoperative drug-induced sleep endoscopy (DISE) evaluation vs patients treated with BRP surgery performed after DISE evaluation of sites/patterns of collapse.

Results We compared 50 patients who underwent BRP without a preoperative DISE evaluation (Group A) and 42 patients (Group B) treated with BRP surgery but preoperatively selected by means of a preoperative DISE. In this second group of patients, after DISE evaluation, 70% of patients were selected for single-level BRP surgery because they showed an isolated velopharyngeal collapse at the DISE evaluation, without obstruction at other upper airway levels evaluated. Both groups of patients showed a statistically significant difference between preoperative and postoperative values of AHI, ODI, and LOS ($p<0.05$ in all cases). Comparing Group A and Group B patients, the therapeutic success rate was found to be 60% in patients treated without preoperative DISE evaluation and 83% in patients treated with preoperative DISE ($p = 0.02$).

Conclusion DISE appears to improve the surgical results of single-level velopharyngeal surgery due to the possibility of excluding patients with obstruction of the base of the tongue, the hypopharynx, and the epiglottis/larynx.

Keywords Obstructive sleep apnea · Barbed reposition pharyngoplasty · Drug-induced sleep endoscopy · OSA surgery · Randomized controlled trial

Introduction

To date, velopharyngeal surgery is the principle therapeutic approach in the surgical treatment of patients with obstructive sleep apnea (OSA) [1, 2]. Various velopharyngeal surgical techniques for OSA treatment have been proposed in the literature. Among these, lateral pharyngoplasty techniques such as expansion sphincter pharyngoplasty (ESP) and barbed reposition pharyngoplasty (BRP) have spread in recent years [1–5].

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These techniques are usually performed as a single-level surgery, which means that only the velo-oropharyngeal structures are remodeled to increase the oropharyngeal space and stabilize the pharyngeal lateral walls [6]. However, the success rate (reduction of the apnea index to less than 20 with at least a 50% reduction from baseline) of these techniques in single-level surgery may be lower than expected, despite the evidence of good postoperative anatomical results [4, 5, 7].

The causes of non-optimal functional results of a single-level surgery could be related to a multilevel upper airway obstruction in patients with OSA [8, 9]. In many of these patients, obstruction at the levels of the soft palate and oropharynx may not be the only ones. In fact, there may be other sites of obstruction, such as the base of the tongue, the hypopharynx, and the epiglottis/larynx whose presence might play a significant role in OSA pathogenesis. A careful selection and preoperative evaluation of candidates to surgery are therefore mandatory and could be considered the key points for improving surgical outcomes and avoiding surgical failures [8–12].

In the past years, the preoperative evaluation of patients candidate to velopharyngeal surgery was based exclusively on awake fibro-laryngoscopy and evaluation of the anatomical features [13, 14]. However, in recent years, the drug-induced sleep endoscopy (DISE) has been introduced into clinical practice for examining OSA patients. DISE allows the identification of sites, types, and patterns of upper airway obstructions/collapse during pharmacologically induced sleep [15–17]. Bharathi et al. [18] employed the DISE as a selection tool for the surgical management of OSA and observed that 40% of enrolled patients had retropalatal airway collapse, 23.3% had airway obstruction at the base of the tongue, 20% had airway obstruction with floppy epiglottis, and 12% had multiple level collapse. Moreover, DISE examination has proved to be superior to the awake fibro-laryngoscopy for identifying sites and collapse patterns in patients with OSA [13, 14].

Therefore, as indicated in the European position paper on drug-induced sleep endoscopy [19], DISE could be useful for guiding clinicians in the choice of the best surgical treatment. If during DISE only a velar and oropharyngeal obstruction is identified, a single-level pharyngoplasty surgery is usually indicated [20–30].

Several studies have attempted to assess the role of DISE in surgical decision-making and in improving the surgical success rate. However, most of these studies were retrospective or non-randomized studies. Therefore, clear conclusions regarding the effective value of DISE in improving the surgical success rate of velopharyngeal surgery have not been reported in literature [31–41].

The aim of this study was to assess the effectiveness of preoperative drug-induced sleep endoscopy in improving surgical results in patients scheduled for single-level barbed pharyngoplasty surgery for OSA, using a prospective randomized model.

Materials and methods

Trial design

This study was designed to evaluate prospectively the effectiveness of DISE in improving the results of barbed pharyngoplasty surgery using a randomized model. The study protocol was a single-center randomized controlled trial with two prospective arms: patients treated with BRP surgery without a preoperative DISE evaluation vs patients who underwent BRP surgery after DISE evaluation of sites/patterns of collapse. Figure 1 shows the trial design in detail.

All patients with a diagnosis of OSA consecutively referred to our Otolaryngology and Head Neck Department, Morgagni Pierantoni Hospital, Forlì, Italy, from January 2017 to February 2019 to evaluate the possibility of velopharyngeal surgery treatment for OSA, were initially considered possible candidates for inclusion in the study.

All patients underwent a preoperative home sleep apnea test (HSAT). The sleep studies were carried out in an unattended way by means of a Polymesam Unattended 8-channel Device. The following parameters were recorded during the sleep study: respiratory movement and airflow, heart rate, arterial oxygen saturation, patient's position, and sleep time.

The apnea-hypopnea index (AHI), Oxygen Desaturation Index (ODI), percentage of total sleep time with an oxygen saturation of < 90% (CT90), and the lowest SpO_2 (LOS) were scored and collected by experts in sleep medicine according to the American Academy of Sleep Medicine (AASM) guidelines [42].

Baseline assessment of all enrolled patients was performed: full medical history and body mass index (BMI) were obtained for all patients. Oropharyngeal and fiber optic rhino-laryngoscopy examinations were also performed: tonsil grade, Friedman palate position, and Friedman lingual tonsil grade were evaluated [28, 29].

Assessment of eligibility for participating in the study was provided by a group of researchers according to the criteria of inclusion/exclusion defined and reported in Table 1. Only patients who met specific criteria for performing single-level surgery at velopharyngeal level were initially enrolled in this study: patients with Friedman Palate position grade 4 and patients with Friedman lingual tonsil grades 3 and 4 were excluded because they were considered not ideal candidates for single-level velopharyngeal surgery. The same went for patients with a BMI >35 and patients showing a complete collapse at the hypopharyngeal base of

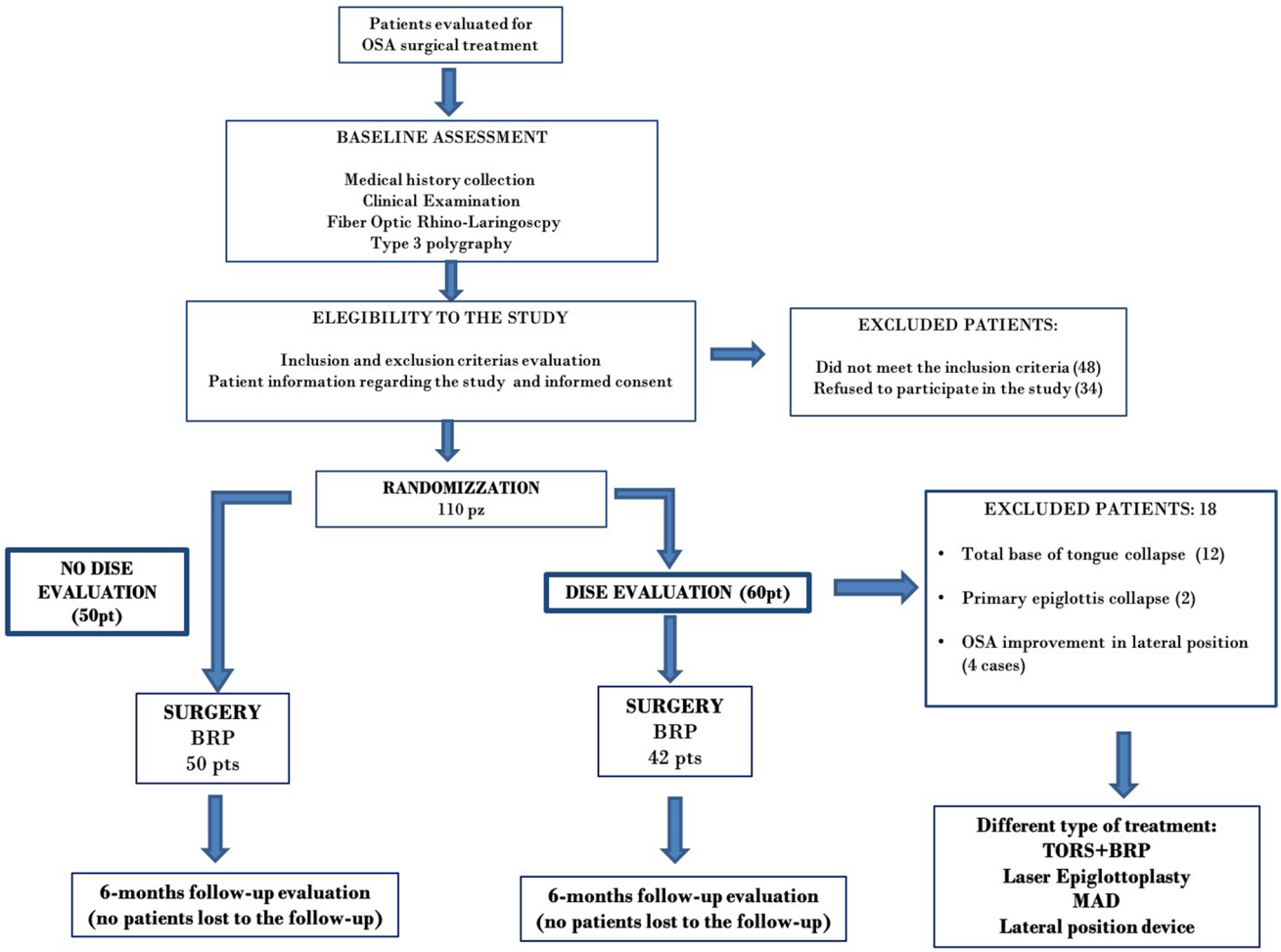

Fig. 1 Flowchart showing the trial design of the study

the tongue at Müller's maneuver to the awake endoscopy. Patients with mild OSA (AHI from 5 and up to 15) and simple snorers (AHI < 5/h) were also excluded from the study. Regarding the patients initially evaluated, 48 were excluded from the study in accordance with the exclusion criteria, whereas 34 subjects refused study inclusion. No blinded procedures were performed.

Table 1 Inclusion and exclusion criteria before patient enrollment and randomization

Inclusion criteria	*Exclusion criteria*
- Patients suffering from moderate to severe OSA (AHI ≥ 15 events/h) - Aged between 18 and 65 - BMI ≤ 35 - Failure of CPAP or low adherence to this treatment during the last 6 months (< 4 h per night)	- Central or mixed apneas events to the PSG - Serious psychiatric, cardiopulmonary, or neurological disease - American Society of Anesthesiologists (ASA) classification risk > 3 - Previous tonsillectomy - Previous palatal surgery for OSA treatment - Previous palatal surgery for snoring treatment - Pharmacological treatment for the OSA or drugs with an impact on the cognitive function - Significant craniofacial anomalies - Pregnant woman - Friedman palate score 4 - Friedman base of tongue classification 3 and 4 - Complete hypopharyngeal base of tongue collapse at Müller's maneuver

Randomization

A total of 110 patients were consecutively enrolled in the study and casually randomized into two groups of treatment. For each patient, randomization was conducted by choosing a piece of paper with a treatment order written on it out of a box (group 1 vs group 2). The chances of picking group 1 or group 2 were 50/50.

After randomization, patients were casually distributed into two groups of study:

- Group A (BRP surgery without preoperative DISE evaluation); 50 patients
- Group B (BRP surgery with preoperative DISE evaluation); 60 patients

Selection of candidates for surgery

All 50 patients included in Group A underwent BRP surgery with only an awake oropharyngeal and upper respiratory airway endoscopic evaluation to define the anatomical features related to the OSA (tonsil grade, palate position, Friedman lingual tonsil grade, and Müller's maneuver). These patients did not undergo other preoperative assessments.

In Group B, 60 patients candidate to single-level velopharyngeal surgery were preoperatively evaluated with DISE in order to define the site, type, and pattern of upper airway collapse.

All the DISE procedures were performed by two of the co-authors of this study (G. I. and C. V.) and were executed in the operating room with an anesthesiologist. A standardized DISE protocol, in accordance to the European position paper on DISE, was employed [19]. The VOTE classification as described by Kezirian et al. [43] was used to summarize the results of sites and pattern of collapse.

Patients were observed firstly in the standard supine primary position and then in lateral decubitus, for assessing significant modification of the upper airways during the latter position, in order to identify positional OSA (POSA).

The efficacy of mandibular advancement (pull-up maneuver) was tested in each patient during the DISE [16–19].

There were no complications related to the DISE procedure in any of the tested patients.

Surgery

After the randomization step, 92 patients underwent the same type of BRP surgery and were enrolled for comparison of surgical and clinical results: 50 patients of Group A and 42 patients of Group B.

All BRP procedures were performed by three senior surgeons with a long experience in OSA surgery and in all cases the standardized technique developed by Vicini et al. was employed (Fig. 2) [30].

Postoperative evaluation

All patients of both groups underwent periodic post-surgical follow-up evaluation (7 days, 3 months, and 6 months) and an HSAT evaluation at 6-month follow-up was performed. The same preoperative HSAT data were scored and collected.

Delta AHI (postoperative AHI - preoperative AHI), Delta ODI (postoperative ODI - preoperative ODI), and Delta LOS (postoperative LOS - preoperative LOS) were calculated in order to express the value of surgical efficacy and to compare the groups of patients. Therapeutic success was defined according to Sher's criteria, that is, the achievement of a postoperative value of AHI < 20 and a 50% improvement in the preoperative AHI value [1, 15–20]. This is the most used score to analyzed results of OSA surgery in the existing literature [31, 32]. The surgical success rate has been also calculated according to more strict criteria for analyzing the results of OSA surgery, that is, the achievement of an AHI <10 or an AHI< 5 [29].

In both groups of patients, the incidence of all possible postoperative complications (dysphagia, pharyngeal foreign body sensation, postoperative bleeding, rhinolalia, suture extrusion) was evaluated and compared.

Statistical analysis and ethical statement

To test the differences among groups, the chi-square test and Fisher's exact test were used for categorical data, while Student's *t* test was used for continuous data. Probability values lower than 0.05 were considered statistically significant. All analyses were performed with the STATA 12.1 software (Stata Corp., College Station, TX, USA).

The Local Ethics Committee approved the study (Ref. Number 4841) and all patients signed an informed consent for inclusion in the study before their enrollment.

Results

Preoperative results

Baseline data concerning age, gender, and anatomical features in both groups are shown in Table 2.

Homogeneity between groups was tested and no statistical differences emerged regarding average values of age, sex,

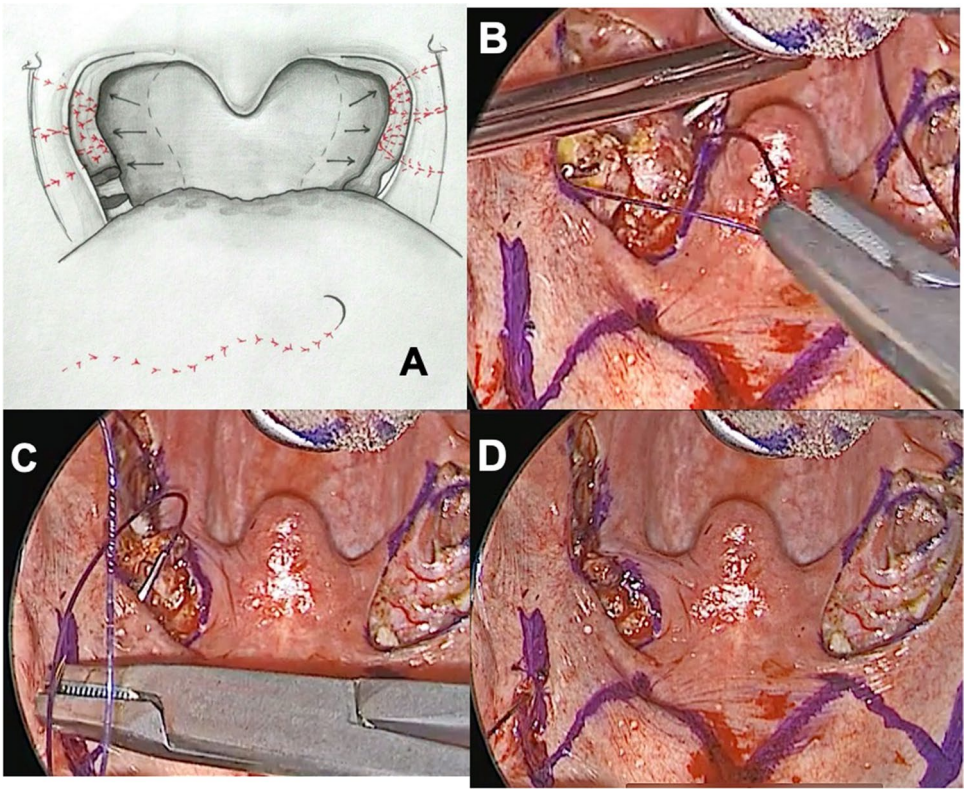

Fig. 2 **A** Schematization of barbed reposition pharyngoplasty (BRP) surgical technique: After bilateral tonsillectomy, meticulous sparing of the palatoglossus and palatopharyngeus muscles is performed. Single barbed suture, bidirectional polydioxanone absorbable monofilament, size 2.0, with transition zone in the middle is generally used. One needle is introduced at the center point and then passed laterally within the palate, turning around pterygomandibular raphe. The needle again is re-introduced close to point of exit, passing around the pterygomandibular raphe, until it comes out into the tonsillectomy bed, and then through the upper part of the palatopharyngeus muscle (**B**). Then, again, the needle is passed back through the tonsillectomy and bed, and then, this suture is suspended around the raphe again (**C**), A gentle traction is then applied on the thread only, and no knots are taken. These steps can be repeated 2–3 times between raphe and muscle until a satisfactory expansion is reached (**D**). The opposite side is done by the same way

anatomical features, pre-AHI, and BMI ($p>0.05$ for each parameter analyzed).

All 50 patients in Group A were surgically treated with BRP without intraoperative problems.

Table 3 summarizes DISE results (according to VOTE classification [43]) in the 60 patients initially enrolled in Group B.

In this group after DISE evaluation, 42 patients (70%) were selected for BRP surgery because they showed total or sub-total velopharyngeal collapse during drug-induced sleep evaluation, without presenting upper airway obstructions at other levels. Of these patients, 19 showed a concentric collapse of the velum (N.B. completed concentric collapse in 18 cases), whereas 12 had an antero-posterior collapse and 11 a lateral collapse of the velum (Table 3).

Eighteen patients (30%) showed a main base of tongue collapse, epiglottis, multilevel obstruction, or a positional sleep apnea and were hence considered not eligible for a single-level velopharyngeal surgery. These patients were excluded from the study protocol (Fig. 1) and were advised to undergo other types of treatment (mandibular advancement device, transoral robotic surgery in a multilevel setting, maxillomandibular advancement surgery).

No significant differences in average values of age, sex, pre-AHI, and BMI emerged between excluded and enrolled patients of Group B ($p>0.05$ for each parameter analyzed).

All 42 patients of Group B were surgically treated with BRP without intraoperative problems

Postoperative results

In Group A, patients presented a mean preoperative AHI value of 30.4 ±12.5 which went down to a postoperative value of 18.0±12.5, with a statistically significant difference ($p = 0.0001$) (Table 4).

In Group B, the patients presented a mean preoperative AHI value of 32.6 ±11.1 and a postoperative value of 13.4 ±7.89, with, in this case too, a statistically significant difference ($p = 0.0001$) (Table 4).

Table 2 Baseline characteristics of both groups of patients

	Group A BRB without preoperative DISE (50 cases)	***Group B BRP with preoperative DISE (42 cases)***	***p***
M/F ratio	47/3	37/5	0.7 (chi-square test)
Age	Mean = 45.5 ± 13.8 High = 65.0 Low=18.0 Median = 48.5	Mean = 47.9 ± 12.9 High = 64.0 Low = 21.0 Median = 50.0	0.3 (Student *t* test)
BMI	Mean = 28.1 ± 3 High = 34.0 Low = 20.3 Median = 27.4	Mean = 27.3 ± 3.3 High = 35.1 Low = 22.0 Median = 27.1	0.2 (Student *t* test)
Anatomical features	Number of cases/percentages	Number of cases/percentages	Chi-square test for contingency
Tonsil size*			0.5
1	12 (24%)	8 (19%)	
2	17 (34%)	14 (33%)	
3	16 (32%)	16 (38%)	
4	5 (10%)	4 (10%)	
Friedman palate position**			0.4
1	31(%)	25 (60%)	
2	17 (%)	12 (29%)	
3	2 (%)	5 (12%)	
4	-	-	
Friedman lingual tonsil grade ***			0.6
0	7 (14%)	5 (12%)	
1	32 (64%)	25 (60%)	
2	11 (22%)	12 (29%)	
3	-	-	
4	-	-	

Tonsil size*: size 1, tonsils are hidden within the pillars; size 2, tonsils are extended to the pillars; size 3, tonsils are extended beyond the pillars but not to the midline; size 4, tonsils are extended to the midline

Friedman Palate score**: position 1 allows visualization of the entire uvula and tonsils/pillars; position 2 allows visualization of the uvula but not the tonsils; position 3 allows visualization of the soft palate but not the uvula; position 4 allows visualization of the hard palate only

Friedman lingual tonsil grade ***: grade 0, complete absence of lymphoid tissue over the tongue base; grade 1, lymphoid tissue scattered over the tongue base; grade 2, lymphoid tissue covering the entirety of the tongue base with limited vertical thickness; grade 3, significantly raised lymphoid tissue covering the entirety of the tongue base, with noticeable vertical thickness approximately 5 to 10 mm in height; grade 4, lymphoid tissue covering the entire tongue base, rising above the tip of the epiglottis, with approximate vertical height 1 cm or more in thickness

Values of ODI, LOS, and CT90% in both groups of the study are reported in Table 4. In all cases, a statistical difference between preoperative and postoperative average values emerged.

Comparing Group A and Group B patients, an interesting finding emerged (Table 5). The therapeutic success rate was found to be 60% in patients treated without preoperative DISE evaluation and 83% in patients treated with preoperative DISE ($p = 0.001$). There were no substantial differences in DISE sites of obstruction/collapse between responders and non-responders in Group B.

Using an AHI <10 as criteria, the surgical success rate decreased to 34% and 54% for Groups A and B, while, considering an AHI <5, the percentage was further reduced to 18% and 21.4% of Groups A and B respectively.

The statistical analysis between the Delta AHI of the two groups of patients revealed a statistically significant difference (−12.4 ± 11.4 vs −19.2 ± 10.5; $p = 0.003$), as well as the Delta ODI (−12.6 ± 10.4 vs −19.6 ± 11.2; $p = 0.004$). Differently, the Delta LOS was calculated as −4.82 ±9.54 and −7.42 ±8.21 without a statistical difference between groups (p=0.15).

Table 6 shows the incidence of postoperative complications in both groups of patients. No differences between groups emerged for all the postoperative complications analyzed ($p > 0.05$ for all complications).

Table 3 Results of DISE evaluation in Group B patients

Results of DISE of 60 patients evaluated for Group B inclusion				
Sites and degree of collapse at DISE evaluation	VOTE classification	Enrolled/excluded in the Group B of the study	Number of patients	Pattern of collapse
Complete or partial velum and oropharyngeal obstruction—no obstruction to the other levels of evaluation	V2O2T0E0 V2O1T0E0 V1O1T0E0 V1O2 T0E0 Total	Enrolled Enrolled Enrolled Enrolled	10 (24%) 22 (52%) 4 (10%) 6 (14%) **42 (70%)**	Velum pattern of collapse Antero-posterior/lateral/concentric 3/1/6 5/5/12 2/2/0 2/3/1 12/11/19 Oropharyngeal pattern of collapse 100% lateral
Complete or partial tongue base collapses—any type of velum and oropharyngeal collapse	V (0-1-2) O (0-1-2) T (1) E (0) V (0-1-2) O (0-1-2) T (2) E (0) Total	Excluded Excluded	2 (3%) 10 (17%) **12 (20%)**	Base of tongue pattern of collapse 100% antero-posterior
Primary laryngeal/epiglottis obstruction	V (0-1-2) O (0-1-2) T (1) E (1) V (0-1-2) O (0-1-2) T (1) E (2) Total	Excluded Excluded	- 2 (3%) **2 (3%)**	Epiglottis pattern of collapse 100% antero-posterior
Positional OSA patients who preferred a noninvasive device for sleeping in lateral position	No sites of collapse in lateral position	Excluded	4 (7%)	-

VOTE classification by Kezirian et al.; degree of obstruction described as one number for each structure: 0, No obstruction; 1, Partial obstruction; 2, Complete obstruction

Discussion

This is the first RCT suggesting that the success of single-level surgery may be improved after a preoperative DISE examination to confirm surgical candidacy.

Patient selection and choice of surgical procedure for OSA have traditionally relied on static examination of the awake patient, and thus may not accurately predict sites of obstruction during the sleeping state [15, 16, 18, 19]. Awake upper airway endoscopy can be done safely in the office setting and it is useful for evaluating any anatomic variants of the upper airway structures such as deviated nasal septum, turbinate hypertrophy, and adenotonsillar hypertrophy as well as for ruling out pathological obstruction such as nasal polyps and tumors [15, 16, 20–30]. Tonsil grade, Friedman palate position, and Friedman lingual tonsil grade have been considered useful scores for identifying patients in whom single-level velopharyngeal surgery should be avoided [28, 29]. Nevertheless, awake upper airway assessment is less useful for predicting the dynamic upper airway soft tissue collapse that occurs during sleep and may not identify some important sites of obstruction/collapse. To better identify the loci of obstruction, a specific examination called drug-induced sleep endoscopy has been proposed in the last years [15–17, 20–25]. DISE is a safe and practical technique for evaluating dynamic upper airway collapse during a drug-induced simulation of sleep.

DISE has been defined as superior to awake fibrolaryngoscopy in identifying sites of obstruction and collapse patterns of patients with OSA [15, 17]. As shown by Soares et al. [15], there is a significant difference between awake fiber optic nasal endoscopy with Müller's maneuver and DISE in the identification of hypopharyngeal/base of tongue collapse. The incidence of severe retrolingual collapse identified via DISE was 84.9% compared to 35.8% via awake fiber optic evaluation ($p < .0001$). Yegïn et al. [13] themselves, comparing DISE and Müller's maneuver for diagnosing the site of obstruction, observed that there was no statistically significant concordance between these two examinations regarding antero-posterior collapse of the tongue (23.8%) and epiglottis (42.9%).

DISE evaluation makes it possible to identify whether obstruction at the base of the tongue, the hypopharynx, and the epiglottis/larynx or more sites of obstruction/collapse is present during sleep and if they play a significant role in OSA pathogenesis [16, 33]. Single-level velopharyngeal surgery may not have the desired therapeutic effects if these obstructions are present. Therefore, some authors have proposed DISE as a useful tool in preoperative planning, identifying which patients are good candidates for single-level surgery and patients who require multilevel surgery [34–36].

Table 4 pre- and postoperative results of AHI, ODI, LOS, and CT90% in Group A and Group B patients

	Pre-AHI	Post-AHI	*p value*	Pre-ODI	Post-ODI	*p value*	Pre-LOS	Post-LOS	*p value*	Pre-CT 90%	Post-CT 90%	*p value*
Group A	30.4 ±12.5	18.0 ±13.5	0.0001	28.0 ±12.5	15.4 ±12.6	0.0001	81.6 ±7.82	86.4 ±7.1	0.002	13.9	6.9	0.0001
Group B	32.6 ±11.1	13.4 ±8.89	0.0001	30.1 ±11.1	10.9 ±7.8	0.0001	80.88 ±7.68	88.3 ± 5.8	0.0001	15.1	4.2	0.0001

CT90% percentage of total sleep time with an oxygen saturation of <90%. Statistical difference evaluated using the Student *t* test

Gillespie et al. [36] compared the surgical planning based on the Muller maneuver with that based on DISE and found that in 62% of cases the surgical plans had been modified after DISE evaluation, due to its results. Similarly, a systemic review of eight studies and 535 OSA patients revealed that surgical planning is modified by preoperative DISE evaluation in 50.2% of cases [40].

The aim of this study was to assess the effectiveness of DISE in improving outcomes of barbed pharyngoplasty for OSA: for this purpose, a prospective randomized model was adopted.

We compared 50 patients who underwent BRP without a preoperative DISE evaluation (Group A) and 42 patients (Group B) treated with BRP surgery but preoperatively selected via preoperative DISE.

Initially, in Group B of our study, after anatomical examination of the static upper airways and casual randomization, 60 patients were enrolled as candidates for single-level velopharyngeal surgery. During DISE evaluation 30% of these patients presented more or different sites of collapse rather than the velopharyngeal region alone and were not considered eligible for a single-level velopharyngeal surgery due to a higher risk of surgical failure. Of the initially evaluated patients, 70% were selected for single-level BRP surgery because they showed a complete velopharyngeal collapse at drug-induced sleep evaluation, without obstruction/collapse at the other upper airway levels evaluated.

Seventy percent of the patients considered eligible for single-level velopharyngeal surgery after DISE evaluation may appear to be a high proportion. However, it should be considered that this high percentage of patients could be related to the pre-selection of patients based on awake examinations and to the clinical characteristics and exclusion criteria adopted in patients candidate to single-level velopharyngeal surgery. The groups analyzed showed similar age, sex, BMI, and anatomical features (no differences in the preoperative tonsil grade, palate position, and Friedman lingual tonsil grade), suggesting that patients with similar features were evaluated after randomization.

Both groups of patients showed statistically significant differences between preoperative and postoperative values of AHI, ODI, and LOS ($p<0.05$ in all cases). However, comparing Group A and Group B patients, the therapeutic success rate was found to be 60% in patients treated without preoperative DISE evaluation and 83% in patients treated after a preoperative DISE evaluation ($p = 0.02$).

The success rate, considering a postoperative AHI <10, was 34% and 54%, in Groups A and group B respectively; it was further reduced considering an AHI <5 (18% Group A and 21% Group B). As logical to expect, the therapeutic success rate was lower using more rigorous successful criteria, though these values appeared in line with results of other authors that have applied these more severe criteria

Table 5 Comparison of Groups A and B regarding Delta AHI, Delta ODI, Delta LOS, and success rate

	Group A BRB without preoperative DISE	*Group B BRP with preoperative DISE*	*p value* Student *t* test
Delta AHI	−12.4±11.4	−19.2±10.5	**0.003**
Delta ODI	−12.6±10.4	−19.6±11.2	**0.004**
Delta LOS	−4.82±9.54	−7.42±8.21	0.15
Success rate defined as AHI < 20 and 50% improvement in AHI	30/50 (60%)	35/42 (83%)	(Chi-square test) **0.001**
Success rate defined as AHI<10	17/50 (34%)	23/42 (54%)	0.05
Success rate defined as AHI<5	9/50 (18%)	9/42 (21%)	0.4

Table 6 Comparison of Groups A and B regarding postoperative complications

Postoperative complications	Group A *(50 cases)*		Group B *(42 cases)*		*p* value (chi-square test - Fisher's exact test)
	n of cases	Percentage	*n* of cases	Percentage	
No complications					
Postoperative bleeding	3	6%	2	5%	1
Partial thread extrusion	6	12%	5	12%	1
Temporary dysphagia	9	18%	7	17%	1
Permanent foreign body sensation in the throat	2	4%	2	5%	1

of surgical success [1, 29]. Besides, Groups A and B still showed a statistical difference in the percentage of patients with a postoperative AHI <10 ($p = 0.05$). Differently, there was no statistical difference, between the two groups, in patients that showed a postoperative AHI <5 ($p = 0.4$). This last result could be probably related to the low number of patients that matched this very rigorous postoperative criteria of surgical success.

These findings show a difference in success rates between patients investigated using DISE and those evaluated by means of awake fibro-laryngoscopy alone.

In the literature, many studies on DISE have been published but few of these have properly assessed its contribution and implication in increasing the success rate of single-level velopharyngeal surgery [31–40]. The results of these studies are very heterogeneous in terms of surgical techniques, type of patients analyzed, and study protocols employed. Different results regarding the impact of DISE on surgical outcomes have been reported, and there is no consensus in the literature regarding the use of DISE for improving the surgical success rate of velopharyngeal surgery [15–17, 25–28, 31–39].

Some studies, in accordance with our results, suggest that DISE improves success rates, probably because it helps to select the most appropriate operative technique [31–35]. A single-center retrospective analysis of 87 patients found that the mean postoperative AHI was lower in patients preoperatively evaluated by DISE than in the non-DISE group (10 versus 19 events/hour, $p = 0.052$). A better surgical success rate also occurred more frequently in the DISE group than in the non-DISE group (86% versus 51%, $p < 0.001$) [44]. Aktas et al. themselves [34] found that the different patterns of airway obstruction seen on DISE could predict different outcomes after tonsillectomy and uvulopalatopharyngoplasty. Twenty OSA patients with soft palate obstruction identified during Müller's maneuver underwent DISE before surgery. The levels of obstruction seen during DISE were categorized into upper airway obstruction (i.e., originating from the uvula, soft palate, and/or tonsils) and lower airway obstruction (i.e., originating from the tongue base and/or epiglottis). A higher surgical success rate was reported in the group with upper airway obstruction identified by DISE ($p < 0.05$). The group with lower airway obstruction had a lower success rate ($p < 0.01$). According to their findings in a multicenter cohort study of 275 participants, Green et al. [33] identified an association between surgical outcomes and certain preoperative DISE findings. In this study, tongue-related obstruction was associated with a lower odds ratio of surgical response.

On the other hand, some authors report that DISE makes no difference to surgical outcomes. Baudouin et al. [38] reported the efficacy of preoperative DISE evaluation in a retrospective single-center study in patients with OSA treated by single-level surgery (tonsillectomy with or without pharyngoplasty). Efficacy was compared between groups without (Group A) and with tongue base or laryngeal collapse evidenced at preoperative DISE evaluation (Group B).

The success rate was 66.7% in Group A and 59.3% in Group B with no statistically significant difference between the two groups ($p>0.1$). However, it should be noted that the retrospective nature of the study and the different rates of surgeries performed in the two groups of study (tonsillectomy + palatopharyngoplasty performed in 55.6% of Group A and 77.8% of Group B cases) could have influenced reported outcomes.

Similarly, in the study performed by Hsu et al. [39], patients with single-level or multilevel obstruction on DISE treated with a single-level palatopharyngoplasty were compared. The authors concluded that patients with multilevel obstruction on preoperative DISE had an AHI outcome similar to those with velopharyngeal single-level obstruction. However, subclassifying patients into 3 groups according to the severity of tongue base obstruction on DISE (group 1 no base of tongue obstruction, group 2 partial or no obstruction, group 3 complete obstruction), different results emerged; the postoperative mean AHI of group 3 was significantly lower than the preoperative AHI mean in the other two groups (15.4 ± 20.5 versus 42.6 ± 20.6, $p = .0002$).

The effect of DISE on surgical outcome was evaluated by Pang et al. [31] in a non-randomized, prospective study comprising 326 patients with OSA. They analyzed 170 patients preoperatively evaluated with DISE and 156 patients surgically treated without preoperative DISE evaluation. In this study, it seemed apparent that the patients in whom a preoperative DISE was not performed had better surgical outcomes compared to those patients submitted to preoperative DISE. This was demonstrated by the percentage change in AHI; the no-DISE group (156 patients) had a 59.8% reduction in AHI compared to the DISE group (170 patients) with a 48.4% reduction in AHI ($p < .001$). The overall mean AHI improvement in the no-DISE group was better than in the DISE group. However, as reported by the authors, some limitations of this study may have altered the results observed: (1) the no-DISE group comprised more patients with nose surgery, with 148 nose procedures performed compared to 113 nose procedures in the DISE group ($p < .001$). The difference was statistically significant; therefore, this could have explained the better success outcomes in the no-DISE group. It has been illustrated that nose surgery relieves the distal airway pressure and results in less negative pressure in the hypopharyngeal region and, therefore, possibly less hypopharyngeal collapse and better overall results; (2) due to the multicenter protocol of the study, the DISE procedure was not uniformly performed in all the involved centers; most centers used intravenous propofol, and one center had included intravenous dexmedetomidine. Besides, the clinicians performing the procedures were different for all the patients; (3) due to the multicentric nature of the study, surgeries were not performed by the same surgeon and may not have been performed with the same method.

There can be no doubt, as claimed by Carrasco-Llatas al [16], that by analyzing previous literature studies, it is not possible to clarify whether DISE patients have better surgical results than patients whose surgery was solely selected by means of UA awake exploration. The lack of prospective randomized trials approaching this issue and the heterogeneity of the study methods, surgical techniques, and DISE evaluation make it impossible to answer to this query.

The results of our prospective randomized study seem to confirm the evidence supporting the theory that preoperative DISE evaluation may improve the surgical success rate of single-level velopharyngeal surgery. Correct selection of candidates for single-level velopharyngeal surgery (possibility of excluding patients with obstruction of the base of the tongue, the hypopharynx, and the epiglottis/larynx) could be the reason for a preoperative DISE evaluation [31–35]. Furthermore, it should be remembered that DISE obstruction characteristics might help to choose one velopharyngeal technique rather than another. For example, patients with CCC appear to have a poor surgical response rate when classical UPPP is the chosen technique and patients with lateral velopharyngeal collapse did not respond to UPPP [31, 35] or to lateral partial muscle resection [32] but might be excellent candidates for lateral pharyngoplasty or expansion pharyngoplasty.

In this study, we have not addressed the differences in subjective outcomes (e.g., Epworth Sleepiness Scale, reduction of reported symptoms) between the patients surgically treated with or without preoperative DISE evaluation. Further studies are under way to verify the difference in postoperative subjective outcomes of patients preoperatively evaluated with DISE.

A possible limitation of preoperative DISE evaluation of patients with OSA, candidates for velopharyngeal surgery, involves the costs of the procedure and timing of surgery. The DISE requires the presence of expert anesthetic staff and a specifically equipped room and this implicates costs for the patient/hospital. This preoperative test could postpone surgery timing, especially in public health care hospitals. DISE is an evaluation technique that must be properly performed in accordance with well-established indications, technique, methods, and interpretations of the resulting data [15–17]. A DISE procedure incorrectly performed could provide confusing information that may lead to erroneous surgical planning.

Conclusions

DISE is a useful tool for investigating the UA of patients with OSA in order to improve the selection of patients candidate to surgery and to identify the best surgical procedure

according to sites and patterns of collapse. DISE appears to improve the surgical results of single-level velopharyngeal surgery owing to the possibility of excluding patients with obstruction of the base of the tongue, the hypopharynx, and the epiglottis/larynx.

We do not purport that DISE is a magical panacea. DISE is an evaluation technique that must be performed properly, with findings that must be interpreted in the light of other clinical characteristics (age, BMI, sex, anatomical findings including tonsil size) in an effort to improve surgical results. Even after treating all the areas of collapse and improving the UA lumen, there is no guarantee of success. A complete view of the patient is mandatory and the physiological traits underlying the UA collapse and OSA (loop gain, arousal threshold, and muscle response) must not be underestimated.

Declarations

Ethics approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Consent to participate Informed consent was obtained from all individual participants included in the study.

Conflict of interest The authors declare no competing interests.

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