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HEAD AND NECK

Suspension-expansion pharyngoplasty: a modified technique for oropharyngeal collapse in obstructive sleep apnea

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Abstract

Background and purpose Lateral pharyngeal wall (LPW) collapse plays a fundamental role in the pathogenesis of obstructive sleep apnea (OSA) and might determine the severity of the disease. This study presents the suspension/expansion pharyngoplasty (SEP) for the treatment of selected cases of OSA. The procedure aimed to splint LPW collapse via supporting and lateralization of both superior constrictor muscle (SCM) and palatopharyngeal muscle (PPM) individually and in two different planes.

Methods Twenty-one adult patients with single-level OSA who showed a lateral pattern of collapse at the oropharyngeal region had the modified procedure (SEP). The basic steps are the individual dissection of the muscular components of the lateral pharyngeal wall: SCM which was sutured anteriorly to the anterior tonsillar pillar and the PPM which was suspended to the pterygomandibular raphe. The supra-tonsillar fat was preserved.

Results At 9–12 months, highly significant improvement was reported as regards the mean Apnea hypopnea index and the mean lowest oxygen saturation ($p < 0.000$). The Epworth Sleepiness Scale and VAS-snoring showed a significant ($p < 0.05$) reduction. The oxygen desaturation index showed significant improvement. Non-significant improvements were reported as regards the percentage of total sleep time with oxygen saturation below 90%. According to Sher criteria, successful outcomes were reported in 17 patients.

Conclusion SEP could widen the pharyngeal airway and could support the collapsible lateral pharyngeal wall guarding against soft tissue collapse. In selected subjects, SEP had reported subjective and objective favorable outcomes with no significant comorbidities. The procedure could be combined with other procedures in multilevel surgery.

Level of evidence 4.

Keywords Obstructive sleep apnea · Lateral pharyngeal wall collapse · Snoring

Introduction

Obstructive sleep apnea (OSA) could harm the general health status of the patient and might end fatally. The disease has other social and economic issues that might harm the stability of the patient's family. Thus, OSA deserved attention among sleep researchers. Although CPAP is considered the first line of treatment in OSA, the surgical role is well-defined, and different surgical techniques were described. The basic idea of these techniques is the reduction of the inspiratory upper airway pressure via widening of the airway space and supporting its collapsible structures [1–7]. In modern sleep surgery, the basic surgical aim is to provide adequate support to these tissues via the implementation of functional, anatomically-based, and non-destructive procedures [8–14].

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Many authors mentioned the importance of the LPW collapse in the determination of the severity of OSA and its evident role in the pathogenesis of the disease [2, 15–22]. The palatine tonsils and the pharyngeal muscles (the superior pharyngeal constrictor; SCM and the palatopharyngeus; PPM) are the basic soft tissue components of the LPW. Surgical procedures were described to address the LPW collapse; these techniques aimed at the reduction of the static tissues (tonsillectomy) with the provision of adequate support and stability to LPW collapsible components; namely: SCM and PPM [1, 2, 7–10]. By review of available English literature, sleep surgeons tend to deal with LPW as a single unit. Moreover, a tendency towards dealing with the PPM was noticed; SCM did not have the same care [1, 2, 10–14].

The authors of this work suggest that individual care of both muscular components of LPW during sleep surgery (for the oropharyngeal area) would splint the whole LPW, would combat its collapse, and might enhance the surgical outcomes; this muscle care should avoid muscular jeopardizing steps.

The current study presents the suspension/expansion pharyngoplasty (SEP) for the treatment of selected cases of OSA (single-level oropharyngeal collapse) with a lateral pattern of collapse. This work aimed to assess the surgical applicability and to report the surgical outcomes of the procedure.

Patients and methods

Settings

This case series was conducted at the ORL-HN surgery department, Zagazig University Hospitals; Egypt from March 2018 to May 2022.

Ethical consideration

The institutional review board approved the research methodology (Zag IRB-9722). This study was conducted according to the declaration of Helsinki on Biomedical Research Involving Human Subjects. Informative consent was gained from all participants.

Inclusion and exclusion criteria

The study included adult OSA patients who had apnea–hypopnea index (AHI) > 10, body mass index (BMI) of ˂ 35 kg/m^2, and showed early grades of tonsillar enlargement (grades 1 and 2). Included subjects had reported a single-level, lateral oropharyngeal collapse (documented during preoperative endoscopic preparation). All included patients were CPAP intolerants.

Exclusion criteria included patients with multi-level upper airway obstruction, macroglossia, and elongated uvula (defined as the extension of the tip of the uvula below the level of the tongue with the maximum mouth opening and the tongue is in a relaxed position resting on the floor of the mouth). Patients with a history of surgical intervention for snoring/OSA were excluded.

Preoperative preparation

All patients had attended overnight polysomnography (PSG; in-lab level-II SOMNO screen TM plus/ SOMNO medics, Randersacker; Germany). On PSG, positional OSA (PP) was considered when the AHI in a supine position (AHI-s) was at least twice that of the non-supine position. Otherwise, the subject was considered as non-positional OSA (NPP) [23–26].

After the detailed sleep history and the otorhinolaryngology examination, an oral examination followed and included a clinical assessment of dentition, soft palate, and tonsil size (grades 1–4). Friedman's anatomic staging system (FAS) was applied [27–29]. Epworth Sleepiness Scale (ESS) was gained from all patients. Assessment of snoring with a 0–10 visual analog scale of snoring (VAS snoring: 0 = no snoring, 10 = maximum snoring loudness) was completed by the bed partners.

Flexible naso-endoscopy (NE) was performed. Site, degree, and pattern of UAC were reported. In our practice, we apply the positional awake flexible naso-endoscopy; the patient is examined by NE in the sitting (MM-S) and in the supine position (MM-P) [21, 22]. DISE was performed in the theatre before induction of general anesthesia. The NOHL grading system was applied for both DISE and NE. The NOHL scale defines the primary sites of UAC; namely: the nose, the oropharyngeal region, the hypopharyngeal region, and the larynx. For the first three levels, the grading of collapse is reported as (grade I) if the collapse is 0–25%, (grade II) if the collapse rages from 25 to 50%, grade III = 50–75%, and grade IV = 75–100%. As regards the pattern of collapse, it can be: lateral (L), concentric (C), or anteroposterior (AP) [15, 16].

Surgical techniques

All surgeries were performed under general anesthesia in the tonsillectomy position by the senior author (Askar SM) or under his direct supervision. Bilateral cold steel tonsillectomy was performed first with preservation of both the anterior and the posterior tonsillar pillars. Then, the supratonsillar triangle mucosa was removed (with the sparing of submucosal fat and the underlying palatal muscles). Then, the palatoglossus (PGM), PPM (longitudinal fibers), and SCM (transverse fibers) muscles were identified. Partial

dissection of the PPM was done: laterally from the SCM (a longitudinal gutter is created between PPM and SCM); the dissection continues till near the lower pole of the tonsil with frequent testing of the degree of mobility of the muscle towards the superior tonsillar pole. At this stage, both muscles (PPM and SCM) were surgically independent (Fig. 1). The SCM was plicated (with two figure-of-eight sutures using a round needle loaded with (Vicryl 2/0) upon itself and was then stitched laterally to the ipsilateral anterior tonsillar pillar. Then, a rounded needle (Vicryl 2/0) passed around the middle third of the partially-free PPM (with its buccopharyngeal fascial covering). The needle was then directed towards the ipsilateral pterygomandibular raphe (PMR), passing through the palatal muscles (no palatal tunnel). This suture was turned around the mid-portion of the PMR and was then returned the same way to the start point (at the middle part of the PPM). A second cephalic suspension suture (between the superior third of the PPM and the superior part of the PMR) was performed in the same fashion. Both suspension sutures were made submucosally and were tightened gently and tension-free to avoid mucosal tears. The same steps were done on the other side. The operative time of SEP was defined as the time taken for completion of the surgical procedure (SEP); the time of tonsillectomy and control of bleeding was not counted.

Postoperative care

Patients were discharged the following morning. The postoperative pain (VAS-pain) values were reported by patients on a daily basis at 5–28 days.

At 9–12 months postoperatively, VAS-snoring and ESS values were considered as the subjective outcome measures. The patient's satisfaction was evaluated by a 0–10 visual analog scale (VAS-satisfaction) where 0 = no satisfaction and 10 = maximum satisfaction. The bed partner was asked to complete VAS-snoring.

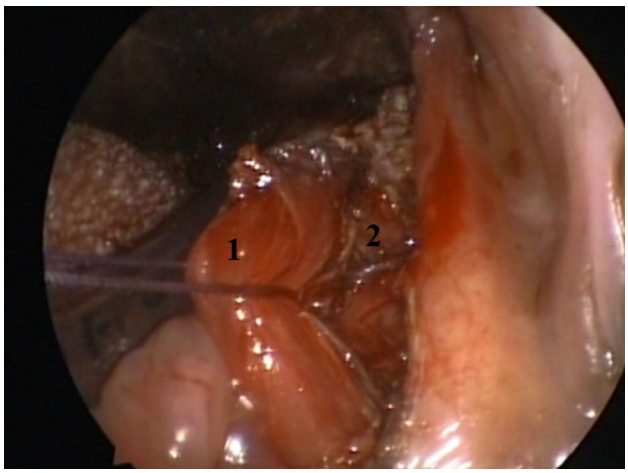

Fig. 1 Bed of right tonsil. 1: the palatopharyngeal muscle; 2: the superior pharyngeal constrictor muscle

MM-S, MM-P, and DISE were performed; the NOHL grading system was followed. The reports of preoperative/postoperative MM-S, and MM-P were gained independently from two sleep surgeons; in case of inconsistency, a third opinion was called. The reporters were blinded by the individual patient's identity.

The objective outcome measures were presented via the parameters of PSG (pre and postoperatively). Postoperative PSG was requested at 9–12 months. On PSG, AHI was recorded in different sleep positions. Also, the oxygen desaturation index (ODI: which is defined as the average number of O_2 desaturation episodes/hour of sleep) and the percentage of total sleep time with O_2 saturation below 90% (T90%) were recorded.

A successful surgical outcome was considered in patients with a postoperative AHI of less than 10. Patients with AHI of 10–20 were recorded as responders. Patients with a postoperative AHI > 20 (or an unchanged/ increased AHI) were reported as non-responders. Also, Sher's criteria for surgical success (≥ 50% decrease from the baseline AHI) were applied [12, 13, 17, 18].

Statistical analysis

Preoperative and postoperative evaluations were statistically compared using SPSS program version 20.0 (SPSS Inc., Chicago, Illinois; USA). Qualitative data were represented as frequencies and relative percentages. Quantitative data were expressed as mean ± SD (Standard deviation). A comparison of the quantitative variables between pre and postoperative was performed using the paired *t* test. The estimation of the power analysis (for the sample size) was 80% and the confidence interval (CI) was set to 95%. $p < 0.001$ indicates highly significant results, $p < 0.05$ was considered statistically significant while $p > 0.05$ was considered non-significant.

Results

Patient characteristics

This study included twenty-one patients (13 males and 8 females; Fig. 2). Table 1 summarizes the basic data of the study group. The tonsil size was reported as grade I in 9 patients (42.86%) and grade II in 12 patients (57.14%). On FAS, 14 patients were nominated as stage II (66.67%) and 7 patients (33.33%) were stage III. During preoperative MM-S, MM-P, and DISE, all included subjects showed single-level lateral oropharyngeal collapse. All patients reported high

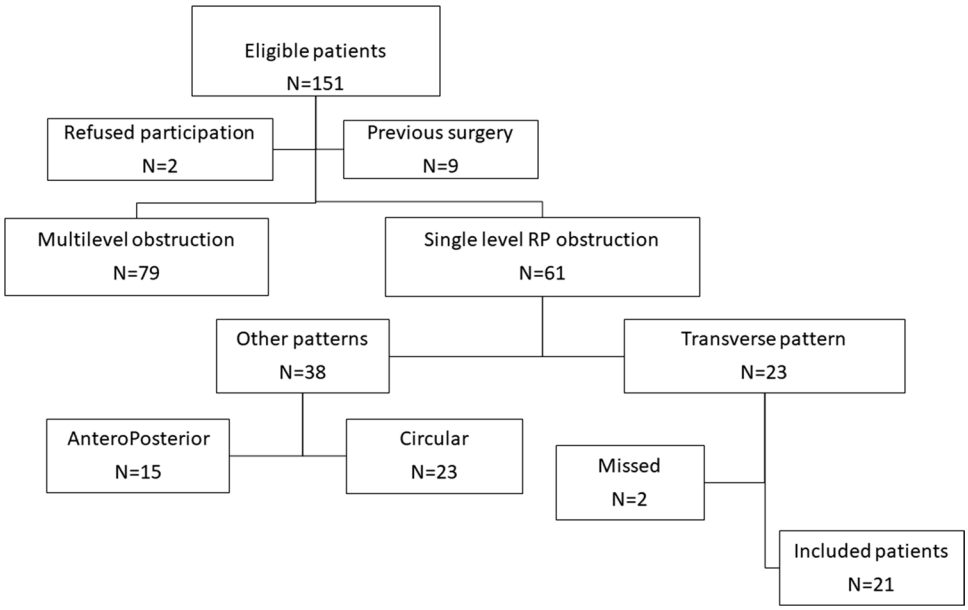

Fig. 2 Flow chart of the study group

Table 1 Basic data of the study group ($N=21$ patients)

Variables	Range	Mean ± SD
Age	23–51 years	33.90 ± 8.40
AHI	19.65–30.02	23.27 ± 6.59
BMI	26.7–32.9	28.05 ± 1.34
NC	39–44	41.26 ± 1.01
Sex	$N=21$	(%)
Male	13	61.9
Female	8	38.1

SD standard deviation, *N* number of participants, *AHI* Apnea Hypopnea Index, *BMI* body mass index, *NC* neck circumference (cm)

grades of collapse (NOHL scale grade 3–4; 75–100%; mean grade of 3.39 ± 0.52 for MM-S, 3.58 ± 0.06 for MM-P, and 3.67 ± 0.19 for DISE). All patients in this series underwent SEP (with tonsillectomy). The follow-up period ranged from 10 to 18 months (mean = 14.26 ± 0.51). The mean operative time was 22.06 ± 1.58 min (range 19–27).

Outcome

Postoperative pain was tolerable and was reported to be significantly improved by the 8th day; patients could regain a normal diet within 2–3 weeks (range = 12–23 days; mean = 15.33 ± 2.07). No early (bleeding, infection, wound dehiscence) nor late complications (velopharyngeal incompetence) were reported. Three female patients initially complained of taste disturbances, and two others (a male and a female) had noticed globus sensations. Those 5 patients were managed with a conservative approach and their complaints had subsided by the fourth to the sixth month. At 9–12 months, no patient had swallowing/phonatory problems. No significant changes were recorded as regards BMI or neck circumference ($p > 0.05$). The comparison of pre Vs postoperative endoscopic evaluation revealed significant improvement (NOHL scale: mean grade of 2.16 ± 0.37 for MM-S ($p < 0.0001$, $t = 8.8320$), and 2.29 ± 0.47 for MM-P; $p < 0.0001$, $t = 12.4765$). Postoperative DISE was performed in 16 patients and showed a mean of 2.34 ± 0.51; $P < 0.0001$, $t = 9.7751$.

In the comparison of pre versus postoperative PSG data, the mean total sleep time was significantly prolonged from 281.05 to 437.53 min ($p < 0.0001$). A highly significant improvement was reported in the mean AHI. None of the included subjects reported worsening AHI. Also, high significant improvements were gained ($p < 0.00$) as regards the mean lowest oxygen (LO_2) saturation. ESS and VAS-snoring showed a significant ($p < 0.05$) reduction (Fig. 3, 4; Table 2). As regards hypoxia-related parameters, ODI showed significant improvement while non-significant improvement was reported with T90% (Table 2).

With common criteria of success, 12 patients (57.14%) were reported as successful and 9 patients (42.86%) were considered responders. According to Sher criteria, successful outcomes were reported in 17 patients (80.95%). The overall percentage of improvement was 65.7 ± 12.6%.

Following Cartwright's criteria (and its modifications), the study group was divided into PP (14 patients; 66.67%) and NPP (7 patients, 33.33%) [23, 25]. Four patients of the NPP (57.14%) had shifted to PP; all PP patients had kept their positional configuration. The mean percentage of improvement was 68.39% for the PP group, while it was 59.77% for the NPP group. Upon comparison of postoperative PSG data of PP and NPP patients, a significant

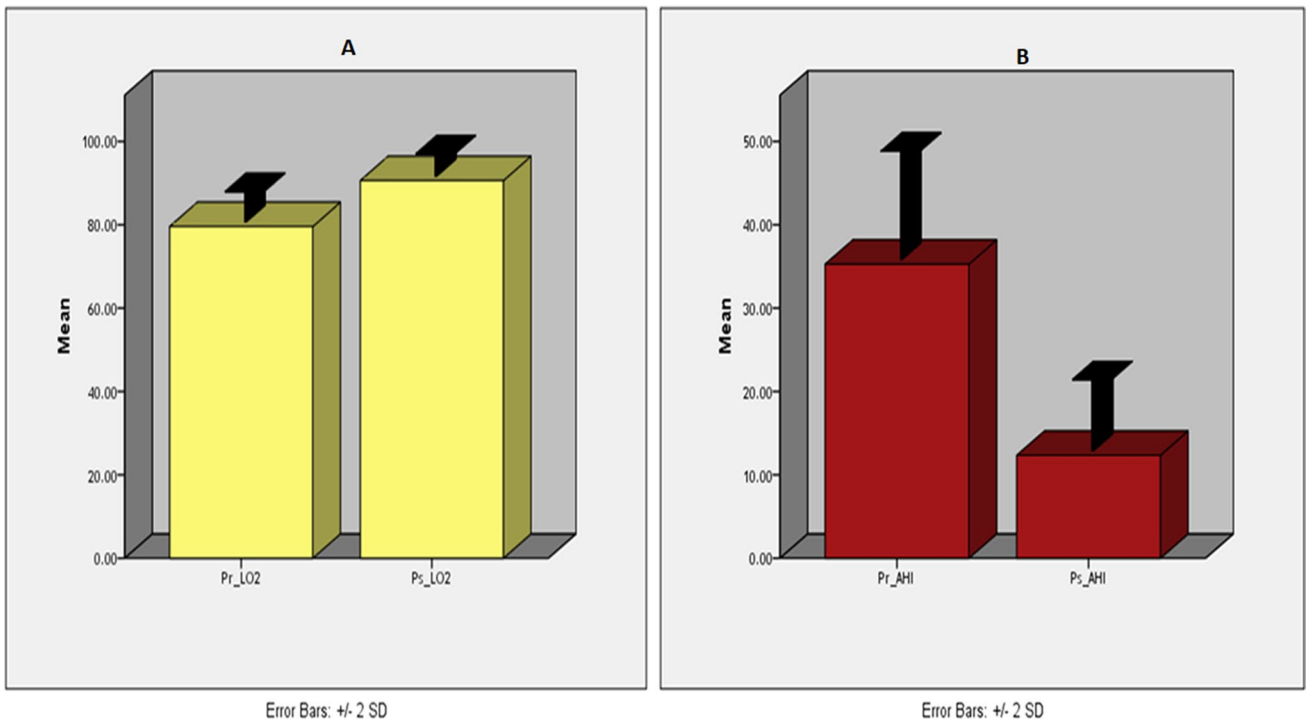

Fig. 3 Error bars ± standard deviation for preoperative and postoperative results of LO_2 (**A**) and AHI (**B**). *SD* standard deviation, *AHI* apnea–hypopnea index, LO_2 lowest oxygen saturation

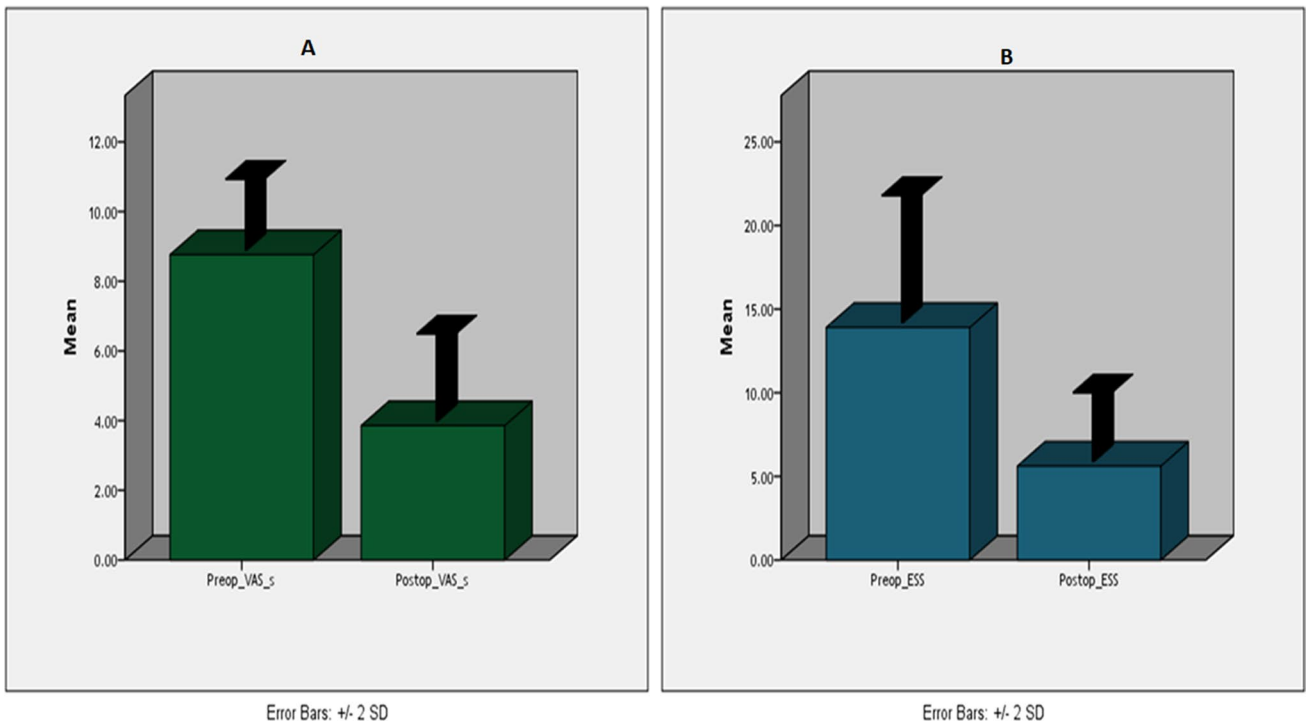

Fig. 4 Error bars ± standard deviation for preoperative and postoperative results of VAS-s (**A**) and ESS (**B**). *SD* standard deviation, *ESS* Epworth Sleepiness Scale, *VAS-s* the visual analog scale of snoring

Table 2 Pre and postoperative results of 21 patients

	Preop	Postop	*p* value	Paired t	% Of imp	CI 95%
AHI	23.57 ± 6.39	11.04 ± 3.15	< 0.0001***	8.0598	− 67.4	9.3880 to 15.6720
LO_2%	84.55 ± 4.60	91.47 ± 2.05	< 0.0001***	6.2968	12.9	− 9.1411 to − 4.6989
ESS	13.20 ± 3.85	9.61 ± 4.06	0.0054*	2.9403	− 59.7	1.1223 to 6.0577
VAS-s	9.06 ± 2.14	6.87 ± 3.27	0.0141*	2.5680	− 46.1	0.4664 to 3.9136
ODI	23.55 ± 12.07	15.31 ± 7.43	0.0111*	2.6641	− 43.25	1.9890 to 14.4910
T90%	9.02 ± 7.36	6.14 ± 5.28	0.1529 NS	1.4570	− 37.03	− 1.1149 to 6.8749

Preop preoperative mean, *Postop* postoperative mean, *AHI* apnea–hypopnea index, *LO_2%* lowest oxygen saturation percentage, *ESS* Epworth sleepiness scale, *VAS-s* visual analog scale for snoring, *CI 95%* 95% confidence interval of the difference, *% Of imp* percentage of improvement, *ODI* oxygen desaturation index, *T90%* percentage of total sleep time with oxygen saturation below 90%, *NS* non-significant

*Significant ($p < 0.05$); ***highly significant ($p < 0.001$)

difference was recorded as regards the mean AHI ($p = 0.007$; $t = 3.64$), while non-significant differences were recorded as regards LO_2, ESS, and VAS-s ($p > 0.05$). Upon comparison of ODI and T90% the difference was highly significant in both pre and postoperative means comparison (< 0.001).

Discussion

The exact pathogenesis of UAC in OSA is yet to be fully defined. Structural narrowing of the pharyngeal passages was considered an important contributing factor to OSA [1–3]. However, researchers could not establish a definite relationship between polysomnographic data and upper airway dimensions. In the recent sleep surgery era, functional neuromuscular mechanisms might play the leading role in OSA [2, 10–14, 19, 20].

The retro-palatal/oropharyngeal region is the most common site of obstruction in OSA patients and surgical interventions targeting it are the commonest practiced among sleep surgeons; the region shows more collapsibility (both structurally and functionally) in OSA patients than their matched controls [8–14]. Therefore, the planned surgical intervention should deal with both factors, via removal of static tissues (tonsillectomy) and support of the collapsible tissues. In recent strategies of sleep surgery, the main surgical target is to splint and support the soft UA tissues aiming to the prevention of their collapse.

Studies had demonstrated an evident role of the lateral pharyngeal wall (LPW) in the pathogenesis of OSA. LPW collapse could be considered the sole independent oropharyngeal factor that might pose a risk factor for OSA. Surgical procedures to splint LPW collapse had been presented [2, 9, 19–22]. The ideal procedure for the treatment of LPW collapse should be effective, anatomically based, non-destructive, and associated with minimal comorbidities [2, 20]. It should be easily conducted, performed within a relatively short time (as it is usually employed in a multilevel surgical plan), and should report consistent results among different surgeons. Such an ideal procedure should address all lateral wall muscular components, be performed with minimal muscular trauma, and should end with a completely mucosa-covered bed. Additionally, economics should be considered. Until recently, such a perfect maneuver is still to have.

Lateral pharyngoplasty (LP) is considered the first described surgical technique to provide support to the LPW in OSA patients with oropharyngeal collapse. In 10 patients, the original LP showed good results with a significant reduction of postoperative AHI. However, significant co-morbidities were experienced; significant dysphagia (for about 3 weeks), velopharyngeal insufficiency, and permanent loss of taste were reported [2, 8]. Pang and Tucker Woodson 2007 presented the expansion sphincter pharyngoplasty (EP). The success rate of EP was 78.2%. Postoperative dry throat and globus sensation were mentioned. Dehiscence of the PPM flap was reported. Noticeably, the procedure had much greater acceptance among sleep surgeons than LP [12]. In 2012, Sorrenti and Piccin presented the functional expansion pharyngoplasty technique (FEP) which was considered a less invasive modification of EP with a postoperative success rate of 89.2%. They reported postoperative tonsillar bleeding and foreign body sensation that lasted for a few months [7, 12]. Later on, Askar and El-Anwar, 2017 described the double suspension sutures technique (DSS). In comparison to the aforementioned techniques, the PPM was not cut. DSS did not have significant comorbidities. All PSG data showed significant improvement and reported good results (87%). However, DSS did not include individual intervention to the SCM and dealt with LPW as a single unit [11].

The current study was inspired by previous efforts; the provided technique (SEP) follows the concept that surgeries on LPW could splint the pharyngeal airway space and thus could prevent collapse in patients with OSA. The procedure was performed within a relatively short time and was associated with minimal comorbidities. SEP might be considered physiologic as it could deal with a basic functional problem (the increased collapsibility of the LPW); a physiological

correction of this collapsibility can be effective by taking the anatomical characteristics of both basic muscular components of LPW (SCM and PPM) via transposition of the vertical PPM antero-superiorly (to the rigid PMR) and the transverse SCM anteriorly to the anterior tonsillar pillar; the basic muscular components of LPW are transposed in two different planes. This idea would result in the widening of the retropalatal airway space with the advancing of the soft palate and would provide more stable support to the LPW. Moreover, the following scar tissues would develop in two planes resulting in a widened and more stable oropharyngeal area. SEP could be considered an anatomically based, non-destructive procedure.

A pivotal surgical point of interest is the transfer of the PPM with its facial covering (the buccopharyngeal fascia) to the ipsilateral PMR providing more effective resistance against collapse and less incidence of stitch dehiscence. Another important point is the preservation of the fat of the supra-tonsillar triangle; this small amount of fat would act as a lubrication area preventing the mechanical shearing between the transposed PPM and the palatal muscles. Thus, it would lead to more stable transposition, and less wound dehiscence; it might have a role in reducing postoperative pain and dysphagia. Moreover, SEP entailed transposition of both muscles with no cuts thus keeping the integrity of the basic muscular components of LPW. Also, it could preserve the basic structures of the soft palate (no palatal tunnels) and the uvula. Moreover, the procedure ends with a completely mucosa-covered bed [30].

Postoperative pain and swallowing difficulties were reasonable with SEP and lasted for a relatively short period. This can be attributed partly to limited tissue resection in SEP, the use of low-thermal injury tools, no muscle cuts, tension-releasing dissection, and complete mucosal covering of all raw areas. Also, SEP reported two cases of transient globus sensations; this mild complaint could be partly attributed to the preservation of the uvular tissues and the palatal mucosa and partly to a completely mucosalized bed which could avoid scarring of the palate and could lessen mucus retention.

This study reported the reflection of the sleeping position on the respiratory events (during both pre and postoperative PSG studies). Standardized frameworks were presented aiming at a better interpretation of surgical outcomes [23–25]. In the current study, fourteen patients were reported as PP while seven patients were NPP. During the postoperative follow-up, four NPP patients became PP. PP is more frequently reported among OSA patients with mild/moderate disease, while NPP is more common in severe OSA. Our data might agree with these data; moreover, our data showed that PP had lower AHI than NPP patients [31–33]. In the comparison of postoperative PSG data of PP and NPP patients, a significant difference was recorded as regards the mean AHI, while non-significant differences were recorded as regards LO_2, ESS, and VAS-s.

AHI was traditionally adopted as the main detector of grading severity in OSA. Sher et al., 1996 reviewed different surgical options for OSA patients and related the surgical success of these surgeries to the achievement of at least a 50% reduction in baseline AHI with postoperative results of less than 10. Also, they considered successful outcomes in those with postoperative reduction of respiratory distress index (RDI) to less than 20 [18]. Later, Sher 2002 presented a grading system (1–3) where grade 1A is the division of postoperative RDI on preoperative RDI to be less/equal to 50%, while grade 3 is the division of postoperative RDI on preoperative RDI to be less/equal to 40%, and is the division of postoperative AI on preoperative AI to be less/equal to 40%, with postoperative AI is less than 10 [34]. However, these numerical criteria have drawbacks. AHI does not reflect the true configuration of abnormal respiratory events (duration and depth). As sleep hypoxia-related complications were considered the main cause of morbidities and mortalities among OSA patients, recent sleep studies reported that hypoxia-related parameters (ODI and T90%) could be better parameters for the assessment of the individual patient [32–36]. The current study reported that PP had a highly significant improvement in postoperative ODI and T90%.

Pang and Rotenberg, 2016 suggested the SLEEP GOAL, as a comprehensive parameter of surgical success. They included the snoring VAS, the latency of sleep onset, the Epworth sleepiness scale, the execution time, the pressure (SBP), the gross weight/BMI, T90%, and AHI reduction by 50% (with AHI > 20), and the life score [37]. These parameters are difficult to interpret; however, they seem to correlate well with the recent advances in sleep science. It would open detailed discussion till a final validation is implemented. We suggest that AHI and hypoxia-related parameters are enough for the validation of surgical success.

Finally, SEP could be considered a cost-effective procedure as no special equipment (surgical microscope), no expensive materials/sutures, relatively short operative time, and the relatively short duration of the postoperative hospital stay and required medications.

Preoperative endoscopic examination showed lateral collapse at the oropharyngeal region by MM-S, MM-P, and DISE (100%). The degree of obstruction showed non-significant differences with a narrower grading difference between DISE and MM-P than DISE and MM-S. Moreover, this grading difference did not exceed one degree in all patients; surgically, this narrow difference would not affect surgical planning. Postoperative DISE was performed in 16 patients after SEP. Many reports suggest that DISE and MM show adequate accordance in the oropharyngeal area as regards degree and configuration of collapse [21, 22, 38–41].

This study has limitations. The relatively small number of included patients; however, we could find it acceptable as regards the narrow selection criteria. The study reports a single institutional/single surgical team experience with a relatively short follow-up period. It lacks a case–control group. We recommend the implementation of the procedure as a sole intervention and in multilevel sleep surgery plans. Long-term results reporting is needed.

Conclusion

This study provides the SEP technique for lateral wall collapse in moderate OSA patients. SEP could widen the pharyngeal airway and could splint the LPW guarding against pharyngeal collapse. SEP had reported subjective and objective favorable outcomes with no significant comorbidities. The procedure could be incorporated into a multilevel surgical plan. Further wide-scale, long-term studies are required.

Author contributions SMA provided the basic design and idea of the work; drafting; analysis of data and final approval of the version to be published. He ensures that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. OHA-H provided drafting, analysis of data and final approval of the version to be published. He ensures that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. AAE-B was responsible for the interpretation of data for the work, revising the work critically for important intellectual content and final approval of the version to be published, and agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. AMA was responsible for the interpretation of data for the work, revising the work critically for important intellectual content and final approval of the version to be published, and agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. AAA-S was responsible for the interpretation of data for the work, revising the work critically for important intellectual content and final approval of the version to be published, and agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Declarations

Conflict of interest Authors declare that they have no conflict of interest.

Ethical approval This article does not contain any studies with animals performed by any of the authors. 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.

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

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