



No-cutting remodelling intra-pharyngeal surgery can avoid CPAP in selected OSA patients: myth or reality?

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Abstract

Introduction Oropharyngeal surgery for Obstructive Sleep Apnea (OSA) has evolved from a radical excision of “redundant” soft tissue for the enlargement of the airway to a minimally invasive reconstruction to fulfill both preservation of pharyngeal function and improvement of sleep apnea. Recently, Alianza surgical technique has been successfully introduced as a new, non-resective procedure aimed to treat concentric pharyngeal collapse at the velum using Barbed Sutures. The aim of this study was to show the effectiveness and safety of Alianza technique as standalone surgical treatment in selected patients with moderate-severe OSA and concentric pharyngeal collapse that refused or did not tolerate Continuous Positive Airway Pressure therapy.

Materials and methods Effectiveness of the surgical procedure was assessed by means of the Epworth Sleepiness Scale (ESS), Home Sleep Test, and a 0–10 snoring VAS.

Results At the end of our selection process, 26 patients were enrolled, with a mean age of 52.7 ± 9.2 years, that undergone Alianza technique. There was a statistically significant reduction in mean post-operative apnea–hypopnea indexes (34.1 ± 11.5 – 16.3 ± 10.3 ; $p < 0.01$), mean oxygen desaturation index (29.0 ± 14.5 – 13.1 ± 9.2 ; $p < 0.01$), and mean ESS scores (12.1 ± 5.8 and 5.8 ± 4.4 ; $p < 0.01$). There was also a significant decrease in mean post-operative snoring VAS scores (7.85 ± 1.23 vs 3.2 ± 1.7 , $p < 0.01$). There were no major complications.

Conclusions Our preliminary results suggest that Alianza technique is a safe and repeatable surgery. Further studies on a larger scale are needed to confirm these encouraging data supporting the role of Alianza alone or in OSA multilevel surgery in selected OSA patients.

Keywords Sleep apnea · Barbed sutures · Barbed pharyngoplasty · Alianza and pharyngeal collapse

Introduction

Obstructive Sleep Apnea (OSA) is a worldwide sleep breathing disorder leading to excessive daytime sleepiness, hypertension, type 2 diabetes, cerebrovascular incidents, and even sudden cardiac death. Continuous Positive Airway Pressure (CPAP) is often used as first line-treatment, however failure in long-term adherence to CPAP treatment was reported in 25–50% of cases. For these reasons, in the last years, OSA and snoring surgical management underwent significant changes [1]. Newer procedures, less invasive or morbid, improving patients’ compliance, makes OSA surgery a reasonable alternative [2]. Oropharyngeal surgery for OSA has evolved from a radical excision of “redundant” soft tissue to a minimally invasive reconstruction to fulfill both preservation of pharyngeal function and improvement

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in sleep apnea [3]. To reduce the invasiveness of surgical procedures for increasing UA tension and given the good tolerability of permanent threads inside the human soft palate, Mantovani et al. [4] introduced a new suturing technology, called Barbed Sutures (BS), special knot-free tissue closure devices that allow homogeneous distribution of tensile closure forces. In 2017 [5], they proposed a new non-resective intra-pharyngeal surgical procedure named Alianza using BS in selected OSA patients with complete concentric collapse (CCC) at the velum, previously documented by means of Drug-Induced Sleep Endoscopy (DISE). This type of BP leads to greater tensioning of the palate and pharyngeal lateral walls. On the basis of the encouraging results recorded by Mantovani et al. [4] in patients with mild to severe OSA, the aim of this study was to show the effectiveness and safety of Alianza technique standing alone as surgical treatment in patients with moderate-severe OSA with CCC that refused or did not tolerate CPAP.

Materials and methods

Study design and population

A prospective clinical trial was carried out analyzing the records of 32 consecutive OSA patients who refused or failed to tolerate CPAP. They underwent non-resective pharyngoplasty with BS named Alianza as standing alone procedure at Campus Bio-Medico University of Rome between November 2018 and November 2020.

Surgical planning

Preoperative assessment included Home Sleep Test (HST) using the Watch-PAT device [6], endoscopic evaluation, sleep history assessment including the Epworth Sleepiness Scale (ESS), and severity of snoring assessed with a numeric Visual Analogue Scale (VAS). All patients underwent a thorough clinical examination that include height and weight measurements, neck circumference, Body Mass Index (BMI), assessment of the nasal cavity, posterior nasal space, oropharyngeal area, soft palatal redundancy, uvula size and thickness, tonsillar size, Friedman tongue position and Epworth Sleepiness Scale (ESS). The inclusion criteria were as follow: adult patients (older than 18 years old) with a diagnosis of moderate-severe OSA having circular palatal collapse at DISE (due to the combination of antero-posterior and latero-lateral palatal collapse), according to VOTE classification, who refused or did not tolerate nasal CPAP therapy as first line treatment, good nasal breathing, small tonsils (tonsil size 1 and 2 according to Friedman Staging System), BMI less than 30 kg/m², and ASA < 2. Exclusion criteria were: patients > 75 years and/or with severe medical

illness; patients with limited mouth opening (interincisive distance < 2 cm), BMI > 30 kg/m², tonsil size ≥ 3 (they were offered tonsillectomy), only antero-posterior palatal collapse or only latero-lateral palatal collapse and patients with less than 6 months of follow-up or lacking pre- and post-operative PSG and ESS data.

Surgical technique

The surgical technique used was Alianza Barbed Pharyngoplasty, as first introduced by Mantovani et al. [4], it combines the surgical steps of the Barbed Anterior Pharyngoplasty (BAPh) with those of the Barbed Roman Blinds Technique (BRBT). All the procedures were performed with patients under general anesthesia and orally intubated, exposed by a McIvor Mouth Gag. The patients were positioned in supine position with an under shoulder inflatable bag to keep the neck hyperextended. We routinely used two interlaced unidirectional barbed threads (Medtronic V-Loc™ 180, size 2–0 or 3–0, length 30 cm, mounted on taper-pointed 26-mm semicircular needle, absorption in 180 days, tensile strength 65% at 21 days) to obtain a bidirectional suture: each needle is passed in the looped-end of the other suture, then a gentle traction is applied to tighten a “flat knot”. To avoid that, the two looped ends were left extruded in the oral cavity to sink

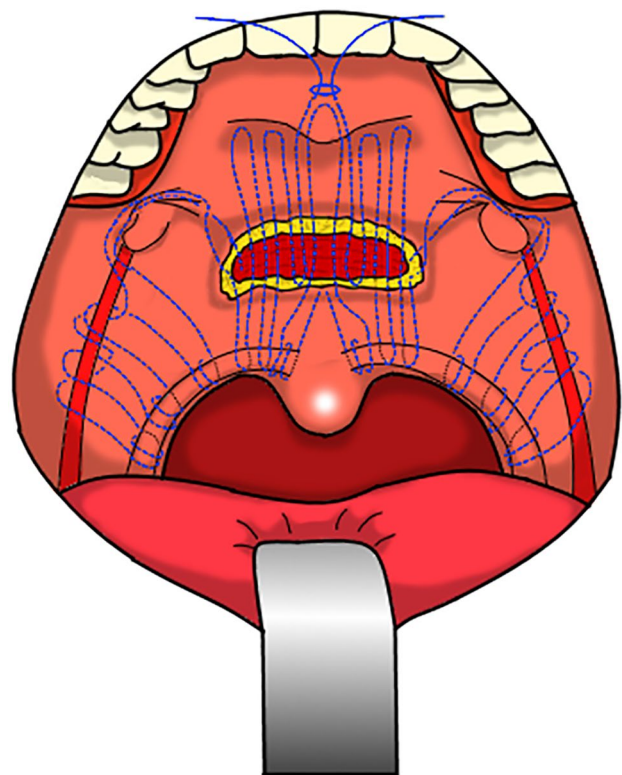


Fig. 1 Surgical drawings illustrating the planning of suture in Alianza technique

into a small incision in the mucosa over the Posterior Nasal Spine (PNS) (about 3 mm) (Fig. 1).

In all cases, Alianza was a single procedure, including if required tonsillectomy (preferably with plasma-mediated radio-frequency-based ablation-coablation), but without any hypopharyngeal/tongue surgery. Nasal procedures were performed before at a different stage than the pharyngeal surgery.

Post-operative care

Patients should be given the same postoperative instructions concerning diet, activity, and the medications of pain and infection as those usually indicated after tonsillectomy. In particular, patient is advised to take liquid diet for the first 24 h and soft diet for the next 2 weeks. Normal diet can be started after 2 weeks. Chlorhexidine mouthwashes after each meal are recommended during the first postoperative week. We give 1 g of paracetamol, three times a day for 5–7 days for analgesia and if the pain is severe, we add Ibuprofen for breakthrough pain. In addition, we give Amoxicillin/clavulanate (875/125 mg) given every 12 h for 5 days.

Follow up

Post-operatively, ENT examination, snoring VAS and PSS assessments and PSG were performed at least 6 months after surgery.

Statistical analysis

Descriptive statistics were used for the patients' demographic and clinical characteristics. The continuous variables were expressed using mean values \pm standard deviation (SD), median values and ranges. The pre- and post-operative comparisons of the PSG parameters (AHI and ODI values), snoring VAS and ESS scores were made using a Wilcoxon's signed rank sum test. Statistical significance was set at a p value < 0.05 , and the data were analysed using STATA 10.0 software (StataCorp, College Station, Texas, USA).

Results

At the end of our selection process, 26 patients who satisfied the inclusion criteria were enrolled (Fig. 2). The average hospitalization period was 2 ± 0.5 days. The mean follow-up was 6.5 ± 2 months. The pre- and post-operative AHI, ODI, ESS and snoring VAS values were showed in Table 1 and Figs. 3, 4, 5, 6.

According to Sher's criteria, surgical success rate was 84.8%. We noted 12 patients with AHI < 10 . There were no deaths and any significant complications such as

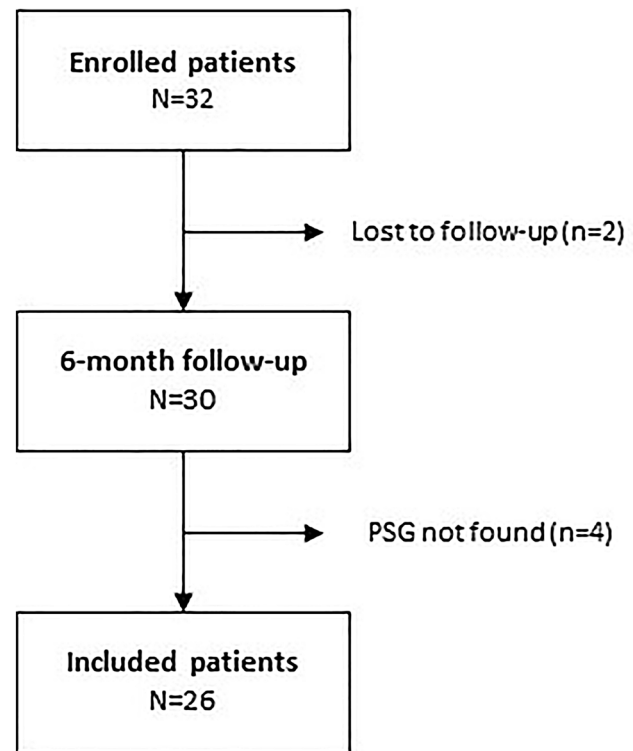


Fig. 2 Enrollment of patients

Table 1 Main demographic and clinical characteristics of the study populations expressed as means and standard deviation

Mean value \pm SD	Baseline	Post-op	p values
Age (years)	52.7 \pm 9.2		
No of males (%)	26 (100%)		
Neck circumference (cm)	39.25 \pm 12.3		
BMI (kg/m ²)	28.1 \pm 3.3	27.8 \pm 2.2	0.43
Tonsil score	0 (n=5) 1 (n=17) 2 (n=4)		
Friedman Tongue Position (FTP)	IIa (n=16) IIb (n=4) III (n=6)		
Friedman staging system	II (n=20) III (n=6)		
AHI (events/h)	34.1 \pm 11.5	16.3 \pm 10.3	< 0.01
ODI (events/h)	29.0 \pm 14.5	13.1 \pm 9.2	< 0.01
ESS	12.1 \pm 5.8	5.8 \pm 4.4	< 0.01
Snoring VAS	7.9 \pm 1.2	3.2 \pm 1.7	< 0.01
T90	9.79 \pm 4.58	3.60 \pm 3.02	< 0.01

post-operative infections or bleeding that required surgical intervention and hemostasis. Only minor complications were recorded such as partial knot extrusions (62.5%) and anterior pharyngoplasty dehiscence (5.45%). Oral feeding was

Fig. 3 Mean pre-operative and post-operative AHI

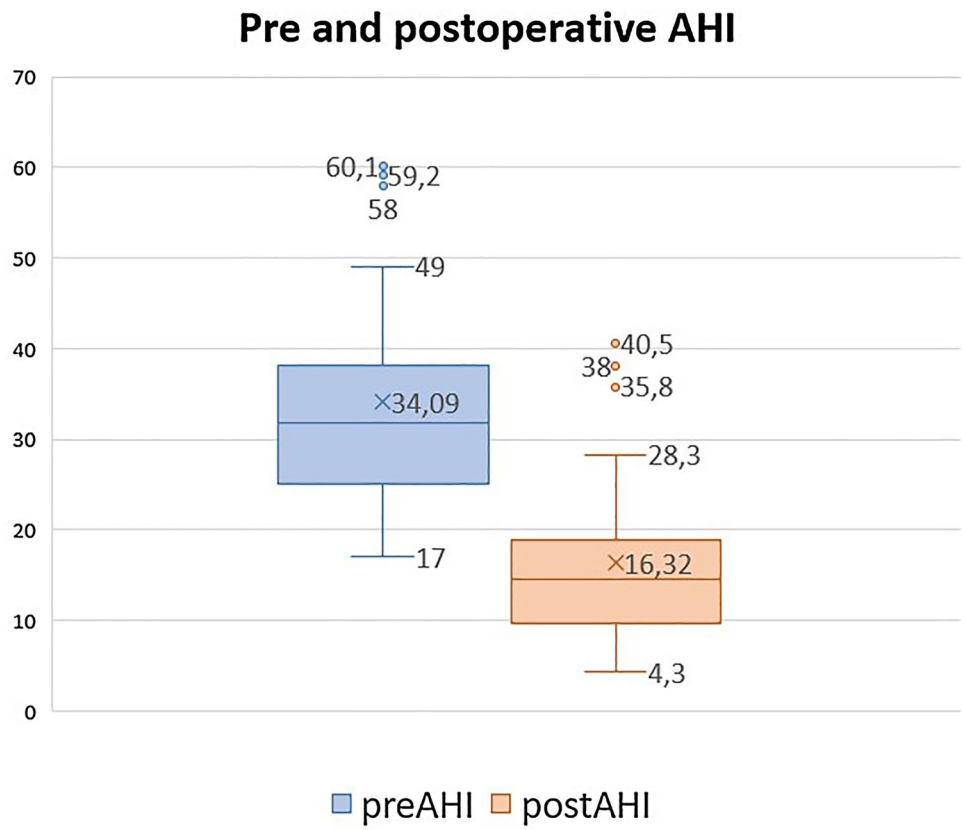


Fig. 4 Mean pre-operative and post-operative ODI

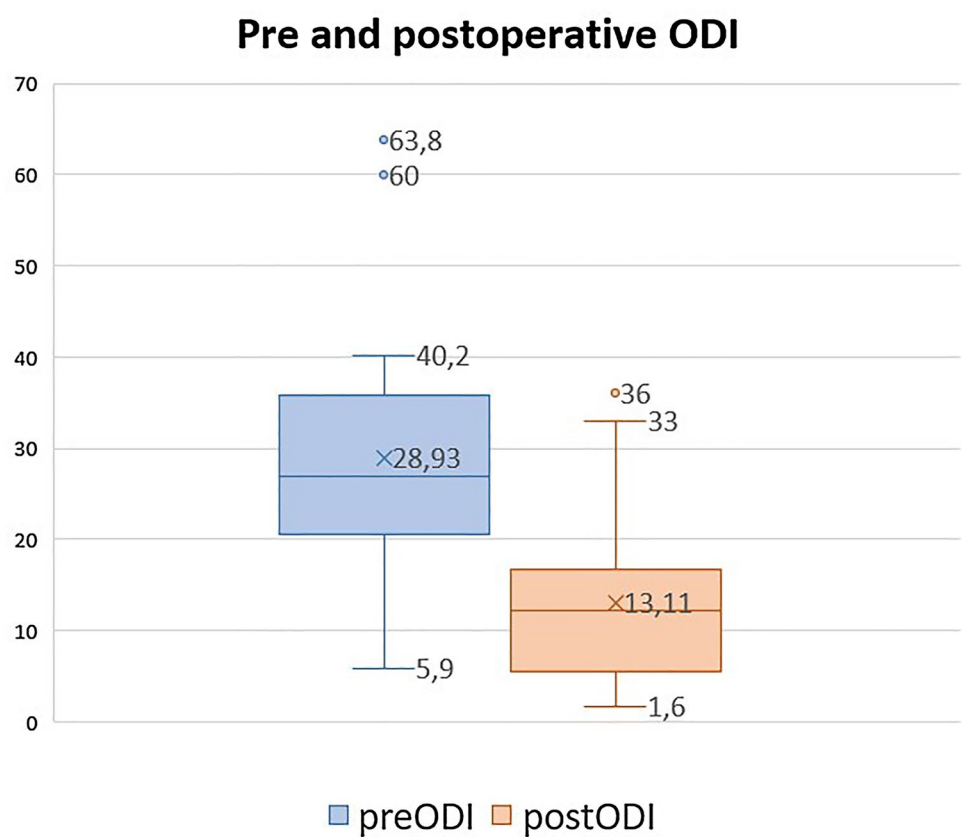


Fig. 5 Mean pre-operative and post-operative ESS scores

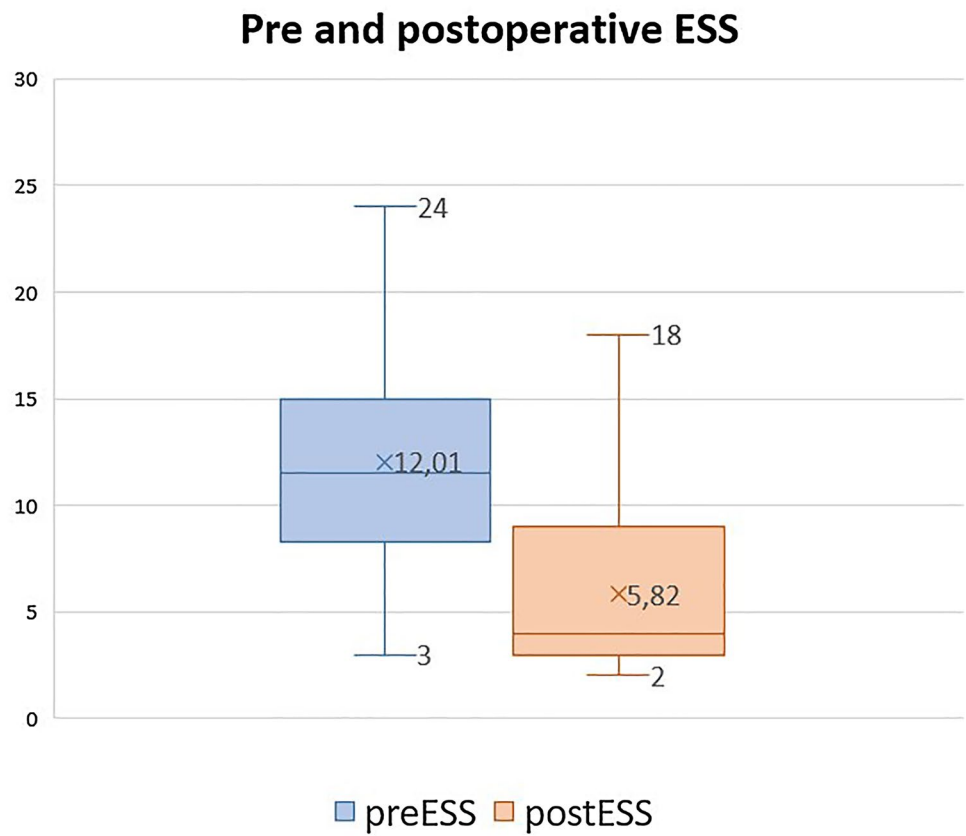
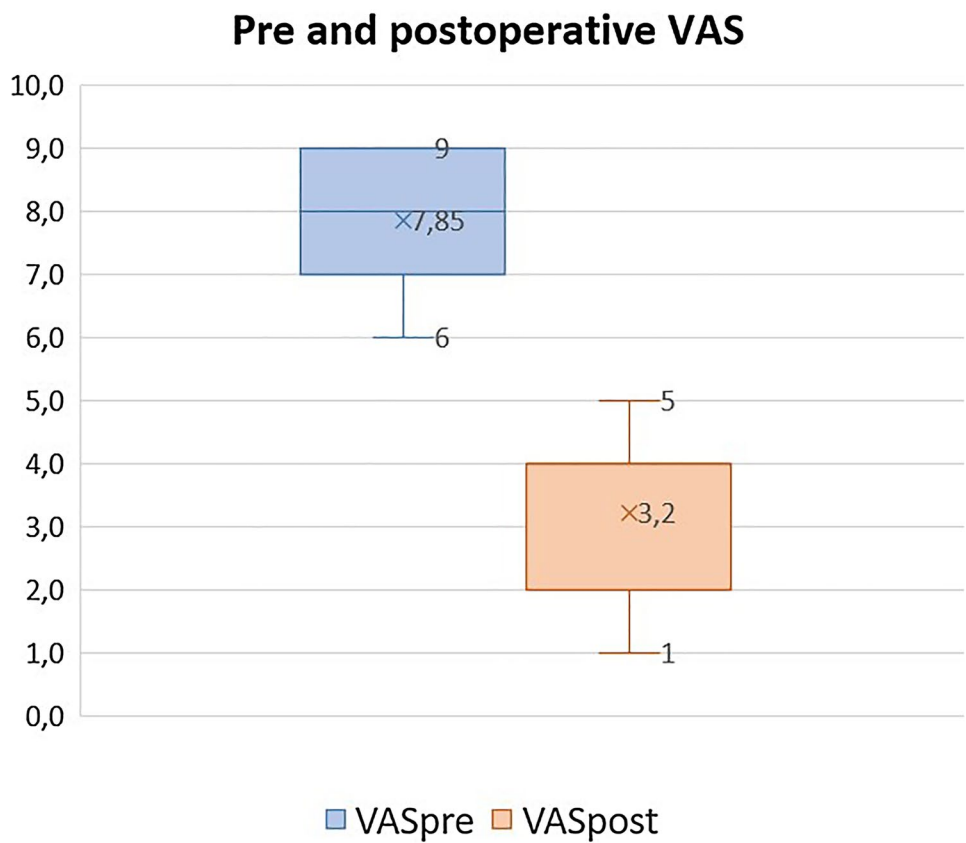


Fig. 6 Mean pre-operative and post-operative snoring VAS scores



restored the next day after surgery, although odynophagia lasted on average seven days in most cases. There was no long-term dysphagia or voice change. Post-operative endoscopic findings also demonstrated significant reduction of lateral pharyngeal wall collapse with most patients having only minimal lateral wall movements on Muller's maneuver. There were no characteristics (anatomical or not) related to success. Clinical and HST data are reported in Table 1.

Discussion

Analyzing the mean pre- and post-operative AHI, ODI and ESS scores, we recorded encouraging results as previously reported [7]. We should highlight that our study is based on Barbed Pharyngoplasty as the standalone procedure for OSA, having had nasal surgery done before. Alianza technique is a non-resective conservative technique without resection of the palatopharyngeal muscle unlike many others Barbed Pharyngoplasties commonly used [7].

BS are special knot-free tissue closure devices which allow a homogeneous distribution of tensile forces, guaranteeing an optimal biological response and improving both postoperative discomfort and wound healing. Through the application of specific direction vectors and the use of BS, by suspension to specific rigid fibro-osseous holds, the surgeon is able to lift, shorten, advance and stiffen the soft palate in the complete anatomic respect of oropharyngeal fibro-muscular structures. These threads induce a reactive fibrosis capable of maintaining the results of the operation by the fourth postoperative week. Although the promising results of remodeling pharyngoplasties, all the BP developed in recent years still include Palatopharyngeus Muscle (PPM) resection or weakness. It is well known that cutting the muscle could presumably expose the patient to an increased risk of late dysphagia in old age [8]. PPM is one of the essential muscles required for proper food swallowing. It assists in the phonation of high-pitched sounds and it is active in the production of oral and nasal speech sounds. In the era of the mini-invasive/conservative surgery, the resection of muscle is questionable. Therefore, is it still necessary to cut this muscle while having the same results with a less invasive procedure? Further OSA-pharyngoplasties comparing studies on a large scale are necessary to confirm the promising results of non-resective PPM management over resective techniques.

Only few minor complications were encountered such as partial knot extrusions, mucosal granulomas, and anterior pharyngoplasty dehiscence. BS extrusion despite being frequent, does not actually affect the functional outcome of the procedure [9]. Major complications were not recorded (i.e., dyspnea; dysphagia, swallowing disturbances and bleeding).

Nevertheless, we also had four failures after Alianza and in all of these cases, we have performed post-operative DISE. Two patients had post-operative positional OSA, thus they were selected for positional therapy; one patient presented an inadequate improvement of pharyngeal space and he was operated again by Expansion Sphincter Pharyngoplasty with BS. Finally, in one case there was a partial tongue base collapse thus the patient underwent treatment with Mandibular Advancement Device (MAD). All these patients had FTP score III and Friedman Staging system III [10].

Alianza is one of the new non-resective pharyngoplasty techniques. However it should be noted that, to date among the different barbed pharyngoplasties described, the most used in the world is Barbed Reposition Pharyngoplasty (BRP) introduced by Vicini et al. [11]. Comparing the surgical success rate, this technique showed superiority over the other palatal surgery techniques (uvulopalatopharyngoplasty, lateral pharyngoplasty, expansion pharyngoplasty) [12]. However, no studies were found about the comparison between different barbed surgical techniques in terms of surgical success and complications. Moreover, more studies are needed about long-term results and complications.

There are several limitations in this study. The study population was small with short-term follow and it is impossible to perform a subgroup analysis. Moreover, no females were enrolled in this study, making generalization difficult. Finally, AHI represent a surrogate variable and may not measure the real benefits of the patients. There is a strong individual night to night variability which must be considered in the sleep data analysis [13]. Surgical success rate depends on accurate diagnosis, careful UA examination, and rigorous technical application.

Conclusions

Our preliminary results suggest that Alianza technique is a safe and repeatable surgery. It is based on the complete anatomical respect of palatal fibro-muscular structures and the stiffening of the soft palate. It is achieved through muscular folding and suspension to rigid holds. BS assures homogeneous tissue tensioning along the full length of the thread, provides excellent tissue grip, avoids the need for knotting, does not alter any muscle function; moreover the action of BS is replaced over time by means of solid and stable tissue scarring. This procedure has promising results, is anatomically sound and has minimal complications. Further studies on a larger scale are needed to confirm these encouraging data supporting the role of

Alianza alone or in OSA multilevel surgery in selected OSA patients.

Declarations

Conflict of interest The authors declare that they have no conflict of interest.

Ethical 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.

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

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