#### **ENT • REVIEW**



# Different barbed pharyngoplasty techniques for retropalatal collapse in obstructive sleep apnea patients: a systematic review

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#### Abstract

**Background** The use of barbed sutures (BS) for the treatment of retropalatal collapse and vibration in patients suffering from snoring and obstructive sleep apnea (OSA) has significantly increased in the last few years. Many surgeons have discovered the advantages and unique properties of the BS and allowed the popular surgical pharyngoplasty techniques to be updated and improved.

**Methods** A systematic review was performed to identify all the clinical studies concerning the different barbed pharyngoplasty (BP) techniques used for the treatment of palatal collapse in snoring and OSA patients. A qualitative analysis of data extracted was conducted.

**Results** We included 12 studies of which 10 are prospective and 2 retrospective: 9 single-arm studies on the efficacy of a specific BP technique, 1 randomized clinical trial on the comparison between BP and control groups, and 2 studies on the correlation between two different BP techniques. To date, in the literature, 5 different types of BP techniques have been described: barbed snore surgery, barbed reposition pharyngoplasty, barbed expansion sphincter pharyngoplasty, barbed suture suspension, and barbed soft palate posterior webbing flap pharyngoplasty. All the studies showed an overall improvement in the primary efficacy parameters investigated (apnea-hypopnea index, oxygen desaturation index, and Epworth sleepiness scale) in each of the surgical techniques performed without any major complications.

**Conclusions** Given the extreme heterogeneity of the studies analyzed, it is necessary to perform more randomized and control studies on large samples aimed to define the best BP technique based on its effectiveness, surgical success rate, patient's compliance, and complications.

**Keywords** Obstructive sleep apnea  $\cdot$  Barbed sutures  $\cdot$  Barbed pharyngoplasty  $\cdot$  Barbed anterior pharyngoplasty  $\cdot$  Barbed lateral pharyngoplasty

# Introduction

In 2013, Mantovani et al. [1] first introduced the use of barbed sutures (BS) for obstructive sleep apnea (OSA) surgery to reduce the collapsibility of the palate-pharyngeal tract of the

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upper airway (UA), adjusting it to an innovative anatomic concept related to a coaxial tube system. They first imagined the UA as composed of an outer tube made of rigid tissues (spina nasalis posterior, posterior edge of the hard palate, hamulus pterygoideus, raphe pterygomandibularis) surrounded by

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an inner coaxial tube made of soft tissues (mucosa, submucosa with its glands and lymphatic tissues, fat, and muscles). According to this concept, they came up with the idea of creating a tensile structure interconnecting the two coaxial tubes to transfer the rigidity of the outer to the inner one, without muscle resection or interruption. BS is a special knot-free self-blocking thread characterized by the presence of directional projections (or barbs) along its entire length, which imparts tensile strength inside the tissues without the need for tying a knot. [2] This thread is reabsorbed within 180 days, allowing for fibrosis of the tissues that will preserve the functional results. The suture employed is usually a bidirectional thread with two needles.

BS can displace and increase the basal stiffness of the anterior and lateral pharyngeal walls by tensioning and anchoring the muscle structures to the surrounding bones (spina nasalis posterior; hamuli pterygoidei) and ligaments (pterygomandibular raphe), maintaining their contractile activity. Surgeons can adapt this technique according to the patient's anatomy and muscular weakness previously observed during drug-induced sleep endoscopy (DISE).

Related to these unique advantages, most of the popular pharyngoplasty techniques such as expansion sphincter pharyngoplasty (ESP), [3] functional expansion pharyngoplasty (FEP), [4] reposition pharyngoplasty, [5] and relocation pharyngoplasty [6] have been updated with these new suture threads. The use of this kind of suture has shown exciting results in simple snorers and OSA patients with promising surgical success rates, significantly fewer complications, and reduced operative time compared with the traditional techniques. However, as the use of BS has become widespread in OSA palatal surgery, there is often confusion among the different pharyngoplasty techniques.

We performed a systematic review of the studies regarding all the potential therapeutic effects of different types of barbed pharyngoplasty (BP) for the treatment of palatal collapse, trying to investigate the clinical and instrumental available data, comorbidity, and complications.

# Methods

The study was performed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. [7]

#### Data source and study searching

An electronic search was performed on PubMed/MEDLINE, Google Scholar, and Ovid databases. An example of a search strategy is the one used for PubMed/MEDLINE: "Barbed" and "Pharyngoplasty"; "Barbed" and "Palatoplasty"; "Barbed" and "Anterior Pharyngoplasty"; "Barbed" and "Lateral Pharyngoplasty"; "Barbed" and "Expansion Sphincter Pharyngoplasty"; "Barbed" and "Suspension Pharyngoplasty"; "Barbed" and "Reposition Pharyngoplasty", "Barbed" and "Snore Surgery"; "Barbed" and "Roman Blinds Technique"; and "Barbed" and "Alianza Technique." The other searches were adjusted to fit the specific requirements for each database. Then, a cross-reference search of the included studies was performed to minimize the risk of missing relevant data. The last search was run on December 2019.

# Inclusion/exclusion criteria

Only prospective studies regarding the effect of different types of BP to treat snorers and OSA patients with velum collapse as a single procedure and/or as a part of multilevel surgery were included according to the PICOS acronym: *Patients* (P), adults suffering from OSA; *Intervention* (I), barbed pharyngoplasty; *Comparison* (C), pre- and posttreatment; *Outcome* (O), PSG (e.g., AHI) and self-reported (e.g., ESS) clinical outcomes; and *Study design* (S), both prospective and retrospective cohort studies. The PICO process is a mnemonic used in evidence-based medicine to frame and answer a clinical or health care-related question.

Exclusion criteria for the study were as follows: (1) studies not in English; (2) case reports, reviews, conference abstracts, letters, and pediatric studies; (3) studies with unclear and/or incomplete data; and (4) studies regarding the comparison between barbed and non-BP techniques.

No publication date restriction was imposed.

# Data extraction and data analysis

Two independent reviewers (A.M. and M.P.) separately searched for related scientific papers. All articles were initially screened by title and abstract; then, the authors independently assessed the full-text versions of each publication and excluded those whose content was judged not to be strictly related to the subject of this review. Data extraction from the included studies was systematically made using a structured form, and two reviewers (A.M., M.P.) independently checked it. A qualitative synthesis analysis was performed considering the selected studies regarding the effects of different BP techniques.

#### Study quality assessment

The National Institute for Health and Clinical Excellence (NICE) quality assessment tool was used to evaluate the quality of the included studies [8].

# Results

The flow diagram shown in Fig. 1 (PRISMA flow diagram) depicts the selection process that includes 12 studies for a total of 383 patients. The baseline characteristics of the studies are reported in Table 1. Six trials were uncontrolled prospective, [5,9–12] two pilot longitudinal studies, [13,14] two retrospective, [15,16] and one randomized clinical trial (RCT) [17]; in the other study, it was not specified. [18] The number of subjects varied from 10 [9] to 111 [19], the mean age from 31 [10] to 65 years [17], and there was an overall prevalence of males in all the studies where gender was reported. The duration of the follow-up ranged from 1 [18] to 12 months. [5,11,15] The different types of BP techniques are reported in Table 2.

Selected studies can be divided into two groups:

- Single-arm studies without a control group investigating the effects of a single BP technique (tot = 9): three studies analyzed barbed snore surgery (BSS) [13,14,18], four studies barbed reposition pharyngoplasty (BRP), [5,9,11,19] one study barbed expansion sphincter pharyngoplasty (BESP), [15] and one study modified barbed soft palatal posterior pillar webbing flap palatopharyngoplasty. [10]
- RCT with a control group (tot = 1): one study compares BRP with a control group (observation). [17]

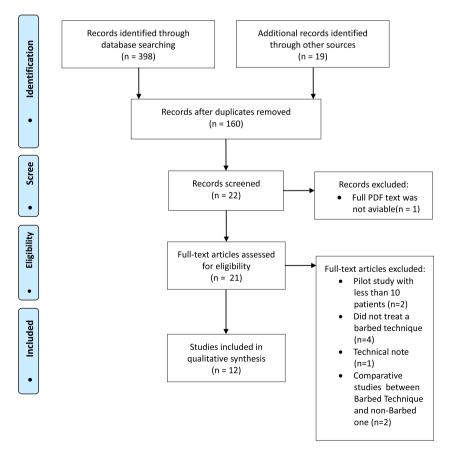
 Comparison studies between different BP techniques (tot = 2): one study compared BRP with barbed suspension pharyngoplasty (BSP) [16] and the other BRP with a modified BRP. [12]

#### The methodological quality of included studies

The NICE quality assessment tool revealed important heterogeneity between studies. Six studies (n = 264, 71.3%) satisfied at least six of the eight quality items. Only three multicenter studies (n = 171, 46.2%) have been published. A majority of patients were recruited prospectively (n = 277, 74.9%) and/or with a consecutive enrollment (n = 204, 55.1%). A stratified analysis of the clinical outcomes was performed only in one study (n = 42, 11.3%).

#### Single-arm studies without a control group

**Barbed snore surgery** Salamanca et al. [18] performed barbed anterior pharyngoplasty (BAP) on 24 patients presenting with heavy snoring (17) or mild OSA with anterior-posterior collapse (7). At the end of the treatment, all snoring patients obtained a consistent reduction in the snoring visual analog scale (VAS) (9.2 to 2.9), while OSA patients experienced a more significant reduction in the apnea-hypopnea index (AHI)



#### Fig. 1 PRISMA flowchart

bjective of th	e study clearly desc	ribed? (3) Ar	e the inclusion and e.	objective of the study clearly described? (3) Are the inclusion and exclusion criteria (case	stratified (e.g., by ¿	stratified (e.g., by abnormal results, disease stage, patient characteristics)?	ase stage, patient c	stratified (e.g., by abnormal results, disease stage, patient characteristics)?	
Author year	Study's general characteristics	acteristics							Quality assessment of included studies
	Country	Follow-up	Study design	No case control	No.	o. Mean age (years)	Sex (M:F)	BMI	Multicenter?
ingle-arm studie Salamanca	Single-arm studies without a control group Salamaca Italy 1 2014	oup 1 month	Not specified	1	5	24 46 (34 to 55)	2.4:1	28.6 (24.3 to 30.1)	No
2014 Mantovani 2015	Italy	6 months	Pilot longitudinal	I	32	2	3:1	< 30	No
·=	Italy	6 months	Longitudinal	I	1	19 $43.8 \pm 8.8$	18:1	$26.2\pm2.7$	No
5 7 hi	Italy Italy Italy, Egypt, Portugal, Sbain, Turkev, and	6 months 12 months 6 months	Prospective Prospective Multicenter prospective	1 1 1	10 10 111	$\begin{array}{cccc} 10 & 53.4 \pm 12.4 \\ 10 & 64 & (45-74) \\ 11 & 46.3 \pm 10.5 \end{array}$	1:0	$28.5 \pm 3.6$ 27.9 (range 21.7-32.5) $27.9 \pm 3.2$	Yes ) No Yes
L	Mexico India	12 months	Prospective	1	50	-	I	I	Yes
2019 Pianta 2018 Elbassiouny 2016	Italy Egypt and Kuwait	12 months 6 months	Retrospective Single-center prospective	1 1	17 21	7 47.8 (23–76) 1 31.3 ± 4.8 (27 to 46)	4.7:1 46) 3.2:1	$27.0 \pm 6.8$ $28.3 \pm 4.7$	No No
			uncontrolled case series						
andomized clinical t Vicini 2019 Italy	Randomized clinical trial with a control group Vicini 2019 Italy 6.8 r	l group 6.8 months	Randomized clinical trial	BRP vs control group (observation)		50 BRP = 44.64 ± 12.82; control group = 50.09 ± 11.51	<ul> <li>82; BRP = 22/3;</li> <li>control</li> <li>± group =</li> <li>20/1</li> </ul>	BRP = $26.49 \pm 2.51$ ; control group = $27.90 \pm 3.53$	No
comparison studies be Barbieri 2019 Italy	Comparison studies between different techniques of barbed pharyngoplasty Barbieri 2019 Italy 6 months Observational	echniques of ba 6 months	trbed pharyngoplasty Observational	BSP vs BRP	42	54 (	9.5:1	I	No
Bebademez 2019	Turkey	6–9 months (mean 8)	retrospective Prospective	Barbed reposition pharyngoplasty (BRP) vs modified barbed reposition pharyngoplasty (MBRP)	oplasty (BRP) vs 34 ion	4 BRP = 39.4 ±7.5 (26-58) MBRP = 40.6 ± 2.4 (27-58)	5 BRP = 14/3 MBRP = 15/2	BRP = 27:9 ± 3 MBRP = 27 ± 2.5	No
Author year	Quality a:	ssessment of in	Quality assessment of included studies						
	Aim?	Inclusion	Inclusion and exclusion criteria?	Outcome?	Prospective?	Consecutive enrollment?		Main findings? Outco	Outcomes stratified?
ingle-arm studies Salamanca 2014	Single-arm studies without a control group Salamanca 2014 Yes	oN dno		Yes	No	No	Yes	No	

Sleep Breath

Mantovani 2015	Yes	Yes	Yes	Yes	Yes	Yes	No
Mantovani 2017	Yes	Yes	Yes	Yes	Yes	Yes	No
Vicini 2015	Yes	Yes	Yes	Yes	No	Yes	No
Vicini 2017	Yes	No	Yes	No	No	Yes	No
Montevecchi 2017	Yes	Yes	Yes	Yes	Yes	Yes	No
Madkikar 2019	Yes	Yes	Yes	Yes	No	Yes	No
Pianta 2018	Yes	Yes	Yes	No	No	Yes	No
Elbassiouny 2016	Yes	Yes	Yes	Yes	No	Yes	No
Randomized clinical trial with a control group	l with a control	l group					
Vicini 2019	Yes	Yes	Yes	Yes	Yes	Yes	No
Comparison studies betw	veen different t	Comparison studies between different techniques of barbed pharyngoplasty					
Barbieri 2019	Yes	Yes	Yes	No	Yes	Yes	Yes
Bebademez 2019	Yes	Yes	Yes	Yes	No	Yes	No

(from 8.9 to 3.8/h). In many cases (19/24), authors described thread extrusion without any velar insufficiency or dehiscence of the wound.

Mantovani [13] investigated the effects of the "Barbed Roman Blinds Technique" (BRBT) in 32 severe OSA patients with retropalatal obstruction. One year later, there was a significant reduction in AHI  $(36.9 \pm 4.5 \text{ to } 13.7 \pm 4.5/\text{h};$ p < 0.001), in the meantime with 90% O<sub>2</sub> saturation and Epworth sleepiness scale (ESS) scores recording a successful outcome in 27 patients (84.4%) with no significant major complications. Moreover, Mantovani [14] described the preliminary experience with barbed snore surgery (BSS) for concentric collapse at the velum with the "Alianza technique" in 19 patients with mild to moderate OSA patients. After 6 months, the authors showed a statistically significant reduction in AHI (22.3  $\pm$  5.1 to 7.0  $\pm$  9.4/h; p = 0.002), ESS (11.3  $\pm$ 5.4 to  $3.9 \pm 4.0$ ; p < 0.001), and snoring VAS ( $9.5 \pm 0.7$  to 2.1  $\pm 1.7$ ; p < 0.001). Only some minor complications were described as knot extrusion, mucosal granulomas, and anterior pharyngoplasty dehiscence.

Barbed reposition pharyngoplasty Vicini et al. in 2015 [9] developed a new variant of "reposition pharyngoplasty" with the introduction of BS in 10 OSA patients with lateral palatal collapse as a part of multilevel surgical treatment (3 trans oral robotic surgery (TORS) with tongue base reduction, seven nasal and/or hyoid surgery). The authors showed after 6 months postsurgery a significant improvement in polysomnography (PSG) parameters: AHI ( $43.65 \pm 26.83$  to  $13.57 \pm 15.41/h$ ; p = 0.007), oxygen desaturation index (ODI)  $(44.7 \pm 27.3 \text{ to } 12.9 \pm 16.3/\text{h}; p = 0.004)$ , and ESS  $(11.6 \pm 4.86)$ to  $4.3 \pm 2$ ; p < 0.01). The main complaints were foreign body sensation at the palate and the extrusion of a short piece of the suture. The same group [5] conducted another similar clinical study investigating the effects of combined BRP and TORS in 10 OSA patients. After 1 year postoperatively, there was a reduction in AHI (32.7/h vs. 16.9/h) and ESS (12 vs. 4), and the treatment was effective in 7 of 10 patients. No patients experienced intraoperative, postoperative, or delayed complications. Furthermore, Montevecchi et al. [19] investigated the effectiveness of BRP in 111 OSA patients as a single procedure, including nasal surgery (94.6%) or as a part of multilevel surgery (4 hyoid suspension, 2 TORS). After 6 months postoperatively, the authors observed a significant improvement in AHI (33.4  $\pm$  19.5/h vs 13.5  $\pm$  10.3/h; p < 0.001), ODI (29.6  $\pm$ 20.7/h vs  $12.7 \pm 10.8$ /h; p < 0.001), and ESS ( $10.2 \pm 4.5$  vs  $6.1 \pm 3.6$ ; p < 0.001). Only some minor complications were described, such as partial thread extrusion and intraoperative suture rupture. The most common patient complaint was transient dysphagia. Similarly, Madkikar et al. [11] investigated the effects of BRP on 50 mild to moderate OSA Indian patients as a single procedure or as a part of multilevel surgery (14 rhinoplasty; 34 septoplasty associated with turbinate

Table 2 Type	Types of surgical techniques					
Author year	Inclusion criteria	Exclusion criteria	DISE	Surgical technique	Mono-/multilevel surgery	AHI-pre AHI-post
Single-arm stuc Salamanca 2014	Single-arm studies without a control group Salamanca Heavy snoring or mild OSA; tonsil 2014 score 0–1 or previous	1	Not speci- fied	Barbed anterior pharyngoplasty (BAPh)	1	8.9 3.8
Mantovani 2015	tonsiliectomy Severe OSA, DISE indicating a retropalatal obstruction; previous tonsillectomy; refused CPAP	Refusal to participate; chronic lower airway diseases; chronic systemic diseases; craniofacial, neuromuscular, psychiatric, syndromic, or defined genetic disorders; drug or alcohol addiction; previous OSAS surgery; BMI > 30 kg/m <sup>2</sup> ; no variation in BMI > 0.2 kg/m <sup>2</sup> during the follow-up period; and	NOTE and NOH- L	Barbed Roman blinds technique (BRBT)	1	36.9±4.5 3.7±4.5
Montavani 2017	Mild to moderate OSA, DISE indicating a concentric pharyngeal collapse at the velum; previous tonsillectomy; refused CPAP	Se	THON	Intraoperatively modulated technique, then with the Roman blind technique, barbed anterior pharyngoplasty for antero-poster collapse, or both (the Alianza technique)	1	22.4±5.17.0±9.4
Vicini 2015	Mild to severe OSA with DISE indicating an obstruction at the retropalatal level with or without retrolingual obstruction; refused	follow-up of < 6 months Severe medical illness; significant craniofacial anomalies affecting airway; patients with limited mouth opening (inter-incisive	Not speci- fied	<ol> <li>patients with barbed reposition pharyngoplasty (BRP)</li> </ol>	TORS (3), nasal and/or hyoid 43.65 $\pm$ 26.83 13.57 $\pm$ 15.41 surgery (7)	<b>43.65 ± 26.83 13.57 ± 15.41</b>
Vicini 2017	CFAT, failed of previous surgery OSA patients, DISE indicating an observation at base of tongue and	I.	NOHL	Barbed reposition pharyngoplasty (BRP)	TORS (10)	32.7 16.9
Montevecchi 2017	Σ	Severe medical illness; significant craniofacial anomalies affecting the airway; patients with limited mouth opening (inter-incisive distance $\leq 2$ cm); less than	Not speci- fied	Barbed reposition pharyngoplasty (BRP)	BRP as a single procedure including if required tonsillectomy and a nasal procedure. In few cases, a tongue base surgery or a	$33.4 \pm 19.5 \ 13.5 \pm 10.3$
Madkikar 2019	Mild to severe OSA, DISE indicating a purely nasal and retropalatal obstruction,	6 months of follow-up Severe medical illness; retrolingual or hypopharyngeal collapse.	Not speci- fied	Barbed reposition pharyngoplasty (BRP)	thyro-hyoidopexy Various nasal surgeries for level 1 obstructions (turbinate surgery,	40.6 0.2

Table 2 (continued)	nued)					
	BMI ≤ 38, not accepting or unwilling to use CPAP				septoplasty, open rhinoplasty, adenoid surgery) and barb relocation palatoplasty for level 2 obstruction	
Pianta 2018	Moderate to severe OSA, DISE indicating an oropharyngeal collapse and without obstruction	Tongue base or epiglottis collapse during DISE	Not speci- fied	Barbed expansion sphincter pharyngoplasty (BESP)	Septoplasty (3), turbinate reduction surgery (7) endoscopic polypectomy to	31.1 7.8
Elbassiouny 2016	at base of tongue, retused of the Snoring and OSA, without non-obstructing nasal conditions, significant soft palatal posterior pillar webbing and hypertrophied tonsils in DISE	I	VOTE	Modified barbed soft palatal posterior pillar webbing flap palatopharyngoplasty		<b>45</b> .7 ± 2.6 12.3 ± 3.9
Randomized	Randomized clinical trial with a control group					
Vicini 2019	<ul> <li>Vicini 2019 Moderate to severe OSA with nasal Serious psychiatric, obstruction planned for BRP and cardiopulmonary, tonsillectomy, with nasal surgery; disease; American grades 1–2 tonsillar hypertrophy; Anesthesiologists aged between 18 and 65 years</li> <li>Anesthesiologists and a for a negative to surgery low adherence; mainly</li> <li>Anesthesion &gt; 3; pregna collapses and severe transversal grades 3–4 tonsille pharyngeal collapses with none mainly lingual/base or mild tongue collapses with none mainly lingual/base</li> </ul>	Serious psychiatric, cardiopulmonary, or neurological disease; American Society of Anesthesiologists (ASA) classification > 3; patients negative to surgery; previous tonsillectomy and OSA surgery; significant craniofacial anomalies; pregnant women; grades 3–4 tonsillar hypertrophy; mainly lingual/base of tongue collapses at DISE; follow-up < 6 months	VOTE	Group A: 25 patients with barbed reposition pharyngoplasty (BRP); group B: 25 patients with observation	Nasal surgery (septoturbinoplasty): number of patients not specified	BRP: preop. 25.58 ± 14.60; postop. 9.82 ± 9.88. Control group: preop. 36.83 ± 23.82; postop. 31.93 ± 21.89
Barbieri 2019	Barbieri 2019 Mild to severe OSA, BMI ≤ 35, DISE indicating a main site of obstruction at the oropharyngeal level, as palatal either lateral pharyngeal wall collapse, failure to tolerate or comply with CPAP, or a mandibular advancement device MAD, treated with non-resective pharyngoplasty	Hypopharyngeal or laryngeal complete collapse; significant craniofacial anomalies affecting the airway; severe comorbidities; contraindications for surgery; incomplete clinical data	THON	Group A: 22 patients with barbed reposition pharyngoplasty (BRP); group B: 20 patients with barbed suspension pharyngoplasty (BSP)	Multilevel surgical procedure for 35 patients: turbinoplasty (12), both septoplasty and turbinoplasty (23)	BRP: preop, 27; postop, 7. BSP: preop, 25; postop, 5
Bebademez 2019	Mill to moderate OSA, BMII < 35, DISE retropalatal obstruction, absence of nasal obstruction due to turbinate hypertrophy or septal problem, and tonsillar hypertrophy more than grade 2	Nasal or hypopharyngeal obstruction; tonsillar hypertrophy > grade 2; BMI ≥ 35	VOTE	17 patients subject to barbed reposition pharyngoplasty (BRP) and 17 subject to modified barbed reposition pharyngoplasty (MBRP)	1	Total: BRP: preop, 29.9 $\pm 17.6$ ; postop, 5.4 $\pm 2.5$ ; MBRP: preop, 32.5 $\pm 17.8$ ; postop, 7.7 $\pm 6.6$ . Supine: BRP: preop, 40 $\pm 7.4$ ; postop, 13.2 $\pm 5.5$ ; MBRP: preop, 49.3 $\pm 26.5$ ; postop, 14 $\pm 8.9$

Table 2 (continued)	inued)			
Author year	ESS-pre ESS-post	Other parameters	Surgical success rate (defined as a postoperative reduction in the AHI of C50% and/or a postoperative AHI of 20/h)	Surgery complications
ingle-arm stu	Single-arm studies without a control group			
Salamanca 2014	I	Snoring VAS; preop, 9.2; postop, 2.9	1	Minor complications: partially extruded thread (19/24)
Mantovani 2015	$15.3 \pm 4.45.7 \pm 2.9$	Time with 90% O <sub>2</sub> saturation; preop, 12.5 $\pm 6.7$ ; postop, 3.5 $\pm 4.2$ ; 2.3 ( $p < 0.001$ )	27 patients (84.4%)	No complications
Montavani 2017	$11.3 \pm 5.4 \ 3.9 \pm 4.0$	Snoring VAS; preop, $9.5 \pm 0.7$ ; postop, $2.1 \pm 1.7$ ( $p < 0.01$ )	17 patients (84.4%)	Minor complications: partial knot extrusion (5), mucosal granulomas (1), and anterior pharyngoplasty dehiscence (4)
Vicini 2015	$11.6 \pm 4.8 \ 4.3 \pm 2$	ODI; preop, $44.7 \pm 27.32/h$ ; postop, $12.9 \pm 16.3/h$ ( $p = 0.004$ )	90.00%	No complications
Vicini 2017	12 4	× 	Effective in 7 of 10 patients	No complications
Montevecchi 2017	10.2 ± 4.5 6.1 ± 3.6	ODI; preop, 29.6 $\pm$ 20.7/h; postop, 2.7 $\pm$ 10.8/h ( $p$ < 0.001)	12 success + 23 cured (tot 73.0%)	Minor complications: intraoperative: 3 partial tread extrusion (3%), 3 intraoperative bleeding (3%), 1 broken needle (1%), 1 suture rupture (1%); postoperative: 7 partial tread extrusion (6%), 6 postoperative bleeding (5%), 23 dysphagia (21%)
Madkikar 2019	13 03	ODI: mean preop, 42.7/h; mean postop, 12.6/h	1	Minor complications: slipping of the palatopharyngeal muscle due to tear through, leading to the barb suture loop showing (2)
Pianta 2018	رد 4	ODI: preop, 32.3/h; postop, 11.2/h $(p < 0.01)$	15/17 patients (88%)	No complications
Elbassiouny 2016	. 1	The snoring VAS preop, $9.4 \pm 1.6$ ; postop, $1.7 \pm 3.2$ ( $p < 0.005$ )	1	Temporary velopharyngeal insufficiency (VPI) occurred in 1 patient (5%) and started to improve at the end of the first week. Excessive postnasal discharge occurred in 4 patients (19% this condition started to improve within 1 month of surgery)
Randomized	Randomized clinical trial with a control group			
Vicini 2019 Comparison stu	<ul> <li>Vicini 2019 BRP: preop, 9.28 ± 3.10; postop, ODI: BRP: preop, 24.</li> <li>3.76 ± 4.42. Control group: postop, 9.30 ± 10.22</li> <li>preop, 10.4 ± 23.68; postop, group: preop, 35.38</li> <li>10.85 ± 3.91</li> <li>Comparison studies between different techniques of barbed pharvngoplasty</li> </ul>	ODI: BRP: preop, 24.38 ± 17.72; postop, 9.30 ± 10.24; Control group: preop, 35.38 ± 23.31; postop, 32.4 ± 22.58	Success rate in BRP group was 74.2%.	Success rate in BRP group was 74.2%. In the BRP group, no major complications (e.g., bleedings and severe dysphagia) were recorded
Barbieri 2019	Barbieri 2019 BRP: preop, 7; postop, 0. BSP: preop, 9; postop, 0	ODI: BRP: preop, 22; postop, 4/h; BSP: preop, 22; postop, 2	All patients: 27 (64%); BRP, 15 (68%); BSP, 12 (60%)	<ul> <li>All patients: 27 (64%); BRP, 15 (68%); Minor complications: henorrhage from tonsillar bed (1), velopharyngeal insufficiency spontaneously solved (2), minimal tread extrusion (5)</li> </ul>
Bebademez 2019	BRP: preop, 7.2 ± 4.7; postop, 2.4 ± 1.5; MBRP: preop, 7.6 ± 3.96; postop, 2.1 ± 1.6	Snoring VAS score: BRP: preop, 6.2 $\pm$ 1.9; postop, 2.2 $\pm$ 1; MBRP: preop, 8 $\pm$ 1.5, postop, 1.8 $\pm$ 0.8	BRP: 82% MBRP: 95%	Most of the patients in both groups reported only a mild pain in swallowing that resolved in a few days; many reported a foreign body sensation on the soft palate that resolved spontaneously in a month

reduction; 2 salpingo-pharyngeal submucosal radiofrequency channeling). He showed a significant improvement in AHI (40.6 to 10.2/h), ODI (42.7 to 12.6/h), and ESS [13 to 3] without any major complications.

**Barbed expansion sphincter pharyngoplasty** Pianta et al. [15] investigated the effects of barbed expansion sphincter pharyngoplasty (BESP) in 17 patients with moderate to severe OSA alone or as a part of a multilevel treatment showing a significant improvement in AHI (31.1 to 7.8/h; p < 0.01), ODI (32.3 to 11.2/h; p < 0.01), and ESS (6 to 4; p < 0.05).

Modified barbed soft palatal posterior pillar webbing flap palatopharyngoplasty Elbassiouny et al. [10] selected 21 patients affected by loud snoring and OSA who underwent modified barbed soft palatal posterior pillar webbing flap palatopharyngoplasty. At 6 months postintervention, physicians recorded improvement in snoring VAS ( $9.4/10 \pm 1.6$  to  $1.7/10 \pm 3.2$ ; p < 0.005), AHI ( $45.7 \pm 2.6$  to  $12.3 \pm 3.9$ ; p <0.005), and O<sub>2</sub> saturation% zenith ( $74 \pm 4$  to  $89 \pm 2$ ; p < 0.005), with only one case of velopharyngeal insufficiency.

# RCT with a control group

Vicini et al. [17] conducted a RCT comparing BRP with observation (control group) showing 6 months after surgery a significant reduction of AHI, ODI, lowest oxygen saturation (LOS), and ESS values in the BRP group. Moreover, the BRP group was shown to be more effective than the control group in AHI, ODI, and ESS values. Logistic regression suggested that preoperative AHI is related significantly to postoperative AHI within the BRP group. Linear regression showed that higher baseline AHI predicts more significant postoperative absolute AHI reduction.

# Comparison studies between different barbed pharyngoplasty techniques

Barbieri et al. [16] compared two different types of barbed pharyngoplasty of 42 mild to moderate OSA patients divided into two groups: group A (22 patients) underwent BRP, according to Vicini et al. [9]; and group B (20 patients), BSP. Both these procedures were made alone or as a part of multilevel surgery (turbinoplasty and septoplasty). After 6 months of the surgical procedure, in both groups, there was a significant reduction in the median AHI, ODI, t90%, and ESS. Finally, Babademez et al. [12] compared the results of BRP with a modified BRP in 34 mild to moderate OSA patients. Both groups showed a significant reduction in AHI, snoring VAS, and ESS without no statistically relevant differences between the two groups.

### Discussion

It has been long purported that continuous positive airway pressure (CPAP) therapy is the "gold" standard in the treatment of OSA, and there is no doubt that CPAP is effective when used properly. However, it is also well known that due to problematic patient adherence, the real-world effectiveness of CPAP is low, with a large proportion of users abandoning the machine within 1 year of prescription. Such patients cannot be said to be effectively treated. UA surgery, for instance, appears to be a promising solution, not presenting the drawback of lack of adherence to treatment. The growing need for alternative therapies, however, is not supported by sufficiently strong evidence, especially in the surgical field. It is recognized that overall treatment success rates with surgery are lower than via CPAP, but this does not hold for the subset of patients with appropriate apnea-specific surgical anatomy wherein rates of successful surgical OSA treatment are very high. Therefore, when the right patient is matched with the right pharyngeal surgical procedure in order to maximize success, important results have been shown especially in the last years with the introduction of BS. [20] BS are special knotfree tissue closure devices that allow a homogeneous distribution of tensile forces, guaranteeing an optimal biological response with improvement of postoperative comfort and scar potential. The use of BS is both modular and customizable, allowing a "tailored" surgery. The use of this suture has significantly increased in OSA palatal surgery, as surgeons have become more familiar with the advantages and disadvantages of this new technology supported by many clinical studies concerning the effectiveness of different BP techniques.

This is the first systematic review on this topic. From 2014 to date, 12 studies on BP have been published: 9 single-arm studies evaluating the effects of a specific BP technique, 1 comparative RCT between BRP and observation, and 2 comparative studies on the effects of two distinct techniques. Five different BP techniques have been described: BSS, BRP, BESP, barbed suture suspension, and barbed soft palate posterior webbing flap palatopharyngoplasty. Most of the studies have been carried out in Italy, suggesting how the use of BS in the otolaryngology field is an Italian invention. All the studies analyzed suggested that each of these BP techniques was able to guarantee a significant improvement in the main parameters investigated such as AHI, ODI, and ESS. Only eight studies showed surgical success rates defined a postoperative reduction in the AHI of C50% and/or a postoperative AHI of 20/h. We did not have data available on the effectiveness of one surgical technique on another. However, there were not enough data to define which of these BP techniques was the most effective in terms of efficacy, complications, and patients' compliance. Except for one RCT included, most of the other studies are single-arm studies without a control group. In the literature, there are no comparative studies

evaluating the effects of this surgical technique with standard CPAP. However, there are some comparative studies between BP and other techniques without the use of BS. In particular, Cammaroto et al. [21] showed both BRP and ESP resulted in better postoperative AHI values and higher surgical success rates in comparison with uvulopalatopharyngoplasty (UPPP). On the other hand, BRP was not more effective than ESP. In particular, ESP surgery time was significantly higher than that of UPPP, while BRP was the quickest procedure. Being quicker, easy to learn, and with a low rate of complications, BRP is a safe, effective, and promising option for treatment of OSA patients. Moreover, Babademez et al. [22] suggested that both ESP with anterior palatoplasty (ESPwAP) and BP are effective, with comparable results. The BP technique may be preferred when possible to avoid soft tissue excision, and seems to be a less invasive procedure with a similar success rate when compared with ESPwAP. However, we observed an elevated heterogeneity across the studies regarding the OSA population, surgical procedure, PSG parameters, and followup visits. In all the studies, the authors included in the same group patients with different degrees of OSA severity: snoring and mild OSA, [18] mild to moderate OSA, [14] mild to severe OSA, [5,9,11,19] moderate to severe OSA, [15] and severe OSA. [13] In one study, it was not specified. Many studies included in this systematic review did not specify the different collapse patterns at the retropalatal area assessed during DISE. Furthermore, the authors used different classification systems to describe obstruction sites and patterns. Five studies [5,9,14,16,19] used NOHL classification, one study [10] used the VOTE classification, and one study [13] used both NOHL and VOTE classification, while in three studies [11,15,18] DISE classification was not specified. The NOHL classification created by Vicini et al. [23], unlike the VOTE classification, takes into account the nose, since it is frequently included in the surgical plan. The inclusion of the nose is a controversial issue. The nose is a rigid structure, which does not change during DISE. However, many studies suggested how septoplasty and turbinoplasty could significantly improve the palatal collapse in over 50% of patients and change the DISE findings, modifying the surgical plan. [24] Sleep endoscopy plays a key role in decision-making for OSA patients by providing evidence of prospective surgical success rate or failure. However, there are some critical issues. First, the DISE procedure performed was not uniform in all the sleep apnea centers. There are different DISE assessmentscoring systems although the VOTE system remains the most frequently used. However, the procedures are not performed the same way or by the same surgeon. Several DISE techniques are reported in the literature. Although many centers still use conventional DISE performed by a manual bolus injection of sedative agents, target-controlled infusion pump (TCI) DISE technique should be the first choice. It increases accuracy, stability, and safety, complementing findings. [25] Understanding the complex mechanical behavior of the UA during sleep in OSA patients remains a challenge.

Today, the question of whether the oral tongue causes retropalatal collapse is debatable. In particular, it has been observed that during sleep, the posterior displacement of the tongue would relax the palatoglossal arch and allow the folding and consequent increase in the volume of the lateral wall, as well as pushing the soft palate backwards, all of which, together, cause circumferential narrowing of the retropalatal airway. [26] In order to understand more deeply the role of the tongue, transoral fiber-optic endoscopic UA assessment becomes fundamental during DISE. It could give additional information in selected patients if the mouth is open. In particular, the degree of tongue retraction and position could be evaluated both from the oral cavity and from the nasopharynx, highlighting a secondary anteroposterior soft palate collapse, due to the tongue position. [27] Previous studies have suggested that open-mouth breathing aggravates OSA, which can be increasing the upper airway's collapsibility. [28] Conversely, a closed oral rest position with intraoral negative pressure may represent an additional physical stabilizing mechanism of the soft palate as well as the tongue. [29] Many pieces of evidence suggested that the good candidate for UA surgery are patients with grade 3-4 tonsillar hypertrophy and anterior-posterior mild/partial collapse at the velum. In contrast, individuals with complete circumferential collapse at the velum and complete anteroposterior collapse at the tongue base may not be suitable for surgical treatment. [30]

Regarding the surgical procedure, BP can be performed alone or as a part of a multilevel surgery aimed at treating simultaneously multiple obstruction places in the same operative session (pharyngoplasty and septoplasty, turbinoplasty, hyoid suspension, TORS) [31]. In particular, it emerged that only four studies [10,13,14,18] evaluated the effects of the single BP, considering "pure" patients suffering alone from palatal collapse without other obstruction sites. The remaining authors assessed the effects of BP in multilevel OSA surgery. In this way, it is not possible to understand objective and subjective improvements due to a single BP technique. Therefore, the use of multilevel surgery could overestimate PSG parameters (AHI and ODI), ESS, and snoring VAS changes. Tonsillectomy is another major confounding factor when analyzing the outcome, and only three studies were performed in a selected population of tonsillectomized patients. [13,14,18] Isolated tonsillectomy can be successful as treatment for adult OSA, especially among patients with large tonsils and mild to moderate OSA [32]. In this patient population, the AHI can be normalized in a majority of patients over a short-term period, with an approximately 82% reduction in AHI seen in all-comers. [33] Moreover, oxygen desaturations, sleepiness, and snoring are likely to improve as well. Patients with morbid obesity or severe OSA may be less likely to respond to surgery despite having large tonsils.

The ideal study should have already tonsillectomy patients to evaluate only the effects of each BP technique. Furthermore, seven of the eleven single-arm studies referred to the use of barbed lateral pharyngoplasty; one study related to the barbed anterior pharyngoplasty [18] study and another the combined action of an anterior and lateral pharyngoplasty (BESP and Alianza technique). [14] BP techniques differ from each other not only for the different passages made with BS at the main landmarks such as the spina nasalis posterior, pterygomandibular raphe, tonsillar fossa, pterygoid hamulus, and palatopharyngeal muscle but also for the different muscle management. Many of the techniques described, such as BRP and BESP, typically use pterygomandibular raphe as a stronghold, Still, this structure is described as totally absent in 36%, partially absent in 28%, and present in only 36% of the population as defined by many anatomical studies. [34,35] This anatomical detail could negatively influence BP long-term outcomes. In the BRP, the palatopharyngeal muscle is initially weakened at the inferior part then it is displaced in a more lateral and anterior position suspending to the pterygomandibular raphe. In the Alianza technique, BS is driven downwards to the pterygomandibular raphe and then direct from laterally to medially throughout the tonsillar fossa to reach and encircle the vertical fibers of the palatopharyngeal muscle. Finally, in the BESP, anterior pharyngoplasty is performed and then the muscle is anchored to the pterygoid hamulus. BP techniques described can be divided into two main categories: myoresective/interruptive surgical procedure, which involves cutting the palatopharyngeal muscle, and nonmyoresective/interruptive surgical procedures. BP, when associated with section/ resection of the palatopharyngeal muscle, could presumably expose the patient to an increased risk of late dysphagia in old age [36]. In the era of the mini-invasive/conservative surgery, the role of a muscular resective/interruptive procedure is guestionable. Is it necessary, therefore, to cut the muscle while having the same results? [37] Unfortunately, there are no large comparative studies on this topic, which should be carefully investigated. Besides, there is an extreme variability also on the time of follow-up. It can range from 1 to 12 months, with an average of 6 months after the surgical procedure. Longterm results regarding this surgical technique are missing. As is well known, OSA relapse after successful operations has been described within the first 5 years without any clear cause. Many studies showed that the initial results of UPPP for OSA decrease progressively over the years. Snoring remained improved, although long-term results were slightly worse compared with 6-month results. Daytime sleepiness relapsed to preoperative levels. Improvement of ODI and response rates defined by different criteria deteriorated during long-term follow-up. [38]

The use of BS can be associated with some minor complications. [39] Montevecchi et al. [19] showed some intraoperative complications such as extruded thread, bleeding, broken needle, and suture rupture. Postoperative complications experienced were [13,14,16,18,19] extruded thread, pharyngoplasty dehiscence, [11,14] postoperative bleeding [19] and dysphagia, [19] velopharyngeal insufficiency, [10,16] hemorrhage from tonsillar bed, [16], pain during swallowing, and body sensation. [12] It is necessary to carry out more standardized clinical studies for assessing the effectiveness of this new technology. It should be useful to understand the AHI gain for each of these procedures. Specifically, it is necessary to define and to study more precisely the patients, grouping them into smaller and homogeneous categories based not only on AHI and other PSG parameters but considering the "OSA phenotype" patient. Finally, yet importantly, it is firmly necessary to evaluate patient compliance to the postoperative instructions and their expectation and satisfaction from the treatment.

Given the paucity and heterogeneity of these evidences, the conclusion calls cautiously. Therefore, in carefully selected OSA patients, palatal surgery and in particular BP could represent valid therapy strategy ensuring a significant improvement of the PSG parameters and symptoms. Further studies on a large scale assessing the role of BP in the absence of tonsillectomy and with longer follow-up are needed in order to confirm these promising results.

#### **Compliance with ethical standards**

**Conflict of interest** The authors declare that they have no competing interests.

**Ethical approval** No institutional review board approval was necessary because of the nature of this project.

**Informed consent** This article does not contain any studies with human participants or live animals performed by any of the authors.

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