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# Barbed suture pharyngoplasty in velopharyngeal complete concentric collapse: a multicentric study

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## Abstract

**Background:** Studies have shown that complete concentric circular collapse (CCC) at the velum is a frequent finding in drug-induced sleep endoscopy, implying a worse prognosis for surgical outcomes in the treatment of obstructive sleep apnea syndrome (OSAS). Our group evaluated the results of pharyngoplasties with barbed sutures for this indication. We selected 48 patients with OSAS and CCC who underwent pharyngoplasty with barbed sutures in 8 tertiary centers. The outcome results were measured by polygraphy or polysomnography and Epworth Symptoms Scale (ESS) at least 6 months after surgery.

**Results:** Apnea Hypopnea Index (AHI) improved from 34.9/h [21.2] to 12.7/h [10.6]. The success rate according to Sher's criteria was 86.7%, the cure rate was 23.9%, and an AHI < 10 occurred in 42.2% of the cases. The oxygen desaturation index improved from 32.5/h [29.9] to 12.5/h SD [11.6], and the ESS improved from 10.2 [5.2] to 6 [3.5].

**Conclusions:** Pharyngoplasty with barbed sutures seems to be a good alternative for patients with OSAS and CCC findings in drug-induced sleep endoscopy.

**Keywords:** Sleep apnea syndromes, Sleep apnea, Obstructive, Snoring, Complete concentric collapse

## Background

Obstructive sleep apnea-hypopnea syndrome (OSAS) is an underdiagnosed disease with well-known consequences for morbidity and mortality [1]. Increasing the diagnosis of the syndrome and improving access to its treatment are mandatory. Treatment consists primarily of continuous positive airway pressure (CPAP) devices. These devices have a dropout rate that ranges from approximately 30 to 50% [2–4]. This high dropout rate has allowed sleep surgery to play a vital role [5].

An increasing surgical success rate is related to a better selection of patients and new surgical techniques. There are various clinical manifestation phenotypes of patients [6] and multiple phenotypes of airway collapse. There is a need to review each particular case in detail to define these features. In recent years, there has been an improvement in selecting patients susceptible to surgery and other treatment therapies by sleep surgeons [7]. The use of drug-induced sleep endoscopy (DISE) [8, 9] has allowed a more precise understanding of airway collapse including different shapes and degrees of severity. The soft palate is the most frequent area of airway obstruction [10]. Various anatomic mechanisms have been shown to produce this collapse, partly due to the soft palate's intrinsic musculature and the lateral oropharyngeal

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musculature. Therefore, there is a need to address these structures to improve outcomes, and multiple surgical techniques with varying success have been described. One of the predictors of failure found for these techniques is complete concentric collapse at the palatal level (CCC) [11, 12], which also depends on the palatal and lateral oropharyngeal muscles. One of the most commonly used classifications in the description of DISE is VOTE [13] (V, velopharynx; O, oropharynx; T, tongue base; and E, epiglottis), with CCC collapse being a V2c that can or cannot be combined with different degrees of collapse in the remaining areas. CCC is a contraindication of unilateral hypoglossal nerve stimulation (HNS) [14] and has been described as an indicator of worse results in the case of exclusive or associated multilevel surgery [11, 12].

Pharyngoplasty with absorbable barbed sutures to expand the soft palate was described by Mantovani et al. [15]. Multiple variants of the original technique have been found to improve palatal collapse and achieve good results. From a physiological point of view, the spatial conformation of the barbed suture's placement could be helpful in CCC; however, the evidence to date is scarce, limited to local series, and not associated with other procedures [16, 17].

The objective of this study was to evaluate the results of pharyngoplasty using barbed sutures in patients diagnosed with OSAS with CCC with or without multilevel surgery.

## Methods

We retrospectively collected data from patients diagnosed with OSAS and CCC in DISE findings who underwent pharyngoplasty with barbed sutures (Stratafix® - Ethicon, USA; Vloc® - Covidien, USA; or Filboc® - Assut, Italy) with or without multilevel surgery in 8 different centers: Clinica Andes Salud (Puerto Montt, Chile), Hospital Universitario Dr. Peset (Valencia, Spain), Clinica Universitaria de Navarra (Pamplona, Spain), Hospital Universitario de Fuenlabrada (Madrid, Spain), Ospedale Campus Biomedico di Roma (Rome, Italy), Ospedale Morgagni-Pierantoni (Forli, Italy), Rabin Medical Center (Tel Aviv, Israel), and Hospital Universitario y Politecnico La Fe (Valencia, Spain). The data collected were provided by surgeons specializing in sleep surgery at each center and were obtained from their databases. Informed consent for the use of these data was obtained from each center.

DISE was performed with target-controlled infusion pump (TCI) using the DISE protocols recommended in the European consensus for sleep endoscopy [8, 9]. Propofol, propofol-midazolam, or dexmedetomidine were used as sedating agents; bispectral analysis (BIS)

from 60–70 were achieved; and no decongestant drugs or topical nasal anesthesia were used.

The patients selected for surgery had a BMI less than 36 kg/m<sup>2</sup> in all cases, without considering the upper cutoff point of the AHI or neck circumference (NC). A CPAP trial was performed in cases of AHI over 15/h, and patients intolerant to its use were included. Cases with an AHI less than 15/h did not necessarily have a CPAP trial and were directly offered surgery.

Physical examination variables such as tonsil grade (measured by the Friedman scale) (g0 = tonsillectomy and Brodsky grades I–IV), Friedman tongue position (FTP), and Mallampati score (MP) were collected. The AHI and ODI were included in the study. The BMI and preoperative Epworth Sleepiness Scale (ESS), together with demographic variables (sex and age), type of surgery (barbed repositioning pharyngoplasty, Alianza, and others), and DISE collapse using the VOTE classification scale, were recorded. Exclusively, primary V2c collapses were selected accompanied or not with other collapses at the oropharynx, tongue base, or epiglottis.

All patients underwent a preoperative polysomnography (PSG) or polygraphy (PG). Postoperative control using PSG or PG was conducted between 6 and 18 months after surgery, and the AHI, ODI, ESS, and BMI were again recorded. When the preoperative sleep study was a PG, the control study was always PG. In the case of baseline PSG, the control was conducted using PSG or PG.

Patients undergoing pharyngoplasty using barbed sutures according to the technique described by Mantovani [15], Alianza [17], or others, with or without multilevel surgery, were included in the study. Multilevel surgery was considered to be any procedure at the level of the base of the tongue or epiglottis, without considering nasal surgery as part of a concurrent multilevel procedure.

We consider Sher's criteria [18] to classify a surgery as successful (reduction of AHI by 50% from the baseline and postoperative AHI less than 20/h). Together with Sher's criteria, we calculated the mean relative reduction for the AHI [19], ODI, AHI less than 10/h, cure percentage (AHI < 5/h), and ESS as a measure of success, considering that Sher only uses the AHI as a parameter of surgery success. The mean relative reduction was calculated based on the formula (AHI pre – AHI post)/AHI pre × 100. It allows evaluating the reduction of each value proportionally and offers a quick visualization of the intervention results. We use this formula to calculate the mean relative reduction of the ODI and ESS using the respective values of these variables in the same direction as when measuring the mean relative reduction in the AHI.

**Table 1** Demographic data

	Min	Max	Media	SD
Age	21	70	46.3	11.2
BMI	19	36	28	4.1
AHI	5	102	34.9	21.2
ODI	1.4	171	32.5	30
ESS	0	22	10.2	5.2
Gender	42 male	6 female		

**Table 2** Physical examination data

FTP	I	IIA	IIB	III	IV
<i>n</i> (%)	7 (14.6)	18 (37.5)	11 (22.9)	10 (20.8)	2 (4.2)
Mallampati	I	II	III	IV	
<i>n</i> (%)	6 (12.5)	18 (37.5)	21 (43.8)	3 (6.3)	
Brodsky	0	I	II	III	IV
<i>n</i> (%)	5 (10.4)	14 (29.2)	14 (29.2)	14 (29.2)	1 (2.1)

**Table 3** VOTE graduation in oropharynx, tongue base, and epiglottis

Shape/grade	0	1	2
O lateral	9 (18.8%)	16 (33.3%)	23 (47.9%)
T anteroposterior	10 (20.8%)	20 (41.7%)	18 (37.5%)
E anteroposterior	18 (37.5%)	18 (37.5%)	12 (25%)
E lateral	0 (0%)	0 (0%)	0 (0%)

### Statistical analysis

The analysis of the results was performed using SPSS v15 for MacOS using parametric or nonparametric tests depending on the case. Statistical significance was established as  $p < 0.05$ .

Due to the small sample size in each category, we did not perform any subgroup analysis according to tonsillar grade, FTP, or MP.

### Results

Forty-eight patients with the previously described characteristics were enrolled (Table 1). Physical examinations found that most of the patients had FTP IIA (18/48, 37.5%) and MP gIII (21/48, 43.8%). The tonsillar grades were similar in all cases, equaling gI, II, and III in 14/48 patients (29.2%) for each grade. There were 5 tonsillectomized patients (10.4%) and one gIV patient (2.1%) (Table 2). The preferred sleep study was PG (37/48, 77%), followed by PSG (11/48, 22.9%).

Cases selected in DISE were V2c O0–2. In all cases, there was some degree of collapse at the level of the base

**Table 4** Barbed sutures pharyngoplasty results in CCC

		Media	SD
AHI <sup>a</sup>	Pre	34.9	21.2
	Post	12.7	10.6
ODI <sup>a</sup>	Pre	32.5	29.9
	Post	12.5	11.6
ESS <sup>a</sup>	Pre	10.2	5.2
	Post	6.0	3.5
BMI	Pre	28.0	4.1
	Post	27.8	4.6

<sup>a</sup> Statistically significant difference

of the tongue (T) and epiglottis (E). Collapse at the oropharyngeal (O) level was found in 81.3% of the cases (Table 3).

The most frequent procedure on the palate was the barbed suture technique described by Vicini et al. [20] (33/48, 68.8%), followed by Alianza [17] (15/48, 31.3%). In 22 patients, multilevel surgery was performed, and in 26, barbed pharyngoplasty as a standalone technique. There were no suture complications (exposure/cut) reported in these patients. The type of surgery performed in the multilevel procedures was not recorded.

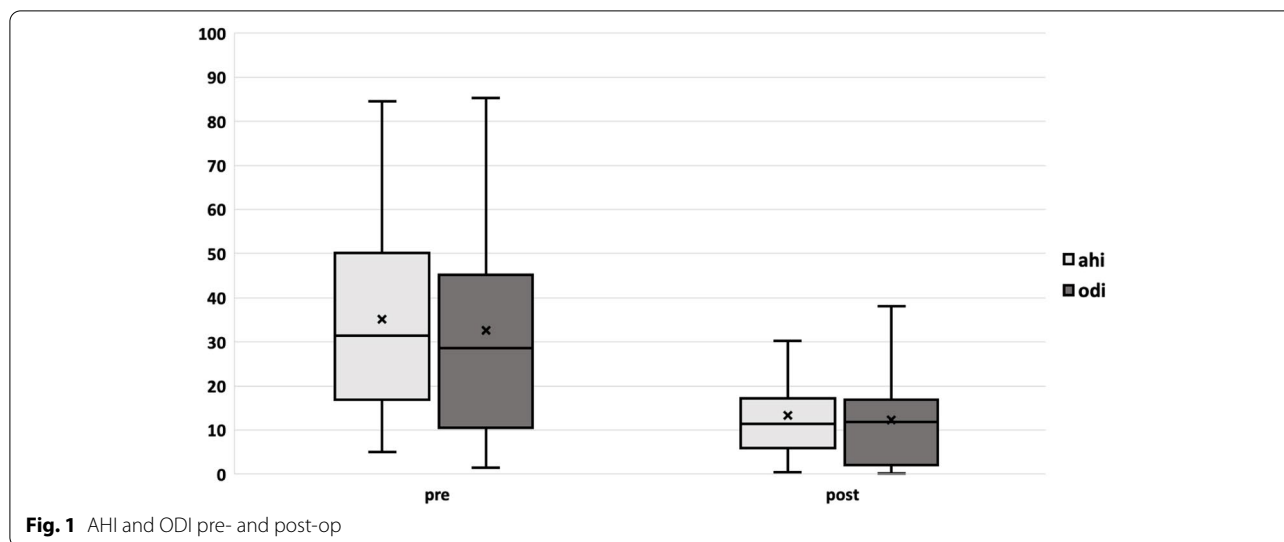
The AHI, ODI, ESS, and BMI changes are shown in Table 4, and visual improvement of AHI and ODI is shown in Fig. 1. The success of pharyngoplasty with barbed sutures in CCC patients based on Sher's criteria was 86.7%, the cure rate was 23.9%, and 42.2% of the cases achieved an AHI < 10. The mean relative reductions in the AHI, ODI, and ESS were 63.7%, 61.6%, and 34.6%, respectively.

### Discussion

To our knowledge, this is the first multicentric study of patients with CCC performing pharyngoplasties with barbed sutures. Following the classical Sher's criteria, our success rate was 86.7%, with a relative reduction in the AHI of 63.7% and a significant reduction in the ESS.

Historically, the CCC collapse pattern has been considered an unfavorable prognostic factor for all types of therapies that aim to improve airway collapse in OSAS, both for mandibular advancement devices (MAD) [21] and surgery [11, 12, 22]. Moreover, patients with CCC require higher PAP pressure [23], increasing the probabilities of discomfort and failure.

Unfortunately, CCC is a frequent collapse pattern. In a series of 1249 patients who underwent DISE [10], CCC, which was associated with higher AHI values and multilevel collapse, was found in 31.46% of the cases. Another study by Steffen et al. [24] found that this type of collapse



was observed in 21.6% of the patients who were candidates for hypoglossal nerve stimulation (HNS), excluding them for this type of therapy [14]. Therefore, some authors advocate performing pharyngoplasty prior to implantation so the pattern of collapse changes [25]. Others even suggest performing pharyngoplasty simultaneously with HNS [26].

Maxillomandibular advancement (MMA) seems to be a good alternative for managing patients with CCC and OSAS; however, its execution is more complex. In a cohort of 14 patients, Kastoer et al. [27] found that the presence of CCC was not associated with a decreased rate of MMA success compared to patients without CCC. Postoperative DISE was performed, showing that the CCC changed in all cases to other more favorable and incomplete types of collapse.

Given the poor prognosis that having a CCC implies, an attempt has been made to search for predictors of its presence. FTP grade IV has been highly correlated with CCC [28] with up to a 4.4-fold higher risk of having CCC than grade I individuals. A recent study by Thuler et al. [29] showed a more significant presence of CCC in patients with transverse maxillary deficiency, mainly when the intermolar distance was less than 27.5 mm. In another article by Steffen et al. [24], CCC was statistically associated with a higher BMI and AHI.

Given this scenario and due to the high frequency of CCC among OSAS patients, it is necessary to seek more successful alternatives than those previously described in soft tissue surgery techniques.

Techniques at the palatal level have evolved from a resective to a repositioning concept, following the ideas of Cahali et al. [30], Pang et al. [31], Salamanca et al. [32], Mantovani et al. [15, 17, 33, 34], and others. These

authors have focused their efforts on eccentrically repositioning the palatopharyngeal muscle and changing the shape of the retropalatal and retropharyngeal spaces responsible for airway collapse in OSAS. In particular, the barbed suture, initially described by Mantovani et al. [35], has received interest in sleep surgery, especially among those who perform palatal surgery. Mantovani's original concept rests on two coaxial tubes: one tube is external, rigid, and made of bone, and the other tube is internal, elastic, and composed of the palatopharyngeal muscles and ancillary soft tissues. Mantovani insisted on the need to increase the tension of the inner tube and anchor these structures to the rigid structures of the outer tube. This is how various forms of suture placement have been conducted. These methods have the repositioning of the palatopharyngeal muscle in the direction of the pterygomandibular raphe, posterior nasal spine, and pterygoid hamulus, structures that allow the support of the muscle in an eccentric direction to the palatal collapse. The barbed suture allows a uniform distribution of forces along each of its multiple barbs, avoiding possible damage to the mucosa caused by knotted sutures, which focus the stress on their placement points. Therefore, our group explored the possibility of a favorable outcome using barbed sutures in patients with CCC due to the extrinsic tension of barbed sutures at the palate and lateral pharyngeal wall placement points, which are in turn responsible for the concentric collapse in CCC patients.

Our group collected 48 patients with CCC and evaluated pharyngoplasty with barbed sutures (68.8% barbed repositioning pharyngoplasty and 31.3% Alianza). The results showed a success rate of 86.7% and that the AHI improved from 34.9 to 12.7, in line with the results of Mantovani et al. in their

initial description of their Alianza technique. Mantovani et al. evaluated their Alianza [17] technique for the placement of barbed sutures in the palate in 19 patients with CCC who had a previous tonsillectomy. They achieved an improvement in the AHI from 22.3 to 7. Subsequently, Hasselbacher et al. [25] evaluated the results of traditional uvulopalatopharyngoplasty in 15 patients with CCC and found worse outcomes, improving the AHI from 34.7 to 20.2. Recently, Oh et al. [36] evaluated a repositioning pharyngoplasty technique in 133 patients with CCC and found that the technique improves the AHI from 37.3 to 21.4 with a 52.9% success rate according to Sher's criteria. Other studies that have evaluated the efficacy of other pharyngoplasty techniques with or without multilevel surgery have found an unfavorable prognostic factor in this type of collapse with relatively poor results [37], and thus, they recommend a different type of therapy for patients with CCC.

We consider that it is probable that the effect of eccentric suture placement allows the retropharyngeal volume to be increased in line with Mantovani's initial postulates and that this technique is a good alternative in cases of CCC. The success of the barbed suture in CCC is such that it does not seem unreasonable to propose it as a first-line treatment in these cases.

Along with this postulate, the contribution of this work in identifying barbed sutures as successful in the management of patients with CCC lies in the reproducibility of the results. Despite the biases of this retrospective multicenter study not being a clinical trial, we observe that the technique has certain advantages that simplify its implementation with reproducible results with a relatively short learning curve.

The limitations of this study were the presence of CCC that was evaluated independently in each center, and videos were not compared to reach a scoring agreement. Moreover, even though DISE was performed according to the European position paper recommendations, there might be intercenter differences that might have affected the results. The use of barbed sutures was common to all the surgeries, but the placement of the sutures within the muscles and the number of loops could have differed.

Although there was an equal distribution of grade 1–3 tonsils, only five patients had a previous tonsillectomy, and one patient had grade 4 tonsils. The volume of tonsils removed could have had an impact on surgery success [38], something we did not record. This possibility is also genuine for other studies where pharyngoplasty was carried out and whose volume of tonsils removed was not recorded, but with better results for our group.

Naturally, the data in this work must be corroborated by a greater number of cases and a greater experience that demonstrates the efficacy of this technique in this particular indication and in the long term.

## Conclusions

Pharyngoplasty with barbed sutures appears to be increasingly promising in the surgical treatment of patients with OSAS. Specifically, in patients with CCC detected by DISE, it can be a successful and reproducible technique. Given our good results with these unfavorable patients, we encourage other colleagues to perform this type of surgery.

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## Authors' contributions

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## Availability of data and materials

All data is available for future research.

## Declarations

### Ethics approval and consent to participate

Informed consent for the use of these data was obtained from each center as follows: Reloncavi Health Service Ethics committee (Puerto Montt, Chile), Fuenlabrada Hospital Ethics committee (Fuenlabrada-Madrid, Spain), Navarra Clinic University Ethics committee (Pamplona, Spain), Dr. Peset Hospital Ethics committee (Valencia, Spain), La Fe Politecnico Hospital Ethics committee (Valencia, Spain), Forli Hospital Ethics committee (Forli, Italy), Campus Biomedico di Roma University Ethics committee (Rome, Italy) and Tel Aviv national survey ethics committee (Tel Aviv, Israel). Consent to participate is not applicable as it is a retrospective study.

### Consent for publication

Not applicable

### Competing interests

The authors declare that they have no competing interests.

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