European Archives of Oto-Rhino-Laryngology (2022) 279:4189–4198
https://doi.org/10.1007/s00405-022-07369-9

MISCELLANEOUS

Anxiety, depression and sleepiness in OSA patients treated with barbed reposition pharyngoplasty: a prospective study

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Received: 16 February 2022 / Accepted: 21 March 2022 / Published online: 9 April 2022

Abstract

Purpose To evaluate the efficacy of barbed reposition pharyngoplasty (BRP) on sleepiness, anxiety, and depression o adult patients with obstructive sleep apnea (OSA).

Methods We performed a prospective multicentric study to assess functional outcomes in 20 OSA patients treated with BRP and compare the results with an observational group of 20 subjects. All recruited subjects performed at baseline and 6-months postoperative follow-up Polysomnography (PSG), daytime sleepiness scoring using the Epworth Sleepiness Scale (ESS), and anxiety and depression evaluation via the Beck Anxiety Inventory (BAI) and the Beck Depression Inventory-II (BDI-II) questionnaires.

Results At follow-up the BRP demonstrated greater improvements in AHI (8.92 ± 2.29 vs. 30.66 ± 2.56; $p < 0.001$) and ODI (7.65 ± 2.39 vs. 24.55 ± 3.20; $p < 0.001$) than control at intergroup analysis. Surgical group reported significant data in daytime sleepiness (5.15 ± 1.19 vs. 13.15 ± 1.35; $p < 0.001$), anxiety (12.65 ± 3.11 vs. 24.2 ± 2.37; $p < 0.001$), and depression domains (5.85 ± 1.19 vs. 17.55 ± 3.24; $p < 0.001$). AHI, ODI, and advanced age have been shown to multiple regression as independent predictors of treatment response for mood domains ($p < 0.001$; $p = 0.02$; $p = 0.041$, respectively).

Conclusions Patients with OSA may benefit from palate surgery, reducing not only the apnea and hypopnea index, daytime sleepiness but also associated mood comorbidities. However, further studies are needed to confirm our preliminary results to validate the evidence to date reported.

Keywords Obstructive sleep apnea–hypopnea · Tonsillectomy · Barbed reposition pharyngoplasty · Anxiety · Depression

Introduction

Obstructive sleep apnea syndrome (OSAS) is a sleep breathing disorder characterized by recurrent partial or complete episodes of upper airway collapse, occurring more than 10 s [1]. OSAS is a very common disease in the general population, with an increasing prevalence and reaching up to 60% of people over the age of 65 [2–5]. It is often an underdiagnosed condition, and frequently the patient develops the different associated comorbidities before full awareness of the pathology [6–8]. Sleep fragmentation and intermittent hypoxia also lead to daytime sleepiness, difficulty concentrating, and behavioral and mood disorders, such as depression and anxiety, especially when associated with other systemic comorbidities, such as cardiovascular, neurological or diabetes [9–11]. Hobzova et al. debated how mood or behavioral disorders are more frequent and of greater severity in patients with long-lasting apnea, underlining the importance of early recognition and treatment of the disease [12]. Although continuous positive airway pressure (CPAP) is still the treatment of choice for OSAS and effectively reduces daytime sleepiness, the effect on anxiety and depressive symptoms remains insignificant or controversial [13–16]. Campos-Rodriguez et al. in a randomized controlled trial (RCT) reported in 151 subjects CPAP treated a significantly greater improvement of daytime sleepiness (-2.92; $p < 0.001$), mood state (-4.24; $p = 0.012$), anxiety (-0.89; $p = 0.014$) and depression (-0.85; $p = 0.016$) [17].

A recent meta-analysis performed by Labarca et al. on RCT in elderly patients also demonstrated the depression

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domain improvement assessed through the Hospital Anxiety–Depression Scale in the CPAP group, yet the quality of evidence of the outcomes was considered low [18].

Another factor to consider is that patients could demonstrate poor compliance and tolerability of CPAP, requiring an alternative approach to medical therapy [19, 20].

Surgical techniques for OSAS demonstrated a significant reduction of lateral wall collapse, proposing both single and multilevel approaches after adequate surgical planning and drug-induced sleep endoscopy (DISE) [21, 22]. Techniques such as expansion pharyngoplasty or barbed reposition pharyngoplasty have shown significant control of both polysomnographic parameters and daytime sleepiness, yet to date, no author has evaluated the repercussions of this method on behavioral disorders. This prospective study aimed to evaluate the effect of the BRP on daytime sleepiness, anxiety, and depression perceived and thus improving patient's QoL.

Methods

Study design and patients

We followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines [23]. This multicentric prospective study was conducted at the ear, nose, and throat (ENT) Units of our Hospitals from January 1, 2020, to December 1, 2021.

We candidated for inclusion all the OSA patients referred to our ENT Units for palatal surgery that failed or refused the CPAP approach. The data were first extracted and evaluated by the principal investigator (M.D.) and subsequently independently (studied) by two senior co-authors (G.I. and A.M.) using standardized data forms. Patients aged 18–65 years with moderate to severe OSAS defined as apnea–hypopnea index (AHI) ≥ 15 at polysomnography (PSG) and with BMI < 35 were included in the study. All subjects included had retropalatal collapses detected on DISE (moderate–severe transverse or circular collapse and no evidence of retrolingual one).

The study design is summarized in Fig. 1.

The randomization was performed utilizing statistical computing web programming (www.graphpad.com/quickcalcs). The random number list was prepared by an investigator not related to this study and thus computer-generated. Consequently, we carried out a random patients' allocation into 50% Group A or active arm (barbed reposition pharyngoplasty group) and 50% Group B or control arm (observation group).

Patients with the following features were excluded from the study:

- prior OSA surgery, such as tonsillectomy, UPPP, or other pharyngoplasty;
- AHI < 15 at preoperative PSG evaluation;
- overall follow-up time < 6 months after;
- incomplete preoperative and postoperative data

Patient assessment and investigated parameters

We evaluated all the subjects included at baseline and after the surgical procedure at baseline and 6 months. The follow-up protocol was also adopted for the control group. Two trained specialists collected clinical features, such as age, sex, BMI, the Italian version of ESS during the in-office control.

Endoscopic evaluation was performed to define palate position, Friedman lingual tonsil grade, and collapse site at Müller's maneuver [24].

Moreover, at pre-randomization, we evaluated all the participants with DISE to confirm the palatal/pharyngeal obstruction applying the VOTE scale [25] and polysomnography criteria (PSG) according to the latest AASM guidelines [1]. In the population analyzed an AHI cutoff of ≥ 5 events/h (hypopneas associated with 4% oxygen desaturations) was adopted, dividing the participants according to three AHI groups mild (5–14), moderate (15–29), and severe (≥ 30).

ODI was graded into three groups: mild (5–14), moderate (15–29), and severe (≥ 30), while participants ODI < 5 were defined as having no oxygen disorders. We collected PSG parameters as AHI and ODI at each control.

QoL and behavioral disorders assessment

Each patient was assessed at baseline and each follow-up through Beck Anxiety Inventory (BAI) [26] and the Beck Depression Inventory-II (BDI-II) questionnaires [27].

The Beck Depression Inventory-II (BDI-II), revised in 1996, is a self-report questionnaire consisting of 21 multiple-choice questions regarding depression symptoms. Scores > 15 were defined as the significant cutoff point for depressive symptoms presence. Thus, the following BDI categories were ranged: normal (0–9), mild (10–15), moderate (16–23), and severe (24–63) depression grading.

Instead, the anxiety was assessed via the Beck Anxiety Inventory (BAI), a self-report questionnaire composed of 21 items, each given a score from 0 to 3. The total score BAI was thus calculated, and the following categories were defined: normal (0–7), mild (8–15), moderate (16–25), and severe (26–63) anxiety grading. These questionnaires were submitted to patients at the end of preoperative and follow-up clinical evaluation and the average administration time was 5–10 min. Two authors (A.M. and G.I.), well trained on

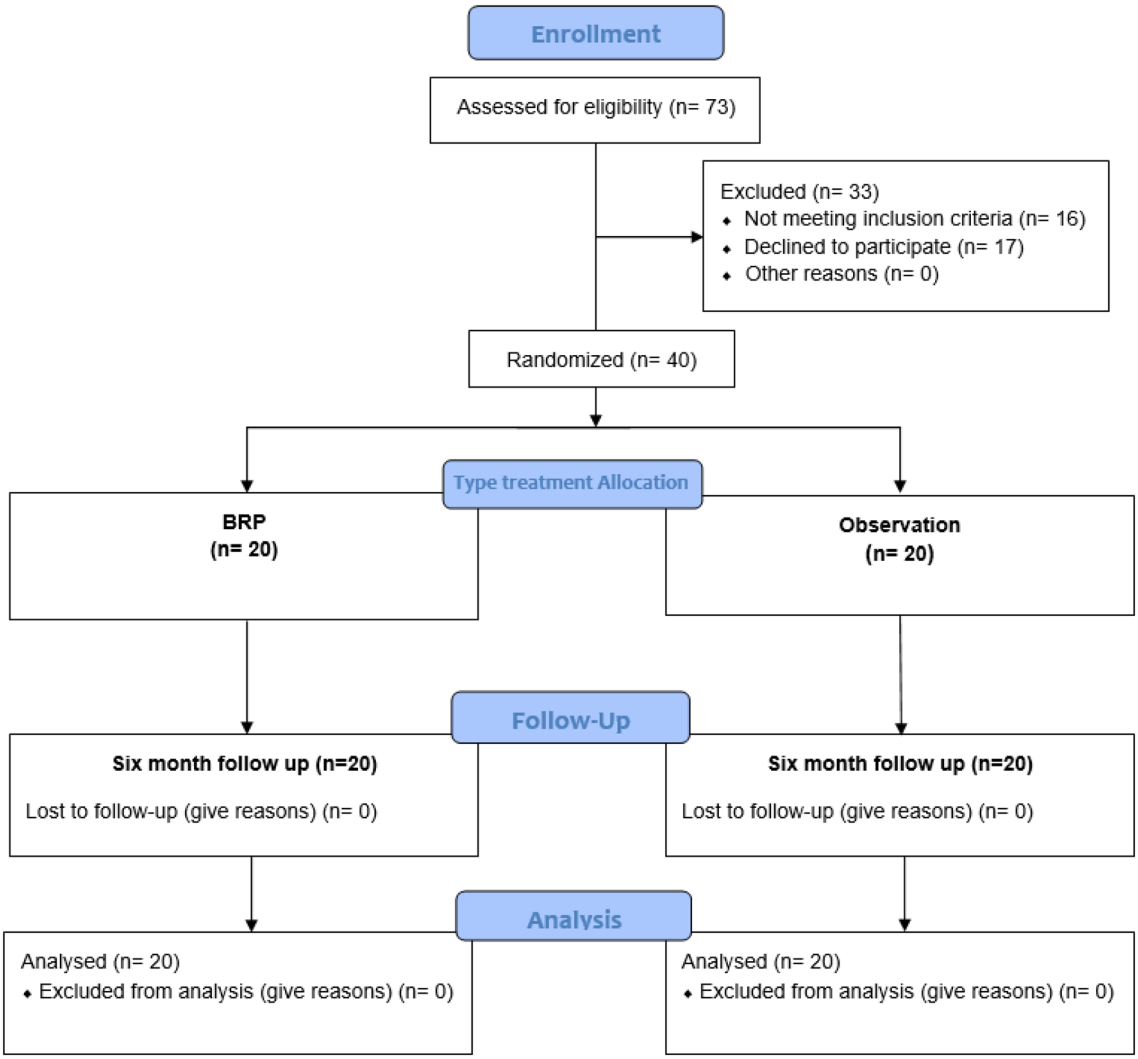

Fig. 1 CONSORT 2010 flow diagram. abbreviations: BRP, Barbed reposition pharyngoplasty

the questionnaire data, took care of interviewing patients to obtain as detailed information as possible.

Operative technique

All surgical procedures were performed by different surgeons using the same operatory settings with patients under general anesthesia, orally intubated in a supine position, exposed by a Boyle–Davis mouth gag together with lateral cheek retractors to give wide access to the surgical field.

The first step is bilateral tonsillectomy with a careful sparing of palatoglossus and palatopharyngeal muscles. After the first surgical step, two partial weakening incisions are made in the caudal part of the palatopharyngeal muscle, and a triangle remotion on the superolateral corner of the palatoglossus muscle is performed.

The suture is started at the level of the posterior nasal spine utilizing a bi-directional barbed wires monofilament up to the pterygomandibular raphe on one side; (Fig. 2a) the same procedure is performed with the bi-directional thread contralaterally (Fig. 2b). The needle is introduced again near into the exit point, through the pterygomandibular raphe, until it comes out in the upper pole twice; the traction will be applied to the thread when the suture is suspended bilaterally around the raphe: as a final result, this maneuver leads to a strengthening and anteriorization of the palate (Fig. 2c, d) [28].

Endpoints and statistical analysis

The primary outcome assessed was the change from baseline to the follow-up end of the AHI, ODI, and Epworth Sleepiness Scale (ESS) score[1, 29]. Secondary outcomes included

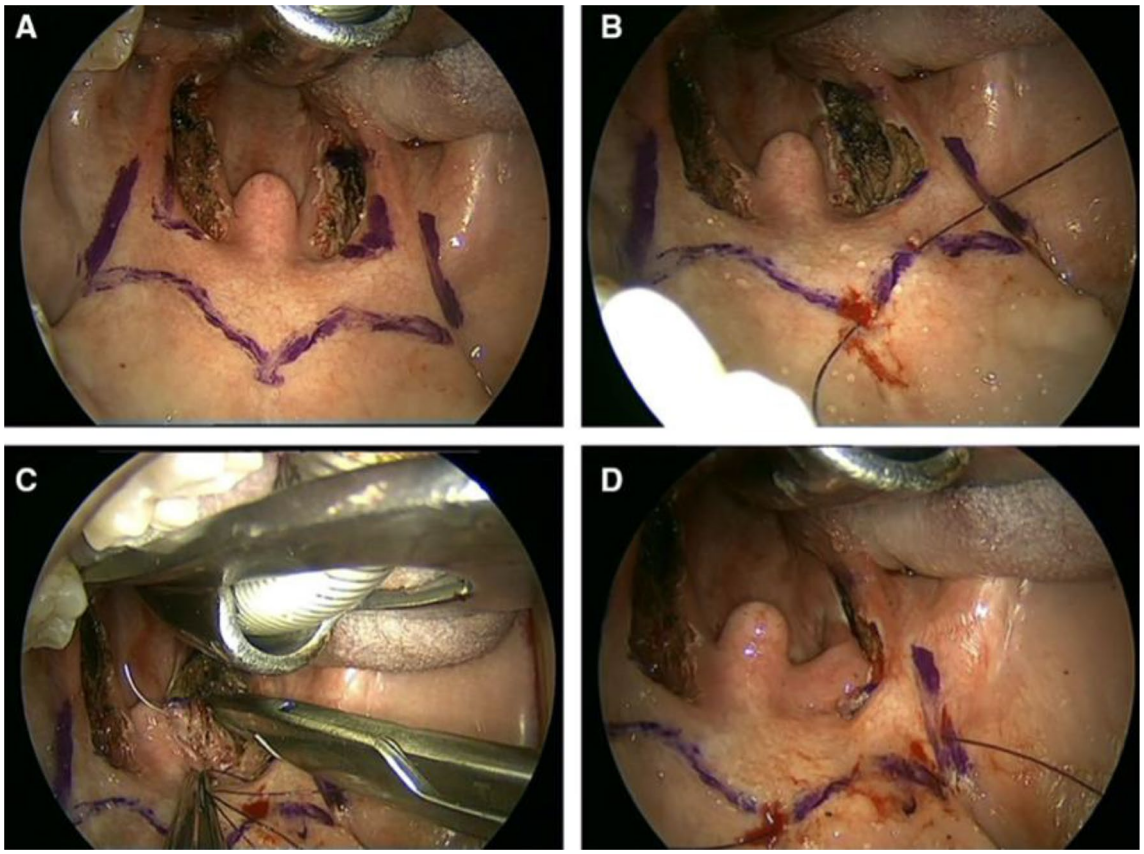

Fig. 2 Further explanation of surgical steps. **a**: Marking the center of palate, pterygomandibular raphe and squaring of anterior pillars; **b**: barbed suture around the upper part of the right raphe and it hangs at the central transition zone; **c**: needle is passed through the upper part of the palatopharyngeus muscle and comes out near to mucosa of posterior pillar not through it; **d**: needle is passed through the upper pole and suspended around the raphe, pulling of barbed suture without taking of knots

changes in anxiety and depression symptoms assessed via the related questionnaires (BAI and BDI domain scores) [26, 27]. According to the criteria proposed by Sher et al. the surgical success was defined as a > 50% decrease in AHI with a post-operative AHI < 20 [30].

We performed data analysis using IBM SPSS Statistics for Windows (IBM Corp. Released 2017, Version 25.0. Armonk, NY: IBM Corp.). The sample size required for the study was calculated assuming a 95% confidence, p value < 0.05, a power of 0.8, and a mean difference set to 2.0. Therefore, at least 15 patients per group were identified, and subsequently, the dropout rate of 30% was added to the sample. Descriptive statistics were reported on average ± standard deviation or proportion, while data normality was assessed using the Kolmogorov–Smirnov test of normality. The T test was used for paired samples to determine the difference between observations. The Mann–Whitney U test was performed to analyze group differences. The tests were two-tailed, and a p value of < 0.05 was considered statistically significant. The ethics committee approved the study protocol of the involved Institution. The preoperative and postoperative outcomes of each patient were put into separate folders, coded, and evaluated by two different examiners (G.I. and M.D.L); the examiners did not know which technique had been used and were, therefore, blinded.

Participants were informed and gave written informed consent of the purpose and procedures of the study, which was conducted according to the Declaration of Helsinki.

Results

Setting and patients

A total of 40 participants, 20 patients in group A (BRP) and 20 in group B (observation), were enrolled. As summarized in Table 1, no significant difference in demographics features as age, gender ratio, BMI, marital status, preoperative AHI, ODI and ESS (Table 1) was found among the two groups. No significance difference was reported among the average follow-up of the two group enrolled (212.75 ± 11.69

Table 1 Main demographic features at baseline and after 6-month follow-up

	Group A ($n=20$)	Group B ($n=20$)	p value
Age	43.35 ± 7.82	38.65 ± 8.78	*0.081*
Follow-up/days	212.75 ± 11.69	214,9 ± 8,55	*0.299*
Gender			
Male	16/20 (80%)	15/20 (75%)	*0.704*
Female	4/20 (20%)	5/20 (25%)	
Marital status			
Yes	15/20 (75%)	18/20 (90%)	*0.211*
No	5/20 (25%)	2/20 (10%)	
PreBMI	26.71 ± 1.11	27.5 ± 1.27	*0.042*
PostBMI	22.8 ± 0.75	26.72 ± 1.35	*< 0.001*
PreAHI	29.71 ± 4.42	29.09 ± 2.62	*0.592*
PostAHI	8.92 ± 2.29	30.66 ± 2.56	*< 0.001*
PreODI	27.55 ± 4.18	25.85 ± 2.35	*0.121*
PostODI	7.65 ± 2.39	24.55 ± 3.20	*< 0.001*

vs. 214.9 ± 8.55; $p=0.299$). None of the patients reported central sleep apnea.

Postoperative outcomes and treatment efficacy

A success rate of the BRP procedure was reported at 76.4%. No complications were recorded in the BRP group after surgery. At intragroup analysis a significant reduction of AHI and ODI was detected in the BRP surgery group (< 0.001), while the control group reported no improvements at 6-months follow-up ($p=0.062$ and $p=0.151$, respectively) (Table 1). Moreover, at intergroup analysis, the BRP group demonstrated greater outcomes in postoperative AHI (8.92 ± 2.29 vs. 30.66 ± 2.56; $p<0.001$) and ODI (7.65 ± 2.39 vs. 24.55 ± 3.20; $p<0.001$) than observational, respectively (Fig. 3).

Moreover, after adjustment for OSA severity classes no significant difference was reported among postoperative improvements between moderate OSA patients (26.45 ± 2.67 to 8.81 ± 2.44) and severe ones (33.66 ± 1.80 to 9. 11 ± 2.52) ($p=0.79$).

In the BRP group at follow-up, the patients presented a significant BMI reduction ($p<0.001$), while no change was observed in the observational group ($p=0.067$).

Sleepiness, anxiety, and depression outcomes

Sleepiness improvements after treatment were recorded in the BRP group (from 12.85 ± 2.35.

to 5.15 ± 1.19; $p<0.001$), while no significant changes were seen in observation group (from 12.45 ± 1.82 to 13.15 ± 1.35; $p=0.175$)(Table 2). At intergroup analysis, the BRP group demonstrated better efficacy in resolving daytime sleepiness disorders ($p<0.001$).

At the 6-months follow-up, the BRP procedure allowed the control of depressive symptoms in all treated subjects; on the contrary, the patients in group observation maintained their depressive symptoms, reporting a significant

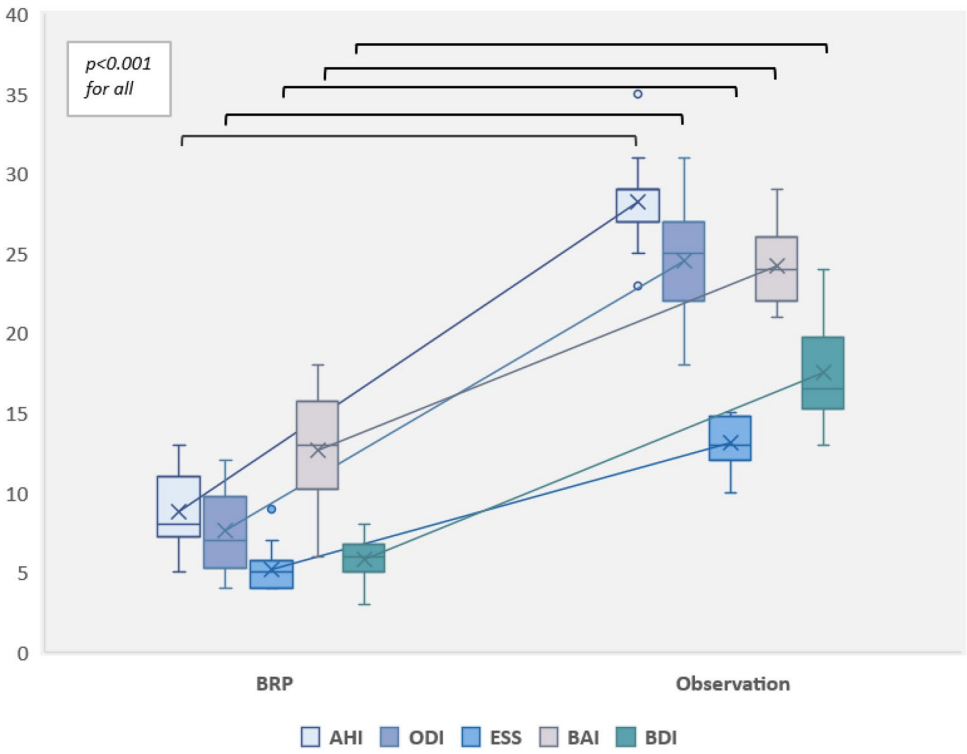

Fig. 3 Six-month outcomes box-plot. BRP group obtained significant improvements in all the parameters assessed

Table 2 Outcomes comparison of sleepiness, anxiety and depression after 6-month follow-up

	Group A ($n=20$)	Group B ($n=20$)	p value
PreESS	12.85 ± 2.35	12.45 ± 1.82	*0.550*
PostESS	5.15 ± 1.19	13.15 ± 1.35	*< 0.001*
PreBDI-II	17.25 ± 5.66	16.15 ± 3.88	*0.477*
PostBDI-II	5.85 ± 1.19	17.55 ± 3.24	*< 0.001*
PreBAI	24.3 ± 5.23	23.25 ± 3.29	*0.452*
PostBAI	12.65 ± 3.11	24.2 ± 2.37	*< 0.001*

difference in the intergroup analysis ($p < 0.001$). At multiple linear regression for BDI independent predictive factors in the BRP group, a significant correlation was found for preoperative ESS (Pearson: 0.547; $p = 0.006$). Instead, no significant correlation was found in the observation group ($p > 0.05$ for all).

Postoperative BAI scores comparison demonstrated higher symptoms control in the BRP group than observation (12.65 ± 3.11 vs. 24.2 ± 2.37; $p < 0.001$). Moreover, surgery achieved a normal to mild score of up to 15/20 (75%) of cases in the BRP, while in the observation, 14/20 (70%) were classified moderate, while 6/20 (30%) severe. At multiple linear regression for independent predictive factors in the BRP, a negative correlation was found for Age (Pearson = − 0.667; $p = 0.001$), while AHI (Pearson = 0.462; $p = 0.020$) and ODI (Pearson = 0.398; $p = 0.041$) demonstrated a positive one (Table 3). Instead, among the observational group, only BMI was demonstrated as a negative predictor (Pearson = − 0.671; $p = 0.001$).

Discussion

To our knowledge, this is the first RCT that assessed sleepiness, anxiety, and depression-related disorders in OSA patients and how treatment administered influenced the patients' outcomes**.**

In the current literature, surgical approaches as pharyngoplasties techniques in patients with moderate to severe OSA and airways collapse DISE-confirmed represent a validated alternative to CPAP treatment [31–33].

A recent meta-analysis compared the efficacy and success rates of lateral pharyngoplasty techniques (LP) vs. uvulopalatopharyngoplasty (UPPP) among adult patients surgically treated for obstructive sleep apnea, analyzing nine articles for a total of 312 surgically treated patients with OSA [34]. Both surgical procedures resulted in significant improvements in apnea–hypopnea index (AHI), Epworth Sleepiness Scale (ESS) score, and lowest oxygen saturation (LOS) ($p < 0.001$ in all cases). However, as demonstrated by Pang et al. in a multicentric study on OSA surgery, UPPP is related to higher complications rates than pharyngoplasties techniques [32].

Our prospective study confirmed the data present in literature, with significant control of sleep apnea in the BRP group at 6 months than controls both for AHI (8.92 ± 2.29 vs. 30.66 ± 2.56; $p < 0.001$) and ODI parameters (7.65 ± 2.39 vs. 24.55 ± 3.20; $p > 0.001$).

Of particular interest is the data reported in our study, which demonstrates how higher BMI improvement was found in the surgery group ($p < 0.001$) compared to the observational arm ($p = 0.067$). The most likely consideration reported in the literature is that lateral repositioning surgery, although less invasive than other techniques, such as uvulopalatopharyngoplasty or expansion pharyngoplasty, still

Table 3 Multiple linear regression of independent predictive factors

Baseline	6-month BDI		6-month BAI	
	Pearson correlation	Sig. (1-tailed)	Pearson correlation	Sig. (1-tailed)
BRP				
Age	− 0.081	0.367	− 0.667	0.001
BMI	0.067	0.390	0.056	0.407
AHI	0.159	0.252	0.462	0.020
ODI	0.175	0.230	0.398	0.041
ESS	0.547	0.006	0.148	0.267
Observational				
Age	− 0.104	0.332	0.362	0.058
BMI	0.145	0.271	− 0.671	0.001
AHI	0.121	0.306	0.11	0.323
ODI	− 0.002	0.496	− 0.12	0.307
ESS	0.169	0.239	0.266	0.128

Predictors constant: ESS, BMI, AGE, ODI, AHI

involves swallowing pain, also due to the presence of barbed sutures [35, 36]. On the other hand, paying attention to the better physical status perceived by the patient predisposes him to increase physical activity and better nutrition again.

On the contrary, the management of cognitive and behavioral comorbidities remains a major issue [37–40]. A study by Ihsman et al. correlates OSA to an increased risk of depression in the study group compared to the control group and also shows a significant correlation between BDI and ESS scores ($r = 0.342$, $p = 0.012$) [41]. Several authors have proposed CPAP treatment in managing daytime sleepiness, anxiety, and depression symptoms[13–16, 42].

Dalmases et al., in an RCT on 33 patients, evaluated at baseline and after 3 months of CPAP treatment, patients' sleepiness (ESS) and mood sleep-related symptoms through the Hospital Anxiety and Depression Scale (HADS) [13]. The active arm reported no significant improvement in the HADS-anxiety ($p = 0.06$) and HADS-depression (3.61 ± 2.91 vs. 4.75 ± 2.84; $p = 0.20$) than controls.

Ponce et al., in 2019, analyzed depression and anxiety scores after CPAP treatment in a randomized sample, treating 73 subjects with CPAP, while 72 were enrolled as a control for 3 months [15]. After CPAP treatment, the authors demonstrated no significant improvement in neurocognitive test or mood symptoms.

Our analysis on sleepiness, anxiety, and depression outcomes demonstrated at 6 months a higher control of symptoms referred for all the domains assessed than control ($p < 0.001$) (Table 2).

However, the literature on this subject does not present sufficient evidence, as demonstrated by a recent meta-analysis in this regard) [17]. Lo Barca et al. recently analyzed the HADS-depression domain after CPAP treatment in 4 studies for a total of 680 participants (343 in the CPAP subjects vs. 337 controls. Indeed, the HADS-anxiety domain was associated with a decrease of 0.42 points after treatment (95% CI 0.07–0.90; $I^2 = 55\%$). Thus, it is not clear if there is a close correlation between different sleep parameters and mood symptoms and any prognostic indices of response to treatment. It is not clear if there is a close correlation between different sleep parameters and mood symptoms and any prognostic indices of response to treatment.

Several pretreatment clinical predictors have been evaluated in the literature, such as age, BMI, OSA parameters, prior surgery, and patient sleep position as possible indicators for treatment success [42–44].

Evans et al., in a cohort of 25 patients, found the preintervention AHI associated with therapy response, with each point of preintervention AHI leading to an average decrease of 1.03 points ($p < 0.001$) [43].

The fundamental role of other preoperative factors such as gender, age, body mass index, neck circumference is currently debated [44–47]. Petri et al. analyzed the mandibular advancement device success predictors in a prospective study of 62 OSA patients [44]. The authors proposed two models with a specificity of 70% and sensitivity of 69% based only on positional OSA and nonsupine AHI, thus generating a receiver operating characteristic (ROC) curve (area under ROC = 0.78).

The visceral fat accumulation along the walls of the lower airways is considered a possible cause of therapeutic failure in patients with high BMI, especially in surgical techniques, where the laxity of the anatomical structures counteracts the stabilization of the collapsing lateral wall [45–47]. Shie et al. the impact of obesity on uvulopalatopharyngoplasty success, comparing obese and non-obese patients evaluated [47]. Treatment success was significantly lower ($p < 0.001$) in the obese group (24.6%) compared with the non-obese group (62.5%) and obesity, together with AHI and ESS, was a significant independent negative predictor of treatment success (adjusted OR = 0.297, 95% CI = 0.114–0.773, $p = 0.013$). To our knowledge, our study is the first evidence of predictive factors analysis in lateral pharyngoplasty treatment. Indeed, our study performed a multiple linear regression of preoperative independent predictive factors, demonstrating in the BRP group a positive correlation and statistical significance of preoperative ESS for postoperative depression outcomes (0.547; $p = 0.006$). Interestingly, in BRP group AHI (0.462; $p = 0.020$) and ODI (0.398; $p = 0.041$) parameters were also positive predictive factor for anxiety outcomes, while Age presented a negative correlation (−0.667; $p = 0.001$) (Table 3).

Instead, no correlation was found in control group except for Age (0.362; $p = 0.058$) for post-operative 6-month BAI outcomes.

Study limitations

The main limitation of this study was the small sample of patients, although the sample size obtained by 30% was exceeded, and no loss of patients during the follow-up occurred. All operated patients were selected through strict inclusion and exclusion criteria, making enrollment more complex. Patients who satisfied the different postoperative controls could be considered a representative sample of the whole, since the baseline variables did not differ from those of the control group population.

A peculiarity of the enrolled cohort and the strict selection criteria performed is the presence of severe cases despite no patient presenting tongue base collapse. As reported by Vroegop et al. in 2014 in a cross-sectional study of 1249 cases, although palatal collapse is up to 80%, it is frequently associated with multilevel collapse (68.2%), combining palatal and combined tongue base collapse in 25.5% [48]. The size of the enrolled sample may also be justified by the high prevalence of enrolled palatal collapses with high AHI

severity. In fact, it is proven in the literature that the highest AHI severity among the various collapse sites available at DISE is reported in patients with tongue base collapse [49].

The relative short follow-up time and the comparison between surgery and observation should also be considered [50, 51]. It is known in the literature that the use of long-term barbed sutures can present a reduction in the rigidity of the lateral and palatal walls. The results presented by us did not evaluate in this respect a sufficient follow-up in both included groups, and therefore, further studies are needed to clarify the stability of the long-term results.

Conclusions

BRP can be considered an effective procedure based on post-operative outcomes in controlling obstructive sleep apnea and mood disorders and associated sleepiness. Predictors of treatment response could consist of age, AHI, and preoperative ODI variables and, therefore, should be considered in treatment planning. This prospective study, although promising, represents the first evidence in the literature on the effects of surgery on anxiety and depression, and therefore, further evidence is strongly recommended to confirm our findings.

Funding Any funding did not support this study.

Declarations

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

Ethical approval All procedures performed in this study involving human participants were following the ethical standards of the institutional and national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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