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Polygraphic findings in simplified Barbed Reposition Pharyngoplasty (BRP) as a treatment for OSA patients

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Abstract

This study aims to compare polygraphic data in patients with OSA treated with Barbed Reposition Pharyngoplasty (BRP) performed with a simplified technique compared to the standard method. Variations of technique were performed and tested with the purpose of promoting tolerability and diffusion of this simplified technique. To evaluate the efficacy of the simplified BRP method, a sample of 99 patients was divided into two groups: Group A was treated with BRP (BRP group) and Group B was treated with simplified BRP (sBRP group). The results obtained on the two groups were compared with the two sample Bootstrap t-tests method, showing a substantial overlap in polygraphic results recorded 6 months after surgery.

Keywords: Barbed reposition pharyngoplasty, Obstructive Sleep Apnea, polygraphy, Home Sleep Apnea Testing device, sleep surgery

1. Introduction

Obstructive sleep apnea (OSA) is a condition characterized by partial or complete repeated obstructions due to the collapse of the upper airway during sleep (Strollo and Rogers 1996). These cause intermittent hypoxia which leads to systemic damages and high risk of morbidity and mortality (Yaggi et al. 2005).
Surgical treatment for OSA uses different and specific options for each level of upper airway obstruction (Georgalas et al. 2010). One of the surgical options for patients with obstruction at the retro-palatal level is Barbed Reposition Pharyngoplasty (BRP), proven to be an effective and safe technique (Vicini et al. 2015; Montevecchi et al. 2018), that is showing wide success (Dachuri et al. 2019). This technique uses suture materials (Knotless Tissue-Closure Device) (Alessandri et al. 2010) never before used in the surgical therapy for OSA and the surgical rationale introduced by Mantovani (Mantovani et al. 2012; Rinaldi, Mantovani, and Pignataro 2017). The premise of the present study is the experience gained from dissection courses and didactic simulations of cadaveric surgical techniques at the palatal level for OSA, which for us constitute the best opportunity to test alternative surgical solutions. In this study we aimed to evaluate the polygraphic results of some simplifications of technique that were supposed to have low-medium impact on the results but that

made the procedure easier to perform for less experienced surgeons and wanting with this to further promote the diffusion of this type of surgery.

2. Material and Methods

99 Patients were recruited into the sleep apnea surgery protocol after being subjected to Drug-induced sleep endoscopy (DISE) procedure from April 2015 to December 2019. Patients' characteristics have been described in (Arigliani et al. 2021).
All patients had never previously undergone other surgery for OSA but had undergone verification of surgical indications by DISE (Kotecha and De Vito 2018) through the 5VsEs instrumentation (Arigliani et al. 2020). A retrolingual obstruction was excluded through DISE procedure. All patients in this study performed tonsillectomy and palatal surgery only.
Of the 99 patients enrolled, 50 had been treated with standard BRP method (BRP group), 49 had been treated with simplified BRP method (sBRP group).
Unattended set polygraphy, DISE and all diagnostic procedures pre- and post-surgery were performed at "Vito Fazzi" Hospital in Lecce (Italy) by the same operator and with the same instrumentation. All surgical procedures were also performed by the same operator. Post-surgical polygraphic evaluation was performed after at least six months for both groups of patients in the study. For this study, we collected the anthropometric data as well as the pre- and post-surgery polygraphic data (Apnoea Hypopnea Index (AHI), (hour/sleep), Oxygen Desaturation Index (ODI), (hour/sleep), Lowest O2 saturation, (%). We based on AASM guidelines 2007 to make the results of our study comparable with previous literature (Berry et al. 2012).
We used the same protocol for post-operative pain management on all patients: the assessment also included an estimate of post-surgical pain on day 3 using a visual Analogue pain scale (Pain VAS scale) (Chiarotto et al. 2019; Williamson and Hoggart 2005).
For the polygraphic evaluation and post-surgery in both study groups refers to (Arigliani et al. 2021).
Research approval was obtained through the ethics committee of the Local Health Authority (ASL LE) at the Vito Fazzi Hospital (verbal no. 43, 3 March 2020), and informed written consent was obtained from all participants. All international ethical standards were respected throughout the study.

2.1. Surgical technique

The surgical procedure for what concerns the standard group was performed respecting as rigorously as possible the surgical technique published by Vicini et al (Vicini et al. 2015). Regarding the sBRP group, the surgical procedure presents a simplification of technique theoretically of medium-low impact on the obtainable results compared with those of standard BRP.
In the sRBP group, we used a Unidirectional Barbed, dual angle, absorbable Knotless wound closure device in Copolymer of glycolic acid and trimethylene carbonate, 30 cm, single needle, needle 37 mm, 1/2 circle, size 0, taper) (Covidien V-Loc 180™) (Alessandri et al. 2010) (Covidien IIc, Mansfield, MA, USA) instead of a Bidirectional (whith transition zone in the middle) Tissue-Closure Device, double needle, in polydioxanone absorbable monofilament, size 0, recommended for suturing both pharyngeal lateral walls in the original description of the BRP procedure.
The sBRP procedure, on the other hand, stops at step 7 and does not continue to step 8 as in the case of the BRP procedure (Figure 1).
In all cases, an additional suture loop was performed to reinforce step 7.
A monopolar or dipolar diathermy was used. Using a second suture thread Barbed dual-angle, Unidirectional, single needle, absorbable, 30 cm, (Covidien V-Loc 180™) (Alessandri et al. 2010) we performed in the same way the sBRP procedure from the opposite side, taking care to balance and managing pulling force between the two sides.

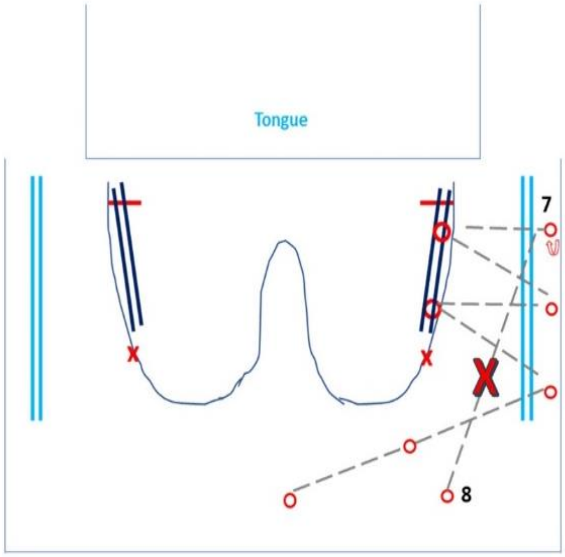

Figure 1. The simplified sBRP procedure with abolition of step 8 compared to the standard BRP procedure. Pterygomandibular Raphe (light blue). Palatopharyngeus Muscle (dark blue).

3. Data Analysis

The sample analyzed is based on 99 patients divided into two groups. In the following subsections the groups are called Group BRP and Group sBRP and a descriptive study is reported for both and then a two sample bootstrap t-test (Brandley and Tibshirani 1993) (Brandley and Tibshirani 1993) is performed with aim to evaluate if there is:

1. A statistical difference between the means for Pre and Post Surgery, in Groups BRP and sBRP, for the following Variables (AHI, BMI, ESS, Lowest SpO_2, ODI).
2. A statistical difference between the means Groups BRP and sBRP, in pre- and post-surgery, for the following Variables (AHI, BMI, ESS, Lowest SpO_2, ODI).

3.1 Descriptive Analysis Group BRP

Table 1 the sample collected (n=50) for the Group A BRP for the five variables measured on the patients for the pre-surgery and post-surgery conditions. For each variable and condition the min, max, mean and standard deviations are reported.

Table 1. Descriptive Indexes group BRP

	Pre				
Variable	*n*	*min*	*max*	*mean*	*sd*
AHI	50	2	70	26,32	15,428
BMI	50	20	34	28,38	2,664
ESS	50	6	16	11,14	2,02
LowSpO2	50	50	94	78,4	10,188
ODI	50	2	75	27,2	15,041
	Post				
Variable	*n*	*min*	*max*	*mean*	*sd*
AHI	50	2	21	7,22	3,507
BMI	50	16	39	27,96	3,865
ESS	50	7	16	9,46	1,681
LowSpO2	50	67	95	84,58	6,263
ODI	50	1	37	12,52	8,922

Body mass index (BMI), Epworth Sleepiness Scale (ESS), Overnight polygraphic values are defined according to the American Academy of Sleep Medicine (AASM) (Berry et al. 2012) the Apnea-Hypopnea Index (AHI) (hour/sleep), oxygen desaturation index (ODI) (hour/sleep), and Lowest saturation O_2 (%).

Figure 2 shows the box-plots for both the phases of the surgery (pre and post) for all the variables. The box-plot helps to read both the central tendency of the variable analyzed (the bold line in the middle of the box is the median) and the variability (based on the size of the box). It is possible to see that all the measures decrease, with the exception of Lowest SpO2, with a reduction of the variability, showing an improvement of stability of the measures.

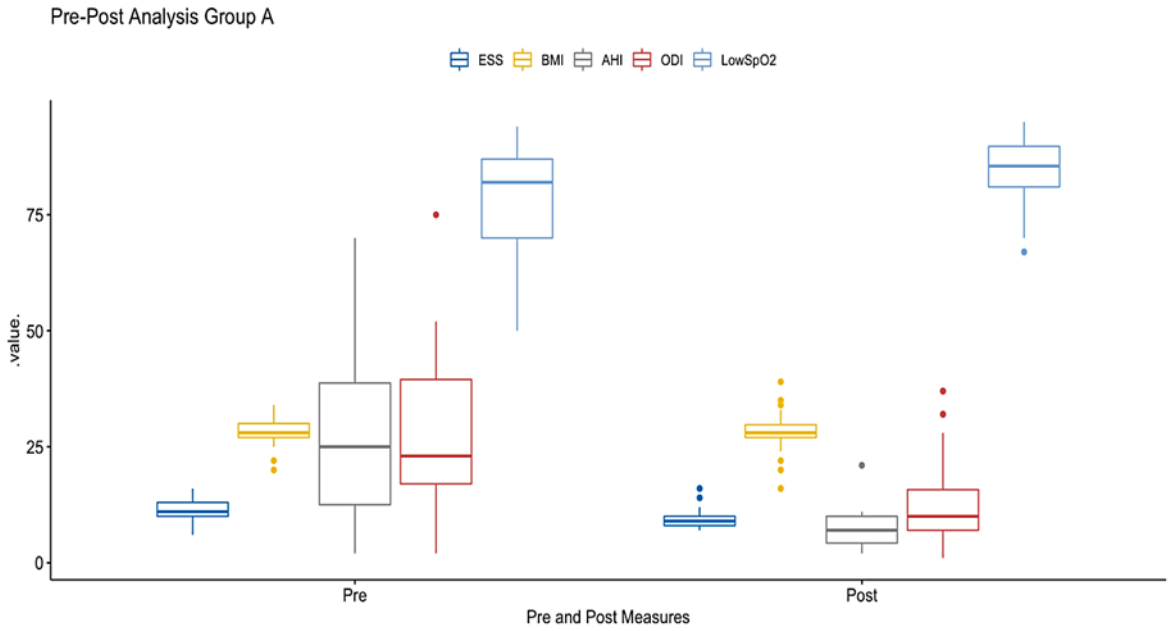

Figure 2. Box-Plot Group BRP

3.2 Descriptive Analysis Group sBRP

In Table 2 are reported the patients' measures of the Group B with a sample size n = 49, for both pre-surgery and post-surgery conditions. For each variable and condition the min, max, mean and standard deviations are reported.

Table 2. Descriptive Indexes group sBRP

	Pre				
Variable	*n*	*min*	*max*	*mean*	*sd*
AHI	49	2	57	23,592	12,297
BMI	49	20	32	27,939	2,794
ESS	49	8	16	10,939	1,983
LowSpO2	49	50	94	80,061	9,675
ODI	49	2	52	21,796	11,13
	Post				
Variable	*n*	*min*	*max*	*mean*	*sd*
AHI	49	1	16	7,408	3,397
BMI	49	20	39	27,714	3,512
ESS	49	7	16	9,388	1,643
LowSpO2	49	68	95	85,694	5,713
ODI	49	2	34	11,592	7,328

Body mass index (BMI), Epworth Sleepiness Scale (ESS), Overnight polygraphic values are defined according to the American Academy of Sleep Medicine (AASM) (Berry et al. 2012) the Apnea-Hypopnea Index (AHI) (hour/sleep), oxygen desaturation index (ODI) (hour/sleep), and Lowest saturation O2 (%).

The visual analysis of the central tendency and the variability is shown by the box-plot reported in Figure 3 for both the phases of the surgery. The group B shows, as for the group A, a reduction of the median, with the exception of Lowest SpO2, and also of the variability for all the variables considered.

3.3 Test the differences in Pre and Post surgery phases

Tables 3 and 4 reports the results of a Bootstrap paired t-test for both Group BRP and Group sBRP. Tables reports in the rows the variables and in the columns: difference between the means, t-test, confidence intervals and p-value. For all the variables, the differences between the means of pre-surgery and post-surgery are statistically significant, with the only exception of the BMI. The results show that the operation reduces all the parameters analyzed, only Lowest O2 increases, with an improvement of the general health conditions.

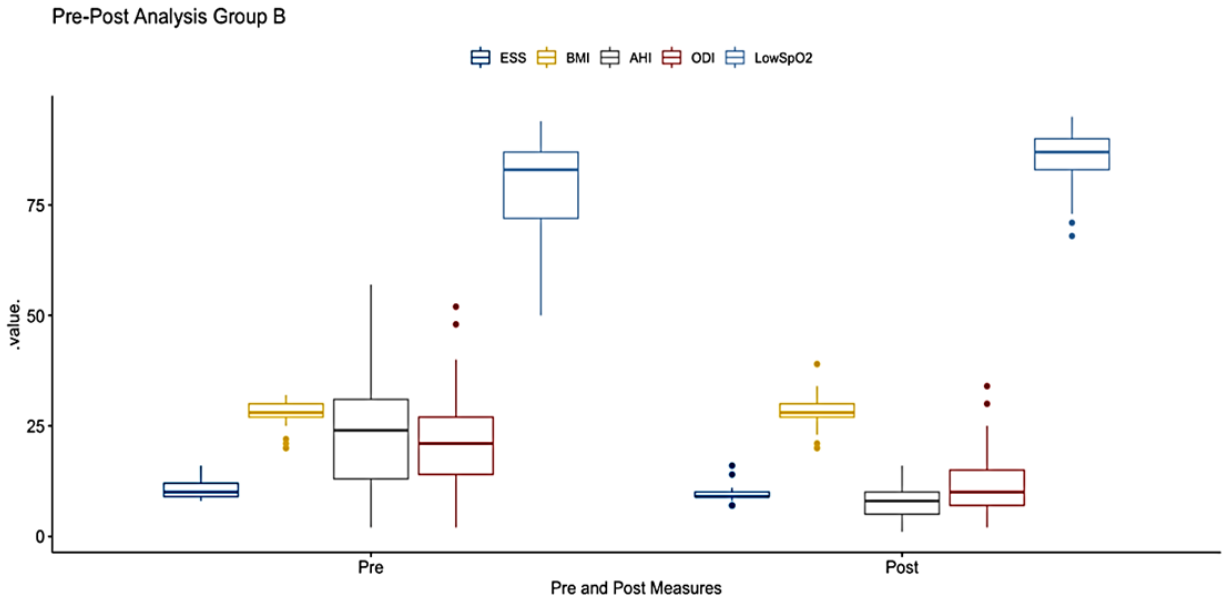

Figure 3. Box-Plot Group BRP

Table 3. Bootstrap paired t-tests. Group BRP

Variable	*mean of the differences*	*t*	*2.5%*	*97.5%*	*p-value*
ESS	-1,68	-7,382	-2,14	-1,26	0
BMI	-0,42	-1,130	-1,16	0,28	0,278
AHI	-19,1	-9,334	-23,16	-15,179	0
ODI	-14,68	-8,139	-18,3	-11,22	0
LowSpO2	6,18	5,619	4,18	8,38	0

Table 4. Bootstrap paired t-tests. Group sBRP

Variable	*mean of the differences*	*t*	*2.5%*	*97.5%*	*p-value*
ESS	-1,551	-5,836	-2,082	-1,041	0
BMI	-0,224	-0,688	-0,816	0,449	0,564
AHI	-16,184	-10,294	-19,367	-13,204	0
ODI	-10,204	-7,131	-13,061	-7,510	0
LowSpO2	5,633	5,066	3,592	7,857	0

For all parameters examined, bootstrap test was conducted to assess the homogeneity of the groups before and after the surgery, with a p-value > 0.05. Thus, for all parameters examined, show that there is no significant difference between the mean of the BRP and sBRP groups. Regarding the functional results, comparison of the mean of the AHI, ODI, and Lowest O_2 saturation parameters pre- and post-surgery in the two groups examined showed no statistically significant differences (two sample bootstrap t-test).

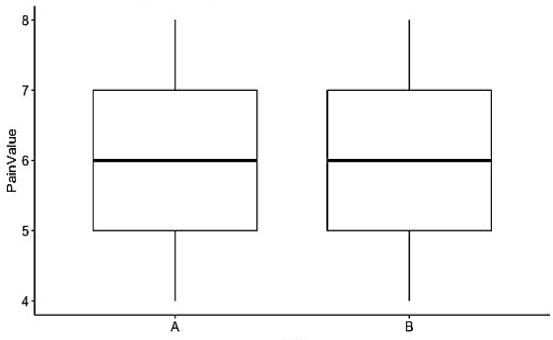

Figure 4. Pain Value Analysis between BRP group and sBRP group.

The results of the pain assessment analyzed at day 3 after surgery using a visual analog scale (VAS 0 -10, with 0 no pain, and 10 Worst imaginable post-operative pain) (Chiarotto et al. 2019; Williamson and Hoggart 2005) show no significant differences between the two study groups (Figure 4).
Only one patient in the standard BRP group had suture extrusion. No patient in the sBRP group had suture extrusion.

4. Discussion

The post-operative polygraphic measurements and the design of this clinical study seem to confirm one of the peculiar characteristics of BRP pharyngoplasty, that it is a procedure that allows the surgeon a certain freedom in its execution. Post-operative polygraphic data at 6

months confirm the efficacy of the technique even in the simplified form described.

We reconciled the conflicting demands of technique simplification with a modest impact on post- operative polygraphic outcomes by using Dual-Angle technology of wound closure Barbed device led to barbs with strong anchoring force. This technology was utilized using a unidirectional, single needle, Knotless, Tissue-Closure Device on each side of the pharynx.

The sBRP does not use the double-needle Barbed suture recommended for the standard BRP in order to couple the potential of dual-angle suture technology with the potential of using a single-needle unidirectional suture on each side of the pharynx: suturing the two sides of the pharynx separately allows a better management of calibration and balancing of pulling forces on soft tissues and this allows to exploit the full potential of dual-angle suture technology.

Separate management of the vector quantities applicable to the sidewalls, which is possible with the use of unidirectional/single-needle sutures, allows us greater freedom in the choice of force application points, which, in this study, do not appear to have adversely affected the functional results.

This separate handling of sidewall collapsibility can also compensate for asymmetries due to technique inaccuracies.

We wanted to eliminate the last step of the standard BRP procedure because in the context of a procedure that is essentially easy to learn, a critical moment for the surgeon performing BRP pharyngoplasty for the first time is the execution of the final step.

Elimination of step 8 also appears to be able to reduce one of the minor complications which is a parcel extrusion of the suture most frequently placed there.

With the elimination of the last step of the BRP, a fundamental vector is eliminated and replaced by an additional loop of reinforcement of the suture between Pterygomandibular Raphe and Palatopharyngeus Muscle. In this way, while fixing only the collapsible lateral pharyngeal wall to a stable structure such as the Pterygomandibular Raphe and eliminating vertical vectors, we had no negative impact on polygraphic outcomes at 6 months post-surgery. Subsequent studies will be performed to compensate for the lack of long-term patient follow-up and to increase the sample population size under study.

5. Conclusion

In cases of OSA from retropalatal obstruction, the sBRP shows functional results at 6 months superimposable compared to the BRP technique from which it derives while being even less invasive. The sBRP version described above is also easier to execute, which benefits its dissemination.

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