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Effectiveness of barbed repositioning pharyngoplasty for the treatment of obstructive sleep apnea (OSA)

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1. INTRODUCTION

Obstructive sleep apnea (OSA) is a common health problem affecting a large number of people all over the world with great psychological and physiological burdens. The overall population prevalence with an apnea-hypopnea index (AHI) ≥5 ranged from 9% to 38%, being higher in males [1].

OSA has consistently been shown to cause a multitude of neurobehavioral issues and is an independent risk factor for cardiopulmonary diseases that significantly increase the risk of death [2].

The gold standard treatment for OSA remains continuous positive airway pressure (CPAP). However, a large proportion of patients does not tolerate or does not show consistent compliance with CPAP and requires an alternative treatment. Surgery, on the other hand, appears to be a promising option not presenting the drawback of lack of adherence to treatment.

Uvulopalatopharyngoplasty (UPPP) is the most commonly performed surgical procedure for treatment of OSA. The challenge of this procedure is to determine the limits of soft tissue resection to be effective. Moreover, the preservation of the elevator palatine muscle is mandatory to maintain normal speech and avoid nasal regurgitation [3].

Lateral pharyngeal muscle wall collapse has been demonstrated to be pivotal in the pathogenesis of OSA in imaging studies [4].

Drug-induced sleep endoscopy (DISE) aided more in the understanding of the effect of the circumferential collapse at the velum level in failure of palatal surgery [5].

The lateral pharyngoplasty (LP), firstly described by Cahali, was aimed at addressing the lateral pharyngeal wall collapse in patients with OSA but it carried severe postoperative dysphagia as relevant drawback. [6] LP showed better PSG results despite not having differences on the postoperative volume of the UA, underlying the importance of changing the mechanical properties rather than removing tissue.

Another frequently used technique is expansion sphincter pharyngoplasty (ESP), which involves rotation of the palatopharyngeus muscle and its anchorage to the pterygoid hamulus, a partial uvulectomy and closure of the anterior and posterior tonsillar pillars [7].
A new palatal surgical technique that has been recently described in the literature is the barbed reposition pharyngoplasty (BRP) [8]. This procedure allows surgeons to achieve widening and stiffening of the nasopharyngeal inlet without any tissue sacrifice by means of a bidirectional barbed suture that is inserted through the fibro-muscular tissues of the soft palate and the posterior tonsillar pillars, and tightened around three steady holds: the posterior nasal spine and the two pterygoid hamulii lateral to the pterygomandibular raphe [8,9].

The growing need for alternative therapies, however, is not supported by sufficiently strong evidence, especially in the surgical field. Browaldh et al. published one of the few RCTs comparing the effectiveness of a palatal procedure (uvulopalatopharyngoplasty (UPPP)) with expectancy for the treatment of OSA and supporting the surgical modality [10].

On the other hand, several retrospective studies evaluating the efficacy of palatal surgeries and comparing different techniques have been published.
A recent meta-analysis by Pang et al shows an overall pooled success rate of 67.5% from the evaluation of fifty-nine papers with a total of 2715 patients treated with palatal procedures [11].

The aim of our randomized clinical trial is to produce stronger evidence supporting barbed repositioning pharyngoplasty (BRP) as a therapeutic option for the treatment of OSA.

2. MAIN STUDY

METHODS

Trial design

The trial was a single-centre randomized controlled trial with two prospective arms: BRP vs Observation. Figure n.1 shows the trial design in detail.

Participants

All patients with OSA referred consecutively to the our Otolaryngology and Head Neck Department, Hospital Morgagni Pierantoni, Forlì, Italy from February 2015 to February 2018 for palatal surgery were possible candidates for inclusion in the study.
Patients who met the criteria for the study were invited to participate and were enrolled in the study by different physicians.

The run-in period started with a type 3 polygraphy. Those who declared an interest in participating and met the criteria after the polygraphy were included in the study by randomization.

Baseline and 6 months follow up polygraphy evaluating the apnea hypopnea index (AHI), oxygen desaturation index (ODI) and lowest oxygen saturation (LOS) were performed.
All the sleep studies were carried out in an unattended way by means of a Polymesam Unattended Device 8-channel; reviewed and scored by the same expert in sleep medicine according to the American Academy of Sleep Medicine Guidelines [12].
Body mass index (BMI) was calculated for all patients before and after surgery.

Full medical history with preoperative and postoperative Italian version of Epworth Sleepiness Scale (ESS) was collected to all patients [13].

Pre-randomization evaluation with DISE was performed for all patients to confirm the palatal/pharyngeal obstruction. DISE was performed by means of a flexible rhinopharyngolaryngoscope in the operating theatre using target-controlled infusion (TCI) of propofol to achieve a complete evaluation of the UA collapse and especially of the lateral pharyngeal walls. BIS was used to check the level of sedation during DISE.
Scoring was performed by the authors by consensus in a manner blinded to outcome and VOTE scale was used [14].

Inclusion criteria

1. Patients suffering from moderate to severe OSA (AHI≥15 events/h) with certain degree of nasal obstruction planned for BRP and tonsillectomy, with nasal surgery (Septo-turbinoplasty)
2. Grade 1-2 tonsillar hypertrophy
3. Aged between 18 and 65 years old
4. BMI ≤ 35.
5. Failure of CPAP or low adherence to this treatment during the last 3 months (<4 hrs per night)
6. Mainly palatal/pharyngeal collapses at DISE (severe circular palatal collapses and severe trasversal pharyngeal collapses with none or mild tongue collapses)

Exclusion criteria

1. Serious psychiatric, cardiopulmonary or neurological disease
2. American Society of Anesthesiologists (ASA) classification >3;
3. Patients negative to surgery;

4. Previous tonsillectomy and OSA surgery
5. Significant craniofacial anomalies
6. Pregnant women
7. Grade 3-4 tonsillar hypertrophy
8. Mainly lingual/base of tongue collapses at DISE
9. Follow up <6 months

Randomization

Randomization was conducted by picking a piece of paper with a treatment order written on it out of a box (BRP or Observation), and then that piece of paper was placed back in the box. The chances of picking BRP or observation were 50/50.
Sample size calculation was performed to determine whether the study had 80% power to detect differences between the groups of 50% (large) and 20% (small), with one-sided test, alpha = 0.05.

Two groups were constituted according to sample size calculation:

Group A: BRP (N= 25)
Group B: Observation (N= 25)

After the study was conducted, BRP was proposed to patients from group B.

BRP was performed as previously described [9,15,16].
After bilateral tonsillectomy meticulous sparing of the palatoglossus and palatopharyngeus muscles is performed. Two weakening or releasing partial incisions are done by a pinpoint bowie (Colorado) at the inferior (caudal) part of the palatopharyngeal muscle. The center of the palate is marked at palatal spine, also the pterygomandibular raphe in both sides are located by digital palpation and marked. Single barbed suture, bidirectional polydioxanone absorbable monofilament, size 2.0, with transition zone in the middle is

generally used. One needle is introduced at the center point then passed laterally within the palate, turning around pterygomandibular raphe till it comes out at the most superior part of the raphe at one side; the thread is pulled until it hangs at the central transition zone which is a free zone present between the two directions of the thread. The needle again is re-introduced close to point of exit, passing around the pterygomandibular raphe, till it comes out into the tonsillectomy bed, then through the upper part of the palatopharyngeus muscle and comes out near to mucosa of posterior pillar not through it. The posterior pillar is entered at the junction between the upper third and the lower two-thirds. Then, again the needle is passed back through the tonsillectomy bed and then this suture will be suspended around the raphe again; a gentle traction is then applied on the thread only and no knots are taken. These steps can be repeated 2-3 times between raphe and muscle until a satisfactory expansion is reached.

The opposite side is done by the same way. Finally, each thread comes out at the raphe of the same side, for locking of the stitches and looseness prevention; a superficial stitch in the opposite direction is taken, and then the thread is cut while bushing the tissue downward for more traction.

The definition of surgical response and success were a reduction from the preoperative AHI of at least 50% (response) and less than 20 events per hour (success).

Statistical analysis

To test the differences among groups the Fisher's exact test was used for categorical data, while the Student's t-test was used for continuous data. ANOVA and MANOVA tests are used as appropriate. The role of each factor (univariate analysis) and their independent effect (multivariate analysis) was explored using logistic regression model as appropriate. Probability values lower than 0.05 were considered statistically significant. All analyses were performed with STATA 12.1 software (Stata Corp., College Station, TX, USA).

Homogeneity between groups was tested and no statistical difference in age, preAHI and BMI was found.

Local ethics committees or institutional review boards approved the study.

RESULTS

Baseline data concerning age and gender in both groups are shown in table 1. Average follow up was 6.8 months. Success rate in BRP group was 74.2%. No complications were recorded in the BRP group.
Oneway Anova was used to test difference in Age, BMI and baseline AHI between groups without finding any significance.
A significant postoperative reduction of AHI, ODI, LOS and ESS values were recorded in BRP group while no significant changes were seen in observation group (Figure 2, Table 2).
Table 3 shows the comparison of changes of all indexes between groups. BRP showed to be more effective than observation. No significant difference in BMI and LOS change was recorded between groups.

Logistic regression was used to test the influence of age, baseline BMI, AHI, LOS and ESS score on the reduction of AHI at 6 months follow up (deltaAHI). Baseline AHI was related significantly to postoperative AHI within BRP group whilst in the control group no factors were associated statistically in reduction of AHI (table 4).
A linear regression was performed to test the relationship between baseline AHI and deltaAHI. The results showed that high values of baseline AHI predict more significant postoperative reductions in AHI (figure 3).

DISCUSSION

Several palatal techniques for the treatment of OSA have been proposed along the last two decades, especially after the development of lateral pharyngoplasties, but few randomized controlled trials have been published in literature.

In the present study BRP was compared to simple observation and the following results were obtained.

Our main finding was the clinically relevant and statistically significant difference in the mean reduction of AHI in favour of the BRP intervention group compared with controls. ODI and daytime sleepiness also improved more significantly in patients undergoing surgery. Success rate in BRP group was 74.2% and no major complications (e.g bleedings and severe dysphagia) were recorded.

Statistical analysis showed that pre-operative high values of AHI predict for more significant reduction of the same index, thus suggesting that high severity of OSA should not be considered as a contraindication for BRP.

Similar outcomes were recorded in the SKUP3 trial [10] where UPPP was compared to expectancy, highlighting the promising role of palatal surgery for the treatment of OSA. However, a significantly higher surgical success rate was observed in our study, suggesting that lateral pharyngoplasties, and in particular BRP, should be preferred over UPPP in the treatment of certain specific OSA patterns observed by means of DISE (e.g. lateral pharyngeal collapses), as recently demonstrated by some retrospective comparative studies evaluating palatal techniques as stand-alone procedures or as part of a multilevel settings [17,18]. In 2016, Pang et al. also proved through a systematic review and metanalysis that expansion sphincter pharyngoplasty (ESP), another variation of lateral pharyngoplasty, provides better outcomes than other traditional methods of palatal surgeries [11].

Similar subjective efficacy of ESP and BRP was recorded by means of a recently proposed questionnaire [19].

On the other hand, the reported success of UPPP as an OSA treatment ranges between 16% and 83% depending on the definition of a positive outcome and selection of patients [20, 21]. According to some authors' experience, success rate of UPPP in unselected patients stands around 40%, and for this reason palatal surgery has not being recommended as a standard treatment for OSA patients along the last decades [22, 23]. Moreover, UPPP side effects include frequent difficulty swallowing/nasal regurgitation, taste disturbances and voice changes that were not recorded in our series [24].

In our study a pre-randomization DISE was performed to rule out patients with prevalent oral tongue or base of tongue collapses and select patients affected by lateral pharyngeal wall obstructions in order to obtain better outcomes. In fact, DISE appears to be an effective tool for the selection of potential candidates for specific surgical procedures [25]. Recent literature evaluating the efficacy of lateral pharyngoplasties has shown higher success rates than previous works including patients treated with UPPP. UPPP articles generally report on patients not selected by means of DISE, thus suggesting the potential role of pre-operative DISE on improving surgical outcomes.

Other surgical options, such as robotic or coblation techniques may help in the treatment of other patterns of collapse in appropriately selected OSA patients (e.g base of tongue collapses) [26]. Non-surgical treatments including positional therapy and mandibular-advancement devices are also considered valid options for the treatment of specific OSA patterns (e.g. positional OSA) [27].

Taking into account the short follow up time and the comparison between surgery and observation the following considerations can be made.
In our opinion, surgical options such as BRP might be considered preferable in specific patterns of patients, being not affected by a potential lack of adherence failure, as seen in CPAP studies.
The study design (RCT) of this paper appears to provide a satisfactory quality of evidence, especially considering the limited number of RCTs evaluating the efficacy of surgical treatments of OSA.

BRP showed to be more effective than observation in the treatment of OSA patients selected by means of DISE. Patients affected by severe OSA may benefit from this surgery with more significant reduction of AHI values.
Therefore, this technique appears to be promising and might be included within the surgical armamentarium of a sleep surgeon.
BRP might also be performed in patients who previously underwent tonsillectomy, without any specific technical modification. In particular, Mantovani et al. demonstrated the efficacy of their barbed technique on this specific subset of patients [28].
The selection of appropriate candidates for this surgery seems to be the key to achieve more satisfactory outcomes, in line with the recent trend towards OSA phenotyping and tailored treatments.
However, further studies with longer follow up, larger series and prospective comparisons with other palatal procedures need to be run in order to obtain stronger evidence supporting the effectiveness of BRP and the stability of its results.

3. RELATED RESEARCH

3.a Evolution of soft palate surgery techniques for obstructive sleep apnea patients: A comparative study for single-level palatal surgeries

METHODS

Local ethics committees or institutional review boards approved the study. The medical charts of patients of the three groups of patients at the department of Otolaryngology and Head-Neck Surgery, Morgagni- Pierantoni Hospital, Forlı, Ausl della Romagna, Italy, between November 2004 and March 2016 were evaluated retrospectively.

Seventy-five patients were included in the study and divided into three groups with twenty-five patients per group: UPPP, ESP or BRP. Patients were recruited from the medical records randomly according to the availability of the pre and postoperative data in addition to those performing only palate and nasal surgery; we tried to match the three groups as much as possible in terms of the AHI, BMI and DISE findings. We considered the BRP group as Gold Standard and performed multiple comparisons using the BRP group as control group versus ESP and UPPP groups.

Full medical history

Full medical history with preoperative and postoperative Italian version of ESS was collected to all patients [13].

Physical examination

Physical examination was performed according to OSA phenotypes which include anatomical and functional phenotypes.

Anatomical phenotypes: Modified Mallampati index [29], Friedman Staging System [30] and Tucker Woodson description for palatal Position [31].

Functional phenotypes: Muller manoeuver [32] and DISE [25] preoperative evaluation with DISE was performed for all patients to confirm the single-level palatal obstruction.

DISE was performed by means of a flexible rhinopharyngolaryngoscope in the operating theatre using target-controlled infusion (TCI) of propofol to achieve a complete evaluation of the UA collapse and especially of the lateral pharyngeal walls. Patients were classified according to the NOHL classification system according to Vicini et al. [33].
Preoperative and 6 months postoperative polysomnographies evaluating AHI, oxygen desaturation index (ODI) and lowest oxygen saturation (LOS) were

performed to compare the results within each group and between the three groups. All the sleep studies were carried out in an unattended way by means of a Polymesam Unattended Device 8-channel; reviewed and scored by the same expert in sleep medicine according to the American Academy of Sleep Medicine Guidelines 2007 [12].
Body mass index (BMI) was calculated for all patients before and after surgery.

Inclusion criteria

Patients suffering from OSA planned for palate surgery and tonsillectomy, with nasal surgery (Septoturbinoplasty), aged between 21 and 65 years old and BMI≤35.

Exclusion criteria

Patients treated with multilevel surgery including tongue base reduction or epiglottoplasty, unfit for general anaesthesia, allergy to propofol, patients with significant craniofacial anomalies, patient refusal, patients who underwent previous OSA surgeries and pregnant women.

Statistical analysis

Data analyses were performed in R using Bioconductor libraries and R statistical packages (http://www.r-project.org/, R Development Core Team, 2008).
Wilcoxon signed-rank test was used to compare pre- and postoperative outcomes within each group (homogeneity between groups was tested), while ANOVA test was used to compare the outcomes between the groups. Pre- and postoperative mean differences of AHI, ODI, ESS and LOS (delta = preoperative – postoperative) were compared between groups.

RESULTS

Preoperative values in all groups are presented in Table 5. Pre- and postoperative mean differences of AHI, ODI and ESS values were calculated, and statistically significant reduction in these parameters was seen in the three groups ($P < .05$), Table 6. On the other hand, LOS decreased significantly in BRP and ESP groups, but not in UPPP group, Figure 4.

The results of the three groups analysis showed that AHI values decreased more significantly in BRP group than ESP (15.76 14.5 vs 10.13 5.3; $P < .05$) and UPPP groups (15.76 14.5 vs 6.08 5.5; $P < .0005$). The mean of differences of ODI values was higher in BRP group than UPPP group (15.09 17.6 vs 7.13 6.8; $P < .0005$) but not than ESP group (15.09 17.6 vs 6.48 7.9; $P > .05$). Furthermore, ESS values decreased more significantly in BRP group than ESP (5.52 4.1 vs 4.84 3.3; $P < .005$) and UPPP groups (5.52 4.1 vs 1.36 1.9; $P < .005$). Finally, the pre- and postoperative means of differences of LOS values were not statistically significant among the three groups ($P > .05$), Figure 5. No statistically significant difference in the pre- and postoperative BMI data between the three groups was observed.

DISCUSSION

Different palatal techniques have been introduced along the last two decades, especially after the evolution of palatal surgeries focused on the lateral pharyngeal wall collapse, from the first lateral pharyngoplasty to the newest BRP [6,8]. Although a lot of publications describing the drawbacks of UPPP can be found in scientific literature, there are still many articles highlighting the improvement of AHI after UPPP, not taking postoperative complications into consideration and not comparing its results with the outcomes of other palatal procedures. Our study was performed on patients undergoing palate surgery with tonsillectomy combined with nasal surgery. The idea was to evaluate the results of the three chosen techniques without the association to surgical procedure addressed to other anatomical districts. Our team chose to compare both ESP and BRP as they are the two most used techniques in our department, with the most performed palatal procedure all over the world (UPPP).

From our results, it appears that both BRP and ESP may allow to achieve better results than UPPP in terms of PSG parameters and ESS score.

The reported success of UPPP as an OSA treatment was between 16% and 83% depending on the definition of a positive outcome and selection of patients [20]. Some authors have defined surgical success after UPPP as a 50% reduction in the AHI, whereas others combine this criterion with an absolute AHI of 20 or less [34,35]. The success rate of UPPP in unselected patients was around 40%, and this is the main reason why it is not recommended as a standard treatment [22,23] Side effects include difficulty swallowing/nasal regurgitation, taste disturbances and voice changes [24].

In 2007, Pang and Woodson concluded that their ESP is a safe and effective procedure in patients with lateral pharyngeal wall collapse, superior to UPPP, and with less short- and long-term complications [7]. In 2016, Pang et al. as well could prove through a systematic review and metanalysis that ESP provides better outcomes than other traditional methods of palatal surgeries [36]. In line with these results, Vicini et al. concluded that as a part of multilevel procedure, including conventional nasal surgery and robotic surgery, ESP seems to be superior to UPPP [37]. Our results were consistent with these studies as the improvement in the postoperative AHI, ODI and ESS was higher in the BRP group followed by the ESP group and the UPPP group.

In 2017, Cammaroto et al. showed similar results in patients treated with palatal surgery combined with transoral robotic surgery (TORS). The study showed no major difference between the BRP and the ESP groups, although both techniques proved to be more effective than UPPP in a multilevel setting [18].

However, BRP was seen to be a quicker and easier technique and provided minimal blood loss and better preservation of the mucosal and muscular tissues in comparison with ESP and, of course UPPP [9,18].

We owe the credit of the better results of both BRP and ESP over UPPP to lateral widening in the retropalatal space provided by the upward and lateral rotation of the palatopharyngeus muscle. Moreover, BRP allows a more anterior soft

palate displacement due to the lateral anchoring of the sutures on the pterygomandibular raphe.
Finally, the concentric scar that usually occurs in UPPP is better avoided to avoid one of the worst complications, that is velopharyngeal stenosis, as mentioned in several case reports [38].

Limitations of the study

More patients should be included in future studies, and prospective randomised control study design would provide us more reliable data. Longer follow-up for the patients will enable us to highlight the short- and long-term results for better judgment on the surgical outcome.

3b. <u>Palatal surgery in a transoral robotic setting (TORS):preliminary results of a retrospective comparison between uvulopalatopharyngoplasty (UPPP), expansion sphincter pharyngoplasty (ESP) and barbed repositioning pharyngoplasty (BRP)</u>

METHODS

Thirty patients were retrospectively evaluated. The patients were randomly selected from the dataset including OSA patients treated surgically from May 2008 to December 2015 at the ENT unit of the Hospital Morgagni-Pierantoni, Forlì, Italy. Incomplete or very recent cases, with a postoperative polysomnographic evaluation shorter than 6 months, were excluded.
Patients met inclusion criteria if they were 18 years of age or older, had failed continuous positive airway pressure as a nonsurgical treatment alternative and had an apnoea-hypopnoea index (AHI) of 20 or above. Patients who had had prior airway surgery, such as UPPP or tonsillectomy, were not eligible.

Preoperative workup also included DISE. Only patients who were found to have significant collapse contemporarily at the retropalatal, retrolingual and hypopharyngeal levels were included.
Three groups, each with 10 patients, were compared. Ten patients underwent UPPP by Fairbanks [38], 10 BRP [9] and 10 a modified ESP already described [7]. All 30 patients were treated with a robotic tongue base reduction with supraglottoplasty (SGP) by Vicini [39] with temporary tracheostomy, tonsillectomy and septo-turbinoplasty.

For all cases, the following data were retrieved and revaluated:
1. age;
2. sex;
3. preoperative BMI;
4. preoperative and postoperative AHI (all sleep studies were carried out in an unattended fashion by means of a Polymesam 8-channel; reviewed and scored by the same expert in sleep medicine according to the American Academy of Sleep Medicine Guidelines 2007 [12];
5. preoperative and postoperative Epworth Sleepiness Scale (ESS), using the Italian version of the Epworth test that was adapted and tested for the Italian-speaking population [13];
6. pain visual analogue scale (VAS; 0–10) for the first 5 days postoperatively;
7. palatal operative time for each surgical technique (excluding tonsillectomy), as measured by our operating theatre electronic system;
8. discharge date;
9. complication types and rate.

The 3 groups were reasonably matched for sex, age, BMI and preoperative AHI.
The definition of surgical response and success were a reduction from the preoperative AHI of at least 50% (response) and less than 20 events per hour (success).
All clinical records were reviewed to examine all the differential features between the 3 groups potentially related to the different palate procedures applied.

The study met the approval of the Local Board of Ethics (Institutional Review Board of the Hospital Morgagni–Pierantoni, Forlì).

Statistical evaluation of pre-postoperative changes between groups was performed by means of Mann–Whitney, Kruskal Wallis and Wilcoxon tests, with the latter used to evaluate pre-postoperative changes in each group.

RESULTS

The 3 groups showed no significant difference in F/M ratio (1/9 in all groups), age, BMI and preoperative AHI (Table 7).
The AHI decreased significantly after surgery in all groups except UPPP.
ESS values, however, decreased significantly postoperatively in all groups (Table 8). No significant differences in post-operative pain, deltaAHI (preAHI-postAHI) and hospital stay were recorded (Table 9).
Surgical success rate was 90% in the ESP and BRP groups, and 50% in the UPPP group. ESP and BRP postoperative AHI values were significantly lower than UPPP.
On the other hand, ESP and BRP did not show any differences in this measure.
Both ESP and BRP post-operative ESS values were significantly lower than the UPPP figure, while no differences were seen between the first two groups. ESP surgery time was significantly higher than UPPP while BRP was seen to be the quickest procedure (Table 10).
No complications were recorded in any group.

DISCUSSION

In our sleep disorder breathing surgical practice, it is routine to perform multilevel surgery at the same surgical session.

In our philosophy, TORS is just a step devised to address tongue base and supraglottic collapse, and is routinely carried out together with nose and palate surgery if required, according to DISE findings.
In the last years, many palatal techniques have been proposed.
The introduction of the Pang ESP technique and, more recently, BRP have changed our OSA multilevel surgical setting [7-9]. These two techniques soon became our first option with the robot-assisted multilevel procedure.
Recently, the effectiveness of ESP was demonstrated in a meta-analysis by Pang [36]. Moreover, our group reported on the superiority of ESP in a multilevel setting when compared to UPPP [37].
However, in a 2015 study by our group it was shown that the BRP technique is feasible, safe and effective in the management of OSA patients [9]. The use of a barbed suture allows to perform a quick procedure and to respect mucosal and muscular structures (Fig. 6-7).
The purpose of the present study was to show the superiority of ESP and BRP compared to traditional UPPP in a multilevel setting, highlighting the advantages of BRP.
Taking into account the retrospective nature of our study and the limited size of the three groups, our preliminary results may be interpreted as follows.
Both BRP and ESP resulted in better postoperative AHI values and higher surgical success rate in comparison with UPPP. On the other hand, BRP was not more effective than ESP. ESP surgery time was significantly higher than UPPP while BRP was seen to be the quickest procedure. Furthermore, in our series no complications were recorded, likely due to the small size of our sample.
However, we assume that the probability of bleeding is significantly lower in BRP patients, as the soft palate and the pharyngopalatine muscle are respected when performing this technique.
No difference in postoperative pain was recorded between groups, probably because all patients underwent tonsillectomy contemporarily.
The higher effectiveness of BRP and ESP may be interpreted considering their more focused action on the lateral wall area. Moreover, the authors feel that circular scarring and tension produce a significantly delayed reduction of

oropharyngeal section in UPPP cases. In ESP, the same scar retraction would probably tend to straighten the angle between the plane of tonsillar fossa and the intrapalatal muscular flap, producing a progressive enlarging vector for the lateral wall and palate.

BRP, instead, allows to displace the posterior pillar (palatopharyngeal muscle) in a more lateral and anterior position to enlarge the oropharyngeal inlet as well as the retropalatal space.

In a previous study published by our group, it was shown how this technique is easy to learn even for non-experienced surgeons, less time consuming and with no significant complications [9].

4. CONCLUSIONS

Our prospective trial showed that surgical options such as BRP might be considered preferable in specific patterns of patients, being not affected by a potential lack of adherence failure, as seen in CPAP studies.

The study design (RCT) of this paper appears to provide a satisfactory quality of evidence, especially considering the limited number of RCTs evaluating the efficacy of surgical treatments of OSA.

BRP showed to be more effective than observation in the treatment of OSA patients selected by means of DISE. Patients affected by severe OSA may benefit from this surgery with more significant reduction of AHI values.

Moreover, our comparative retrospective studies showed that BRP is more effective than resective techniques such as UPPP in single and multilevel settings. Therefore, this technique appears to be promising and might be included within the surgical armamentarium of a sleep surgeon.

The selection of appropriate candidates for this surgery seems to be the key to achieve more satisfactory outcomes, in line with the recent trend towards OSA phenotyping and tailored treatments.

However, further studies with longer follow up, larger series and prospective comparisons with other palatal procedures need to be run in order to obtain stronger evidence supporting the effectiveness of BRP and the stability of its results.

5. ACKNOWLEDGMENTS

"Just don't give up trying to do what you really want to do. Where there is love and inspiration, I don't think you can go wrong." Ella Fitzgerald.

Since my residency programme I have felt that research had to be part of my professional career. This visceral need comes from my belief that research certainly allows physicians to approach clinical practice in a more critical way, taking into account all plausible explanations.

The passion for research has surely been enhanced by some professionals I have come through during my short career. I am deeply grateful to Prof Galletti, chief of the ENT department of the University of Messina, who basically introduced me to my beloved specialty and allowed me to expand my knowledge outside my university, during my Spanish experience in Barcelona and my internship in Forlì, the place where I had the luck of meeting Prof Vicini. I feel I have to express my sincere gratitude to Prof Vicini, a real mentor and an international expert in sleep surgery, who has always stimulated me both in the clinical and the research activities. Prof Vicini has given me the opportunity of developing an expertise in a specific niche (sleep medicine) that has become my main field of interest. I also had the chance of working under the supervision of Prof Kotecha, probably the most eminent expert in sleep surgery in London, who I have to thanks for his support during my British adventure.

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6. FIGURES AND TABLES

Figure 1. Flow chart of the trial design

Figure 2. Box plot graph showing baseline (Pre) and 6 months follow-up data (Post) in both groups (BRP group, Observation group; asterisks mark significant changes)

Figure 3. Linear regression testing the relationship between preAHI (y axis) and deltaAHI (=postAHI-preAHI) (x axis)

Figure 4. A, Boxplots represent AHI, ODI, ESS and LOS values of post-surgery time and pre-surgery time in BRP group. B, Boxplots represent AHI, ODI, ESS and LOS values of post-surgery time and presurgery time in ESP group. C, Boxplots represent AHI, ODI, ESS and LOS values of post-surgery time and pre-surgery time in UPPP group. The bottom and top of the box are the first and the third quartiles, and the band inside the box is the median; whiskers represent 1° and 99° percentiles; values that are lower and greater are shown as circles

Figure 5. A, Overall mean of differences of AHI, ODI, ESS and LOS values between post-surgery time and pre-surgery time. B, Difference of AHI, ODI, ESS and LOS values between post-surgery time and pre-surgery time among three groups as visualised by the boxplot. The bottom and top of the box are the first and the third quartiles, and the band inside the box is the median; whiskers represent 1° and 99° percentiles; values that are lower and greater are shown as circles, asterisks represent significance (P-value < .05)

Figure 6. Descriptive scheme of all BRP steps highlighting the anchoring points for the barbed suture.

Figure 7. Pre-operative and post-operative images of a patient treated with a BRP technique: the improvement of the anterior-posterior diameter is shown.

Table 1. Baseline data concerning age and gender in both groups.

Table 2. Paired T-test comparing baseline (Pre) with 6 months follow-up data (Post) in both groups

Table 3. Unpaired T-test comparing 6 months follow-up modifications between groups

Table 4. Logistic regression to test the influence of age, baseline (Pre) BMI, AHI, LOS and ESS score on the 6 months follow up (Post) reduction of AHI (deltaAHI=postAHI-preAHI)

Table 5. Preoperative values (means standard deviation). No differences between groups were found

Table 6. P values of within groups analysis (Wilcoxon test)

Table 7. Pre-operative intergroup analysis.

Table 8. Intragroup analysis: pre-postoperative variations.

Table 9. Post-operative intergroup analysis (not significant).

Table 10. Post-operative intergroup analysis.

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Group	Age (mean)	P	Age (sd)	P	M/F ratio	P
BRP	44.64	0.53	12.82861	0.62	22/3	0.88
Control	50.09524		11.51479		20/1	

Table 1

Group	N	preAHI	postAHI	P	preODI	postODI	P	preLOS	postLOS	P	preESS	postESS	P	preBMI	postBMI	P
BRP	25	25.58±14.60	9.82±9.88	**0.00**	24.38±17.72	9.30±10.24	**0.00**	80.56±7.50	85.84±7.93	**0.01**	9.28±3.10	3.76±4.42	**0.00**	26.49±2.51	25.42±2.40	0.13
CONTROL	25	36.83±23.82	31.93±21.89	0.50	35.38±23.31	32.4±22.58	0.68	74.84±10.39	78.61±9.63	0.24	10.4±23.68	10.85±3.91	0.71	27.90±3.53	27.48±3.78	0.71

Table 2

Group	deltaAHI	P	deltaODI	P	deltaLOS	P	deltaESS	P	deltaBMI	P
BRP	-15.75±14.47	**0.01**	-15.08±17.93	**0.01**	5.28±9.16	0.69	-5.52±4.12	**0.00**	-10.6±1.67	0.08
CONTROL	-5±13.75		-2.84±14.55		4.15±9.24		0.42±1.88		-0.24±1.35	

Table 3

Table 4. Logistic regression model				
BRP Group	Coefficient	p	95% Confidence Interval	
PreAHI	0.6	<0.01	0.18	1.07
PreBMI	1.71	0.07	-0.15	3.6
PreESS	0.4	0.53	-0.58	0.91
Pre LOS	0.16	0.65	-0.58	0.91
Age	-0.21	0.21	-0.56	0.13
Control group				
PreAHI	0.27	0.3	-0.28	0.82
PreBMI	-0.69	0.65	-3.89	2.5
PreESS	0.17	0.9	-2.73	3.07
Pre LOS	-0.01	0.98	-1.1	1.1
Age	0.14	0.8	-1	1.29

Table 4

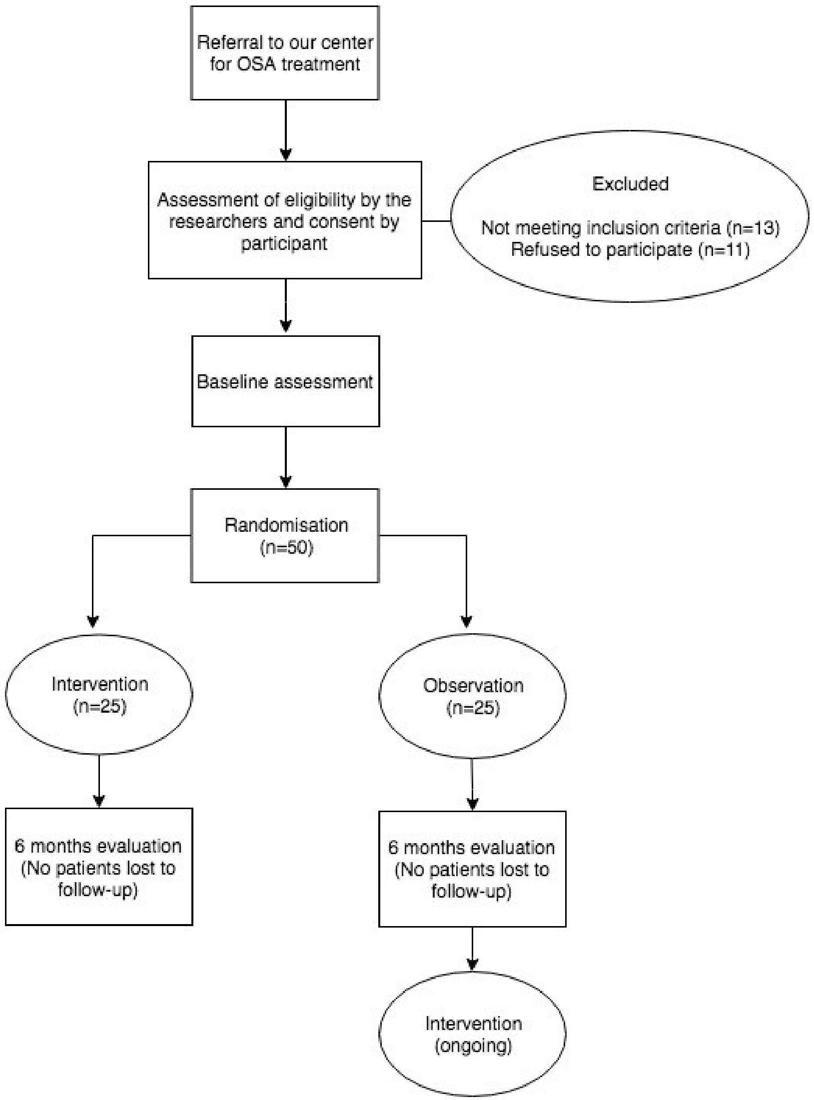
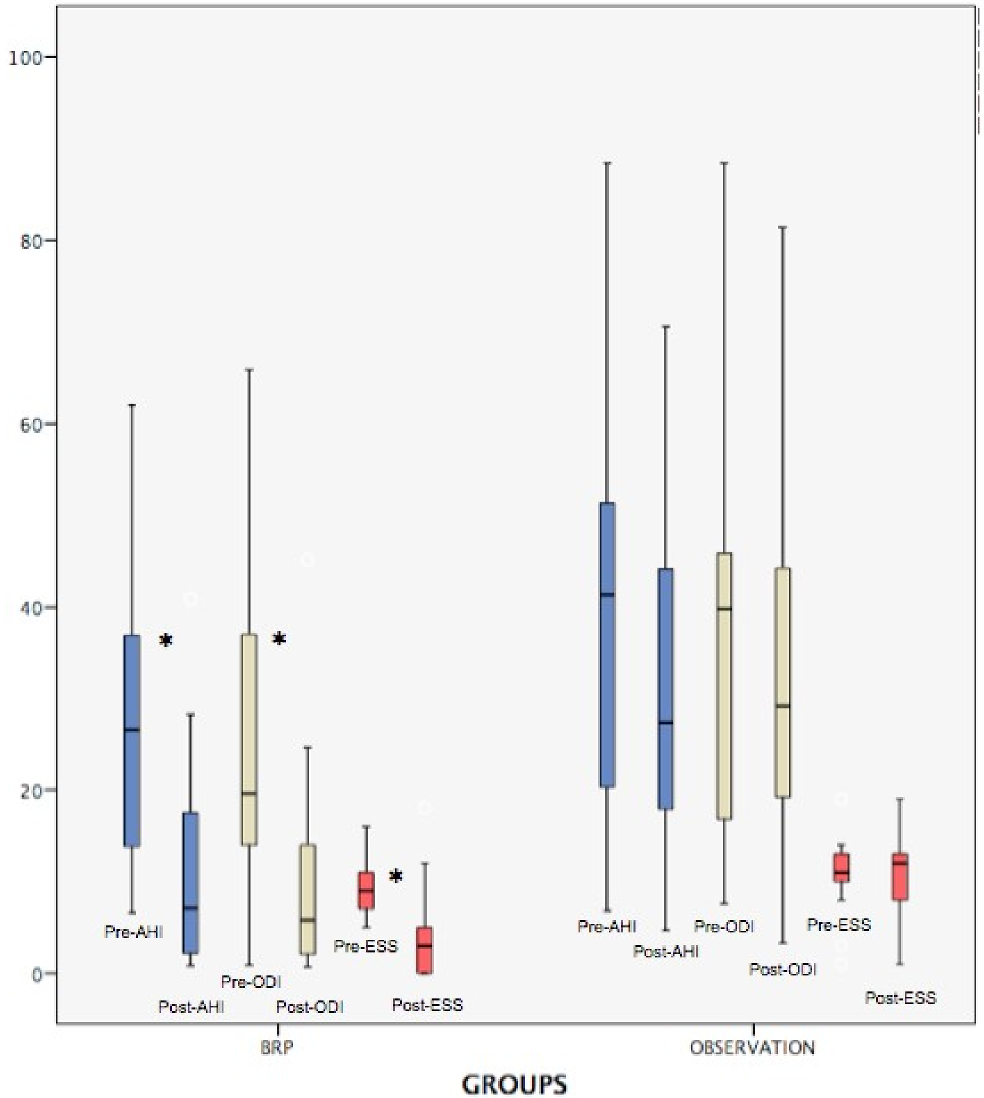

Referral to our center for OSA treatment
Assessment of eligibility by the researchers and consent by participant
Excluded
Not meeting inclusion criteria (n=13)
Refused to participate (n=11)
Baseline assessment
Randomisation (n=50)
Intervention (n=25)
Observation (n=25)
6 months evaluation (No patients lost to follow-up)
6 months evaluation (No patients lost to follow-up)
Intervention (ongoing)

Figure 1


100
80
60
40
20
0
*
*
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Pre-AHI
Post-AHI
Pre-ODI
Post-ODI
Pre-ESS
Post-ESS
Pre-AHI
Post-AHI
Pre-ODI
Post-ODI
Pre-ESS
Post-ESS
BRP
OBSERVATION
GROUPS

Figure 2

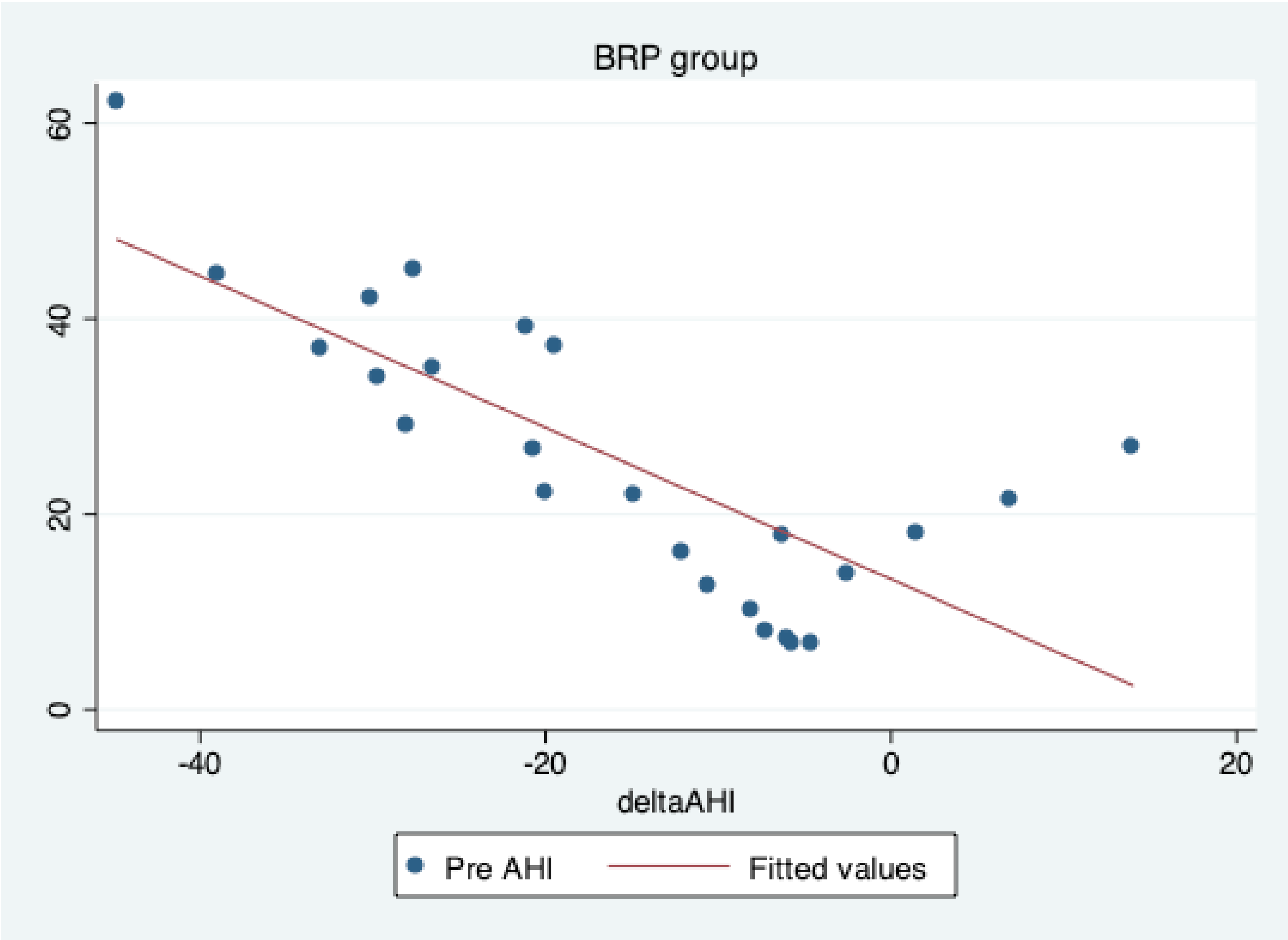


Figure 3

Group	AHI	ODI	ESS	LOS	P
BRP	25.58 ± 14.60	24.39 ± 17.73	9.28 ± 3.10	80.56 ± 7.51	NS
ESP	19.14 ± 9.66	16.30 ± 8.95	8.96 ± 3.36	86.52 ± 4.64	
UPPP	18.96 ± 17.79	17.56 ± 16.64	8.80 ± 3.23	77.60 ± 12.04	

Table 5

Groups	Delta - AHI	Delta - ODI	Delta - ESS	Delta - LOS
BRP	<.0001	.0001	<.0001	.0018
ESP	<.0001	.0005	<.0001	<.0001
UPPP	<.0001	<.0001	.0001	.1084

Table 6

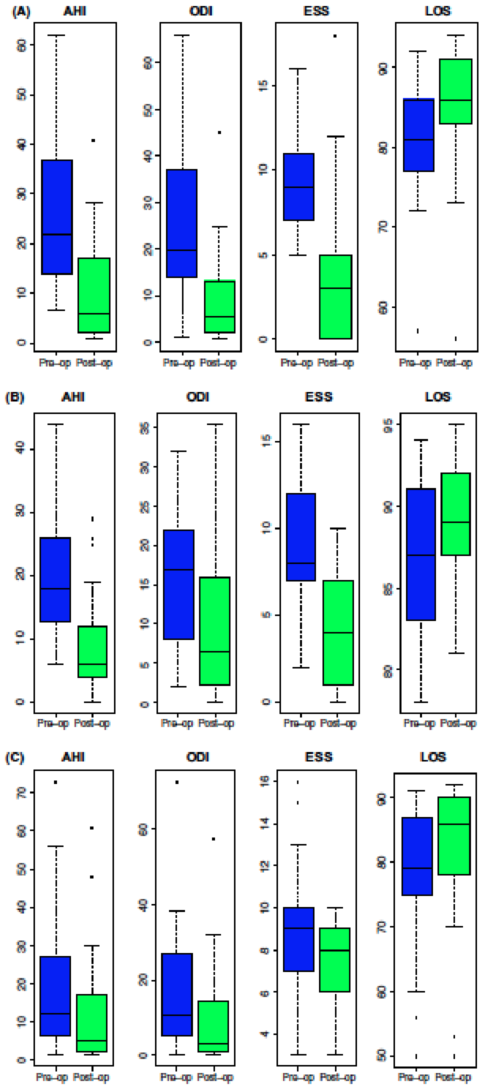

(A)
AHI
ODI
ESS
LOS
Pre-op
Post-op
(B)
AHI
ODI
ESS
LOS
Pre-op
Post-op
(C)
AHI
ODI
ESS
LOS
Pre-op
Post-op

Figure 4

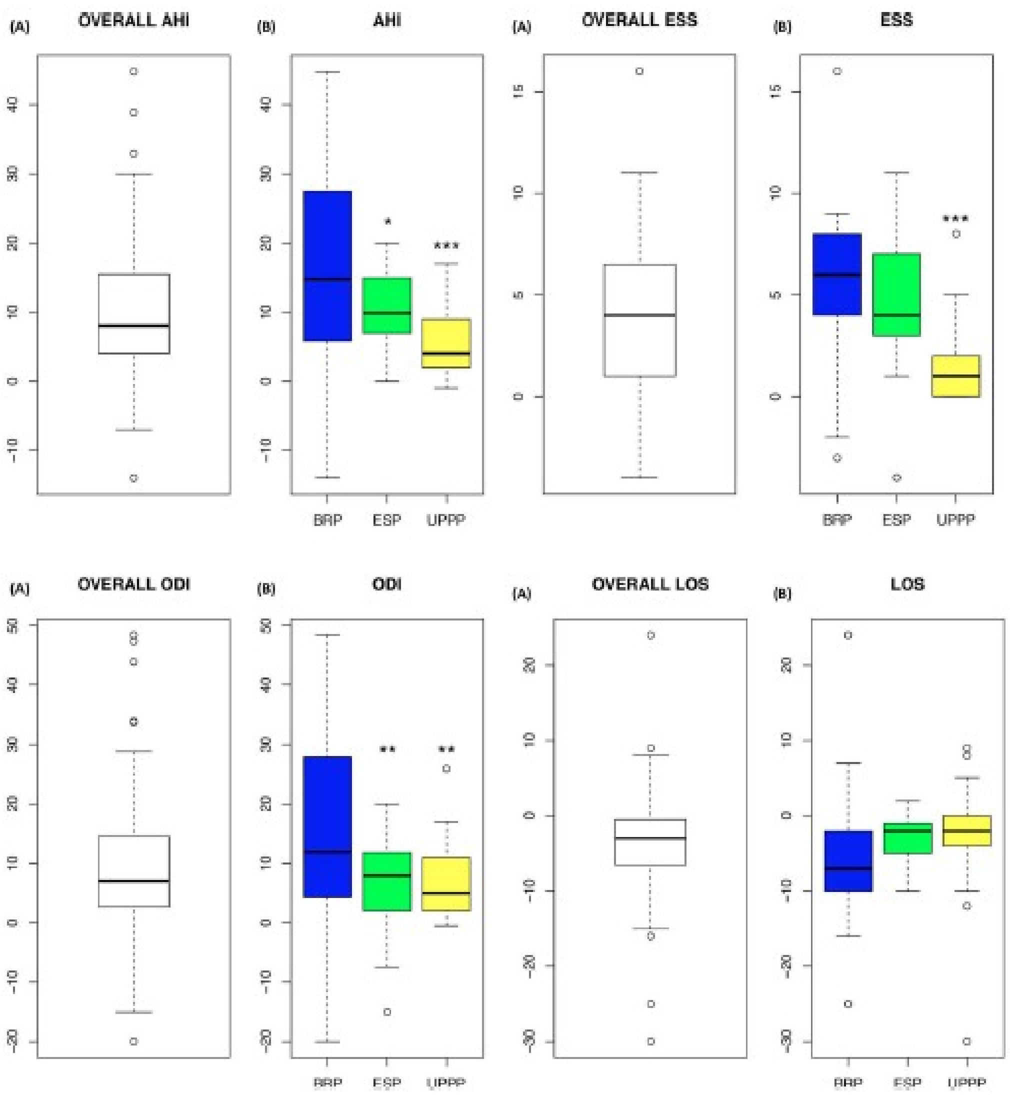

(A) OVERALL AHI
(B) AHI
(A) OVERALL ESS
(B) ESS
(A) OVERALL ODI
(B) ODI
(A) OVERALL LOS
(B) LOS
BRP ESP UPPP
*
***
**

Figure 5

		N	Mean	Std. deviation	P
Age	UPPP	10	58.40	9.90	0.170
	ESP	10	52.80	11.39	
	BRP	10	48.20	11.39	
	Total	30	53.13	11.36	
BMI	UPPP	10	26.79	3.72	0.181
	ESP	10	27.03	2.12	
	BRP	10	28.77	2.56	
	Total	30	27.53	2.92	
preAHI	UPPP	10	34.04	14.03	0.953
	ESP	10	35.59	13.87	
	BRP	10	37.84	21.60	
	Total	30	35.82	16.37	

Table 7

	Group	Mean	Std. Deviation	P
preAHI	BRP	34.04	14.03	0.005
postAHI		13.53	7.76	
preESS		10.40	2.50	0.008
postESS		3.90	3.57	
preAHI	ESP	35.59	13.87	0.005
postAHI		9.63	9.25	
preESS		13.00	4.49	0.005
postESS		4.90	3.87	
preAHI	UPPP	37.84	21.60	0.059
postAHI		22.92	13.30	
preESS		12.30	4.24	0.021
postESS		8.50	5.42	

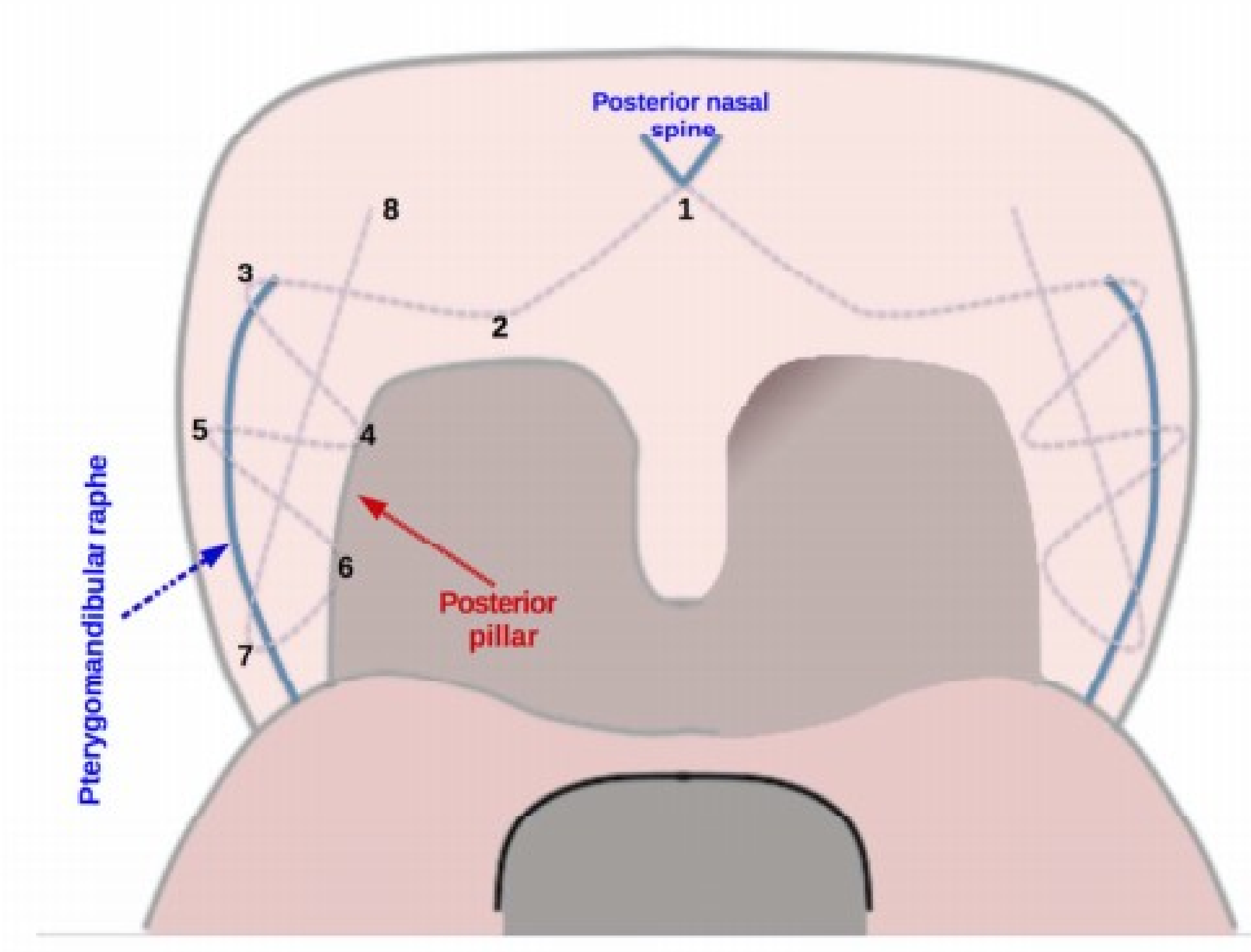
Table 8

		N	Mean	Std. Deviation	P
Pain	UPPP	10	1.69	0.62	0.416
	ESP	10	1.79	0.90	
	BRP	10	2.79	2.02	
	Total	30	2.09	1.37	
Hospital stay	UPPP	10	6.70	1.25	0.811
	ESP	10	7.10	1.52	
	BRP	10	7.10	3.24	
	Total	30	6.96	2.12	
deltaAHI	UPPP	10	20.51	12.45	0.313
	ESP	10	25.96	13.95	
	BRP	10	14.92	26.83	
	Total	30	20.46	18.78	

Table 9

	Group	Mean	Std. Deviation	P
palatalTIME	BRP	15.70	2.16	0,00
	UPPP	28.20	2.29	
postESS	BRP	3.90	3.57	0,019
	UPPP	8.50	5.42	
postAHI	BRP	13.53	7.76	0,043
	UPPP	22.92	13.30	
PalatalTIME	BRP	15.70	2.16	0,00
	ESP	37.60	4.59	
postESS	BRP	3.90	3.57	0,62
	ESP	4.90	3.87	
postAHI	BRP	13.53	7.76	0,29
	ESP	9.63	9.25	
palatalTIME	ESP	37.60	4.59	0,00
	UPPP	28.20	2.29	
postESS	ESP	4.90	3.87	0,013
	UPPP	8.50	5.42	
postAHI	ESP	9.63	9.25	0,019
	UPPP	22.92	13.30	

Table 10



Posterior nasal spine
1
8
3
2
5
4
6
7
Pterygomandibular raphe
Posterior pillar

Figure 6

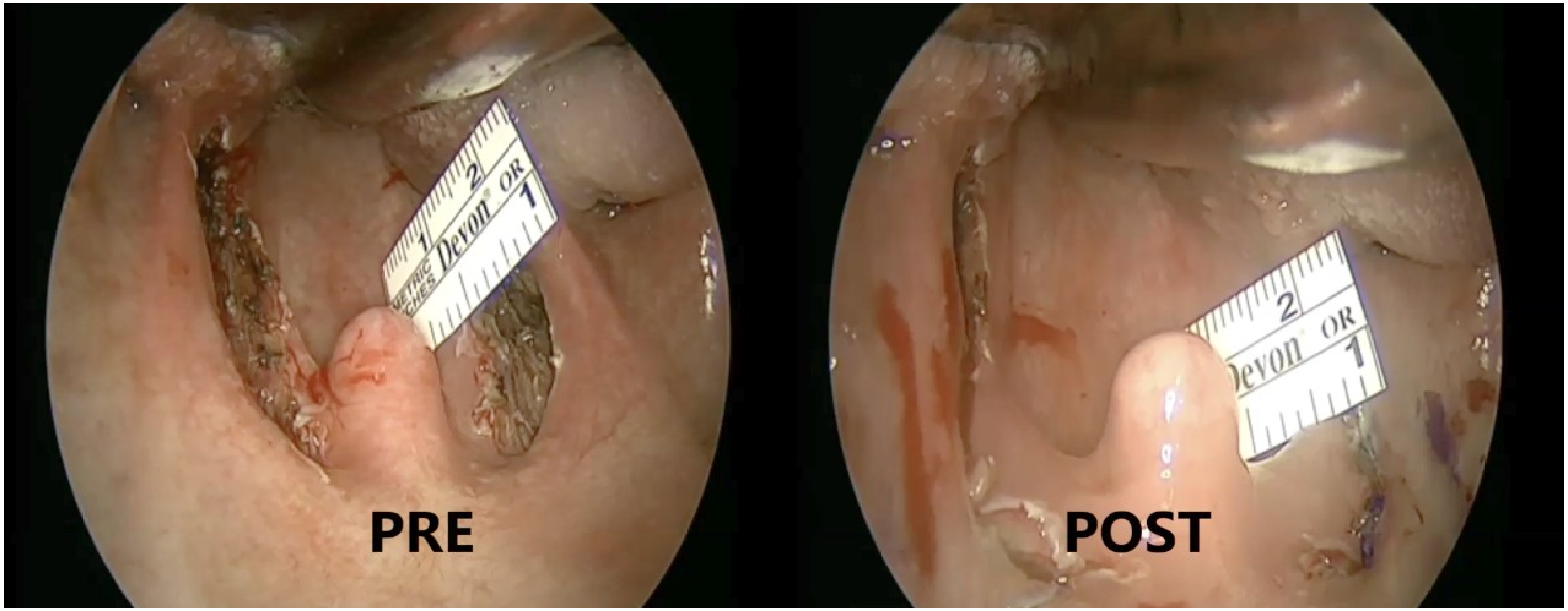


Figure 7