

# Quality of life improvement after Obstructive Sleep Apnea treatment: Continuous Positive Airway Pressure versus Multilevel Transoral Robotic Surgery.

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## Abstract

**Objectives:** The aim of this study has been to analyze effects on Quality of Life (QoL) of the multilevel surgery for Obstructive Sleep Apnea (OSA). Also, we have compared the impact on QoL of two different treatments for patients with moderate to severe OSA such as CPAP and transoral robotic surgery (TORS). **Design:** 67 OSA patients who underwent multilevel robotic surgery and 67 OSA patients treated with CPAP were enrolled in a Group 1 and Group 2 respectively. The Glasgow Benefit Inventory (GBI) questionnaire has been administrated to all patients to evaluate the changes in the QoL after the different OSA treatment. Respiratory outcomes pre and post treatment were evaluated and compared. **Results:** Group 1 showed a GBI total average value of +30.4, whereas the group 2 a value of +33.2. No statistical difference emerged ( $p=0.4$ ). General benefit score showed no difference between groups ( $p = 0.1$ ). Better values of social status benefit ( $p= 0.0006$ ) emerged in CPAP Group, whereas greater physical status benefit ( $p=0.04$ ) was showed in TORS Group. Delta-AHI ( $-23.7 \pm 14.3$  vs  $-31.7 \pm 15.6$ ;  $p = 0.001$ ), Delta-ODI ( $-24.5 \pm 9.5$  vs.  $-29.4 \pm 10.5$ ;  $p = 0.001$ ) showed better values in CPAP group. Therapeutic success rate of Multilevel TORS Group was 73.1% and 91% in CPAP group ( $p = 0.01$ ) respectively. **Conclusion:** Multilevel TORS and CPAP

have a positive effect in quality of life of OSA patients. Greater social support has been reported in CPAP group and better physical health status in TORS group.

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**Conclusion :** Multilevel TORS and CPAP have a positive effect in quality of life of OSA patients. Greater social support has been reported in CPAP group and better physical health status in TORS group.

**Keywords:** Robotic surgery, CPAP, OSAS, Quality-of-Life, sleep-questionnaire

## KEYPOINTS

1. Obstructive Sleep Apnea is characterized to a lower quality of life
2. Multilevel Robotic surgery and CPAP treatment improve quality of life in OSA patients
3. CPAP and TORS seems to be equally effective in terms of general quality of life improvement
4. Greater social support is needed in patients treated with CPAP
5. Better physical health status has been demonstrated in patients underwent multilevel TORS
- 6.

## INTRODUCTION

Obstructive Sleep Apnea (OSA) syndrome is a respiratory sleep disorder characterized by a reduction (hypopnea) or complete cessation (apnea) of airflow in the upper airways during night, in the presence of breathing effort (1–3).

The available literature suggests that OSA, in untreated adults, is associated with a poor health-related quality of life (HRQoL), probably due to symptoms and complications related to this disease.(4,5)

Continuous Positive Air Pressure (CPAP) is considered the gold standard treatment for severe OSA and has been shown to be effective in reducing the apnea-hypopnea index (AHI), improving sleep quality [3] and decreasing cardiovascular comorbidities. (6). Besides, it has been proven that CPAP treatment, by restoring the sleep quality and OSA symptoms, is directly correlated to an improvement in the quality of life (QoL) of these patients.

Over the years different types of surgeries of the velo-pharyngeal region and/or on the tongue base, as an alternative to the ventilatory therapy, have been proposed. Trans- Oral- Robotic- Surgery (TORS) allows, in selected cases of OSA patients, the muscular and lymphatic resection of the tongue base, increasing the respiratory space and stabilizing the collapse of this anatomical region. In the last years, many papers have confirmed the efficacy of TORS, performing it as a single level surgery or as part of multilevel surgery (7–11).

Surgical treatment in OSAS patients has some important benefits (12–14). These include the possible resolution of the apneas/hypopneas, which allows patients to avoid the use of devices during the night. Besides, most side effects of CPAP therapy (pressure effect of the mask, poor compliance, etc.), could be avoided with surgery.

How is the post-operative quality of life of patients surgically treated with TORS? Could there be differences between CPAP and multilevel surgery in the post-operative quality of life of OSA patients?

To our knowledge, no studies in literature have evaluated patient's quality of life after surgical treatment for OSA with a multilevel surgery including TORS. Besides, no studies have compared changes in patient's quality of life of surgical and non-surgical OSA treatments.

The aim of this study has been to analyze effects on QoL of the multilevel surgery for OSA. Also, we have compared the impact on QoL of two different treatments for patients with moderate to severe OSA such as CPAP and TORS.

## MATERIALS AND METHODS

### Trial design and subjects of the study

This retrospective bi-center study was performed at the Otolaryngology, Head and Neck and Oral Surgery Department of <Blinded for review> and at the ENT Department of ' <Blinded for review>.

Subjects eligible for the study inclusion were retrospectively selected from patients with OSA diagnosis treated in these centers. In order to evaluate and compare the effect on quality of life of two different type of treatments for OSA (CPAP and multilevel surgery), two groups of study were defined:

Group 1, OSA patients treated with TORS in a multilevel surgery setting.

Group 2, OSA patients treated with CPAP device.

The study design flow chart with inclusion and exclusion criteria of the study has been reported in Figure 1 .

In Group 1 were enrolled patients, with age between 18 and 65, treated with multilevel surgery to the <Blinded for review>, from January 2017 to February 2019. Multilevel surgery consisted in a resection of the tongue base using the Transoral Robotic Surgery (TORS) + epiglottoplasty + tonsillectomy + Barbed Repositioning Pharyngoplasty (BRP) + settoplasty and/or turbinoplasty. This combined multilevel surgical approach is a standardized protocol, well described in the literature, that has been performed at our center for more than 10 years. Surgical steps were performed in all patients as reported in the original study of Vicini et al.(8,10,15).

In Group 2, on the other hand, have been enrolled patients treated with CPAP at the Sleep Medicine Center of the <Blinded for review>. For the study inclusion only patients with an auto-CPAP device and with a mean age between 18 and 65 years were considered.

An identical number of patients were enrolled in two groups in order to better compare results of the two groups.

### *Quality of Life investigation*

The Glasgow Benefit Inventory (GBI) (16,17) questionnaire has been used to evaluate the changes in the QoL of investigated patients (17). It is a validated questionnaire to measure the QoL changes related to a specific surgical or medical intervention. It is designed for only post-intervention use and it is the most widely used method to evaluate the improvement of QoL in Otorhinolaryngology and in other medical and surgical disciplines.

All patients considered eligible to the study enrollment were contacted by two co-authors of the study (C.A.M.L.I. e I.C.V.) and to each patient was administered the validated Italian version of the Glasgow

## Quality of Life questionnaire.

The questionnaire, which can be completed by interview or self-completed by patients, consists of 18 questions answered using a five-point Likert scale, addressing change in health status (post treatment for OSA).

The 18 questions of the GBI were evaluated, and a total score (Overall Benefit) was calculated. The total score can range from -100 (poorest outcome) through 0 (no change) to +100 (best outcome). It indicates the overall impact of the surgical or medical treatment on patient's quality of life.

The Glasgow Benefit Inventory is further subdivided into three distinct subscales. Twelve questions focus on general changes in health status, as well as changes in psychosocial health status identifying the 'General' subscale. Moreover, three questions are related to the amount of social support needed in relation to the condition being questioned (Social). The remaining three questions address changes in physical health status including medications requirement and number of visits to doctors required (Physical). So, in addition to the total score, it is possible to obtain a partial general score, a partial score on social support and one on physical health.

## Evaluation of OSA treatment outcomes

To each patient of both groups, the home sleep apnea study (HSAT) performed before either surgery or CPAP treatment were re-examined and all respiratory data collected. In the TORS group the post-treatment respiratory outcomes were collected to the HSAT performed at the last follow-up. In the CPAP group the respiratory outcomes were extracted from an HSAT performed simultaneously with the last control of the device (at least 6 months after CPAP activation).

In all cases the sleep studies were performed in an unattended way by means of a Polymesam Unattended 8-channel Device. The following parameters were recorded during the sleep study: respiratory movement and airflow, heart rate, arterial oxygen saturation, position of patient and sleep time.

The apnea-hypopnea index (AHI), Oxygen Desaturation Index (ODI), and the lowest SpO<sub>2</sub> (LOS) were collected and recorded by experts in sleep medicine according to the American Academy of Sleep Medicine (AASM) guidelines [42].

Delta AHI (postoperative AHI minus preoperative AHI), Delta ODI (postoperative ODI minus preoperative ODI) and Delta LOS (postoperative LOS minus preoperative LOS) were calculated in order to express the value of surgical efficacy and to compare the two groups of patients. Therapeutic success was defined, in according to the existing literature (Sher's criteria), as the achievement of a postoperative value of AHI < 20 and a 50% improvement in the preoperative AHI value (18).

Patients with incomplete HSAT data or recent treated cases (post-treatment HSAT evaluation shorter than 6 months) were excluded to the study.

## Statistical Analysis and Ethical statement

To test the differences among groups, chi-square test was used for categorical data, while Student's t test was used for continuous data. Probability values lower than 0.05 were considered statistically significant. All analyses were performed with the STATA 12.1 software (Stata Corp., College Station, TX, USA).

Given the retrospective nature of the study and anonymity, Ethic Committee approval was not required.

## RESULTS

Sixty-seven patients were enrolled in group 1 and group 2, respectively. Baseline data concerning age, gender and number of comorbidities in both groups are shown in Table 1 .

Patients of the two groups didn't show difference in average value of age and sex (Table 1). Moreover, the analysis of the number of comorbidities present in each individual of each groups did not show statistical differences ( $p > 0.05$  for each class analyzed).

## Quality of Life

In patients treated with TORS a GBI total average value of +30.4 was obtained, with a maximum of +75.0 and a minimum value of -16.7. In the group of patients treated with CPAP a total GBI average value resulted to be +33.2 with a range between +88.9 and -11.1. No statistical difference emerged comparing the two study groups regarding the total GBI value ( $p=0.4$ ) (Table 2).

General benefit, social benefit score and the physical score of both groups showed positive values; values are reported in Table 2. Comparing the two groups of patients, there was no statistical difference in the general benefit score ( $p = 0.1$ ). Differently, the two groups of patients studied, showed a statistical difference in the values of social status benefit ( $p= 0.0006$ ), that appeared better in the CPAP group, and in the physical status benefit ( $p=0.04$ ) that on the contrary, was greater in the TORS group.

(Table 2)

Figure 2 shows the box plot that summarize the distribution of GBI sub-scores results in the two groups of study.

## OSA treatment outcomes

In group 1, patients presented a mean preoperative AHI value of  $40.3 \pm 15.7$  which was reduced to a postoperative value of  $16.7 \pm 13.4$ , with a statistically significant difference ( $p = 0.0001$ ) (Table 3).

In group 2 the patients presented a mean preoperative AHI value of  $37.7 \pm 15.8$  and a postoperative value of  $6 \pm 4.1$ , so that also in this case a statistically significant difference emerged between preoperative and postoperative values ( $p = 0.0001$ ) (Table 3). ODI and LOS data of the two groups of the study are reported in Table 3. In both groups a statistical difference between preoperative and postoperative average values of these parameters emerged.

The Delta-AHI ( $-23.7 \pm 14.3$  vs  $-31.7 \pm 15.6$ ;  $p = 0.001$ ), as well as the Delta-ODI ( $-24.5 \pm 9.5$  vs.  $-29.4 \pm 10.5$ ;  $p = 0.001$ ) of the two groups of patients revealed best values in CPAP group, with a statistically significant difference compared to the TORS group.

The therapeutic success rate was found to be 73.1% in patients treated by multilevel surgery and 91% in patients treated with CPAP ( $p = 0.01$ )

(Table 4).

## DISCUSSION

Few papers in literature have investigated the improvement on quality of life after OSA treatments (19,20), therefore limited data about this topic are available in literature. Turner et al (21), have observed a statistically significance improvement ( $p<0.04$ ), in terms of working memory, long-term memory, quality of life and positive attitude after CPAP treatment. In a meta-analysis study Kuhn et al.(19) proved, using the SF 36 questionnaire, a positive effect of CPAP treatment on the HR-QoL of patients with OSA.

Despite these published evidences, no studies in literature have analyzed QoL after multilevel robotic surgery for OSA and no authors have compared multilevel surgery and CPAP therapy in QoL improvement of OSA patients.

In the surgical treated patients of our study a GBI total average value of +30.4 emerged with a maximum of +75.0 and a minimum value of -16.7. The general benefit score was calculated as +31.3 (range -63.8 to +88.3), and the social benefit was +11.5 (range 0 to +66.7), whereas the physical score resulted to be +24.8 (range -16.7 to +50). These positive values over +20 points indicate an effective improvement in all aspects of the QoL.

Patients treated with CPAP showed an excellent improvement in quality of life as well (+38.6 range -20.3 to +100). However, despite a higher mean value of the total GBI in this second group, no statistical differences emerged in the total GBI score (Overall Benefit) with patients surgical treated. These results

could be explained by the good clinical and respiratory outcomes obtained in both treatments analyzed(22); a significative difference between pre-treatment and post-treatment AHI values ( $p=0.0001$ ) was observed in both groups of patients. Probably for the same reason, by comparing the two groups of study a not-statistically significant difference was likewise found in the general partial score ( $p= 0.1$ ). Similar results have been described by Robinson et al.(23). They, in a clinical study, did not observe a statistically significant difference between CPAP and Upper Airway Surgery (UAS) in terms of general quality of life ( $p=0.308$ ).

In terms of social subscale, we reported higher values in CPAP group (mean 26.9) than in TORS-multilevel surgery (mean 11.6), with a statistical difference ( $p= 0.0006$ ). This subscale investigates the social support in terms of the help provided by relatives and friends in the management of daily life, in relation to the pathology and the proposed therapy. This explains the possible reason why the TORS group has reported significantly lower values in this subscale. In fact, patients treated with C-PAP require more attention in managing the disease, the related symptoms and the device itself. Therefore, they probably need more care and support from their friends and relatives. The physical score analyzes the benefit in physical health status including frequency of illness, need of medicament or medical consult. Regarding the scores of this subscale, statistical difference emerged between groups with higher values in the TORS group (mean 24.8) than in the CPAP group (mean 18.7  $p<0.04$ ). In case of surgical success(24), multilevel surgery could lead to a reduction of medical necessities and consults. Contrarily, patients that use the CPAP need constant device setting and medical consults. Furthermore, this device is characterized by poor mask comfort with a sense of pressure during the night. These aspects should not be underestimated, as they could be the cause of a poorer physical score reported in CPAP patients than in TORS subjects(25).

Although important results about the impact of CPAP and TORS on quality of life and its aspects have emerged, this study has some limitations such as its retrospective nature and the not extensive number of patients enrolled. Moreover, surgically treated patients require a longer follow-up to confirm these statements, while the mean follow up of 1.4 year described in this study is large but not sufficient to have definitive results. Further prospective large-series studies are underway to validate these outcomes.

## CONCLUSIONS

Multilevel surgery and CPAP treatment have a positive impact in the quality of life in OSA patients. Both therapies appear to be equally effective in the improvement of the general quality of life (total and general GBI scores), without statistical differences among them. Data show a greater social support in patients treated with CPAP, while patients undergoing robotic multilevel surgery report a greater improvement in their physical health status.

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Figure 1 Flowchart of the study

Figure 2 Distribution of GBI sub-scores in the two groups

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