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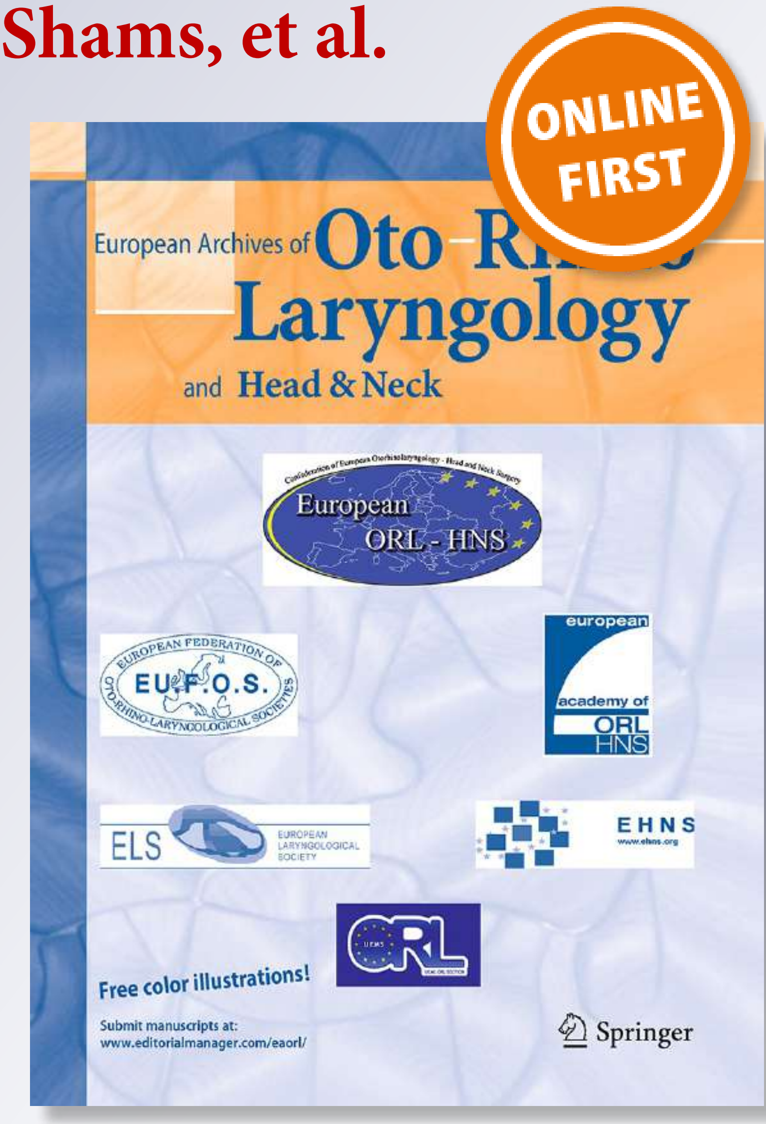

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REVIEW ARTICLE

Transoral robotic surgery for the management of obstructive sleep apnea: a systematic review and meta-analysis

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Abstract Obstructive sleep apnea–hypopnea syndrome (OSAHS) is a serious social health problem with significant implications on quality of life. Surgery for OSAHS has been criticized due to a lack of evidence to support its efficacy as well as the heterogeneous reporting of published outcomes. Moreover, the transoral robotic surgery (TORS) in the management of OSAHS is still in a relative infancy. Nevertheless, a review and meta-analysis of the published articles may be helpful. Among 195 articles, eight studies were included in the analysis. The mean of enrolled patients was 102.5 ± 107.9 (range 6–289) comprising a total of 820 cases. The mean age was 49 ± 3.27 and 285 patients underwent a previous sleep apnea surgery. The uvulopalatopharyngoplasty (UPPP) was the most common palatal procedure. The mean rate of failure was 34.4 % (29.5–46.2 %). Complications occurred in 21.3 % of the patients included in the analysis, most of them were classified as minor. Transient dysphagia represented the most common complication (7.2 %) followed by bleeding (4.2 %). TORS for the treatment of OSAHS appears to be a promising and safe procedure for selected patients seeking an alternative to continuous positive airway pressure (CPAP), although further researches are urgently needed.

Keywords Transoral · Robot · Sleep apnea · Base of tongue · Complication · Outcome

Introduction

Obstructive sleep apnea–hypopnea syndrome (OSAHS) is a common disorder that affects 2–4 % of the adult population. It is a serious social health problem with significant implications on quality of life as well as long-term health. OSAHS 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 [1, 2]. The gold standard treatment for OSAHS 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 for OSAHS has been criticized due to a lack of evidence to support its efficacy as well as the heterogeneity of outcomes in published studies. Interpretation of the current literature has been problematic due to the different apnea-hypopnea index (AHI) criteria [3] and the variation in AHI thresholds for defining surgical success or improvement [4]. The concept of transoral robotic surgery (TORS) as a treatment of OSAHS was first introduced in 2009 by Vicini et al. [5] in their feasibility report for the treatment of hypertrophy of the base of tongue. Since then, TORS has been shown to

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be an effective treatment option for both isolated retrolingual obstruction and when combined with other techniques in cases of multilevel obstruction. TORS permits to overcome surgical access issues to the base of tongue that have previously limited the introduction of different safe and effective treatments in the routine practice.

Our goal in this study was to present a systematic review and a meta-analysis of TORS in the management of OSAHS. Firstly, we focused the attention to the potential bias and applicability of studies that examine TORS in the management of OSAHS. In addition, we pooled the data to evaluate the outcomes in a large series of patients.

Materials and methods

Literature search protocol

A comprehensive review of the English language literature on the robotic surgical management of sleep apnea was performed using PubMed, EMBASE, the Cochrane Library and CENTRAL electronic databases (see Fig. 1). Three searches using the keywords (1) surgery OR robotic OR TORS OR transoral, (2) base of tongue OR tongue base OR hypertrophy, and (3) obstructive sleep apnea OR sleep apnea OR OSA. These searches were combined with the AND function to find all relevant articles. The following inclusion criteria were applied to each article: (1) available information on outcome data, (2) data concerning the type of surgical treatment: exclusive robotic surgery, associated with palatal/nose surgery, previous surgical treatment and (3) data regarding the pre-operative and post-operative values of Apnea-Hypopnea Index (AHI), Body Mass Index (BMI), lowest Saturation of Peripheral Oxygen (SpO_2), Epworth Sleepiness Scale (ESS), and hospital stay, complications, starting of oral feeding, and tracheostomy. When multiple papers were published by a single institution with updated follow-up on their patient populations, the last recent publication is included, whilst the publications with a smaller series of patients were excluded from the analysis to maximize accuracy of follow-up data and reduce the risk of redundancy [2, 6–10]. Exclusion criteria were: articles missing one or more of the above mentioned inclusion criteria [11], articles about the use of TORS for other pathologies [12], case reports without significant outcome data, reports on surgical technique without significant outcome data [1, 2, 13]. To further reduce the risk of incomplete literature search, a manual search through the references of the included papers was performed.

Analysis protocol

Data from the studies were first extracted and assessed by the principal investigator (MG), and thereafter independently by two co-authors (CG and MF) using standardized data forms. Articles were examined for data resolution with the intent to perform a meta-analysis. Different methods of meta-analyzes were considered in reviewing the literature to seek results that would provide meaningful analysis with the least risk of introducing biases. The quality assessment of studies (QUADAS-2) tool was used to evaluate relevant study design characteristics of the included studies. This type of quality assessment was designed in 2003 and updated in 2011 to help judge the risks of bias and applicability [14]. Publication bias was tested using the funnel plot (Fig. 2). A funnel plot is a type of scatter plot that can be useful to understand study heterogeneity of meta-analysis. The funnel plot examines the sample size on the *y*-axis (plotted as the standard error of the log odds ratio) and

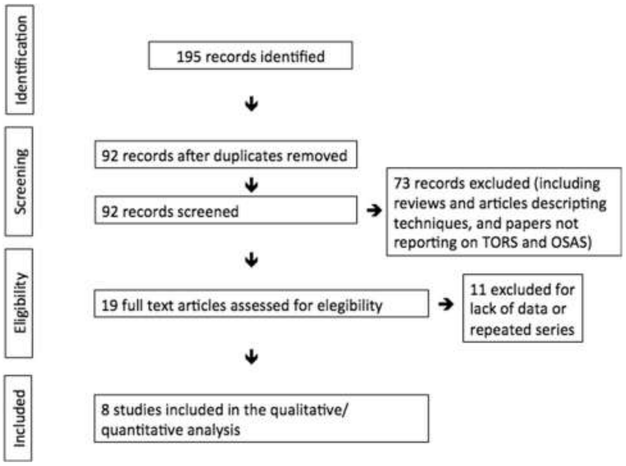

Fig. 1 Flowchart of study selection

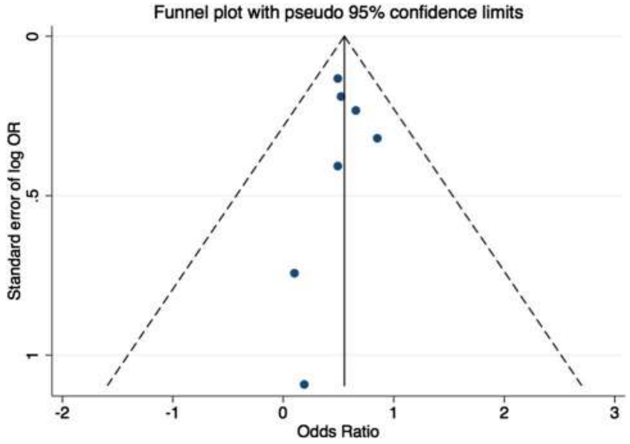

Fig. 2 Funnel plot analysis of publication bias for included studies analyzing the failures

treatment effect on the *x*-axis (plotted as the odds ratio). Treatment effect in this study was defined as success of sleep apnea surgery, defined as 50 % reduction of pre-operative AHI and an AHI <20.

The manuscripts were analyzed to extrapolate all information for each treated patient about age, gender, pre-operative and post-operative AHI, BMI, ESS, lowest SpO_2, hospital stay, surgical time, starting of oral feeding, volume of tissue removed. The articles were also reviewed for data concerning the occurrence of perioperative and postoperative complications. A major complication was defined as at least one reported event of: intra-operative or post-operative bleeding, prolonged intubation, pneumonia and pharyngeal laceration. Attention was mainly focused on episodes of bleeding. Minor complication was noted as at least one reported event of: transient dysgeusia, transient dysphagia and globus sensation.

Statistical analysis

Random effect models were used to generate pooled estimates. Data were analyzed using generic inverse radiance method and $p < 0.05$ is regarded as statistically significant. Combined summary statistics of the standardized (STD) paired difference in mean for the individual studies are shown. Combined STD paired differences in means were calculated and a two-sided p value <0.05 was considered to indicate statistical significance. A 2-based test of homogeneity was performed and the inconsistency index (I^2) statistic was determined. If I^2 was >50 or >75 %, the studies were considered to be heterogeneous or highly heterogeneous, respectively. If I^2 was below 25 %, the studies were considered to be homogeneous. If the I^2 statistic (>50 %) indicated that heterogeneity existed between studies, a random-effects model was calculated. All analyzes were performed with STATA 12.0 software (Stata Corp., College Station, TX, USA).

Results

The search was performed in November 2015 and yielded 195 articles, of which eight articles met inclusion's criteria [15–22]. The graphical display of QUADAS-2 shows that while the applicability of these studies is very high, there is a risk on bias when considering patient selection and the flow of the studies (Fig. 3). Moreover, when examining the eight studies in this meta-analysis, the data showed a pooled modest treatment effect with the best fit line at approximately 0.53. The largest series of TORS was published by Hoff et al. [17] (see Table 1).

Among the included publications, there were two multicenter retrospective studies [16, 17] and four single-institution retrospective studies [15, 18–20], as well as one case-series [21] and one prospective [22] study. The mean of enrolled patients was 102.5 ± 107.9 (range 6–289) comprising a total of 820 cases. The mean age was 49 ± 3.27 and 285 patients underwent a previous sleep apnea surgery which consisted of nasal surgery in most cases. The preoperative and post-operative characteristics are shown in Table 2.

The uvulopalatopharyngoplasty (UPPP) was the most common palatal procedure (71.3 %), followed by expansion sphincter pharyngoplasty (ESP) (15.3 %). Epiglottoplasty was performed in association with robotic tongue base reduction in 48.5 % of cases. Four papers report on TORS as a part of a multi-level setting [15, 16, 18, 22] while only one article evaluates robotic surgery as a stand-alone procedure [19]. The remaining included articles include multi-level and single-level settings but do not

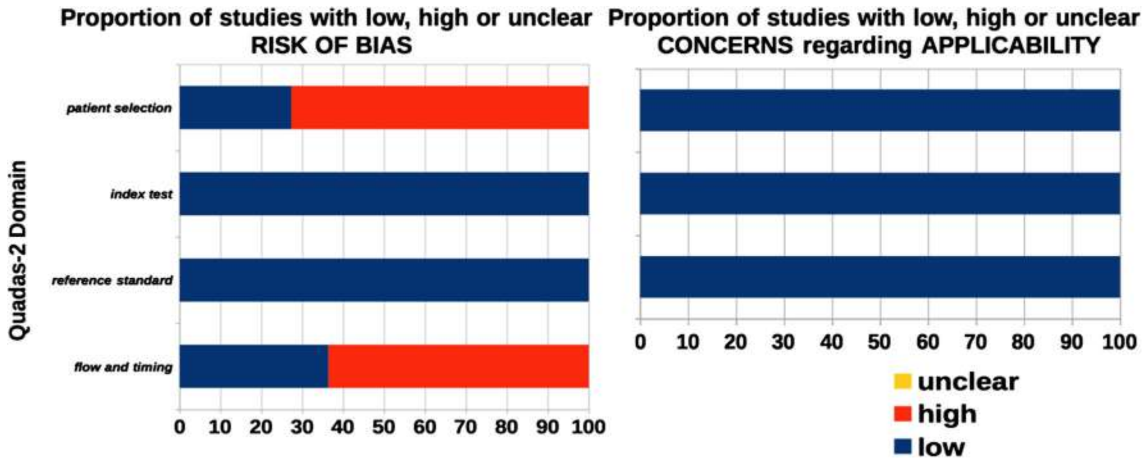

Fig. 3 Graphical Display for QUADAS-2 results

Table 1 Overview of studies on robotic surgery for obstructive sleep apnea syndrome

Study	Year	Design	No. of patients	No. of palatal surgery	No. of nasal surgery	No. of epiglottoplasty	No. of tracheostomy	No. of complications	No. of failures
Friedman et al. [15]	2012	Retrospective	27	27	0	0	0	0	9
Vicini et al. [16]	2014	Multicenter retrospective	243	243	209	243	–	51	81
Hoff et al. [17]	2015	Multicenter retrospective	289	258	–	49	1	77	–
Toh et al. [18]	2014	Retrospective	20	20	0	20	0	9	2
Mudderis et al. [19]	2014	Retrospective	6	0	0	1	0	6	1
Hoff et al. [20]	2014	Retrospective	121	–	–	55	0	–	42
Lin et al. [21]	2015	Case series	39	21	–	26	4	0	18
Thaler et al. [22]	2015	Prospective	75	75	0	0	0	6	30

Table 2 The pre-operative and post-operative characteristics ($n = 820$)

	Mean	Standard deviation	Minimum	Maximum
Pre-op AHI	44.4	9.8	27.5	57.5
Pre-op lowest SpO_2	78.2	3.2	72.9	81.6
Pre-op BMI	29.9	2.4	26.9	32.9
Pre-op ESS	13.9	1.3	12.2	15.6
Post-op AHI	18.8	7.8	6.3	31.4
Post-op lowest SpO_2	84.3	1.4	83.1	86.5
Post-op BMI	28.6	2.7	26.2	32.4
Post-op ESS	5.9	0.7	5.4	7.1

Pre-op pre-operative, *Post-op* post-operative, *AHI* Apnea-Hypopnea Index, *SpO_2* saturation of peripheral oxygen, *BMI* Body Mass Index, *ESS* Epworth Sleepiness Scale

compare the outcomes considering this main difference [17, 20, 21].

The mean surgical robot time was 58.2 min (range 47.7–87.3). The intra-operative and clinical course data are shown in Table 3.

The comparison among pre-operative and post-operative parameters showed a significant decreasing in post-operative AHI, ESS and an increasing of the lowest SpO_2 value (see Fig. 4). In all but one articles, the success rates was defined as 50 % reduction of pre-operative AHI and an AHI <20. The mean rate of failure was 34.4 % (29.5–46.2 %).

Taking into consideration papers about TORS as a part of a multi-level setting the following can be highlighted: pre-operative and post-operative AHI means were, respectively, 46.88 and 20.24 with a mean rate of failure of 36.1 % ($n = 365$).

Complications were recorded in only one study [20]. Complications occurred in 21.3 % of the patients included in the analysis ($n = 820$). Transient dysphagia represented the most common complication (7.2 %) followed by bleeding (4.2 %). Minor complications, such as post-operative pharyngeal edema were registered in 1 % of cases. The complication rate in patients treated with TORS as part of a multi-level intervention was 17.75 % ($n = 365$). The rate of complications for each study is shown in Fig. 5.

Discussion

The role of surgery for the treatment of OSAHS is much debated [23] and currently lacks a comprehensive randomized evidence base due to the heterogeneous nature of the disease itself and the range of surgical techniques used. Although many patients benefit from the use of CPAP (the gold-standard therapy), non-compliant patients require an alternative to have the reduction of risks of their disease. Surgery, in suitable patients, offers this alternative. The application of TORS to the surgical

Table 3 Intra-operative and clinical course of patients undergoing TORS for OSAHS ($n = 820$)

	Mean	Standard deviation	Minimum	Maximum
Robotic setting time (min)	58.2	20.3	41.9	87.3
Surgical time (min)	90.7	6.5	86.7	98.2
Volume of removed tissue (cm^3)	10.4	6.1	4.4	22.2
Hospital stay (days)	3.1	1.5	1.6	5.3
Oral feeding recovery (days)	5.6	9.2	0	19.3

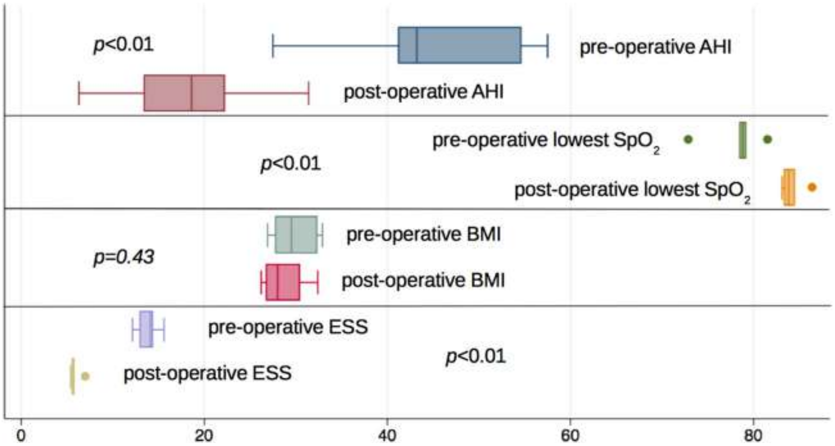

Fig. 4 Comparison among pre-operative and post-operative parameters

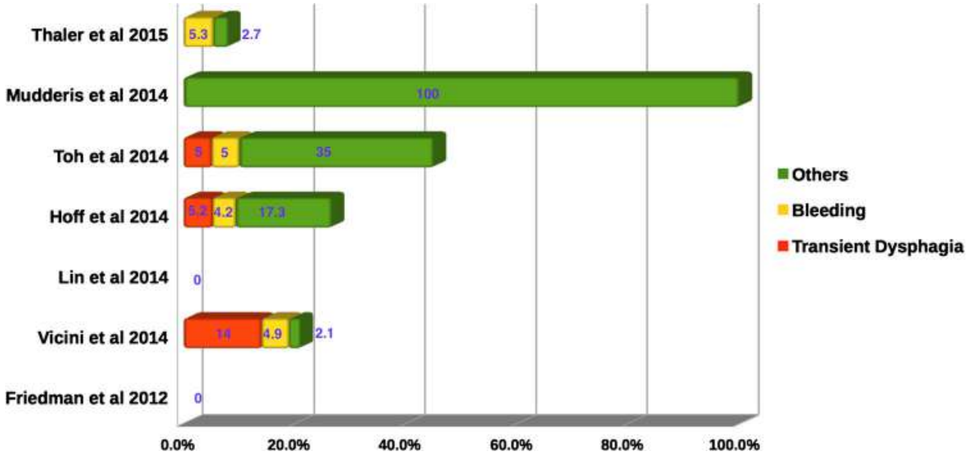

Fig. 5 Graphical display for complication ratio in each included study

treatment of OSAHS is still in its infancy. The heterogeneity nature of OSAS is a relevant but inevitable bias and it is present in most of the published studies, especially regarding the surgical approach to the disease. In fact, some patients might benefits a multilevel surgical approach, in one or deferred steps, with the combinations of nasal, palatal, hyoid procedures, and TORS might be involved in this framework or be the exclusive surgical treatment. For these reasons, examination of the quality of reported data is important to understand the inherent bias and applicability of published studies. Using the QUADAS-2 tool, we found high applicability of the above studies, with some concern for the selection of patients and flow and timing. Selection bias can occur in surgical studies because only a certain proportion of patients present to surgeons for treatment, after failure of other therapies. While this is a bias when considering the success of surgery for all patients with OSAHS, patients who tolerate CPAP are not considered for surgery given the excellent risk reduction with this modality of treatment. Thus the selection of patients is a necessary bias so that only patients who failed CPAP are considered for treatment.

The funnel plot is another useful way to examine bias in a meta-analysis. The funnel plot in our study shows a significant treatment effect in these studies.

Compelling outcomes in reducing the AHI and daytime sleepiness have been demonstrated in the current body of published studies. The rate of success, defined as 50 % reduction of pre-operative AHI and an AHI <20, is achieved in up to 76.6 % of patients with a range between 53.8 and 83.3 %. Unfortunately, reliable predictors the surgical response remains an area of active research. Hoff et al. [20] showed that BMI is <30 is a predictor of success, and Spector et al. [25] have shown that patients undergoing multilevel surgery including TORS base of tongue resection can be successfully treated in unfavorable anatomy (Friedman stage 2 and 3). However, Lin et al. [21] demonstrated that AHI <60, BMI <30 and no lateral velopharyngeal collapse are independent predictive factor of surgical success. The safety of this approach is reasonable as the main complication (bleeding) affected 4.2 % of patients (range 4.2–5.3 %). However, transient dysphagia (7.2 %; range 5–14 %) does compromise the quality of life and must be discussed with patients preoperatively. In a retrospective study, Eesa et al. [24] evaluated the short and long term swallowing outcomes following TORS for OSAHS. In the short-term (1 month post-operatively), there was minimal significant impact on the swallowing function ($p = 0.56$) based on the MD Anderson Dysphagia Inventory (MDADI) questionnaire. The degree of dysphagia was not correlated with the volume of tissue removed from the base of tongue as demonstrated by video fluoroscopic swallow study (VFSS) ($p = 0.72$). There were no complaints of swallowing dysfunction in the long term (up to 32 months post-operatively), and any complaints spontaneously resolved within 3 months post-operatively in all patients with initial abnormal findings on VFSS.

When focusing on TORS as a part of a multi-level intervention no major differences in terms of surgical failure and complication rate were seen in comparison with the overall analysis. Only Muderris et al. [19] evaluated patients treated with TORS as a stand-alone procedure but unfortunately the size of the series is too limited to obtain significant results. Moreover, no studies comparing robotic single-level and multi-level procedures have been published yet.

Furthermore, TORS as a therapeutic option for OSAHS should be compared to other surgical procedures focused on the treatment of the base of the tongue. Coblation is perhaps the most used alternative tool in this sense and many trans-mucosal and sub-mucosal techniques supported by this technology have been proposed during the last decade.

In a study by Friedman et al., a mean failure rate of around 35 % and a complication rate of 15 % in patients treated with palatal and Coblation surgery were reported [26]. Apparently, these results do not seem to be significantly different from our TORS findings.

Friedman et al. also published the only article comparing TORS and Coblation as part of a multi-level setting in the treatment of OSAHS [15]. The authors highlighted that patients undergoing robot-assisted surgery took longer to tolerate normal diet and to resume normal activity, even though the most significant reduction of AHI was seen in TORS patients compared to coblation. On the other hand, Friedman underlined that procedural costs and operating room time were increased with the robotic technique. A retrospective case–control study demonstrated the adding value of use coblation in multilevel surgery [27]. The same authors, in a previous study, evaluated the feasibility of coblation [28]. They showed a mean operative time of 42.6 ± 13.7 min.

In our analysis, intra-operative data demonstrates a mean surgical robot time of 58.2 min; this time is representative of experienced TORS surgeons and should not be extrapolated to the novice surgeons. Similarly, mean surgical time is also reflective of an experienced TORS surgeon and team (90.7 min). A prospective case study [29], in fact, has demonstrated significant decreases in operative time, length of intubation, and hospital stay related to surgeon and institutional experience. Finally, the expertise represents an important factor in improving the performance of the robotic surgical approach [30].

Conclusion

Robotic-assisted surgery for the treatment of OSAHS appears to be a promising and safe procedure for patients seeking an alternative to traditional therapy. While there is an inherent selection bias in the treatment of CPAP failures, appropriate patient selection remains an important consideration for successful implementation of this novel surgical approach requiring further research.

Compliance with ethical standards

Ethical approval This article does not contain any studies with human participants performed by any of the authors.

Conflict of interest Giuseppe Meccariello declares that he has no conflict of interest. Giovanni Cammaroto declares that he has no conflict of interest. Filippo Montevecchi declares that he has no conflict of interest. Paut T. Hoff declares that he has no conflict of interest. Matthew E. Spector declares that he has no conflict of interest. Hesham Negm declares that he has no conflict of interest. Medhat Shams declares that he has no conflict of interest. Chiara Bellini declares that she has no conflict of interest. Ermelinda Zeccardo declares that she has no conflict of interest. Claudio Vicini declares that he has no conflict of interest.

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