

OSAHS

# Treatment of primary epiglottis collapse in OSA in adults with glossoepiglottopexy: a 5-year experience

## Glossoepiglottopexia per il collasso epiglottico primario negli adulti affetti da OSA: esperienza quinquennale

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### SUMMARY

**Objective.** To review our 5-year experience with a modified version of glossoepiglottopexy for treatment of obstructive sleep apnoea syndrome (OSA) in two hospitals.

**Methods.** A retrospective analysis was carried out on a cohort of adult patients affected by OSA suffering from primary collapse of the epiglottis who underwent a modified glossoepiglottopexy. All patients underwent drug-induced sleep endoscopy, polysomnographic and swallowing evaluation, and assessment with the Epworth Sleepiness Scale (ESS).

**Results.** Forty-nine patients were retrospectively evaluated. Both the apnoea-hypopnoea index (AHI) (median  $AHI_{post} - AHI_{pre} = -22.4$  events/h;  $p < 0.001$ ) and oxygen desaturation index (ODI) showed a significant postoperative decrease (median  $ODI_{post} - ODI_{pre} = -18$  events/h;  $p < 0.001$ ), as did hypoxaemia index (median  $T_{90\% post} - T_{90\% pre} = -5\%$ ;  $p < 0.001$ ). The ESS questionnaire revealed a significant decrease in postoperative scores (median  $ESS_{post} - ESS_{pre} = -9$ ;  $p < 0.001$ ). None of the patients developed postoperative dysphagia.

**Conclusions.** Our 5-year experience demonstrates that modified glossoepiglottopexy is a safe and reliable surgical technique for treatment of primary epiglottic collapse in OSA patients.

**KEY WORDS:** OSA, glossoepiglottopexy, epiglottis collapse, surgery

### RIASSUNTO

**Obiettivo.** Analisi della nostra esperienza a 5 anni con una versione modificata di glossoepiglottopexia su una coorte di pazienti affetti da sindrome delle apnee ostruttive del sonno (OSA) e collasso primario dell'epiglottide in due diversi centri ospedalieri.

**Metodi.** Un'analisi retrospettiva è stata effettuata su una coorte di pazienti affetti da OSA e collasso primario dell'epiglottide trattati con glossoepiglottopexia modificata. Tutti i pazienti sono stati valutati con endoscopia in sedazione, valutazione polisomnografica, con questionario Epworth Sleepiness Scale (ESS).

**Risultati.** Quarantanove pazienti sono stati inclusi nell'analisi. I seguenti valori hanno mostrato una significativa diminuzione postoperatoria: l'indice di apnea ed ipoapnea (mediana  $AHI_{post} - AHI_{pre} = -22,4$  eventi/h;  $p < 0,001$ ), l'indice di desaturazione (mediana  $ODI_{post} - ODI_{pre} = -18$  eventi/h;  $p < 0,001$ ), l'indice di ipossiemia (mediana  $T_{90\% post} - T_{90\% pre} = -5\%$ ;  $p < 0,001$ ). Il questionario ESS (mediana  $ESS_{post} - ESS_{pre} = -9$ ;  $p < 0,001$ ). Nessuno ha sviluppato disfagia postoperatoria.

**Conclusioni.** La nostra esperienza dimostra che la glossoepiglottopexia modificata è una tecnica chirurgica sicura e affidabile per il trattamento dei collassi epiglottici primari nei pazienti affetti da OSA.

**PAROLE CHIAVE:** OSA, glossoepiglottopexia, collasso epiglottide, chirurgia

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## Introduction

Obstructive sleep apnoea syndrome (OSA) is a prevalent disease affecting around 20% of the population (reaching up to 60% in those over 65 years) <sup>1</sup> with potentially life-threatening consequences as it is associated with other comorbidities such as cardiovascular events, neurocognitive impairment and stroke. The gold standard in the management of upper airway collapse in OSA is continuous positive airway pressure (CPAP). Despite its proven efficacy, a significant number of patients cannot tolerate this form of treatment and seek other alternatives. In this regard, surgery has a role in non-compliant patients who are not willing to receive CPAP therapy and in cases where CPAP therapy fails to restore normal breathing <sup>2</sup>. In this setting, the effectiveness of surgical treatment in reducing OSA-related cardiovascular morbidity and mortality has been demonstrated <sup>3</sup>.

In recent years, the role of surgery in the management of OSA has been evolving: the development of new techniques, together with a better understanding of their indications, has allowed for more precise selection of patients in order to tailor surgery to the multitude of anatomical conditions that characterise OSA <sup>4</sup>. When choosing the right technique, structured pre-operative work-up is essential: drug-induced sleep endoscopy (DISE) is crucial, as it is the only exam that can recreate sleeping conditions and allow surgeons to identify the site and mechanism of obstruction <sup>5</sup>. Moreover, DISE facilitates the recognition of obstructive patterns that are not evident during awake flexible transnasal video endoscopy, such as epiglottic collapse <sup>6</sup>. Epiglottic collapse is well known in the literature as one of the possible conditions implicated in paediatric laryngomalacia. In adults, while laryngomalacia is more of an anecdotic entity that has not been clearly described, primary collapse of the epiglottis can be related to treatment failure of CPAP <sup>3</sup>. This happens as CPAP-generated airflow pushes down the epiglottis, closing the laryngeal aditus, and consequently worsening the airway obstruction <sup>7</sup>. Non-surgical treatment has been demonstrated to be inadequate to treat this condition, with mandibular advancement devices (MADs) leading to disappointing results <sup>8</sup>. In this respect, a surgical modification of the Monnier's glossoepiglottopexy was developed and published with preliminary data in 2017, demonstrating encouraging results <sup>7</sup>. Herein, we describe our experience with this technique together with the results obtained in a cohort of patients suffering from primary collapse of the epiglottis treated at two hospitals.

## Materials and methods

### *Study design and population*

A retrospective multicentric analysis was carried out on a

period from January 1, 2015 to December 31, 2019 on a cohort of patients affected by OSA who underwent glossoepiglottopexy at the Department of Otorhinolaryngology and Head and Neck Surgery of the University of Genoa and the Department of Otorhinolaryngology - Fabrizio Spazioli Hospital in Frosinone.

For patients in whom multilevel surgery was performed, all procedures were considered in the analysis. Tonsillectomy was carried out by preserving the palatoglossus and palatopharyngeus muscles. Septoplasty and turbinoplasty were performed under rhinoscopy <sup>9</sup>. Non-resective pharyngoplasty was performed using the barbed suspension pharyngoplasty technique (BSP) <sup>9</sup>, barbed reposition pharyngoplasty (BRP) <sup>10</sup>, functional expansion pharyngoplasty (FEP) <sup>11</sup>, modified expansion sphincter pharyngoplasty (MESp) <sup>12</sup>, or barbed anterior pharyngoplasty (BAPh) <sup>13</sup>.

Inclusion criteria were: OSA confirmed by polysomnography study with an apnoea-hypopnoea index (AHI) > 15 episodes/h; body mass index (BMI) < 35 kg/m<sup>2</sup>; primary epiglottic collapse diagnosed by DISE; and ease of laryngeal and oropharyngeal exposure (Laryngoscore < 6). The latter was evaluated with the Laryngoscore instrument, which is commonly employed in our hospitals to select patients for transoral procedures <sup>14</sup>. As is standard policy at our clinics, we strongly suggest CPAP therapy, especially to patients with an AHI > 30, and reserve surgical treatment only for those who are not compliant or who do not respond to non-surgical therapy. Major comorbidities, severe tongue base hypertrophy, cranio-facial malformations, laryngeal dysfunction (swallowing, motility disorders, and laryngeal stenosis) and other sleep-related disorders were considered exclusion criteria.

All patients underwent a standard preoperative evaluation protocol consisting of awake flexible transnasal video endoscopy, polysomnographic assessment and DISE evaluation. Postoperative evaluation was performed at 6 months after surgery by clinical, polysomnographic and endoscopic assessment. All data were extracted from a single database.

### *Clinical evaluation*

Preoperatively, all patients underwent thorough otolaryngologic physical examination. Clinical history was collected focusing on sleep habits and sleep disturbances. BMI was also reported. The Epworth Sleepiness Scale (ESS) was used to rate daytime sleepiness <sup>15</sup>, while swallowing function was assessed by the Eating Assessment Tool (EAT 10) <sup>16</sup> and the penetration aspiration scale <sup>17</sup>.

### *Respiratory polygraphic study*

All patients underwent a sleep study with cardiorespiratory monitoring (Vital night, Vital aire, Milan Italy). The

cardiorespiratory analysis comprised nocturnal snoring sound, arterial oxygen saturation, body position, nasal and mouth airflow, thoracic and abdominal respiratory movements and heart rate. To determine the severity of sleep apnoea, we considered the AHI, oxygen desaturation index (ODI) and T < 90% (percent of total time with oxygen saturation less than 90%).

#### *Drug-induced sleep endoscopy*

At both centres, DISE was performed with the patient in a supine position. Transnasal flexible endoscopy was performed using a high definition fibreoptic video-endoscope connected to an Evis Exera II CLV-180B light source (Olympus Medical Systems Corporation, Tokyo, Japan).

During the examination, head rotation and positioning of the patient in lateral decubitus were performed to assess the positional component of the collapse. Moreover, chin lift and mandibular pull up manoeuvres were routinely performed to evaluate the possible benefit in applying a MAD. Midazolam was administered with intravenous repeated bolus in a range of 1-3 mg, while propofol was administered intravenously via target-controlled infusion. At the end of the procedure, flumazenil was used to antagonise the effects of midazolam. The use of a low dose of midazolam and propofol allows sedation to be as physiologic as possible, with snoring, apnoea events, controlled desaturations and rapid recovery<sup>18</sup>. The NOHL classification was used to assess the obstruction severity at multiple levels<sup>19</sup>.

#### *Surgical glossoepiglottopexy*

The glossoepiglottopexy procedure has been previously described<sup>7</sup>; the main steps are briefly summarised as follows. The procedure is carried out under microlaryngoscopy with the patient lying in Boyce-Jackson's position; firstly, the surgeon with a Sataloff laryngoscope (Microfrance Sataloff Laryngoscopes 124, Medtronic ENT, Jacksonville FL USA) exposes the base of the tongue, the entire valleculae and the epiglottis. Secondly, with a CO<sub>2</sub> laser (Ultrapulse Dualpro Laser CO<sub>2</sub>, Lumenis, Yokneam, Israel) coupled with a microscope, the operator vaporises the mucosa overlying the valleculae and the base of the tongue. Finally, from outside of the neck, two 16-gauge needles are inserted projecting out of the valleculae, serving as a guide to apply, through a loop, number 1 Premilene® sutures (Premilene, Braun, Melsungen Germany) that embrace the hyoid bone and stitch the lingual surface of the epiglottis to the base of the tongue. Both wires are then fixed outside of the neck, anteriorly to the larynx, using a Silastic sheet to protect the skin from local trauma.

#### *Outcome evaluation*

Surgical success was evaluated at least 6 months after surgery, performing a respiratory polysomnographic study and repeating the ESS questionnaire<sup>15</sup>. Criteria for evaluation of the outcomes are in agreement with Montevecchi et al.<sup>20</sup>. Cured: AHI < 5 and ESS < 10 and reduction of both >50%. Success: AHI < 20 and ESS < 10 and reduction of both > 50%. Failure: AHI > 20 and any ESS value and reduction of both < 50%.

#### *Statistical analysis*

The results are expressed as mean ± standard deviation, median, or percentage. Sample size was calculated by assuming effect size = 0.45, α = 0.05, power (1-β error probability) = 0.80 for a two-tailed paired test. With these parameters, a minimum sample size of 43 patients was required. The Shapiro-Wilk test was used to assess normal distributions of continuous variables. Categorical variables were analysed with χ<sup>2</sup> test or Fisher's exact test as appropriate. Comparisons between continuous variables were performed with the Mann-Whitney-Wilcoxon rank sum test. The evaluation of the continuous variables before and after treatment was carried out using the Wilcoxon signed-rank test, plotting them with paired boxplot and adding lines to points for each patient to show the trend change. Considering the binary successful outcome, pre-treatment clinical and polysomnographic covariates were investigated with univariable and multivariable logistic regression models. Statistical significance was assumed in each test with a two-tailed p value < 0.05. Statistical analysis was carried out using the R software/environment (version 3.6.3; R Foundation for Statistical Computing, Vienna, Austria).

## **Results**

From January 2015 to December 2019, 49 patients affected by OSA with primary epiglottic collapse underwent glossoepiglottopexy. By DISE, the most frequent pattern of epiglottic collapse was complete anteroposterior collapse, followed by partial anteroposterior collapse; in our series, no patients showed a lateral collapse of the epiglottis. In 37 patients (75.5%), concomitant to glossoepiglottopexy, a non-resective pharyngoplasty was also performed according to the palatal collapse. Furthermore, tonsillectomy was performed in 26 patients (53.1%), and septoplasty and turbinoplasty in 9 patients (18.4%). The main patient characteristics are reported in Table I. During the postoperative period, concomitant with polysomnographic assessment, no significant change in BMI was observed [mean ΔBMI = 0.035 (95% CI -0.123, 0.193), p = 0.66]. Complications occurred in 2 of 49 procedures: one patient

**Table I.** Main characteristics of the patients enrolled.

	Overall (n = 49)
<b>Age</b>	
Mean (SD)	50.7 (11.7)
Median (min, max)	50.0 [24.0, 74.0]
<b>Sex</b>	
F	9 (18.4%)
M	40 (81.6%)
<b>Tonsillectomy</b>	
No	23 (46.9%)
Yes	26 (53.1%)
<b>Septo-turbinoplasty</b>	
No	40 (81.6%)
Yes	9 (18.4%)
<b>Pharyngoplasty</b>	
BAPh	1 (2.0%)
BRB	4 (8.2%)
BRP	12 (24.5%)
BSP	11 (22.4%)
FEP	6 (12.2%)
MESP	3 (6.1%)
No	12 (24.5%)

F: female; M: male; BAPh: barbed anterior pharyngoplasty; BRB: barbed Roman blinds; BRP: barbed reposition pharyngoplasty; BSP: barbed suspension pharyngoplasty; FEP: functional expansion pharyngoplasty; MESP: modified expansion sphincter pharyngoplasty.

had suture breakage at 7 days post-operatively, but flexible transnasal video endoscopic control revealed the stability of the glossoepiglottopexy, while the other had the epiglottis lacerated by the sutures that were probably placed too high. Neither bleeding, dysphagia, nor aspiration occurred in any case, and postoperative AHI improved from 66 to 10 and from 37 to 9, respectively.

Comparisons between paired parameters measured before and after surgery are reported in Table II, whereas the trends for each patient are shown in Figure 1. AHI showed a significant postoperative decrease [median  $AHI_{post} - AHI_{pre} = -22.4$  events/h (95% CI -25.7, -19.0;  $p < 0.001$ )],

as did ODI [median  $ODI_{post} - ODI_{pre} = -18$  events/h (95% CI -13.0, -20.0);  $p < 0.001$ ] and  $T_{90\%}$  [median  $T_{90\% post} - T_{90\% pre} = -5\%$  (95% CI -5.0, -7.0);  $p < 0.001$ ]. Daytime sleepiness, assessed by the ESS questionnaire, also showed a significant decrease in postoperative scores evaluated at 6 months after surgery [median  $ESS_{post} - ESS_{pre} = -9.63$  (95% CI -7, -11);  $p < 0.001$ ].

Clinical swallow evaluation was negative and EAT-10 scored 0 in all patients after surgery. All patients received a score of 1 at the penetration-aspiration scale evaluation postoperatively. Post-treatment AHI was  $< 5$  in 40.8% of patients ( $n = 20$ ) and postoperative ESS scored less than 7 points in 89.8% of cases ( $n = 44$ ).

Considering the criteria for outcome evaluation, a successful procedure was obtained in 34 cases (69%) and failure in 15 (31%); notably, 8 of these failures were due to  $ESS_{post} > 10$  (1 patient) or its improvement  $< 50\%$  (7 patients); on the other hand, only 4 failures were due to an  $AHI_{post} > 20$ , as shown in Figure 2. The analysis of pre-treatment clinical and polysomnographic covariates showed that higher  $ESS_{pre}$  values were associated with a higher chance of successful surgery at both univariable (OR = 1.24, 95% CI 1.08-1.47,  $p = 0.005$ ) and multivariable analysis (OR = 1.22, 95% CI 1.06-1.46,  $p = 0.013$ ), whereas older age was related to a lesser chance of success (OR = 0.94, 95% CI 0.88-0.99,  $p = 0.035$ ), which was not confirmed after adjustment for the ESS effect ( $p = 0.152$ ; Tab. III, Fig. 3). None of the other clinical variables were associated with post-treatment outcomes.

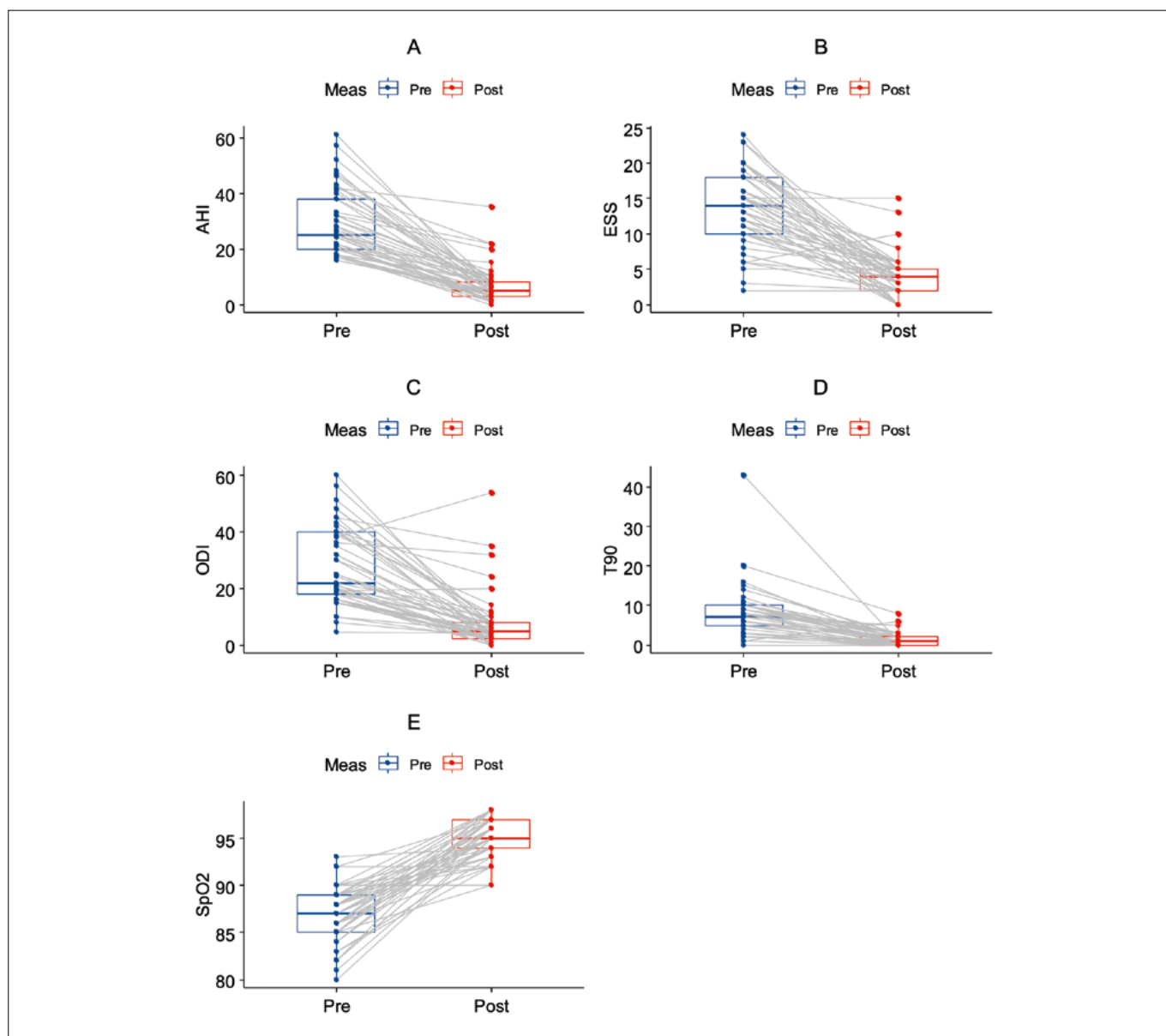
## Discussion

In adult patients suffering from OSA, collapse of the epiglottis may be primary or secondary: the latter occurs when a bulky tongue base pushes the epiglottis backward. On the other hand, primary collapse of the epiglottis may result from an altered conformation of the epiglottis (cartilage deformation due to pharyngeal wall compression during sleep or laxity of the glossoepiglottic ligament) in combination with the high negative intrathoracic pressure

**Table II.** Comparison between variables measured before and after surgery (mean values and SD).

Variable	Before surgery	After surgery	P value
AHI	29.37 ± 1.81	7.02 ± 6.51	< 0.001
ESS	13.65 ± 5.41	4.02 ± 3.15	< 0.001
ODI	27.87 ± 13.79	7.75 ± 9.92	< 0.001
$T_{90\%}$ (%)	7.96 ± 6.55	1.35 ± 1.79	< 0.001
$SpO_2$ (%)	86.80 ± 2.86	95.04 ± 2.14	< 0.001

AHI: apnoea-hypopnea index; ESS: Epworth sleepiness scale; ODI: oxygen desaturation index;  $T_{90\%}$ : percent of the total time passed with an oxygen saturation level lower than 90%;  $SpO_2$ : mean peripheral capillary oxygen saturation.



**Figure 1.** Box-plots for comparisons between variables measured before (Pre) and after surgery (Post), with trends in each patient. (A) apnoea-hypopnea index (AHI); (B) Epworth sleepiness scale (ESS); (C) oxygen desaturation index (ODI); (D) percent of the total time passed with oxygen saturation level less than 90% ( $T_{90}$ ); (E) mean peripheral capillary oxygen saturation ( $SpO_2$ ).

generated during obstructive events<sup>7</sup>. This deformity of the epiglottis can be congenital or created by the pressure of parapharyngeal fat pads and chronic collapse of the retroglottal airway.

In OSA patients, both medical and surgical treatment must be tailored to the physiopathology of the individual case. New tools have been developed to improve patient selection and the therapeutic solutions that can be offered. One such tool is DISE, which allows to accurately identify patterns of collapse that cannot otherwise be seen with

awake investigations. In awake findings, the laryngeal obstruction may be only hypothesised as being due to the deformed epiglottic shape, while the direct visualisation of the laryngeal collapse in many cases is possible only during the sedated state<sup>21</sup>. The introduction of DISE in the diagnostic routine has revealed the high incidence of laryngeal obstruction due to primary and secondary collapse of the epiglottis, as widely documented in the literature, reaching up to 73% of cases<sup>3,6</sup>.

OSA is a disease with multiple treatment modalities



been described. Tongue base advancement or hyoid suspension are theoretical surgical options in OSA, but to date there are no studies that have demonstrated their direct effect on epiglottis collapse<sup>23</sup>. Partial epiglottectomy has been the most widely described technique; however, it should be noted that excessive resection of the epiglottis can lead to aspiration, whereas insufficient resection might not cure the OSA. Moreover, there is no standard method to assess the volume of the epiglottis to excise without causing postoperative sequelae. Subsequently, more cautious approaches have been developed. Bourolias et al. proposed a transoral conservative technique to treat epiglottic collapse. A laser beam was delivered on the lingual surface of the epiglottis in order to model it in a new curved shape, warping towards the direction of laser beam application thus freeing the laryngeal inlet. Nevertheless, the technique has been studied only on anatomical ex-vivo models<sup>24</sup>.

In order to treat primary epiglottic collapse without ablating it, a surgical technique called epiglottis stiffening was recently developed: it consists of cauterising the lower half of the lingual side of the epiglottis in the area between the lateral glossoepiglottic folds, and avoiding reaching the free margin of the epiglottis itself<sup>25</sup>. By maintaining the free edge unharmed, the risk of dysphagia and aspiration is overcome. However, in our view, adding two nylon sutures to embrace the hyoid bone ensures safer and long-lasting results, while maintaining the important epiglottic function of glottic plane protection.

In the present work, this technique was demonstrated to be a safe and reliable choice to treat primary collapse of the epiglottis in OSA patients. In our series, the complication rate was very low (4%) and none of these cases experienced dysphagia or inhalation. Regarding outcomes, our results showed significant ( $p < 0.001$ ) post-operative improvement of AHI, ODI,  $T_{90\%}$  and ESS after surgical treatment with mean values approaching the normal population. In our opinion, these results are consistently achievable if reasonable selection criteria are respected. As a general rule, patients should not be affected by severe OSA with  $> 30$  AHI and should also not be obese: otherwise, CPAP should be always advised in the first instance and surgical treatment should be reserved only for those who do not respond to or who refuse treatment with positive airway pressure.

Further research needs to be carried to determine if glossoepiglottopexy can enhance compliance and increase the effectiveness of CPAP in this category of patients. In our cohort, considering pre-treatment clinical and polysomnographic variables, ESS score was the only covariate that independently associated with surgical outcomes as previously observed in patients treated with palatal or lateral oropharyngeal collapse<sup>4</sup>. This finding may be explained by

the role of ESS reduction in defining successful treatment in the applied classification<sup>20</sup>. In 7 (47%) of our patients, the definition of failure was due only to not achieving ESS reduction  $< 50\%$ , despite having an  $ESS_{post} < 10$  and obtaining recovery of AHI parameters. In fact, low values of baseline ESS in non-symptomatic patients are less likely to change, despite recovery by polygraphy. These findings may help to improve this classification in defining surgical outcomes.

Finally, we acknowledge that the present study has intrinsic limitations considering its retrospective nature. Moreover, the cohort of patients analysed is limited, even though to our knowledge it is one of the largest case series present in the literature on this specific category of patients<sup>3</sup>. In fact, OSA is a complex disease, and many factors can contribute to upper airway collapse. A clear understanding of such a complex condition, by identifying the key factors that play a role in the different upper airway obstruction patterns can aid in the definition of better therapeutic protocols and targeted compound surgical strategies.

## Conclusions

Our 5-year experience demonstrates that glossoepiglottopexy is a safe and reliable surgical technique for the treatment of primary epiglottic collapse in OSA patients. By not producing major anatomical alterations, it maintains oropharyngeal and laryngeal functions. In addition, it is capable of improving the main polysomnographic parameters and has the potential to increase compliance and efficacy of positive airway pressure devices in this category of patients.

### *Conflict of interest statement*

The authors declare no conflict of interest.

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### *Authors' contributions*

Conceptualisation: MF, MB. Data curation: MF, CS, FM. Formal analysis: FM, GS. CS. Investigation: CT, RV, FI, MF. Methodology: MF, FI, AM, CT, GS, VR. Supervision: GP, MB, AM. Writing – original draft: CS, MF. Writing – review and editing: FM, MB, GP.

### *Ethical consideration*

This study was approved by the Institutional Ethics Committee (CER Liguria) (approval number/protocol

number 230/2019).

The research was conducted as a retrospective study on patient records in accordance with the ethical standards of the institutional and/or national research committees and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. Informed consent for disclosure of privacy in managing personal data for scientific purposes was obtained from all participants included in the study.

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