Laser-assisted uvulopalatoplasty for snoring: does it meet the expectations?

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ABSTRACT: The high prevalence of habitual snoring (35% of the general population) and the increasing demand for an effective treatment have led, in the last decade, to the generalisation of laser-assisted uvulopalatoplasty (LAUP). However, acceptable studies on its effectiveness are lacking.

The present randomised, placebo-controlled study included 25 nonapnoeic and mild obstructive sleep apnoea snorers to evaluate LAUP effectiveness for snoring. Group I received a one-stage LAUP treatment and group II a placebo (simulated snore surgery followed by an oral placebo). Before each treatment and 3 months after, the variables and procedures assessed were: body weight; sleepiness (Epworth sleepiness scale); quality of life (SF-36); subjective snoring intensity (0–10 analogue scale); objective snoring intensity (average decibel intensity); snoring index (number of snores per hour); and apnoea/hypopnea index.

No differences were observed in body weight, sleepiness, quality of life, subjective and objective intensity, and frequency of snoring, and apnoea/hypopnea index between the groups before and 3 months after treatment.

In conclusion, this study provides evidence of the lack of effectiveness of one-stage laser-assisted uvulopalatoplasty for snoring in nonapnoeic and mild obstructive sleep apnoea patients, with the result that it does not meet the expectations generated by the procedure.

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Laser-assisted uvulopalatoplasty (LAUP) is an outpatient procedure that involves partial resection of the uvula and soft palate using a laser. It is usually offered as a treatment for snoring or as an alternative treatment in mild obstructive sleep apnoea (OSA). However, methodologically accepted studies on the effectiveness of this treatment are limited since randomised placebo-controlled studies are lacking [1]. The high prevalence of habitual snoring (35% of the general population) [2] and the increasing demand for an effective treatment have led, in the last decade, to the generalisation of LAUP. Its indication has probably been favoured by the widespread belief that surgical procedures are more decisive. Furthermore, disparate results concerning this procedure have been published on the basis of objective measurements of snoring before and after treatment [3–5]. This, together with the potential risks and complications of LAUP [1], has cast doubt on the need for treating nonapnoeic snorers [6], and the high cost of treating a growing number of patients has led to the usefulness of LAUP being challenged. Thus, further evidence in support of this treatment is warranted. Accordingly, the authors of the present study conducted a prospective, randomised, placebo-controlled study in patients whose main symptom was disruptive snoring (male sex, age range 30–60 yrs, body mass index (BMI) range 25–30 kg·m⁻², apnoea/ hypopnea index (AHI) ≤30 and considered to be palatal snorers) to evaluate the effect of LAUP in relieving snoring both subjectively and objectively.

Material and methods

Study subjects

Entry criteria specified: an initial complaint of disruptive snoring; male sex; age 30–60 yrs; BMI 25–30 kg·m⁻²; and screening AHI \leq 30. Patients were excluded if snoring was not due to palatal flutter, *e.g.* if it appeared to be due to tongue base collapse or collapse of other soft tissues in the oro- or hypopharynx. Subjects with significant nasal pathological conditions and those with medical contraindications to surgery (bleeding disorder, receiving anticoagulant therapy, contraindications to local anaesthesia, palatal dysfunction) were excluded.

Study design

Using a table of random numbers, subjects were randomised to either the LAUP group (group 1) or the placebo group (group 2). Before therapy and 3 months after, body weight was recorded, the patients completed three questionnaires and underwent an overnight full polysomnography. Snoring was recorded on four consecutive nights. Informed consent was obtained from all patients. Patients were told that the placebo treatment might improve upper airway

function in sleep and reduce snoring. The human ethics committee approved the protocol.

Methods

Upper airway evaluation. All patients underwent fibreoptic nasendoscopy with Müller's manoeuvre [7], rhinomanometry and computed tomography (CT) scanning of the upper airway. Normal surface values for the CT scan were considered, at the level of the soft palate, between 110–190 mm², and between 153–223 mm² at the level of the hypopharynx [8].

Sleep studies: polysomnography and objective snoring recording. The sleep study included a baseline conventional polysomnography (PSG) (SleepLab 1000P; Aequitron Medical Inc., Minneapolis, MN, USA), according to the established standard criteria [9]. Arterial oxygen saturation (Sa,O₂) was measured continuously with a finger probe using a pulse oximeter (504 Critical Care System Inc.; Waukesha, WI, USA). Ribcage and abdominal motion were monitored employing bands placed over the thorax and abdomen. Airflow was assessed with a nasal cannula. All signals were recorded continuously with a polygraph, SleepLab 1000P (Aequitron Medical Inc.). Respiratory events were scored as apnoea when there was a cessation of airflow lasting ≥10 s, and as hypopnoea when any clear discernible reduction in airflow lasting ≥ 10 s was observed, associated with an arousal or with $\geq 3\%$ dip in S_{a,O_2} . Arousals were defined according to the scoring rules of the American Sleep Disorders Association [10]. A PSG AHI >10 was considered abnormal.

The objective assessment of snoring and position was carried out by a portable respiratory recording device (PRRD) (Sibel Home-300; Sibel SA, Barcelona, Spain). The PRRD is a 10-channel digital recording device with a 10-bit analog-to-digital converter. The PRRD is a validated system for the detection of sleep apnoea and hypopnoea at home in a general population [11]. Only snoring and body position were recorded, in order to simplify the use of the device at home. Sound recordings were monitored through an electric subminiature microphone, type Electret condenser microphone (dynamic range: 60 dB; frequency response range: 10-10,000 Hz; sensitivity: 20 mV (0.25 dB)). The microphone was encapsulated standing 2 mm from the skin to avoid the noise caused by rubbing and it was taped above the larynx. Data were stored on the controller board with a total of 32 KB of RAM. The device had a sufficient memory to record continuously for ~32 h. Data were downloaded to a personal computer and analysed using software specially developed for this purpose which automatically scored the number of events and their intensity. Snoring sounds were defined based on voltage or intensity and duration in order to reject noise originating from heart beats and nonsnoring sounds. If a sound exceeded 45 dB and 1 s it was qualified as a snore. The duration of the study was calculated as the time between switch on and switch off. Values of number of snores per hour (snoring index (SI)) and average decibel intensity of the snores (dB med) were obtained. Patients were trained for the use of the device at home. After the first night recording at the sleep laboratory, three overnight recordings were done at each subject's home.

Group 1 (laser-assisted uvulopalatoplasty). A one-stage LAUP procedure under local anaesthesia was performed. The same experienced ear, nose and throat physician carried out all the LAUP procedures. The patient adopted a sitting position wearing protective eye glasses. Anaesthesia was initiated with a 10% lidocaine spray directed at the palate and

at the base of the tongue. After the spray took effect, 1 mL of 2% mepivacaine was infiltrated on either side of the base of the uvula. A CO2 laser was used with hand pieces for pharyngeal surgery (15201; Sharplan, Laser Industries, London, UK) with the "backstop" fitted. The laser was set in the superpulse mode at a continuous power of 8 W. Vertical transpalatal incisions, each ~1 cm in length, were made bilaterally through the soft palate just lateral to the base of the uvula, at the level of the palatal arches. The uvula was partially vaporised or cut depending on its length. A section of 5 mm of this uvula was kept in order to ensure proper clearing of the secretions of the posterior pharyngeal wall. The postoperative care included paracetamol with codeine (2 g and 90 mg daily, respectively) for 1 week.

Group 2 (placebo). The placebo treatment consisted of: an injection of 0.5 mL of saline on either side of the base of the uvula under local anesthesia of the palate (10% lidocaine spray); simulated snore surgery with an appropriate scenario; followed by an oral placebo consisting of white rice starch capsules (Servei de Farmacología, Hospital Clínic, Barcelona), which were prescribed at one tablet per week for 12 weeks.

Assessments

Before each treatment and 3 months after, the variables and procedures assessed were: body weight; sleepiness (Epworth Sleepiness Scale) [12]; quality of life (SF-36) [13]; subjective snoring intensity (dB subj; 0–10 on an analogue scale: 0=no snoring, 10=patient and bed partner have to sleep in separate rooms), objective snoring intensity (dB med), SI and AHI.

Statistical analysis

In accordance with published results suggesting an average improvement in subjective snoring intensity after LAUP of $\sim 90\%$ [14], and assuming an expected placebo effect of 20%, the estimated required sample was calculated to be 11 subjects per group (α =0.05; power=0.90). An independent t-test was applied at baseline between group 1 and group 2. Differences between pre- and post-treatment values were calculated for each variable and group. A two-sample Mann-Whitney U-test was then used to compare these differences between the groups. Statistical significance was accepted at p<0.05.

Results

Thirty-three consecutive patients fulfilled the selection criteria and, of these, 28 agreed to participate in the study. Subsequently, three patients declined to participate (two refused treatment after screening polysomnography and one patient failed to keep his appointments). A total of 25 patients completed the study (fig. 1).

Baseline data from these patients consisted of: age: 44±7 yrs; BMI: 27.1±2.9 kg·m⁻²; AHI: 15±13; dB subj: 6.96±2.23; SI: 298±168 snores·h⁻¹; dB med: 53.5±4.8 dB sound pressure level (SPL). No significant differences were found in the baseline data between the two study groups for the parameters in table 1, rhinomanometry, and CT-scan cross-sectional areas at the levels of rhino-, oro- and hypopharynx. The main results are summarised in table 1. No differences were observed in body weight (p=0.76), sleepiness (p=0.78), quality of life (p=0.62 for SF-36 physical, p=0.29 for SF-36 mental), subjective (p=0.24) and objective intensity (p=0.71) and frequency (p=0.36) of snoring, and

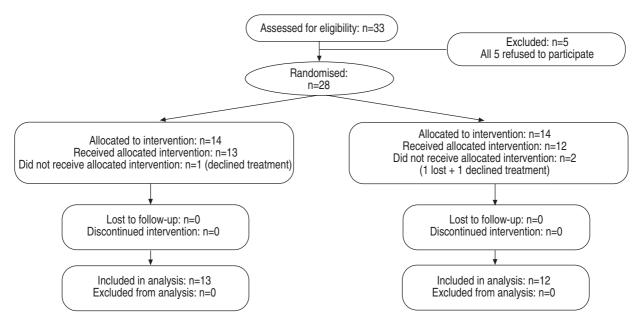


Fig. 1.-Flow chart of the study design.

apnoea/hypopnea index (p=0.36) between the groups before and 3 months after treatment.

Only minor complications were observed. Postoperative pain was present in 100% of cases, with 8–19 days duration in the LAUP group. Minimal complaints during 24–48 h were present in the placebo group. The current authors observed minor bleeding 24 h after LAUP in one patient at the level of the transpalatal incision, controlled by electrocautery in the office.

Discussion

Although the present study was designed to obtain objective evidence of the effectiveness of LAUP for snoring in nonapnoeic and mild OSA (AHI <30) patients, no differences were observed between groups in subjective or objective snoring measurements (average intensity and number of snores per hour), AHI, sleepiness and quality-of-life questionnaires, before and 3 months after treatment (table 1). Thus, the current study data does not support the routine use of LAUP for snoring in nonapnoeic and mild OSA patients.

Benefits of LAUP for snoring have been evaluated in earlier studies [3–5, 15–21]. These studies showed subjective improvement in snoring. However, this improvement was not confirmed when objective measurements of snoring were used to assess the effectiveness of LAUP [4], thus arousing controversy. Moreover, the recently published analysis of the Standards of Practice Committee of the American Academy of Sleep Medicine [1] has drawn attention to the lack of conclusive evidence in support of this technique. This committee recommended "the use of objective measures for evaluating outcomes, and sham or sub-therapeutic controls" to assess the effectiveness of LAUP. In order to obtain evidence of the effectiveness of LAUP it is necessary to perform both reliable and objective snoring recordings or to compare LAUP with a placebo, which is expected to have, in this particular case, a considerable effect. The performance of both procedures at the same time enhances the evaluation of the study. Accordingly, the present study conducted a placebo-controlled trial to evaluate the efficacy of LAUP for snoring. To the best of the current authors' knowledge, this is the first placebo-controlled study of the effectiveness of snoring surgery. Although the placebo chosen may arouse

Table 1.-Results at baseline and 3 months after treatment

	Group 1		Group 2		Pre-post group comparison
	Pre-T	Post-T	Pre-T	Post-T	p-value#
Subjects	13	13	12	12	
BMÏ	27.2 ± 1.9	27.4 ± 1.8	27.0 ± 3.8	27.2 ± 3.9	0.76
AHI	13.6 ± 8.3	15.1 ± 17.5	17.0 ± 18.2	11.5 ± 10.7	0.36
ESS	10.4 ± 3.8	9.6 ± 3.8	10.9 ± 5.6	10.5 ± 5.4	0.78
SF-36 physical	53.0 ± 3.8	54.6 ± 4.0	49.6 ± 10.0	49.8 ± 11.1	0.62
SF-36 mental	51.8 ± 7.0	49.1 ± 6.3	48.8 ± 12.6	48.1 ± 9.8	0.29
dB subj	6.6 ± 2.2	5.5 ± 2.5	7.2 ± 2.2	6.6 ± 2.1	0.24
dB subj SI [¶]	330 ± 197	270 ± 167	267 ± 139	313±181	0.36
dB med [¶]	54.6±4.9	53.9 ± 4.4	52.5±4.7	52.9±5.0	0.71

Data are presented as mean ±SD. Pre-T: pre-treatment; Post-T: post-treatment; BMI: body mass index; AHI: apnoea-hypopnea index; ESS: Epworth sleep score; SF-36: quality of life; dB subj: subjective snoring intensity (0–10 analogue scale); SI: snoring index, number of snores h⁻¹ (using the portable respiratory recording device (PRRD)); dB med: objective snoring intensity, using the PRRD. #: the differences in group 1 are compared to differences in group 2; ¶: n=10.

some criticism, it was considered to be the best available, given that it must be believable, must not interfere with the results and must have no side-effects [22].

The one-stage LAUP procedure used in the current study is comparable to other LAUP techniques in effectiveness [15–19] and does not account for the negative results obtained. A follow-up of 3 months should be enough to reveal differences between the groups. Moreover, other studies report that long-term effectiveness of LAUP decreases over time [21]. Confounding factors, such as changes in weight, which may critically influence snoring [14], were taken into account and no pre- or post-treatment changes in weight and BMI were observed in the current study. Another potential objection could focus on the sample size. However, given results published earlier suggested an average improvement of ~90% [14], and assuming an expected placebo effect of 20%, the estimated sample size to show significant differences was 11 subjects per group (α =0.05; power=0.90).

The objective evaluation of snoring did not constitute a limitation of the present study. It goes without saying that objective snoring recordings have to be reliable. Some studies have shown objective reductions in snoring after LAUP [3, 5], while others have not [4]. This raises the question of whether snoring recordings are reliable. Despite all the interest in snoring, the objective measurement of the snoring sound has encountered problems: lack of standardisation [20, 23]; lack of the definition of snoring [14]; and variability of snoring [24]. The lack of standardisation renders the comparison between different studies difficult. There is no agreement on the placement and on the type of microphone, which could critically influence the acoustic signal. The present study employed a microphone attached above the larynx. This minimises background noise and eliminates fluctuations in loudness caused by differences in the distance between the subject and the microphone [25, 26]. Perhaps the main problem in the objective study of snoring is the absence of a suitable definition of snoring. In line with other authors, snores were defined on the basis of intensity and duration of sound [25, 27, 28]. A snore was defined as any sound whose intensity exceeded a certain threshold (>45 dB SPL), lasting >1 s. The 45 dB SPL measurement threshold employed in the current study seems to be adequate, considering the average intensity obtained (53.5±4.8 dB SPL). Another difficulty encountered in the measurement of the snoring sound is the variability of snoring itself. Snoring shows a night-to-night variability [24], and is influenced by head and body position and sleep stages [29]. SERIES et al. [28] found differences between snoring measured at home and during polysomnographic studies. To minimise the variability of snoring, the recording time was increased. The average recording time in this study was 25.51 ± 4.51 h pre-treatment and 23.97 ± 0.98 h post-treatment, corresponding to four consecutive nights. Most studies report recording times between 2–8 h [25, 27]. Finally, problems can arise at each patient's home due to a lack of supervision. This could explain the 11.7% failure rate in the recordings and could account for missing data observed in earlier studies [29, 30]. No differences were observed between groups in objective snoring measurements (average intensity and number of snores per hour) before and after

The present study provides considerable evidence of the lack of effectiveness of one-stage LAUP in the relief of snoring in nonapnoeic and mild OSA patients. Hence, this treatment does not meet the expectations generated by the procedure. The accurate evaluation of objective snoring carried out in the present study (4 days at baseline and 4 days at 3 months after treatment) and the lack of improvement call into question this procedure as an acceptable alternative for snoring. Although earlier clinical trials provide

evidence of subjective snoring relief in most patients who have undergone LAUP (90% improvement in subjective snoring intensity), they do not compare LAUP procedure with simulated snore surgery using objective variables.

To the best of the current author's knowledge, this is the first placebo-controlled study to evaluate the effectiveness of one-stage laser assisted uvulopalatoplasty in relieving snoring.

In conclusion, the results of the present study differ from previously published data and, despite the current popularity of surgical snoring procedures, one-stage laser-assisted uvulopalatoplasty is a questionable treatment for most persons afflicted with snoring. Although the current authors cannot generalise these results to multi-step laser-assisted uvulopalatoplasty procedures, the presented data suggest that the indiscriminate use of surgery to treat snoring should be approached with caution. Moreover, the present study could have important policy implications, since what is essentially a placebo cannot be justified by the high cost of the procedure. It goes without saying that given the prevalence of snoring, the magnitude of the problem becomes apparent with far-reaching implications for the medical community and healthcare systems.

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