## **Original Article**

# Local-anaesthesia, one-step sleep surgery

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### **ABSTRACT**

**INTRODUCTION.** This report presents a single-institution prospective case series evaluating the feasibility and effect of outpatient local anaesthesia radiofrequency ablation-assisted soft palate volumetric tissue reduction (RFA-SP) and turbinoplasty (RFA-T) for treatment of patients with obstructive sleep apnoea (OSA) and/or snoring.

METHODS. A total of 72 patients with Apnea-Hypopnoea Index (AHI) > 5 and/or subjective snoring treated in 2024 were evaluated after surgery, including cardiorespiratory monitoring (CRM) and patient questionnaire evaluation. Main endpoints were AHI, Snore Index (SI), Epworth Sleepiness Scale and scored impact of sleep-disordered breathing on quality of life.

**RESULTS.** We conclude that the procedures have low morbidity and high patient satisfaction. Approximately one in two patients had improved symptoms. However, improvement in AHI and SI was mainly seen in total or non-supine positions. The main limitations of our study are: the placebo effect in patient self-evaluations, the relatively small study population, the availability of comprehensive and recent pre- and post-surgery CRMs and the underlying premise that the mechanisms of sleep-disordered breathing remain poorly understood.

**CONCLUSIONS.** Outpatient RFA-SP and RFA-T under local anaesthesia effectively improve symptoms and quality of life in patients with OSA and snoring, producing complete resolution in selected cases. The best outcomes are seen in non-supine OSA, highlighting the need for careful preoperative assessment to optimise patient selection.

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**TRIAL REGISTRATION.** The study protocol was approved by the Aarhus University Hospital Management. The Central Denmark Region Committees on Health Research Ethics were consulted and found the project non-notifiable.

Patients seeking treatment for obstructive sleep apnoea (OSA) and snoring are faced with a tough choice between continuous positive air pressure (CPAP) treatment and surgery. CPAP is a readily available and well-substantiated option. Nevertheless, the CPAP adherence within the first six months is low, estimated at a mean 4.3 h/night relative to an optimum of 7.0 h/night [1]. In light of this low compliance, surgery may seem like the preferable option. However, the various procedures are often painful, requiring several weeks of sick leave, and in many cases require multilevel surgery; all without any guarantee of a lasting cure. Therefore, a more tolerable and efficient approach to initial treatment is warranted. Outpatient radiofrequency ablation (RFA) under local anaesthesia - in this case soft palate volumetric tissue reduction (RFA-SP) and turbinoplasty (RFA-T) - may be a suitable option owing to the low cost, low morbidity [2-4], minimal surgical training requirements and ease of clinical implementation.

Following an initial promising pilot, local anaesthesia outpatient RFA-SP and RFA-T procedures were implemented as routine surgery in 2024 at our tertiary referral centre at Aarhus University Hospital, Denmark. This single-institution prospective case series presents our evaluation of the feasibility and outcome of the first

year of treatment.

### Methods

### Study population

All patients with OSA who were non-compliant with CPAP therapy - defined as an Apnoea-Hypopnoea Index (AHI) > 5 in any sleep position and/or complaints of snoring - were consecutively offered RFA-SP, with or without concomitant RFA-T, under local anaesthesia. The inclusion criteria were age > 18 years and a BMI < 30 kg/m<sup>2</sup>. However, procedures were not cancelled if patients exceeded the BMI threshold between scheduling and the date of surgery. All patients were scheduled for follow-up 3-4 months after surgery, including cardiorespiratory monitoring (CRM).

Patients treated from 1 January 2024 to 31 December 2024 were invited to participate in our study. From this group, 72 patients were recruited. See **Table 1** for baseline characteristics. No other intercurrent surgery was performed. Participants received no preferential treatment but were asked to answer pre- and post-operative questionnaires. Written informed consent was obtained from all participants.

**TABLE 1** Baseline characteristics.

Sex ratio, male/female, n	62/10
Preoperative DISE, n/N	8/72
Prior surgery on nasal septum, turbinates, palatine tonsils or lingual tonsils, n/N	23/72
Age, median (range), yrs	47 (23-66)
BMI, median (range), kg/m²	27.3 (20.4-32.7)

DISE = drug-induced sleep endoscopy.

Primary endpoints were AHI, Snore Index (SI), Epworth Sleepiness Scale (ESS), and pre- and post-surgery evaluations, including patient-reported scores of the impact of sleep-disordered breathing on quality of life. For all scoring, an 11-point numeric rating scale (NRS) ranging from 0 to 10 was used. Our questions and scoring tools are unvalidated, with the exception of the ESS.

The CRM data were recorded by home monitor type 3 devices and assessed using Noxturnal or RemLogic software with automated scoring systems. Positional AHI and SI were included only if the time spent in position exceeded 2% of the total analysis duration.

### Procedure

RFA creates an electrosurgical, submucosal, coagulative necrotic lesion that leads to scarring and volumetric tissue reduction. Both procedures aim to reduce pharyngeal collapsibility and thereby obstruction during sleep. RFA-SP targets retropalatal collapsibility; whether the supposed mechanism is changed airway anatomy or stiffening of the palatal structure is debated. RFA-T aims to reduce overall pharyngeal collapsibility by increasing nasal airflow by decreasing nasal resistance at the lower turbinates through decongestive scarring and turbinate outfracture [5].

Treatment was performed with patients seated upright. Both procedures used the RaVoR electrode for bipolar radiofrequency volume reduction using the CURIS 4 MHz radiofrequency generator, 10 W settings.

For the RFA-SP procedure, the palate was sprayed with xylocain 100 mg/ml followed by submucosal lidocaine-adrenaline 20 mg/ml +  $5 \mu$ g/ml injection in three application sites in the line between the hard and the soft

palate, corresponding to application of the electrode medially and, depending on the anatomy, one or two applications laterally to the right and left. Care was taken to abort radiofrequency at each site if white discolouration of the mucosa was observed, to avoid inducing surface lesions.

The RFA-T procedure was applied if feasible, i.e., sufficient mucosal swelling for a meaningful reduction, as judged by the surgeon during anterior rhinoscopy. For RFA-T, topical anaesthesia was achieved using lidocaine-epinephrine  $20 \text{ mg/ml} + 5 \text{ \mug/ml}$  nasal drops applied on cottonoid patties, followed by submucosal injection of lidocaine-adrenaline into the inferior turbinates. Three RaVoR lesions were then created along each inferior turbinate under direct vision with a nasal speculum. Outfracture using an elevator was performed when adequate lateralisation was not achieved. No post-operative treatment, including nasal packing, was required. Patients recovered for 30 minutes in an adjacent waiting area without supervision before discharge. No patients required post-operative assistance. Four days of sick leave and non-strenuous activity were advised.

*Trial registration:* The study protocol was approved by the Aarhus University Hospital Management. The Central Denmark Region Committees on Health Research Ethics were consulted and found the project non-notifiable.

#### **Results**

Both individually and combined, the procedures were easy to perform and efficient, taking only a few minutes. Nearly all patients complied with the procedures except for one, who aborted the RFA-T procedure.

### Sleep quality

A total of 36% of respondents reported an improvement in sleep disturbance and/or daytime tiredness. Only 3% experienced a worsening of their symptoms. The mean score for the impact of disturbed sleep and/or tiredness on quality of life, measured using an 11-point NRS, decreased significantly by –2.2 points (95% CI: –3.0; –1.4) following surgery. Similarly, the mean ESS score showed a significant –2.6 point reduction (95% CI: –3.7; –1.5).

Changes in AHI values are presented in **Table 2**. A statistically significant improvement in total AHI was observed in patients with a baseline > 30, and for non-supine AHI with a baseline > 15. In contrast, a significant worsening of AHI in any position was observed in patients with no baseline OSA, i.e AHI < 5, and in supine AHI if the baseline was 15-30.

**TABLE 2** Changes in total and positional Apnea-Hypopnoea Index (AHI) for all patients and in subgroups defined by a baseline value. Note that baseline levels of AHI pertain to baseline total, supine- and non-supine AHI, respectively, in each column.

Subgroup	Parameter	Δ total AHI	Δ supine AHI	Δ non-supine AHI
All patients	Mean value (95% CI)	-2.4 (-5.6; 0.8)	3.3 (-2.6; 9.1)	-2.7 (-5.5; 0.2)
	Median value	-1.3	2.8	-0.7
	Group size, n	71	65	64
AHI < 5	Mean value (95% CI)	5.4 (2.5; 8.3)*	12.8 (2.9; 22.6)*	4.4 (1.5; 7.3)*
	Median value	5.1	16.8	1.5
	Group size, n	5	3	25
AHI 5-15	Mean value (95% CI)	3.2 (-0.3; 6.7)	9.4 (-3.4; 22.2)	-1.6 (-5.2; 2.0)
	Median value	1.6	1.4	-4.4
	Group size, n	22	9	21
AHI 15-30	Mean value (95% CI)	-1.6 (-6.6; 3.3)	13.1 (5.2; 21.0)*	-11.3 (-18.3; -4.2)*
	Median value	-3.4	11.7	-13.3
	Group size, n	28	20	12
AHI > 30	Mean value (95% CI)	-14.0 (-22.0; -6.1)*	-5.2 (-14.4; 3.9)	-20.3 (-29.2; -11.5)*
	Median value	-22.3	-7.6	-23.4
	Group size, n	16	33	5
Preoperative DISE performed	Mean value (95% CI)	-12.4 (-20.7; -4.0)*	-12.4 (-25.8; 1.0)	-13.5 (-21.1; -6.0)*
	Median value	-16.8	-11.4	-5.9
	Group size, n	8	7	7
Underweight to healthy weight: BMI < 25 kg/m <sup>2</sup>	Mean value (95% CI)	0.3 (-4.3; 5.0)	7.5 (-4.8; 19.9)	-2.2 (-6.8; 2.4)
	Median value	1.2	2.8	-0.5
	Group size, n	14	12	11
Overweight: BMI 25-30 kg/m <sup>2</sup>	Mean value (95% CI)	-2.1 (-6.8; 2.5)	0.7 (-8.1; 9.5)	-3.0 (-7.0; 1.0)
	Median value	-2.4	0.6	-0.8
	Group size, n	38	34	36
Obese: BMI > 30 kg/m <sup>2</sup>	Mean value (95% CI)	-7.9 (-15.4; -0.4)*	1.7 (-9.8; 13.2)	-1.7 (10.2; 6.7)
	Median value	-4.5	4.5	-0.4
	Group size, n	13	13	12
Age < 30 yrs	Mean value (95% CI)	-16.6 (-28.3; -4.9)*	-29.9 (-49.0; -10.7)*	-5.7 (-13.3; 1.8)
	Median value	-16.1	-34.6	-5.9
	Group size, n	4	4	3
Age 30-50 yrs	Mean value (95% CI)	-2.3 (-6.5; 1.9)	5.3 (-3.0; 13.6)	-2.9 (-6.5; 0.7)
	Median value	-0.8	4.5	-0.9
	Group size, n	37	33	33
Age > 50 yrs	Mean value (95% CI)	-0.7 (-5.8; 4.5)	5.5 (-3.0; 14.1)	-2.1 (-7.1; 2.9)
		10.00		0.5
	Median value	1.3	5.1	-0.5

DISE = drug-induced sleep endoscopy.

### Snoring

A total of 38% of respondents reported improvement in their snoring, whereas 3% experienced worsening. When asked to rate the impact of snoring on their quality of life, the change in mean NRS score was insignificant.

Changes in SI are shown in **Table 3**. Concerning statistically significant changes; SI worsened regardless of sleeping position if the baseline was < 25%, but total SI and non-supine SI improved for those with a baseline SI > 30%.

<sup>\*)</sup> Statistically significant with p < 0.05.

**TABLE 3** Changes in Snore Index (SI) for all patients and in subgroups defined by a baseline value. Note that the baseline levels of SI pertain to baseline total, supine- and non-supine SI, respectively, in each column.

Subgroup	Parameter	Δ total SI	Δ supine SI	Δ non-supine SI
All patients	Mean value (95% CI)	5.8 (-0.4; 12.0)	12.3 (4.7; 19.9)*	1.0 (-7.0; 9.0)
	Median value	4.9	10.2	3.6
	Group size, n	66	35	34
SI < 25%	Mean value (95% CI)	14.5 (8.0; 21.1)*	18.7 (9.9; 27.5)*	8.6 (3.5; 13.6)*
	Median value	8.8	15.5	6.0
	Group size, n	40	21	24
SI ≥ 25%	Mean value (95% CI)	-7.5 (-17.9; 2.8)	2.7 (-9.6; 15.0)	-17.9 (-39.3; 3.5)
	Median value	-8.0	7.8	-18.6
	Group size, n	26	14	10
SI > 30%	Mean value (95% CI)	-13.0 (-24.8; -1.2)*	2.7 (-9.6; 15.0)	-29.2 (-52.6; -5.8)*
	Median value	-13.1	7.8	-37.1
	Group size, n	19	14	7
SI > 50%	Mean value (95% CI)	-31.9 (-41.7; -22.0)*	-16.7 (-37.6; 4.2)	-37.4 (-57.6; -17.1)*
	Median value	-34.5	-16.9	-37.3
	Group size, n	10	4	6
Preoperative DISE performed	Mean value (95% CI)	2.0 (-25.6; 29.5)	12.5 (-1.2; 26.2)	-2.2 (-14.9; 10.5)
	Median value	2.7	8.7	0.5
	Group size, n	7	3	3
Under- to healthy weight: BMI < 25 kg/m²	Mean value (95% CI)	6.1 (-7.7; 19.9)	11.7 (-4.0; 27.5)	1.9 (-11.4; 15.3)
	Median value	8.1	17.0	5.3
	Group size, n	11	9	8
Overweight: BMI 25-30 kg/m <sup>2</sup>	Mean value (95% CI)	5.6 (-2.0; 13.3)	14.2 (4.1; 24.4)	1.6 (-8.7; 11.9)
	Median value	3.0	9.8	0.5
	Group size, n	36	18	19
Obese: BMI > 30 kg/m²	Mean value (95% CI)	9.5 (-8.9; 27.9)	16.8 (-4.3; 37.9)	-10.3 (-52.8; 32.1)
	Median value	8.8	9.8	-14.5
	Group size, n	13	4	4
Age < 30 yrs	Mean value (95% CI)	-19.7 (-49.2; 9.9)	8.7 (-)	7.4 (-)
	Median value	-12.2	8.7	7.4
	Group size, n	4	1	1
Age 30-50 yrs	Mean value (95% CI)	8.9 (0.0; 17.7)*	14.0 (2.5; 25.5)*	-3.0 (-12.1; 6.0)
	Median value	7.0	7.9	0.5
	Group size, n	33	17	18
Age > 50 yrs	Mean value (95% CI)	6.0 (-2.9; 14.9)	15.6 (5.5; 25.7)*	5.7 (-8.9; 20.3)
	Median value	2.4	16.1	14.8

DISE = drug-induced sleep endoscopy.

### In general

At follow-up, 15% of patients reported no significant residual complaints of sleep-disordered breathing. Overall, 47% of patients experienced symptom improvement, whereas 7% reported worsening. Motivation for further surgical treatment, assessed using the 11-point NRS, did not change significantly among those without symptom improvement. However, motivation decreased significantly, by -1.8 points (95% CI: -3.0; -0.6), among those with symptom relief. Similarly, motivation for CPAP treatment declined by -1.1 points (95% CI: -2.0; -0.3) among those with symptom relief. The procedure was well tolerated, with patients rating pain during the intervention at a mean NRS score of 2.6 (95% CI: 2.0; 3.2) and other discomfort at 2.7 (95% CI: 2.2; 3.2). Adverse effects were reported by 36% of respondents. Reported short-term (< 2 weeks) adverse effects included dysphagia, pain, throat dryness and epistaxis. Reported long-term adverse effects included throat dryness, swollen uvula, dysphagia, foreign body sensation and dysgeusia. Additionally, increased upper airway phlegm, rhinitis, pain, epistaxis and pharyngitis were reported without specification of duration. One patient had a telephone

<sup>\*)</sup> Statistically significant with p < 0.05.

consultation due to pain, and another was consulted due to worsened snoring. One patient developed a pulmonary embolism two months after surgery. No other relevant healthcare contact was reported. Regret regarding surgery was reported by 3% of the respondents.

The self-reported average duration of sick leave was 2.5 days if the patient's occupation was physically demanding, 2.0 days if not.

### Discussion

In general, we found that symptoms improved after surgery, but improvements in AHI and SI were observed only in patients with a baseline total AHI > 30, a non-supine AHI > 15 and a total or non-supine SI > 30%. Patient evaluations are naturally susceptible to the placebo effect, and thus there are limits on any conclusion drawn from a case series without a control group. Other mechanisms may, however, be in play; as previously demonstrated, subjective tiredness does not necessarily correlate with AHI [6]. Moreover, in our opinion, assessment of sleep disordered breathing needs to be more nuanced than what can be evaluated by CRM. We consider subjective symptom relief a primary endpoint in sleep surgery. The drop in ESS was statistically significant but hardly relevant, considering a minimal clinically important difference of 2 [7]. The insignificant change in the scored impact of snoring on quality of life seems contrary to the reported subjective improvement in snoring; however, the discrepancy might be due to patients not experiencing their own snoring firsthand, which makes scoring ambiguous and difficult.

With short median and average follow-up lengths of 133 and 136 days, respectively, this report does not address any long-term effects of the treatment regimen.

Internal agreement between the used Remlogic and NoxT3 automated scoring systems is good [8], but the error on individual CRMs remains unknown, and the standard was only one recorded night. Additionally, the preoperative CRM could be recorded several years before the procedure. Polysomnography (PSG) is considered the gold standard for sleep monitoring because it accurately distinguishes sleep from wakefulness, thereby preventing dilution of the AHI and SI by wake periods. Moreover, PSG registers arousals as hypopnoeas in addition to events associated with  $\geq$ 3% oxygen desaturation. Only two patients had available PSG data.

The mean interval between preoperative CRM and the procedure was 692 days, and we cannot exclude intermediate age-related changes in the upper airway physiology. Weight changes between the pre- and post-operative CRMs may also have influenced our results. We evaluated the association between changes in AHI, SI and BMI by linear regression with calculated correlation coefficients (R) and coefficients of determination ( $R^2$ ). Linearity between AHI and BMI has been established in previous literature [9]. Furthermore, we assumed linearity between SI and BMI, given the similar hypothesised pathophysiology of snoring. The correlation between changes in AHI and BMI was significant but weak for total AHI (R = 0.30 (95% CI: 0.061; 0.54)) and supine AHI (R = 0.34 (95% CI: 0.087; 0.59)). The proportion of change in AHI attributable to changes in BMI was estimated at 9% for total AHI and 11% for supine AHI, based on  $R^2$ . The correlation between changes in SI and BMI was significant and moderate for non-supine SI (R = 0.44 (95% CI: 0.12; 0.77)). The proportion of change in non-supine SI attributable to the change in BMI was estimated by  $R^2$  at 20%.

As expected, the procedures had low morbidity, and we consider the incident with pulmonary emboli unrelated. In our experience, mucosal surface lesions after RFA-SP heal spontaneously without intervention. Notably, no patients in our study reported lesions when prompted to report adverse effects at follow-up.

### **Conclusions**

This study indicated that outpatient RFA-SP and RFA-T under local anaesthesia is an effective treatment for patients with OSA and/or primary snoring, producing symptomatic relief and improved quality of life. In selected cases, complete resolution of OSA was observed. The primary limitation appears to be persistent supine-predominant OSA, which was associated with less favourable outcomes. Objective improvements were most consistent in relation to snoring. Given the variability in the observed CRM data, updated preoperative assessments are advised to optimise patient selection. Based on patient-reported outcomes and treatment efficacy, we recommend initiating this treatment approach in patients with non-supine OSA and snoring.

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