Radiofrequency of the soft palate for sleep-disordered breathing: A 6-year follow-up study

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KEYWORDS
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Abstract
Objective: To determine the long-term (>3 years) outcome of patients suffering from simple snoring or non-severe obstructive sleep apnea syndrome (OSAS) treated by radiofrequency ablation of the soft palate.

Study design: Observational retrospective study.

Setting: Tertiary care university hospital.

Subjects and methods: Seventy-seven subjects were included between 1999 and 2006. Twenty-seven suffered from mild or moderate OSAS. All patients were treated by radiofrequency-assisted stiffening of the soft palate, with or without uvullectomy. Snoring (assessed on a 10 cm visual analog scale (VAS)), marital status, presence of cardiovascular risk factors or pathologies and follow-up time were evaluated by postal questionnaire.

Results: Mean follow-up time was 6.3 ± 2.3 years. Mean snoring intensity decreased significantly in the immediate postoperative period (8.1 ± 2.9 to 3.5 ± 2.2 cm on VAS). Over the longer term, however, we observed a significant increase in snoring intensity (5.7 ± 2.9 cm), which nevertheless remained below the preoperative values (P < 0.001). Bed-partners noticed a relapse of snoring in 92.7% of cases. Nine percent of couples separated. Hypertension and diabetes were diagnosed during follow-up in 12.1% and 6.6% of the subjects, respectively. A majority of patients failed to undergo repeat polysomnography or further treatment.

Conclusion: Relapse of snoring was observed in nearly all patients in the long run, although intensity appears to remain lower than preoperatively. Most patients did not comply with the follow-up instructions and did not seek other forms of treatment when recurrence occurred.

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1. Introduction

Chronic snoring can be the cause of a significant social discomfort. Obstructive sleep apnea syndrome (OSAS) can be responsible for excessive daytime sleepiness, metabolic disorders and cardiovascular diseases.
Many different therapeutic options may be proposed to patients suffering from simple snoring or mild to moderate OSAS. Apart from sleep hygiene, dietary counseling, mandibular advancement appliances, continuous positive airway pressure (CPAP), surgery can be offered. Four techniques targeting the soft palate can be performed: uvulopalatopharyngoplasty (often combined with tonsillectomy), laser treatment, palatal implants and radiofrequency-assisted stiffening. Despite their different modes of action, these procedures share the same goals, which are to reduce the vibration of the soft palate and decrease its tissue bulk. Although there is no gold standard in the treatment of snoring, radiofrequency (RF) has become more popular in the last decade due to its low morbidity and the fact that it shows similar efficacy to the other procedures [1].

The short-term efficacy of this treatment and the persistence in time of its effect on pharyngeal obstruction and soft-tissue vibration may impact on various disease-related parameters, including marital status and cardiovascular variables (particularly when OSAS is present). Because RF is a very simple procedure, some patients underestimate the severity of their condition. This can lead to failure to attend follow-up visits or to undergo repeat polysomnography (PSG). In such cases, residual disease may remain undiagnosed and therefore untreated.

In the literature, good initial results have been documented for velopharyngeal surgery and laser procedures, but their efficacy has been shown to wane over time [2–4].

Few studies have assessed the mid-term results of RF stiffening, but there also appears to be recurrence of symptoms after a few years [5–8]. To our knowledge, no study has attempted to determine the long-term effects of this treatment. Therefore, the main goal of our study was to elucidate clinical outcome in a population of patients with snoring or mild/moderate sleep apnea after RF treatment of the soft palate.

2. Methods

From 1998 to 2006, 228 patients were treated with RF stiffening of the soft palate (with or without shortening of the uvula) in our department. All patients were simple snorers or suffered from mild to moderate OSAS.

Pre-therapeutic investigation included history focusing on marital status, medical history such as hypertension and diabetes, and the Epworth sleepiness scale. A complete otolaryngologic physical examination was performed and body mass index (BMI) was recorded. All subjects underwent polysomnography (level I, II or III). Treatment options were chosen according to morphologic parameters and the apnea/hypopnea index (AHI) and all suitable options were proposed. RF was offered as an option, especially when the velar area was considered clinically to be the main site of vibration or obstruction on physical examination, and in the absence of macroglossia (stages 3 and 4 of Friedman’s classification), obesity (body mass index > 30 kg/m²), patient’s complaint of nasal obstruction or AHI > 20/h. The patient had the final choice. The procedures were performed in 1 to 3 sessions, every 8 weeks, until the bed-partner considered the outcome to be satisfactory. RF stiffening was associated to resection of the uvula and/or ablation of the lower part of the soft palate when these were considered clinically to be hypertrophic or elongated, the goal being to treat the whole subsite. Ablative procedures were performed during the first session for some patients and during a subsequent session in others.

Over the studied period, five different RF generators were used, comprising both monopolar and bipolar devices. For soft palate stiffening, Select Sutter (bipolar), Ellman (monopolar), Somnum (monopolar), Coblator (bipolar) and Olympus (bipolar) were used. Uvuloplasty and ablation of the lower velum were performed using a diode laser (Diomed) or an RF generator (Select Sutter or Olympus).

All subjects received counseling about the importance of a follow-up visit 2 months after the last session. For patients with known OSAS, repeat polysomnography was prescribed 4 to 6 months after treatment.

Patients were treated according to indications and RF techniques derived from previous studies which had been submitted to our local ethics committee. The present study was retrospective. It was based on the data from the previous studies plus a long-term evaluation by postal questionnaire. Therefore, it did not require specific approval from our local ethics committee.

2.1. Inclusion criteria

Subjects included in this study had a minimum 3 years’ follow-up. Each patient had a pre-therapeutic snoring intensity evaluation performed by the bed-partner on a visual analog scale (VAS), 0 indicating no snoring and 10 a snore sound audible in another room or justifying sleeping in a separate bedroom. A short-term VAS was also completed 2 months after the last treatment session. For OSAS patients, AHI between 5 and 20/h was used as a selection criterion. Snoring intensity was a subjective variable, in the ear of the bed-partner. In order not to exacerbate the subjectivity of the assessment, especially in the long term, we only used snoring volume as assessment criterion, and not satisfaction.

2.2. Exclusion criteria

Patients were not included in analysis if they had failed to answer the short-term questionnaires or if their data were not interpretable. Similarly, subjects who had changed bed-partners during the follow-up period were not included in the calculation of the recurrence rate of snoring and of the long-term snore intensity.

2.3. Evaluation of long-term outcome

A postal questionnaire was sent to all included patients. The first section of the survey aimed to evaluate the evolution of the snoring sound. A VAS was filled out by the same bed-partner as at the initial evaluation. If the patient was currently receiving a treatment (oral appliance, CPAP or other), the evaluation had to be undertaken without it. Open questions were asked about possible recurrence of discomfort, its onset, subjective intensity compared to the pre-therapeutic state and intermittent or permanent
nature and whether it manifested during the whole night or only a part of it. The second section evaluated the impact of the snoring on the couple (the most extreme outcome being separation). The third section was evaluation of daytime sleepiness on the Epworth sleepiness scale. Although this score is a global evaluation of daytime sleepiness and not directly indicative of OSAS, it gave us a hint as to the “possible” onset of OSAS in a simple snorer or a “possible” aggravation of a previously diagnosed disease. Section four measured cardiovascular risk factors such as hypertension, diabetes and increase in BMI. Section five targeted the post-operative follow-up: attendance for the post-therapeutic PSG and follow-up visits, and whether or not the patient had sought further treatment in case of symptom recurrence.

2.4. Outcome measures

Snoring intensity was evaluated by a VAS completed by the bed-partner before and shortly after treatment and at the time of the postal survey. Three groups were formed according to the scores on the short- and long-term post-treatment VASs: improvement, stabilization and aggravation. We identified, beforehand, 4 factors that could possibly influence snoring aggravation over time: the magnitude of the initial reduction in sound intensity, BMI variations, the type of procedure performed (with or without uvulectomy) and an associated diagnosis of OSAS.

2.5. Statistical analysis

The short- and long-term values of the variables were compared using a paired Student t test. For proportions, Chi² tests were performed to compare means, and a one-way Anova for repeated measures was used to compare the VAS scores. When a significant difference was observed, bilateral comparisons were performed by post-hoc analysis by Fisher’s exact test. Values of P less than 0.05 were considered statistically significant. Statistical tests were run using the StatView 5 package (SAS Institute, Grenoble, France).

3. Results

3.1. Study population

Two hundred and twenty-eight patients underwent soft palate RF treatment for snoring. Eighty-three patients did not have complete (pre- and postoperative) snoring evaluation and 22 patients had an apnea-hypopnea index > 20/h.

Overall, 123 patients met the inclusion criteria and were sent the postal survey. Forty-three failed to return the questionnaire (including 28 who had moved during the follow-up period). Three questionnaires were not filled out correctly. No statistical difference was found between responders and non-responders to the questionnaires for age (P = 0.32), sex (P = 0.97), BMI (P = 0.48), associated uvulectomy (P = 0.29), pre- and postoperative snore intensity (P = 0.09 and P = 0.98 respectively) and AHI (P = 0.27). Overall, 77 patients were included in the analysis. All were treated between 1998 and 2006. Fifty subjects were simple snorers and 27 suffered from mild or moderate OSAS (AHI < 20/h). The cohort comprised 59 males and 18 females. The mean age of the study population at the first treatment session was 52.2 ± 10.9 years. It was 59.4 ± 11.2 years at the time of completion of the survey. Mean follow-up time was 6.3 ± 2.3 years (range, 3 to 11 years).

Patients were treated with RF stiffening either alone or combined with uvulectomy. Among patients who had stiffening alone (n = 34), 10 had only a single session while 21 had two and 3 had three sessions. Among patients who also had uvulectomy (n = 43), 4 were treated in a single session while 7 had two sessions and 32 received three sessions.

Data regarding weight change was available for 73 patients. No significant difference was found between pre-therapeutic and long-term mean BMI (respectively 24.7 kg/m² and 25.3 kg/m², P = 0.19).

3.2. Snoring

We were excluded from this analysis all subjects who had changed bed-partners during the follow-up period (n = 10) or for whom long-term snoring intensity was not properly documented on the VAS (n = 9). Overall, 58 patients could be evaluated. Mean age was 58.9 ± 11.3 years. Mean AHI was 9 ± 6/h. The mean follow-up time for this subgroup was 6 ± 2.3 years. Thirty-nine patients were simple snorers while 19 suffered from OSAS.

According to most bed-partners (92.7%), snoring recurred at some point during the follow-up period. The relapse occurred less than 6 months after treatment for 39 subjects (67.2%), between 6 and 12 months for 8 (15.7%) and between 12 and 24 months for 8 patients (15.7%). Snoring was considered to be continuous over the entire night in 29.2% of the cases. It was present every single night in 76% of the cases and periodic for 24%.

Snoring sound intensity was assessed on the VAS. We found a significant difference between the preoperative (mean VAS = 8.1 ± 1.5) and immediate postoperative scores (mean VAS = 3.5 ± 2.2) (P < 0.0001). A significant increase was found between the short- and long-term postoperative scores (mean VAS = 5.7 ± 2.9) (P < 0.0001). However, the long-term VAS scores remained significantly lower than the preoperative values (P < 0.001). Twenty-seven percent of the bed-partners reported a long-term VAS score lower than 3.

Most bed-partners (65.5%) reported an increase in snore sound intensity over time after treatment; stable or reduced snoring volume was noted in equal numbers of subjects (17.2%). Among patients who worsened, 47.3% showed an increase of 3 points or more on the VAS. Four variables were thought to be related to snoring recurrence (Table 1). Of these, the two most significant were a greater decrease between the pre- and postoperative VAS scores, and conservation of the uvula. The role of the number of treatment sessions could not be evaluated because of the heterogeneity of the groups, with very few patients with 1 or 3 sessions.

3.3. Conjugal status

Nine percent of the couples separated during the follow-up period.
Table 1 Factors studied to evaluate their influence on long-term variation in snoring.

<table>
<thead>
<tr>
<th></th>
<th>Snoring improved in LT</th>
<th>Snoring stable in LT</th>
<th>Snoring worsened in LT</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF ST results = mean differential VAS score</td>
<td>2.6 ± 1.9</td>
<td>4</td>
<td>5.2</td>
<td>0.03</td>
</tr>
<tr>
<td>ST versus initial preoperative VAS</td>
<td>7.2 ± 1.9</td>
<td>7.8 ± 1.8</td>
<td>8.4 ± 1.2</td>
<td>0.19</td>
</tr>
<tr>
<td>Change in BMI (kg/m²) LT versus initial</td>
<td>+0.03</td>
<td>-0.54</td>
<td>+0.59</td>
<td>0.08</td>
</tr>
<tr>
<td>Associating uvulectomy (% patients with RF + cut)</td>
<td>90</td>
<td>50</td>
<td>47.4</td>
<td>0.002</td>
</tr>
<tr>
<td>Presence/absence of initial OSA (% of snorers)</td>
<td>60</td>
<td>70</td>
<td>68.4</td>
<td>0.27</td>
</tr>
</tbody>
</table>

RF: radiofrequency; ST: short term; LT: long term; VAS: visual analog scale; BMI: body mass index; OSA: obstructive sleep apnea.

Daytime sleepiness

The mean Epworth score was significantly higher preoperatively (7.8 ± 4.6) compared with the immediate postoperative values (6.3 ± 4.2, P = 0.0005). No significant difference was found between the short and long-term (7.2 ± 4.7) postoperative periods (P = 0.069), or between the preoperative and long-term values (P = 0.22).

3.4. Cardiovascular risk

3.4.1. Weight

For this analysis, patients were separated into three groups: weight loss, stable weight and weight gain. Eighteen subjects (24.6%) lost weight during the follow-up period (mean 4.6 kg, BMI decreased from 24.1 to 22.5 kg/m², P = 0.0002). Twenty-five (34.2%) did not show any significant weight change (mean BMI 24.7 kg/m²). Thirty-four patients (46.5%) gained weight (mean 4.7 kg, BMI increased from 25.2 to 26.8 kg/m², P = 0.0001).

3.4.2. Blood pressure and diabetes

Before treatment, 3 patients suffered from arterial hypertension (4.1%). Two of these patients also suffered from OSAS. Two patients suffered from diabetes (2.7%); they were both diagnosed with OSAS.

At the long-term follow-up, hypertension was reported by 12.1% of patients and diabetes (not requiring insulin) by 6.6%. These complications were not related to weight gain.

3.4.3. Follow-up

Only 7.7% of patients underwent post-treatment polysomnography, including 3 simple snorers and 3 OSAS patients. Therefore, 24 patients with preoperative OSAS (88.8%) did not have a control recording after treatment.

Six subjects had a complementary treatment: 3 patients used an oral appliance, 2 patients used CPAP and 1 had velopharyngeal surgery.

Of the 77 evaluated patients, 58 (59.7%) claimed they would be willing to undergo a second course of RF treatment for their snoring.

4. Discussion

Radiofrequency stiffening and ablation of the soft palate is now widely used to treat snoring, although few controlled trials studied its efficacy. Stuck published the only randomized placebo-controlled trial, which included 23 patients with 6 to 8 weeks’ follow-up [9]. Similarly, few studies assessed the mid- and long-term results of this treatment or the rate of symptom recurrence. Back et al. studied 21 patients with a mean follow-up of 12 months [5]. Li et al., [6] and Said et al., [7] respectively studied cohorts of 22 and 39 patients, with a mean follow-up of 14 months. Only 1 prospective trial examined the long-term (19.3 months) results of this technique, on a cohort of 19 patients [8]. To our knowledge, our study has the longest published follow-up time (6.3 years) on a large cohort of patients (n = 77).

All of the above studies showed that snoring recurred after RF treatment. Recurrence rates were 11% [7], 20% [5], 30% [10], 37% [8] and 41% [6]. Our results also confirm this relapse over time, although we found a much higher rate, with 92.7% of bed-partners who reported a qualitative increase in snoring intensity in the long term. VAS scoring showed a more modest increase: 65.5% of bed-partners reported a significant increase. This recurrence rate, higher than previously reported, is probably the result of our longer follow-up time.

Some studies reported that BMI was the main factor affecting the short-term results of soft palate RF [10,11]. Consequently, we looked at weight gain as a risk factor for snoring recurrence [2]. Our results did not confirm this hypothesis statistically, although a trend was observed towards it; one reason could be that mean weight gain in our population was mild. These results are in agreement with those published by Stuck et al. [8]. Similarly, we did not find any difference in recurrence rates between simple snorers and mild to moderate OSAS patients.

Our results show that the initial response to the treatment affects the recurrence rate. We observed that a greater decrease in snoring intensity in the short term was associated with a greater risk of recurrence as measured with the long-term VAS. This might not appear to be logical, but could possibly be explained by the fact that greater variations in sound intensity are more perceptible than minor ones. When snoring has been greatly decreased or completely suppressed, a recurrence might be more perceptible than a similar increase from a louder starting point. The second factor influencing recurrence is uvulectomy, which appears to decrease the recurrence rate. This might be explained by the fact that the stiffened portions of the velum can soften with time, whereas a shortened uvula will not regrow. Moreover, even if the uvula did not participate in the vibration initially, it can become part of the snoring mechanism over time.
Given the good tolerance and low morbidity of the treatment in the short term, a new RF session could be considered, especially as 60% of patients reported that they would be ready to do it again. Of course, the uvula should be shortened at that time if it had been left intact previously.

Our results show the importance of informing patients about the risk of recurrence before they undergo RF treatment, even if short-term results are favorable. All patients should be counseled about repeat polysomnography, the need for a long-term follow-up and the possibility of a second course of treatment in the future. However, even in presence of recurrence, the snore sound intensity generally remains below the initial values.

The prevalence of hypertension in our high-risk population increased from 4.1% to 12.1% during follow-up. Similarly, the proportion of subjects suffering from diabetes went from 2.7% to 9.6%, and the Epworth score significantly increased. The occurrence of these conditions can be the result of onset of OSAS in simple snorers or of worsening when it was already present. Only comparative randomized studies will show whether treating patients with simple snoring or mild to moderate sleep-disordered breathing can prevent them from having cardiovascular complications such as high blood pressure.

In our study, only 7.7% of subjects underwent post-treatment polysomnography. Almost 90% of the previously known OSAS subjects were not controlled postoperatively. Confirming the efficacy of the treatment and keeping track of these patients is a difficult task but is essential. Our utmost attention should be focused on improving the follow-up protocols for these patients.

Our study has limitations. The design was retrospective and unfortunately not a longitudinal prospective study with a non-treated control group, but this type of study is difficult to perform over such a long period of time and on a large population, at least in France. The number of excluded patients (lost to follow-up + questionnaires not correctly filled out) was fairly high (46/123) and may have introduced biases; mean follow-up, however, was longer than 6 years. Regarding the surgical technique, 2 types were used: interstitial radiofrequency, with or without uvulectomy. To perform these two techniques, several RF generators (with different waveforms) and electrodes (monopolar or bipolar) were used (as part of a previous comparative study) and this may seem to raise a methodological problem; comparing 4 of these different systems, however, as reported in the previously published article, did not find any difference in terms of efficacy [12]. Although evaluation at the various time-points was performed with the same tools and the same bed-partners, some factors, such as hearing levels or personal relationships, may have been subject to evolution.

5. Conclusion

Radiofrequency treatment of the soft palate reduces snoring in the short term. We demonstrated a significant recurrence rate in the long term, but with a lesser intensity than pre-operatively. This can be due to softening of the scar tissue. Good initial results do not guarantee long-term results and even appear to influence them negatively. It is therefore important to counsel patients properly about these issues. Given the good tolerance and low morbidity of RF, further sessions can be considered in order to improve quality of life. In fact, most patients would be willing to undergo further treatment. Regarding follow-up, few control polysomnographies were performed, although it is essential to obtain objective follow-up measures to monitor a possible worsening of the disease towards OSAS. All patients must therefore be properly counseled about short and long-term follow-up.

Disclosure of interest

The authors declare that they have no conflicts of interest concerning this article.

References