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ORIGINAL ARTICLE

Uvulopalatopharyngoplasty in 158 OSAS patients failing non-surgical treatment

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Abstract

Conclusions: Uvulopalatopharyngoplasty (UPPP) in patients with obstructive sleep apnoea syndrome (OSAS) who had failed treatment with continuous positive airway pressure (CPAP) and mandibular retaining device (MRD) was effective and safe. The satisfaction rate was high. We recommend UPPP in selected OSAS patients, especially younger patients. **Objectives:** To evaluate the efficacy and complication rate of UPPP. **Patients and methods:** This was a non-randomized prospective study of 139 men and 19 women, median age 45 years (range 20–75), median body mass index (BMI) 29 (range 20–48), who underwent UPPP. One year follow-up comprised ambulant sleep apnoea recordings and questionnaires with the Epworth Sleepiness Scale (ESS). **Results:** In all, 76% of the patients underwent sleep recordings preoperatively and postoperatively. The oxygen desaturation index (ODI₄) decreased from median 23 (range 6–100) to 8 (range 0–60), $p < 0.001$. Criteria of success ($>50\%$ reduction and ODI < 20), was 64%. The ESS value decreased from median 12 (range 0–21) to 6 (0–22), $p < 0.001$. In all, 88% of the patients were satisfied. Four of 158 patients (2.5%) had serious postoperative complications. There was neither sequel of complications nor mortality.

Keywords: Obstructive sleep apnoea, surgery, tonsillectomy, bleeding complications, treatment failure, UPPP, CPAP failure

Introduction

Obstructive sleep apnoea syndrome (OSAS) is a common disease, with a prevalence of 4% among men and 2% among women [1]. Snoring, daytime sleepiness and non-refreshing sleep are frequent symptoms. Narrowing or collapse of the upper respiratory tract during inspiration causes apnoeas and hypopnoeas during sleep [2]. Common risk factors for developing OSAS include obesity, hypertrophied tonsils, deviant facial structure, smoking, heredity and male gender. The sleep quality is worsened because of apnoeas and hypopnoeas causing oxygen desaturations and frequent arousals. There is a strong relationship between OSAS and cardiovascular diseases, such as hypertension, stroke and early death [3], as well as between OSAS and type II diabetes [4].

Continuous positive airway pressure (CPAP) was introduced by Sullivan et al. in 1981 [5] and is the first treatment of choice worldwide. A custom-made

mandibular retaining device (MRD) is often used as a second choice in the Nordic countries, as the reduction of apnoea/hypopnoea index (AHI) is less successful compared with CPAP [6]. Both CPAP and MRD have a rather low median compliance rate, 61% after 1–3 years [7] and 56% after 5 years, respectively [8]. However, the compliance rate from MRD studies is based on questionnaires, since it is not possible to perform objective measurements. Both CPAP and MRD are lifelong treatments and studies of the compliance rate after more than 5 years are lacking; it probably decreases further with time. Furthermore, there are no follow-up studies of patients having tried both CPAP and MRD. Failure of such treatment is due to many reasons such as phobia, nasal symptoms from CPAP, tenderness in the jaws from MRD, costs for the patients and psychological effects of a never-ending treatment.

Until now there has been no ultimate alternative treatment for OSAS patients who are failing

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non-surgical alternatives. Weight reduction is often difficult to achieve and maintain. Treatment of nasal obstruction, changes in lifestyle, avoidance of alcohol, hypnotics and supine position may be helpful but lack evidence-based evaluation. Surgical procedures are designed to relieve the obstruction, but only tracheostomy completely eliminates OSAS. Uvulopalatopharyngoplasty (UPPP) was introduced by Fujita et al. in 1981 [9], but the enthusiasm for this method has declined since analyses have shown a rather low success rate of 50% over time in unselected patients [10]. Furthermore, severe adverse postoperative effects have been reported. On the other hand, our experience is that the 'learning curve' improves for surgeons as well as for anaesthesiologists concerning the pre-, intra- and post-operative care of these high-risk patients. A study from the Department of Veterans Affairs (VA) in the USA shows a serious complication rate of 1.5% and a mortality rate of 0.2% in a large cohort of 3130 patients [11]. When analysing the risk factors for surgery, a high body mass index (BMI), a high AHI, medical comorbidity and concurrent retrolingual procedures were associated with an elevated risk of complications [12].

There is a paucity of efficacy and safety studies of UPPP with a large group of OSAS patients, who have failed or not accepted CPAP and MRD, and who wish surgery. The primary aim of this study was therefore to evaluate the efficacy of UPPP in this selected group of patients, by measuring changes in numbers of nocturnal oxygen desaturations and daytime sleepiness score. Other aims were to evaluate the rate of patients' satisfaction and rate of complications caused by surgery.

Patients and methods

The primary outcome was changes in number of nocturnal oxygen desaturations $\geq 4\%$, ODI₄. Other outcomes were changes in Epworth Sleepiness Scale (ESS), rate of satisfaction and rate of serious complications.

Patients

Inclusion criteria comprised ambulant sleep apnoea recordings showing ODI > 5 and/or AHI > 9 as well as daytime symptoms of OSAS. The patients should have failed or not accepted CPAP and MRD treatment. Exclusion criteria were negative attitude to surgical treatment, severe heart, pulmonary, psychiatric or neurological disease, American Society of Anesthesiologists (ASA) class > 3 and coagulopathy.

All consecutive women and men who fulfilled the criteria and underwent UPPP at the ORL department during 2002–2006 were included (Table I). A total of 158 patients, 139 men and 19 women, with a median age of 45 years (range 20–75) and a median BMI of 29 kg/m² (range 20–48) participated in the study. Their median preoperative ODI was 23 (range 6–100) and the patients' median ESS was 12 (range 0–21).

Upper airway examination included fibre-endoscopy and grading of tonsil size on a scale of 1–4 (where 4 is maximum), similar to that used by Friedman et al. [13]. None of the patients had previously undergone tonsillectomy. Of the 158 patients, 38% had hypertrophied tonsils (size 3–4).

Characteristics of the drop-out group

Thirty-eight of 158 patients (24%) did not turn up for a second sleep recording and were defined as drop-outs (Table I). They were all men and were significantly younger ($p = 0.035$, two sample t test) with significantly bigger tonsils ($p = 0.038$, Pearson's chi-squared test) than the patients who fulfilled the study. There were no differences concerning ODI, ESS or BMI.

Safety programme and anaesthesiological aspects

A safety programme, very similar to the report of the AASM Clinical Practice Review Committee [14], is routinely used at our clinic. The surgery was performed under general anaesthesia. It was induced with rapid sequence induction. Remifentanyl infusion and sevoflurane were used to maintain the anaesthesia. All patients were extubated immediately after surgery. Thereafter, they were transferred to the postoperative care unit for careful monitoring of vital signs for between 6 and 24 h. All patients received oxygen and/or CPAP if needed. Penicillin was given as infection prophylaxis. The patients had the opportunity to stay a second night on a ward, but if the course was uncomplicated they went home the day after surgery.

Surgical procedure

No concurrent surgery, for example of the nose or tongue, was performed. Twelve ear, nose and throat surgeons performed a conservative UPPP with tonsillectomy, using a modified method of Fujita et al. [9] with cold-steel instruments comprising scalpel and scissors. Local anaesthesia was used (bupivacaine 5 mg/ml). The mucosa from the anterior soft palate and anterior tonsil pillar was reduced by approximately 2–3 mm, in the upper lateral corner by 3–4 mm. The mucosa between

Table I. Characteristics of patients before surgery.

Parameter	All	Male	Female	Drop-outs
Number of subjects	158	139	19	38
Age (years)	45 (20–75)	43 (20–75)	49 (31–71)	38.5 (20–62)
BMI (kg/m ²)	29 (20–48)	29 (22–48)	29 (20–39)	29 (22–42)
ODI ₄	23 (6–100)	24 (6–100)	15 (8–77)	25.5 (7–85)
ESS	12 (0–21)	12 (0–21)	14 (4–19)	11.5 (1–21)
Tonsil size (1–4)	2 (1–4)	2 (1–4)	2 (1–4)	3 (1–4)

Values are presented as median and range. BMI, body mass index; ODI₄, oxygen desaturation index $\geq 4\%$; ESS, Epworth Sleepiness Scale.

anterior and posterior pillar was removed. The posterior tonsil pillar was preserved. The uvula was cut to a width and length of approximately 1 cm. Extracapsular tonsillectomy was carried out with a sharp elevator. Haemostasis was achieved with bipolar diathermy. The posterior pillar was lifted up laterally and sewn up to the anterior pillar with separate inverted sutures (4/0 Monocryl). In the upper lateral corners two or three sutures also included fibres from the palatopharyngeal muscle. Finally, there was suturing of the soft palate and uvula. If the patients had a profuse bleeding or pharyngeal oedema postoperatively, desmopressin and tranexamic acid or cortisone was injected intravenously.

Follow-up

All patients were followed up at a visit to the surgeon 2 months after surgery and by a letter with questionnaires 1 year after surgery. Furthermore, they were referred to the Department of Clinical Neurophysiology for ambulant sleep apnoea recordings, before and approximately 1 year after surgery. Patients with a severe degree of OSAS were offered the opportunity to undergo recordings within 6 months, to identify those who failed surgery and offer them additional treatment.

Sleep apnoea recordings and laboratory criteria of success

All ambulant recordings were performed with Embletta (Medcare Flaga, Reykjavik, Iceland), which included monitoring of respiratory movements of chest and abdomen, nasal air flow, snoring and pulse oximetry, as well as body position. The ODI measuring the number of oxygen desaturations $\geq 4\%$ per sleeping hour was determined, ODI₄. The AHI measured by the thermistor was not considered to be a consistently reliable measure of the air flow at this time, and was therefore excluded. All recordings were interpreted by specialists in neurophysiology, from the same laboratory department.

The patients were categorized into responders or non-responders according to two laboratory criteria

of success. The first, and most commonly used criterion, was a reduction in ODI $>50\%$ and ODI values <20 ; the second criterion was a reduction in ODI $>50\%$ and ODI values <10 .

Questionnaires

All patients answered the ESS, which consists of eight questions concerning their likelihood of falling asleep in a variety of commonly encountered situations [15]. An extra question was added: 'Are you satisfied with the operation?'. The question was answered with a 'yes' or 'no'.

Complications

The medical complications in connection with the surgery and type of reoperations, caused by complications, were recorded and classified for each patient. Severe bleeding or pharyngeal oedema leading to re-intubation were classified and shown as a serious complication. Less severe complications were not shown.

Ethics

The study was approved by the Regional Ethical Review Board in Stockholm.

Statistical analyses

Comparisons were made between unpaired groups with the Mann-Whitney U (MWU) test, Pearson's chi-squared test or the *t* test. The Wilcoxon signed rank (WSR) test for paired groups and the Spearman rank correlation (SRC) for correlation tests between variables were used. Missing values for drop-outs were imputed by using their baseline values +1. Hence, for drop-outs we assumed a very small increase between baseline and follow-up. This approach was used to have a conservative imputation method not favouring a positive treatment effect. Logistic regression (log reg) analysis was used to identify factors predicting 'success'. The first criterion of success, $>50\%$ reduction and ODI <20 , was

used in these analyses. p values <0.05 were considered significant.

Results

Objective results

In all, 120 of 158 patients underwent a second sleep apnoea recording at a median 12 months (range 2–34) after surgery, which showed a significant decrease in ODI from a median of 23 (range 6–100) to 8 (0–60) ($p < 0.001$, WSR test) (Figure 1, Table II). Intention to treat analysis for all 158 patients showed a significant decrease in ODI ($p < 0.001$, WSR test).

With the use of the first criterion of success ($>50\%$ reduction and $\text{ODI} < 20$), the success rate for the group of 120 patients was 64%. When dividing the group according to tonsil size, i.e. small (size 1–2) and large (size 3–4), the success rates were 63% and 67%, respectively, with no significant difference between the groups.

With the use of the second criterion (50% reduction and $\text{ODI} < 10$), the success rate was 54% for the group of 120 patients.

Median BMI for 117 patients was unchanged after surgery. Preoperative tonsil size, BMI and ESS did not correlate significantly with changes in ODI or ESS, respectively (SRC test). There was a significant correlation between preoperative ODI and changes in ODI ($p < 0.001$, SRC test). Success factors were female gender ($p = 0.023$, log reg) and low age ($p = 0.044$, log reg). There was an indication that low preoperative ODI ($p = 0.07$, log reg) was also a

success factor, but not large tonsils, low BMI or surgeon's experience.

The follow-up time for the postoperative sleep recordings of the 120 patients varied for different reasons. Ninety-nine patients underwent the recordings as planned, approximately 1 year after surgery. Eighteen patients with more severe OSAS underwent the early follow-up, between 2 and 8 months after surgery. Twelve of them were much improved and not interested in a second follow-up recording. The six non-responders were offered additional treatment with MRD or CPAP and were not called for the 1-year follow-up. Patients who did not turn up for the planned follow-up sleep recording were reminded by mail. Thereafter, seven patients underwent the recordings, 22–34 months after surgery. Six of them were responders. There was no significant correlation between follow-up time and changes in ODI, according to the SRC test.

Subjective results

Responses to the ESS questionnaire were obtained before and after surgery from 107 of 158 patients. Their median values showed a significant decrease of ESS score from median 12 (range 0–21) to 6 (range 0–22) ($p < 0.001$, WSR test) (Figure 2, Table II). In the intention to treat-analysis the ESS decreased significantly for all 158 patients ($p < 0.001$, WSR test).

The question concerning satisfaction was answered by 104 patients, 92 of them (88%) were satisfied with the surgery.

Figure 1. A total of 120 patients underwent sleep apnoea recordings after approximately 1 year, and there was a significant decrease in oxygen desaturation index (ODI), from median 23 (6–100) to 8 (0–60), $p < 0.001$ (Wilcoxon sign rank test, WSR). Boxes indicate median values, 25 and 75 percentiles. Bars indicate non-outlier range. Round symbols indicate outliers and asterisks indicate extreme outliers. Note the significant difference, $p < 0.001$.

Postoperative complications

Four of 158 (2.5%) patients had serious complications at the postoperative care unit, and were reintubated. Two of them had profuse bleeding from the tonsillectomy. The bleeding did not stop with medical treatments but with reoperation. Two patients had substantial pharyngeal oedema. One of them was directly tracheotomized for safety reasons. After 2 weeks he was decannulated without complications; he was still satisfied with surgery 1 year after the procedure. The other patient was successfully treated with steroids and extubated the day after surgery. None of these four had any known risk factor, i.e. high BMI, ODI or age. None received blood transfusion. All complications were immediately taken care of and no patient has suffered from sequelae caused by these complications. There was no mortality.

Table II. Results of changes in oxygen desaturation index and daytime sleepiness after UPPP.

Parameter	Baseline		Follow-up		Changes	
	Mean (SD)	Median (range)	Mean (SD)	Median (range)	Mean (SD)	Median
BMI (<i>n</i> = 117)	29.2 (4.3)	29 (20–47.7)	29.2 (4.3)	29 (20.3–47.7)	0 (1.8)	0
ODI ₄ (<i>n</i> = 120)	27.2 (20.1)	23 (6–100)	10.8 (11.5)	8 (0–60)	16.4 (18.2)	12.6
ESS (<i>n</i> = 107)	11.3 (5.7)	12 (0–21)	6.7 (5.2)	6 (0–22)	4.6 (4.8)	5

Values are presented as mean, standard deviation (SD), median and range. BMI, body mass index; ODI₄, oxygen desaturation index $\geq 4\%$; *n*, number of patients; ESS, Epworth Sleepiness Scale.

Discussion

The present study has shown that UPPP was both effective and safe in OSAS patients who had failed or not accepted non-surgical treatment, when using a conservative surgical procedure and a safety programme. There was a significant and marked decrease in nightly oxygen desaturations as well as in daytime sleepiness 1 year after surgery. The intention to treat analysis with imputed postoperative values of the drop-outs showed similar results. The success rate, as measured with sleep apnoea recordings and with different criteria, varied between 64% and 54%, and the satisfaction rate was 88%. Therefore, we consider both the objective and subjective results to be surprisingly good in this group of patients, who would otherwise probably have been left untreated.

Surprisingly, the preoperative BMI did not correlate with success as regards improvement of the nightly oxygen desaturations. Our results differ from those in a study by Larsson et al. [16], in which 50 OSAS patients with a preoperative BMI <30 had a higher success rate than those with a higher BMI. An

explanation for the diverging results may be that the number of patients in our study was larger. Friedman et al. [13] reported similar results to ours concerning patients with BMI up to 40. However, they suggested that patients with BMI over 40 should not undergo UPPP. There were only two patients in the present study with a BMI over 40, both had enlarged tonsils; one was a drop-out, the other was a responder. In terms of the ODI values, the study of Larsson et al. showed that low preoperative ODI was a success factor. In this study there was a tendency for low preoperative ODI to be correlated with success.

It was also surprising that no significant differences were found in success rate between the groups of patients with large (67%) and small tonsils (63%). This finding indicates that the effect of the surgery was a result of our modified UPPP with lateralization of tonsil pillars, irrespective of tonsil size. Our results differ from those presented by Friedman et al. [13]. They found in a retrospective study of 134 OSAS patients that patients with hypertrophied tonsils in combination with a high palatal position had a considerably higher success rate of 80% compared with 8% for patients with small tonsils and low palatal position. However, Friedman's grading system was not published at the start of our study. Therefore, we only estimated the tonsil size. Female gender was correlated with success. However, it is difficult to draw any major conclusions from only 19 women who underwent surgery. Another success factor was low age. This could be explained by the expression 'heavy snorer's disease', which is a progressive local vibration-induced neuropathy in the pharynx [17]. Younger patients probably do not have the same amount of local neuropathy and/or inflammatory tissue as older ones, and therefore younger individuals may respond better to surgery.

Drop-outs in this study were defined as not undergoing the postoperative sleep recordings and the drop-out rate was quite low, 24%. The group of drop-outs was significantly younger and had larger tonsils compared with the investigated group. As low age was a significant success factor, and large tonsils

Figure 2. A total of 107 patients evaluated their sleepiness before and 1 year after surgery and there was a significant decrease in Epworth Sleepiness Scale (ESS) value from median 12 (0–21) to 6 (0–22), $p < 0.001$ (Wilcoxon sign rank test, WSR). Boxes indicate median values, 25 and 75 percentiles. Bars indicate non-outlier range. Note the significant difference, $p < 0.001$.

a slightly positive factor, the outcome may have been even better with fewer drop-outs. Furthermore, the intention to treat analysis showed significant reductions of ODI values and daytime sleepiness for the whole group.

The gold standard for diagnosing obstructive sleep apnoea (OSA) is a full-night polysomnography (PSG) as specified by the American Academy of Sleep Medicine (AASM) [2]. However, in the Nordic countries and Great Britain ambulant sleep apnoea recordings are widely used and have been validated against PSG [18]. The specialized neuro-physiologist who interpreted the sleep recordings in the present study did not consider the AHI to be a reliable parameter at the start of the study. Therefore, the changes in ODI were chosen as the primary outcome factor. As the same recordings were used pre- and postoperatively, and the interpretations were performed by the same specialist, we consider the results of changes in ODI to be valid.

Both OSAS and obesity are known risk factors for surgery under general anaesthesia [19]. Thus, awareness of these risks is of great importance. Mortality may be avoided by careful postoperative observation and early treatment of complications. The rate of serious complications of bleeding and oedema in the present study was 2.5%, and there was no mortality. However, the number of patients was relatively small. Our results can be compared with a previous report of more than 3000 patients showing a rate of serious non-fatal complications of 1.5% and a mortality rate of 0.2% [11]. The authors concluded that concomitant tongue or nasal procedures are associated with increased risks of serious complications [12]. Therefore, no types of surgery other than UPPP were performed in the present study.

A limitation of this study is that the design is not a randomized controlled trial. Such trials of UPPP are still few as the procedure comprises removal of tissues and tonsils under general anaesthesia, which is difficult to blind. There are also ethical aspects of having a group of untreated patients. Other non-randomized studies have evaluated UPPP as a primary treatment in unselected patients [16,20]. These cohort studies have shown improvement in daytime symptoms and nocturnal respirations, as well as in driving performance. In addition, surgery is often demanded by patients who have failed non-surgical treatments, as it is the only treatment with a one-stage procedure.

We consider the strengths of the present study to be several; the evaluation of our conservative method of UPPP with a large number of patients undergoing postoperative sleep recordings after 1 year, using the validated questionnaire (ESS), the

safety programme and the selection of patients who have failed or not accepted CPAP and MRD. As compliance with such devices is still inadequate, there is an obvious need for safe and efficient surgery to offer these patients. Finally, the general applicability is strength, as the study reflects our daily clinical routines, including several different surgeons.

Conclusions

This study showed that UPPP can be effective and safe in OSAS patients failing or not accepting CPAP and MRD, when using a conservative method and a safety programme. We recommend clinicians to offer this increasing group treatment with conservative UPPP in selected patients, especially younger patients.

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