Nasal-CPAP, Surgery, and Conservative Management for Treatment of Obstructive Sleep Apnea Syndrome*

A Randomized Study

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Study objective: To assess separately the effectiveness and safety of nasal-continuous positive airway pressure (N-CPAP) and that of surgery in comparison to conservative management in patients with obstructive sleep apnea syndrome (OSAS).

Design: A randomized study with 1-year follow-up.

Setting: A university hospital acting as a referral center for OSAS.

Patients: Symptomatic patients with OSAS (72 male and 4 female patients aged 18 to 65 years), who had oxygen desaturations in the overnight recording.

Interventions: After the initial diagnostic workup, patients were considered to be candidates for either N-CPAP (44 patients) or surgical treatment (uvulopalatopharyngoplasty [UPPP] with or without mandibular osteotomy) (32 patients). Within the groups, the patients were then randomized to either the assigned treatment or conservative management.

Main outcome measures: The number of nocturnal oxygen desaturation events of 4% or more per hour in bed (ODI4); daytime somnolence; side effects.

Results: N-CPAP Group: Compliance with N-CPAP therapy at 1 year was 13 of 21. The most common reason for noncompliance was general intolerance of CPAP. All compliant patients had a normal ODI4 (<10), whereas 1 of 20 of their control subjects had a normal finding. Patients receiving active treatment were significantly less somnolent than their control subjects at 1 year (p<0.05).

Surgery Group: At 1 year, 7 of 18 of the surgically treated and 1 of 14 of the conservatively treated patients had a normal ODI4 (p<0.001). Daytime somnolence was significantly less severe in the surgically treated patients compared with their control subjects (p<0.001) both at 3 and 12 months. The overall postoperative complication rate was 22%.

Conclusions: N-CPAP is an effective therapy for OSAS, but compliance is a problem. Surgical therapy (UPPP with or without mandibular osteotomy) needs further evaluation.

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Key words: nasal-CPAP; obstructive sleep apnea syndrome; randomized clinical study; upper airway surgery; UPPP

Abbreviations: CPAP=continuous positive airway pressure; N-CPAP=nasal-CPAP; ODI4 and ODI10=oxygen desaturation index of 4% or 10% per hour in bed; OSAS=obstructive sleep apnea syndrome; UPPP=uvulopalatopharyngoplasty

Obstructive sleep apnea syndrome (OSAS) is a disorder characterized by excessive snoring and periodic breathing with repetitive apneas, hypopneas, and arousals leading to fragmented sleep. This leads to daytime somnolence and cardiovascular complications.

In a recent study by Young et al,1 2% of women and 4% of men in the middle-aged workforce met the diagnostic criteria for OSAS.

Currently various therapeutic approaches for the management of OSAS are available. Conservative management consists of weight loss and positional therapy as well as avoidance of tranquillizers and alcohol at bedtime.2-5 Continuous positive airway pressure (CPAP) provided via nasal mask6 is the most widely used nonsurgical therapy for OSAS. Uvulopalatopharyngoplasty (UPPP), lingualplasty, and maxillofacial surgery are applied as surgical alternatives.7,8

The aim of this randomized study was to clarify the
therapeutic role of nasal CPAP as well as that of operative treatment (UPPP with or without mandibular osteotomy) in comparison to conservative management in patients with OSAS.

**MATERIALS AND METHODS**

**Patients**

Mental or physical effects were required for a diagnosis of OSAS in addition to a diagnostic finding in an overnight polygraphic recording (the oxygen desaturation of 4% or 10% per hour of time spent in bed) and a “periodic breathing” pattern in both static-charge-sensitive bed and thermistor channels. Results of daytime polysomnography (EEG, electromyogram, and electrocardiogram, in addition to parameters of the overnight polygraphic recording) were consistent with OSAS in all patients.

Furthermore, mental or physical effects were required. During the time period 1987 to 1992, 268 patients between the ages of 18 and 65 years with previously untreated OSAS fulfilling the above criteria were seen at our hospital. Patients with asthma and other COPD (n=28), periodic leg movements syndrome (n=2), hypothyroidism (n=2), or other serious concomitant illness, e.g., recent ischemic cerebral or coronary incident (n=50), were excluded as well as patients for whom somnolence could cause risk or incapacity to work (n=39). Patients with body mass index greater than 40 kg/m² (n=20) were excluded from this study. They participated in a randomized active weight-loss study. Of the remaining 121 patients fulfilling the criteria, 45 refused to be randomized. The characteristics, i.e., age, body mass index, and oxygen desaturation index of 4% or more per hour in bed (ODIₜ) of these 45 patients did not differ in any significant way from those who were finally included in the study. The characteristics of the study population are shown in Table 1.

**Study Design**

All patients were assessed by a team of experts consisting of a pulmonary specialist, a neurologist, a clinical neurophysiologist, an ear, nose, and throat specialist, and a maxillofacial surgeon. Based on clinical history, medical examination, sleep recordings, naso-fiberoscopy, and cephalometric findings, patients were considered more suitable for nasal-CPAP (N-CPAP) or for surgery (UPPP with or without mandibular osteotomy). Patients with more than 50% obstruction at the palatal level in the Mueller’s maneuver but less than 50% obstruction at the epiglottic level were considered to be suitable for UPPP alone. Mandibular osteotomy with hyoid myotomy suspension was performed together with UPPP if the patient had a narrow posterior airspace, an inferiorly positioned hyoid, and a sharp sella-nasal-mandibular angle.

Within both groups, patients were randomized to either the assigned treatment or to conservative management (Fig 1) and were evaluated 3 and 12 months later. The follow-up included an overnight polygraphic recording, symptom monitoring, and clinical assessment. Patients using N-CPAP were recorded with the CPAP therapy.

**Monitoring**

Transcutaneous arterial oxygen saturation was monitored with an oximeter finger probe (Biox 3700; Ohmeda; Boulder, Colo), airflow through the nose and mouth by thermistor, body position with a sensor, and respiratory and body movements with a static-charge-sensitive bed sensor (Bio-matt; Biorec Inc; Helsinki, Finland). Variables were automatically analyzed by a computer-based program, but all recordings were also visually evaluated. The number of oxygen desaturation events of 4% or more per hour in bed (ODIₜ) and 10% or more per hour in bed (ODIₜₒ) were calculated to characterize the severity of OSAS. Mild disease was defined as an ODIₜ of 10 to 20, and moderate to severe disease as showing a higher index.

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**Table 1—Baseline Characteristics of the Patients**

<table>
<thead>
<tr>
<th></th>
<th>N-CPAP</th>
<th>Surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cons (n=23)</td>
<td>Active (n=21)</td>
</tr>
<tr>
<td>Female/male</td>
<td>1/22</td>
<td>2/19</td>
</tr>
<tr>
<td>Age, yr, median (range)</td>
<td>51 (30-65)</td>
<td>51 (38-63)</td>
</tr>
<tr>
<td>Body mass index, kg/m², median (range)</td>
<td>33 (24-41)</td>
<td>29 (24-38)</td>
</tr>
<tr>
<td>ODIₜ, median (range)</td>
<td>29 (10-96)</td>
<td>25 (10-92)</td>
</tr>
<tr>
<td>ODIₜₒ, median (range)</td>
<td>7 (0-79)</td>
<td>7 (0-88)</td>
</tr>
</tbody>
</table>

*In the N-CPAP group, patients were randomized either to conservative management (Cons) or treatment with N-CPAP. Patients selected for surgical treatment were randomized either to conservative management (Cons) or surgery (UPPP with or without mandibular osteotomy).

VAS=visual analog scale: 0=none; 100=very severe.
**Evaluation of Symptoms**

Excessive daytime somnolence was assigned with a visual analog scale.\(^1\) The patients also filled in a sleep questionnaire evaluating common symptoms of OSAS. Two questions concerned snoring: “How often do you snore?” (1=never; 2=less frequently than once a week; 3=once or twice a week; 4=3 to 5 nights a week; 5=every or almost every night) and “How does your snoring sound?” (1=do not snore; 2=quietly; 3=quite loudly; 4=very loudly; 5=extremely loudly and irregularly). Excessive daytime somnolence was evaluated with the questions: “Have you felt like falling asleep during the day when not in bed during the last 3 months?” and “Have you felt tired during the day?” (5=daily; 4=to 5 days a week; 3=1 to 2 days a week; 2=less frequently than once a week; 1=never or less frequently than once a month).

**Treatments**

On each visit, all affected patients were advised about smoking cessation and avoidance of alcohol as well as weight reduction, but no specific treatments were programmed.

Treatment with N-CPAP was initiated at hospital during two consecutive nights. CPAP was administered via a nasal mask fitted and adjusted individually to abolish all apneas and desaturations. Patients used the Nightbird (Bird Products Co; Palm Springs, Calif) or Respironics Sleep Easy System III (Respironics Inc; Monroeville, Pa) or Resmart (Respironics Inc, Murrysville, Pa) equipment.

UPPP was performed according to the method of Fujita.\(^7\) Mandibular osteotomy was performed according to the method of Powell et al.\(^5\)

**Statistical Analysis**

If we expect a difference of 22 in the ODI\(_4\) index with an SD of 20 for any treatment, each group will need to contain at least 13 patients for the study to have an 80% power to detect a difference at the 5% significance level.

Mann-Whitney U statistics were used for the testing of two independent samples. In the cross-tabulations, the \(\chi^2\) test was used to compare events in the different groups and at different assessment points. Fisher’s Exact Test was used when the cell size was less than 5.

The study was approved by the Ethics Committee of the Department of Pulmonary Medicine. All patients gave their informed consent.

**RESULTS**

Of the 21 patients randomized to treatment with N-CPAP, 6 were not willing to continue CPAP after the first night because of failure to adjust to the machine. Two further patients discontinued CPAP treatment due to nasal problems. These eight patients had no uniform findings as regards severity of disease or other characteristics.

Based on intention to treat, compliance with CPAP at 1 year was 62% (13/21). For those patients who continued therapy after the initial hospital nights, the compliance rate was 87% (13/15). Compliant patients used the machine a minimum of 5 nights a week and a minimum of 4 h a night. This information was based on the machine’s built-in counter combined with self-reports. The median pressure required was 10 cm H\(_2\)O (range, 7.5 to 18.5). The 13 patients who used N-CPAP regularly reported the following side effects: rhinorrhea (7), dry throat and nose (2), mask discomfort (2), and disturbance by the noise of the machine (1).

Of the 32 patients, who fulfilled the criteria for surgery, 18 were randomized to surgery and 14 to conservative treatment. For 13 patients, UPPP alone was performed, whereas 5 patients underwent both UPPP and mandibular osteotomy.

All postoperative complications following UPPP were minor: 2 of the 13 patients experienced velopharyngeal insufficiency. Of the 5 patients in whom UPPP and mandibular osteotomy were performed, 1 had a tracheotomy for 1 month postoperatively and 2 had reoperations for removal of infected material. The overall complication rate was 22% (4/18).

**Cardiovascular Mortality and Morbidity**

A 58-year-old man considered to be a candidate for N-CPAP and randomized to conservative management died during the study period. The immediate cause of his death was cardiac arrest, confirmed at autopsy. Another patient randomized to conservative management in the CPAP group experienced a transient ischemic cerebral attack. None of the patients receiving N-CPAP experienced any cardiovascular complications. During the study period, among the patients who had undergone surgery, one non-Q myocardial infarction and one transient ischemic cerebral attack occurred.

** Overnight Polygraphic Recordings**

All of the 12 CPAP patients and 1 of the corresponding control group had a normal ODI\(_4\) (\(\leq 10\)) at 1 year (\(p<0.001\)) (Table 2). Seven of the surgical patients and 1 of their control subjects had a normal ODI\(_4\) at 1 year (\(p<0.02\)).

When patients who were operated on were compared with their control subjects, improvement in ODI\(_4\) and ODI\(_{10}\) failed to reach statistical significance either at the 3- or 12-month assessment. However, the patients who underwent surgery had postoperatively statistically significantly lower ODI\(_4\) at 1 year in comparison to initial assessment (median ODI\(_4\) 14 vs 45; \(p<0.01\)).

**Clinical Monitoring**

Subjective symptoms were evaluated at 3- and 12-month visits. In the questionnaire, a change of at least two value points was regarded as significant. When patients receiving N-CPAP were compared with their control subjects, the improvement in excessive daytime somnolence reached statistical significance at 12 months (\(p<0.01\)) by means of the visual analog scales method, and also when assessed with the question, “Have you felt like falling asleep during the day when not in bed during the last 3 months?” (\(p<0.05\)). The
patients who had been operated on were significantly less somnolent than their control subjects both at 3 (p<0.001) and 12 months (p<0.05) when evaluated with the visual analog scale (Tables 2 and 3). In the questionnaire, reported somnolence symptoms were significantly less for surgically treated patients at 3-month (p<0.01) and 12-month (p<0.05) visits. Reported snoring disappeared or diminished only moderately in the patients receiving N-CPAP. At 1 year, the surgically treated patients had benefited from the operation in regards to snoring. 40% reported less frequent snoring, and 75% reported less disturbing snoring.

Four patients who had been randomized to conservative management either had to be placed on a regimen of N-CPAP (n=1) or had to be operated on (n=3) during the study period because of their worsening symptoms, particularly their tendency to fall asleep while driving. Five patients refused to come to the follow-up visits because of moving to another place or some other personal reasons. They all were known to be alive at the end of the study.

**Discussion**

This study was planned to compare the therapeutic effect of N-CPAP and surgery (UPPP with or without mandibular osteotomy) with conservative management in the treatment of OSAS. To our knowledge, only one randomized study about the effects of N-CPAP has been published before our study. Our results are in concordance with those earlier results.16 However, we believe that our study is the first randomized trial about the effects of upper airway surgery in the treatment of OSAS.

We were slow in recruiting, because many patients were not willing to be randomized. Our study population, however, did not differ significantly regarding the severity of OSAS or other patient characteristics from those not participating. Thus, our study is not biased in this respect.

The diagnosis of OSAS at our hospital is based on polygraphy using the static-charge-sensitive bed method, oximetry, and thermistors for monitoring ventilation. This method has been validated previously.13,14 In a previous study, Douglas et al17 have shown that the sleep apnea/hypopnea syndrome can be diagnosed with clinically relevant accuracy without polysomnography by recording oximetry combined with breathing pattern and time spent in bed.17 Our method with overnight polygraphic recording will detect patients with OSAS who have apneas/hypopneas with

Table 2—Findings in the Patients With Sleep Apnea Syndrome Randomized to Either Conservative Management (Cons) or N-CPAP at 3 and 12 Months After Randomization

<table>
<thead>
<tr>
<th></th>
<th>3 mo</th>
<th></th>
<th>12 mo</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cons (n=22)</td>
<td>Active (n=14)</td>
<td>Cons (n=20)</td>
<td>Active (n=13)</td>
</tr>
<tr>
<td>ODI4, median (SD)</td>
<td>27 (2-78)</td>
<td>1 (0-7)*</td>
<td>15 (0-73)</td>
<td>0 (0-2)*</td>
</tr>
<tr>
<td>ODI20, median (SD)</td>
<td>4 (0-75)</td>
<td>0 (0-3)*</td>
<td>1 (0-57)</td>
<td>0 (0-0)*</td>
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<tr>
<td>Symptoms</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heavy snorers, No.</td>
<td>16</td>
<td>8</td>
<td>13</td>
<td>5</td>
</tr>
<tr>
<td>Excessive daytime somnolence</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VAS, median score (SD)</td>
<td>36 (0-93)</td>
<td>15 (5-63)</td>
<td>49 (8-81)</td>
<td>24 (0-41)*</td>
</tr>
<tr>
<td>Falling asleep when not in bed, No.</td>
<td>11</td>
<td>3</td>
<td>7</td>
<td>1</td>
</tr>
</tbody>
</table>

*p<0.001, with conservatively managed patients compared with patients receiving N-CPAP.

Table 3—Findings in Patients With Sleep Apnea Syndrome Randomized to Either Conservative Management (Cons) or Operative Treatment (UPPP, With or Without Mandibular Osteotomy) at 3 and 12 Months After Randomization

<table>
<thead>
<tr>
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<th></th>
<th>12 mo</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cons (n=13)</td>
<td>Active (n=17)</td>
<td>Cons (n=10)</td>
<td>Active (n=16)</td>
</tr>
<tr>
<td>ODI4, median (SD)</td>
<td>24 (5-62)</td>
<td>13 (0-62)</td>
<td>23 (4-68)</td>
<td>14 (3-54)</td>
</tr>
<tr>
<td>ODI20, median (SD)</td>
<td>5 (0-33)</td>
<td>1 (0-55)</td>
<td>6 (0-37)</td>
<td>3 (0-40)</td>
</tr>
<tr>
<td>Symptoms</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heavy snorers, No.</td>
<td>11</td>
<td>7</td>
<td>10</td>
<td>7*</td>
</tr>
<tr>
<td>Excessive daytime somnolence</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VAS, median score (SD)</td>
<td>56 (1-100)</td>
<td>13 (0-71)*</td>
<td>72 (33-86)</td>
<td>27 (5-86)*</td>
</tr>
<tr>
<td>Falling asleep when not in bed, No.</td>
<td>11</td>
<td>3*</td>
<td>7</td>
<td>3*</td>
</tr>
</tbody>
</table>

*p<0.01, with conservatively managed patients compared with surgical patients.

See Table 1 footnote.

*p<0.001, with conservatively managed patients compared with surgical patients.

*p<0.05, with conservatively managed patients compared with surgical patients.
desaturations. Furthermore, patients with obstructive pulmonary disease were excluded.

All patients who used the CPAP machine regularly had an ODI4 within the normal range. If we consider those 13 patients of the 21 who used the CPAP regularly as treatment successes, acceptability of CPAP was 62% (13/21). One of 23 patients in the conservatively treated group had an ODI4 within the normal range at 1 year.

Thirty-eight percent of the patients randomized to CPAP did not even start the therapy or used CPAP less than 4 h per night. This finding confirms the results of Hoffstein et al18 that most patients use N-CPAP only part of the night and not always every night. Furthermore, in accordance with prior studies, our noncompliant patients had no specific pretreatment characteristics that would have predicted poor compliance.18,19 Because excessive daytime somnolence has been reported to decrease rapidly after starting CPAP treatment,20 it is possible that our patients did not apply N-CPAP for long enough periods to ensure maximal subjective benefit.

Most of our surgical patients underwent UPPP only. If an ODI4 value in normal range, ie, <10 and not merely a reduction in that index, is considered to indicate long-term success following treatment of OSAS, only one third of our patients were successes after operative treatment. This is despite the fact that prior to selection of the treatment, we applied all the criteria suggested by Fujita7 and Powell et al8 for evaluation of operative suitability. Our results, however, are in accordance with other studies reporting follow-up after UPPP.21 Furthermore, the therapeutic effect of UPPP at 1 year may even lead to an excessively optimistic view of the longer-term results.22

The patients in this study who were treated operatively showed definite improvement in daytime somnolence despite insufficient improvement of ODI1 or ODI10. The fact that subjective symptoms improve more than do objective polygraphic findings following UPPP has been documented also by other studies.23 Theoretically, this might indicate that threshold for arousal diminishes. Such a situation might lead to more severe and prolonged apneas and thus to an increased frequency of cardiovascular complications. Following UPPP, all patients regardless of symptoms, should preferably have a repeated overnight recording and objective measurement of daytime sleepiness. Unfortunately, owing to financial reasons, we were not able to evaluate daytime sleepiness objectively, ie, with the multiple sleep latency test.

In this study, the complication rate following UPPP was low compared with that reported in the literature.9 This may be due to chance. The complications following mandibular osteotomy in our study may reflect initial methodologic obstacles that lessened the surgeon’s eagerness.

In conclusion, N-CPAP is effective in the treatment of OSAS, but suboptimal compliance is a problem. UPPP with or without mandibular osteotomy in the treatment of OSAS has a poor success rate even in well-preslected patients. Long-term follow-up studies regarding different treatment regimens are still needed.

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