

Therapeutic NCPAP was more effective than subtherapeutic NCPAP in obstructive sleep apnea

Jenkinson C, Davies RJ, Mullins R, Stradling JR. Comparison of therapeutic and subtherapeutic nasal continuous positive airway pressure for obstructive sleep apnoea: a randomised prospective parallel trial. *Lancet*. 1999 Jun 19;353:2100-5.

QUESTION

Is therapeutic nasal continuous positive airway pressure (NCPAP) more effective than subtherapeutic NCPAP for reducing excessive daytime sleepiness and improving self-reported functioning and well-being in patients with obstructive sleep apnea?

DESIGN

Randomized (allocation concealed*), blinded (patients and outcome assessors)*, controlled trial with 1-month follow-up.

SETTING

A sleep unit in the South Midlands, England, United Kingdom.

PATIENTS

107 men between 30 and 75 years of age (mean age 49 y) with excessive daytime sleepiness (Epworth sleepiness score ≥ 10) and obstructive sleep apnea ≥ 10 episodes/h of $> 4\%$ decrease in arterial oxygen saturation caused by pharyngeal collapse, measured during an overnight sleep study). Exclusion criteria were patient choice of an alternative therapy, need for urgent

NCPAP, or mental disability. Follow-up was 94%.

INTERVENTION

Men were allocated to therapeutic computer-titrated NCPAP ($n = 54$) or subtherapeutic NCPAP (about 1 cm H₂O) ($n = 53$). All patients had telephone access to specialist nurses for advice, if needed.

MAIN OUTCOME MEASURES

Subjective daytime sleepiness (Epworth sleepiness score), objective daytime sleepiness (maintenance-of-wakefulness test), and self-reported scores for energy and vitality and for the mental component summary of the Short Form (SF)-36 questionnaire.

MAIN RESULTS

Patients in the therapeutic NCPAP group had greater use of NCPAP than did those in the subtherapeutic NCPAP group (5.4 vs 4.6 h/night, $P = 0.035$). Therapeutic NCPAP was associated with greater reductions in subjective daytime sleepiness (difference in Epworth sleepiness score between baseline and 1 month, -2.0 vs -9.0 ; $P < 0.001$) and

objective daytime sleepiness (difference in maintenance-of-wakefulness test between baseline and 1 mo, 0 vs 6.75 min; $P = 0.005$), and greater improvements in general health perception ($P = 0.002$), energy, and vitality ($P < 0.001$) and in the mental component summary of the SF-36 questionnaire ($P = 0.002$) than subtherapeutic NCPAP.

CONCLUSION

Therapeutic nasal continuous positive airway pressure reduced excessive daytime sleepiness and improved self-reported energy, mental well-being, and general health perception more than did subtherapeutic nasal continuous positive airway pressure in men with obstructive sleep apnea.

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*See Glossary.

COMMENTARY

Although NCPAP has been shown to be effective in abolishing sleep apnea in the sleep laboratory, few studies have shown its benefit among outpatients. No study has included an NCPAP placebo and examined benefits on hypersomnolence and quality of life. Moreover, concerns about patient compliance (1) raise the question of whether in-laboratory efficacy translates into effectiveness in the home. Questions about the reality of sleep apnea morbidity and the effect of NCPAP therapy on it have also been raised (2).

In this trial, patients were given NCPAP or sham NCPAP. This study shows that NCPAP can improve excessive daytime sleepiness, along with quality-of-life measures reflected in self-reported daytime functioning and well-being. This study also reinforces the findings by Ballester and colleagues (3) of an odds ratio of 6.52 for patient "treatment response" among those receiving NCPAP compared with those treated with conservative therapy alone.

Although the long-term benefits of conservative therapy, uvulopalatopharyngoplasty, and mandibular advancement devices have not been shown, these studies clearly support NCPAP as the treatment of first choice not only in the laboratory but in the

home as well. The ongoing Sleep Heart Health Study is likely to show that sleep apnea has morbidity, and perhaps even mortality, associated with it. The long-term effect of NCPAP on these outcomes remains to be shown. However, the association of daytime sleepiness with sleep apnea, and the reversal of it, along with improvement in quality of life after NCPAP therapy, is no longer in question.

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