Clinical trials in obstructive sleep apnoea

TOMADO: A CROSSOVER RANDOMISED CONTROLLED TRIAL OF ORAL MANDIBULAR ADVANCEMENT DEVICES FOR OBSTRUCTIVE SLEEP APNOEA-HYPOPNOEA

Introduction Obstructive sleep apnoea-hypopnoea (OSAH) causes excessive daytime sleepiness (EDS), impairs quality of life (QoL), and increases cardiovascular disease and road traffic accident risks. Continuous positive airway pressure therapy is effective but undermined by intolerance and cost effectiveness is borderline in milder cases. Mandibular Advancement Devices (MADs) are another treatment option but evidence is lacking regarding their effectiveness compared to no treatment in milder disease. This study compared clinical and cost effectiveness of a range of MADs and no treatment in these patients.

Methods This 4-period, randomised, controlled crossover trial was undertaken at a UK sleep centre. Adults with mild to moderate OSAH and EDS (Apnoea-Hypopnoea Index (AHI) 5–<30/ hour; Epworth Sleepiness Scale score (ESS) > = 9) underwent 6 weeks of treatment with three non-adjustable MADs: self-moulded (SP1); semi-bespoke (SP2); fully-bespoke (bMAD); and 4 weeks no treatment. Primary outcome was AHI scored by a polysomnographer blinded to treatment and analysed by intention to treat. Secondary outcomes included ESS and QoL. Cost effectiveness was evaluated using validated tools, treatment costs and healthcare usage.

Results Ninety patients were recruited. Sixteen withdrew before trial end. Seven did not complete any treatment and were excluded from analyses. All devices reduced AHI against no treatment, by 26% (95%CI 11%, 38%, p = 0.001) for SP1 to 36% (95%CI 24%, 45%, p < 0.001) for bMAD. ESS was 1.51 (SP1) to 2.37 (bMAD) lower versus no treatment (p < 0.001 for all). Compliance was lower for SP1 which was unpopular at trial exit. All devices were cost-effective compared with no treatment at a willingness to pay (WTP) of £20,000/quality-adjusted life year (QALY), based on mean costs and QALYs. SP2 was most cost-effective up to a WTP of £39,800/QALY after which, bMAD superseded it. Serious adverse events occurred in four patients (4%).

Conclusions Mandibular Advancement Devices achieve clinically important improvements in mild to moderate OSAH syndrome and are cost effective. A semi-bespoke non-adjustable MAD would appear to be the appropriate first choice in most patients. Future work should explore whether adjustable MADs give additional clinical and cost benefits in this patient group.

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EFFECT OF CONTINUOUS POSITIVE AIRWAY PRESSURE (CPAP) THERAPY ON COGNITIVE FUNCTION IN OLDER PEOPLE WITH SLEEP DISORDERED BREATHING (SDB) AND CO MORBIDITY

Objective To evaluate the effectiveness of continuous positive airway pressure (CPAP) in reducing blood pressure, sleepiness and sleep apnoea severity in patients with minimally symptomatic obstructive sleep apnoea (OSA).
Design  Systematic review and meta-analysis using individual participant data.

Data sources  Individual patient data were obtained from eligible randomised controlled trials found by searching the electronic databases Medline, Embase and the Cochrane Central Register of Controlled Trials and reference lists of all identified articles.

Eligibility criteria for selecting studies  Trials were eligible if they included patients with minimally symptomatic OSA, had randomised them to receive CPAP or either sham-CPAP or no CPAP, and had measured blood pressure at baseline and at a follow-up visit.

Results  Five eligible trials were found (1219 patients) from which the necessary data from four studies (1206 patients) was obtained. There was some evidence that CPAP treatment was associated with a small increase in systolic blood pressure of 1mmHg (95% confidence interval: -0.1 to 2.2), p = 0.079, with a larger increase in those patients using CPAP less than four hours/night ( + 2.7mmHg, 95% CI (1.1 to 4.2), p = 0.001). There was no overall effect on diastolic blood pressure (DBP), however, there was evidence of a reduction in DBP in patients using CPAP more than four hours/night ( -2.1mmHg, 95% CI (-2.1 to -0.3), p = 0.013) and an increase in those using it less than four hours/night ( + 1.2, 95% CI (0.1 to 2.3), p = 0.035). CPAP treatment reduced both subjective sleepiness and OSA severity (both p<0.001), with larger reductions in patients using treatment more than four hours/night.

Conclusions  Although CPAP treatment reduces OSA severity and sleepiness, it seems not to have a beneficial effect on blood pressure (and possibly a detrimental effect on systolic BP) in patients with minimally symptomatic OSA, unless they use CPAP for more than four hours a night.

Short term use of continuous positive airway pressure (CPAP) by obese patients with obstructive sleep apnoea syndrome (OSAS) diagnosed during assessment for bariatric surgery

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Introduction  Advice about driving is a key component of the management of OSAS patients. No objective tests have been shown to predict reliably whether an individual is safe to drive or not and therefore the advice given will depend upon the opinion of clinicians. We evaluated the current practice of advice given regarding fitness to drive in OSAS patients.

Methods  Clinicians were invited to participate in a web-based survey. The questionnaire included six clinical vignettes describing a variety of OSAS patients. For each the respondent chose from options ranging from driving without restriction to advising not to drive at all. For ease of presentation the data are summarised as whether would allow driving or not.

Results 467 respondents completed the survey. The advice given by the respondents to various clinical vignettes was variable (figure-1). In the least contentious scenario (vignette-1) there was 1 in 14.6 chance and in the most (vignette-4) there was a 1 in 2 chance of an individual being told whether they could drive or not. Respondents were more likely to advise patients to refrain from driving if the AHI was worse (P < 0.0001, OR=3.9), if the Epworth sleepiness score was high (P< 0.0001, OR=23.5) and if OSA severity was more severe (P<0.0001, OR=23.5) and if OSA severity was more severe (P<0.0001, OR=23.5).