BSS Abstract – TOMADO Yr2

Presentation Type: Poster Presentation

Title: Randomised Controlled Trial of Mandibular Advancement Devices for Obstructive Sleep Apnea (TOMADO): Two year follow-up

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Source of funding: This project was funded by the National Institute for Health Research Health Technology Assessment (NIHR HTA) Programme (project number 08/110/03) and is published in full in Health Technology Assessment. The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the HTA programme, NIHR, NHS or the Department of Health.

Abstract:

Objectives: Mandibular advancement devices (MAD) are used to treat obstructive sleep apnoea-hypopnoea syndrome (OSAHS). The TOMADO study demonstrated clinical and cost-effectiveness of a range of MAD against no treatment in mild to moderate OSAHS[1]. Here we present 1 and 2 year follow-up data.
Methods: The open-label, randomised, controlled, crossover trial recruited 90 adults with Apnoea-Hypopnoea Index 5-<30/hour and Epworth Sleepiness Scale (ESS) score ≥9 to undergo 6 weeks of treatment with 3 non-adjustable MADs: self-moulded (SP1); semi-bespoke (SP2); bespoke (bMAD); and 4 weeks no treatment. Outcomes recorded 1 and 2 years after trial exit included ESS, treatment satisfaction and compliance.
Results: Sixty of the 74 (81%) patients who completed the trial continued treatment with a MAD. After 1 year, 40 of the 58 patients completing follow up continued the same treatment, with 32 (53%) still using a MAD (6 SP1, 9 SP2, 17 bMAD). Patient reported MAD compliance averaged 7 hours/night for 88% of nights.
After 2 years 38 patients completed follow-up. Of these 20 (a third of those choosing a MAD at trial exit) still used one (5 SP1, 8 SP2, 7 bMAD). Compliance averaged 6.6 hours/night for a mean of 81% of nights, but was device-dependent (4.6 SP1, 7 SP2, 7.5 bMAD /hours). Treatment satisfaction remained high and sleepiness (ESS) within normal range for those still using a device.

Conclusions: Longer term outcomes assessment of MAD therapy is often limited by attrition of the sample size from patients being lost to follow-up[2]. However our data are similar to others' in showing that a proportion of patients continue using MAD in the longer term, with good compliance and continued benefit[2].

Reference

1. Quinnell et al. Thorax 2014;69:10 938-945
2. Doff et al. SLEEP 2013;36(9):1289-1296

Word Count: 285 words
(MAX:300)