

Surgical procedures and non-surgical devices for the management of non-apnoeic snoring: a systematic review of clinical effects and associated treatment costs

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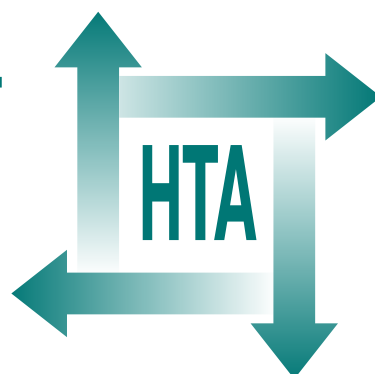
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Executive summary

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Executive summary

Background

Snoring is the hallmark symptom of a spectrum of sleep-related breathing disorders (sleep-disordered breathing, SDB). The pathophysiological cause of SDB is sleep-induced airway obstruction. Minimal airway obstruction causes non-apnoeic, or simple, snoring. At the other extreme, complete airway obstruction causes obstructive sleep apnoea syndrome (OSAS).

Snoring is very common in the general population, with around 35–45% of men and 15–28% of women reporting habitual snoring. However, although the clinical significance of non-apnoeic snoring remains equivocal, its psychosocial impact is easily recognised. Loud intrusive snoring affects bed partners, family and even neighbours. Noise pollution and its resulting social disability and relationship disharmony is an important reason why an individual will seek medical advice.

There are a number of surgical procedures and non-surgical devices for the management of non-apnoeic snoring, and the most appropriate treatment option depends on the level of airway obstruction, the intensity of the snoring sound, and the characteristics of the individual patient. Prior to being considered for surgery or use of a CPAP machine all patients must have a diagnosis of sleep apnoea excluded by undergoing either overnight polysomnography (PSG) or modified PSG. Additionally, the site of airway obstruction will be examined to ensure adequate patient selection for each procedure.

Objectives

To review the evidence on the clinical effects and associated treatment costs of surgical procedures and non-surgical devices for the management of non-apnoeic snoring.

Methods

A systematic review was undertaken. MEDLINE, EMBASE, CINAHL, Cochrane Controlled Trials

Register (CCTR) and NHS EED were searched for relevant studies of clinical effects and treatment costs published between 1980 and 2007.

Randomised controlled trials (RCTs), cross-over trials, controlled clinical trials (CCTs), and pre-post studies that reported an objectively assessed outcome measure in patients eligible for surgical procedures or the use of non-surgical devices for non-apnoeic snoring were included. Non-surgical devices included were: continuous positive airway pressure (CPAP); mandibular advancement splints (MAS); and tongue-retaining devices (TRD). Surgical procedures included were: surgery for coincidental nasal obstruction; uvulopalatopharyngoplasty (UP3) with or without tonsillectomy; laser-assisted uvulopalatoplasty (LAUP); uvulopalatal elevation palatoplasty (UEP); uvulectomy alone; palatal stiffening techniques (injection snoreplasty, cautery-assisted palatal stiffening, diathermy assisted uvulopalatoplasty, Pillar implants); radiofrequency ablation (RFA) of the soft palate or tongue base; and tongue base suspension procedures. Studies of mandibular/maxillary advancement procedures were excluded. All interventions were compared with each other, placebo, lifestyle modification techniques or no intervention.

Outcome measures of interest were objective snoring sound indices; patient- and/or bed partner-reported snoring severity; PSG parameter measurements; and cephalometric radiographs or magnetic imaging scans of palatal width or length. Treatment complications and the need for repeat procedures were also assessed.

Review methods and data synthesis

Studies were screened for inclusion, data extracted, and quality assessed independently by two reviewers. Results were broadly grouped according to the intervention and comparator, where applicable, and study design. Results were combined using a narrative synthesis with relevant quantitative results tabulated.

Treatment costs

The indicative costs of the surgical procedures and non-surgical devices included initial treatment costs, as well as the ongoing costs of care associated with the interventions. The cost of diagnostic tests, i.e. PSG or modified PSG to exclude a diagnosis of sleep apnoea, were not included in the treatment costs. No studies were identified by the searches that had assessed the costs associated with any of the included interventions. Costs were therefore estimated based on the NHS reference costs (2006), data from device manufacturers, and clinical opinion. It was not possible to estimate a cost associated with RFA of the soft palate or tongue base, as the cost of the somnoplasty generator and electrodes was considered to be 'commercial in confidence' on approach to the device manufacturers, and was not otherwise available in the public domain.

The limited analysis of rough cost estimates for the other surgical procedures assumed that each procedure would entail an initial consultation with an ear, nose and throat (ENT) surgeon, specific inpatient or day-case procedure time, device costs (where relevant) and a follow-up consultation. For UP3 it was assumed that the procedure would entail an inpatient stay of 1 day, and for LAUP (which can be conducted as a 1-, 2- or 3-stage sequential procedure) that each additional procedure was associated with one additional follow-up visit. For CPAP, as there are numerous machines and face masks available, the mean cost of the devices available was used and a device life of 7 years with an annual replacement cost of the face mask assumed. Additionally, it was assumed that patients would undergo an initial consultation and a session with a specialist nurse for device titration. For costs associated with MAS, it was assumed that the dentist provided a Thornton Adjustable Positioning® (TAP) device, and that the device life was 2 years. For each subsequent year of MAS use, it was assumed that an annual check-up would be necessary. Costs of both the CPAP machine and MAS were expressed as equivalent annual costs using the discount rate of 3.5%.

Results

A total of 1903 titles and abstracts were screened for inclusion, with 27 studies reported in 30 publications meeting the inclusion criteria. The identified studies assessed a broad range of interventions. These could broadly be grouped into studies assessing UP3 versus LAUP ($n = 2$),

UP3 alone ($n = 7$), LAUP alone ($n = 3$), palatal stiffening techniques (Pillar implants and injection snoreplasty) ($n = 5$), RFA of the soft palate or tongue base ($n = 7$), CPAP ($n = 1$) and MAS ($n = 2$). No studies were identified that assessed surgery to improve coincidental nasal obstruction alone, uvulectomy alone, DAUP or tongue base suspension procedures.

Studies were generally of a low methodological quality with small sample sizes. A total of 1191 patients had been included. The evidence consisted of three randomised controlled trials (11%), two controlled clinical trials (7.5%), and 22 pre-post studies (81.5%). In the five controlled studies, very few between-group comparisons were reported, with data analysed as a change in the pre- and post-treatment mean for each group separately. Lack of any between-group comparisons and heterogeneity between the studies in the interventions assessed, treatment protocols and outcome measures means that few between-study comparisons could be drawn.

Uvulopalatopharyngoplasty versus laser-assisted uvulopalatoplasty

On subjective measures of snoring, evidence from one RCT ($n = 47$) and one CCT ($n = 60$) on the effects of UP3 versus LAUP is equivocal. Where there were significant differences between the procedures, these favoured treatment with UP3 ($n = 45$), but on other measures there were no significant differences. This finding is consistent with evidence that both procedures were effective at reducing the number of snores per hour postoperatively ($n = 23$), but there were no significant differences between the procedures. Additionally, both UP3 and LAUP were effective at reducing snoring loudness ($n = 23$), but this reduction is modest (3.8 dB). Adverse events between the two procedures were comparable ($n = 47$), except for levels of postoperative pain, which were significantly higher in the UP3 group ($n = 18$).

Uvulopalatopharyngoplasty alone

Evidence on the effects of UP3 from seven pre-post studies ($n = 538$) shows that UP3 is effective in reducing a number of subjectively reported snoring indices. Overall results from four studies that assessed objective measures of snoring sound parameters were equivocal ($n = 184$). Postoperative pain, where reported, was moderate, but all morbidity associated with the procedure was minor.

Laser-assisted uvulopalatoplasty alone

Limited evidence from three pre–post studies ($n = 58$) on LAUP supports the fact that subjectively assessed snoring status or scores were improved after the procedure. None of the studies on LAUP had assessed objectively evaluated snoring sounds. Levels of postoperative pain were mild to moderate, and all adverse events were minor.

Radiofrequency ablation of the soft palate

Results from six pre–post studies ($n = 142$) show that RFA is associated with a postoperative reduction in partner-assessed snoring intensity. Snoring intensity was reduced from a mean pre-treatment range of 6.5–8.4 to a mean post-treatment range of 2.75–5.2 as assessed on a 10-point visual analogue scale. Evidence for effects of RFA on an objective reduction in snoring sound levels from three studies ($n = 50$) is mixed. Levels of postoperative pain, swallowing, speech, taste and pharyngeal irritation were rated as low to moderate. Rates of mucosal blanchings and erosions ranged from 15% to 40%.

Pillar implants

Four pre–post studies ($n = 107$) indicated that Pillar implants are effective at reducing partner-rated snoring intensity. Snoring intensity was reduced from a mean pre-treatment range of 7.1–7.9 to a mean post-treatment range of 4.7–4.8. Evidence on the effects of Pillar implants on objective snoring indices from one study ($n = 40$) showed no significant differences between pre- and post-treatment levels. Postoperative pain levels were either mild or moderate, whilst swallowing and speech difficulties were rated as mild. The rate of implant extrusions ranged from 0% to 11%.

Continuous positive airway pressure

The only available evidence on the effects of CPAP for the treatment of non-apnoeic snoring came indirectly from a two-group parallel pre–post study with nine patients in the treatment group. Results showed that use of CPAP at 5.3 cmH₂O (range: 3–8 cmH₂O) reduced the number of snores per hour from a mean of 387 (SD: 150) to a mean of 15.1 (SD: 2.5). No subjective snoring scores were evaluated.

Mandibular advancement splints

Evidence on the effects of MAS from three studies ($n = 72$) was limited to objective snoring sound outcomes. This suggests that MAS significantly improve a number of objective snoring sound parameters. Data from one study ($n = 35$) reporting adverse effects showed that the percentage of minor side effects was relatively high, particularly for muscular and temporomandibular joint discomfort in the initial days of MAS use. Minor side effects remained relatively common but these all decreased within the first month of use.

Summary of costs

Limited analysis indicates that the cost for UP3 is approximately £1230, assuming that patients have a 1-day hospital stay, but rises to approximately £1550 if patients require an additional day of hospitalisation. For LAUP, the cost associated with one procedure is approximately £790 but rises to £1430 for a two-stage sequential procedure and £2070 for a three-stage procedure. The treatment costs associated with the use of Pillar implants range from £1110 to £1160 (depending on the manufacturer's discount). When use of either a CPAP machine or MAS is considered, the approximate annual treatment costs associated with the use of each device are £220 and £130 respectively.

Conclusions

There appear to be no consistent significant differences in effects between UP3 compared with LAUP on snoring levels. UP3, LAUP, RFA of the soft palate and Pillar implants are all associated with a significant reduction in patient- or bed partner-reported snoring levels. However, the rate of relapse on subjectively assessed outcomes is variable and ranges from approximately 6% to 24%, depending on the procedure and the length of postoperative follow-up. There is no strong evidence that subjectively assessed snoring outcomes are associated with objective reductions in snoring sound levels.

Very limited evidence on CPAP and MAS shows that both devices are associated with a significant reduction in objective snoring sound parameters, which if realised may translate into a significant reduction in bed partner-assessed snoring intensity.

In terms of UP3, LAUP and Pillar implants, there is no procedure that is clearly the least-cost option based on the crude and limited analysis conducted. For use of CPAP or MAS, use of MAS appears cheaper than use of a CPAP machine. However, there is considerable variation in the cost of both devices, and use of more expensive MAS and less expensive CPAP machines may reverse the cost relationship.

Publication

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NIHR Health Technology Assessment Programme

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Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search, appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

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