A MODEL TO FACILITATE OUTCOME ASSESSMENT OF OBSTRUCTIVE SLEEP APNEA

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Abstract

Objectives: Obstructive sleep apnea is a common disorder with significant morbidity and effects on quality of life. Management can include a range of mechanical, behavioral, and surgical approaches. This paper aims to devise a model of management options to assist in initial cost-effectiveness investigations.
Methods: In the absence of practice pattern data and widely accepted guidelines, we reviewed published literature and devised a model of treatment options to facilitate initial studies of outcomes, costs, and cost-effectiveness.
Results: Obstructive sleep apnea is rarely addressed by conservative behavioral-based strategies because these options, while inexpensive, have only limited effectiveness. Effective treatment most often relies on nasal continuous positive airway pressure, but poor tolerance or compliance sometimes leads to treatment with oral appliances or surgery. Patients treated by one modality may try another if the initial strategy is ineffective. Laboratory evidence that sleep apnea is effectively treated, and long-term follow-up, are necessary regardless of the treatment modality chosen.
Conclusions: Each patient's treatment plan must be individually tailored, but the management model proposed here reflects available evidence-based literature and the authors' impression of current practice patterns. This model should be useful for initial cost-effectiveness investigations.

Keywords: Obstructive sleep apnea, Continuous positive airway pressure, CPAP, Oral appliance, Uvulopalatopharyngoplasty, Maxillary and mandibular advancement, Genioglossus advancement, Hyoid suspension, Outcome, Model

Obstructive sleep apnea syndrome (OSAS) is characterized by recurrent upper airway obstruction and cessation of breathing during sleep (45). A population-based survey of 3,513 middle-aged adults followed by polysomnography in a defined subsample of 602 subjects suggested that 2% to 4% of the original sample had OSAS (2;65). In this study, OSAS was defined as five or more apneas or hypopneas per hour of sleep in association with excessive daytime sleepiness. Another population-based study of 2,202 adults reported a minimum prevalence of 3.6%, based only on the presence of 15 or more apneas or hypopneas per hour of sleep (39). A third study used a location-stratified probabilistic approach, based on 1991 U.K. census data, to survey 4,972 adults and estimate that 1.9% met internationally-defined history-based criteria for OSAS (38). Despite lack of uniformity in research criteria for OSAS and uncertainty about the extent to which even milder (and more common) levels

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of OSAS could have adverse impact on health (48), population-based studies consistently suggest that clinically significant OSAS affects a large number—2% or more—of adults. Furthermore, most patients with OSAS are not yet treated (64).

Acute consequences of OSAS include arousals, sleep fragmentation, and recurrent hypoxemia that can be extreme, with oxyhemoglobin saturation below 50%. Chronic consequences include excessive daytime sleepiness, impaired cognition, cardiovascular complications, and decreased health-related quality of life (HRQOL) (6). As recently as 1997, health outcomes specialists—sponsored by a government health service more reluctant than some to support OSAS treatment—concluded that randomized controlled trials do not yet show that OSAS has consequences other than excessive sleepiness (63). However, this report elicited much disagreement (1;10;13), and subsequent randomized controlled trials documented that effective treatment of OSAS provides improvement in sleepiness(14;15), cognitive ability (12), mood (12), blood pressure (15), HRQOL (15), and bed-partner sleep quality (32). Even patients with mild levels of OSAS (sleepiness and 5 to 15 apneas or hypopneas per hour of sleep) also showed most of these effects in a randomized controlled trial (11). Additional clinical evidence from studies with less rigorous design nonetheless suggest that OSAS leads to systemic or pulmonary hypertension (16;21), cardiac arrhythmias, cor pulmonale, polycythemia, occupational accidents, motor vehicle accidents (37), and increased mortality (18). Predisposing risk factors for OSAS include upper-body obesity, adenotonsillar hypertrophy, retrognathia, hypothyroidism, nasal obstruction, and evening alcohol ingestion (57).

The standard treatment for most patients with OSAS is continuous positive airway pressure (CPAP), administered by a nasal mask worn during sleep. Other treatment options include behavioral strategies (e.g., sleeping in a lateral position), weight loss, medication (e.g., to relieve chronic nasal obstruction), oral appliances that help to open the throat, and a variety of surgical procedures (43). However, little work has been done to compare these treatments or their outcomes. Such data are central to determination of cost-effective management of obstructive sleep apnea (40;55), an essential goal because more than 80% of men and 90% of women who have OSAS are not yet diagnosed or treated.

Although any individual's treatment for OSAS involves many considerations, a schematic, generally applicable representation of current approaches would facilitate calculations of utility, cost, and cost-effectiveness of different approaches. This paper describes current management options and proposes a model that could be useful in relevant cost-effectiveness models (8).

METHODS

To review the literature on management of OSAS, we used Ovid MEDLINE (National Library of Medicine, 1966–2001) and performed a systematic search of English-language journals and other electronic databases. We used major MeSH headings and text words, including "sleep," "sleep apnea," "obstructive sleep apnea," "treatment," and "clinical management." In addition, we evaluated selected references cited in articles for pertinence and applicability, and we scanned recent sleep and otolaryngology journals to avoid omission of applicable articles not yet indexed. All articles that appeared to be reviews, original research studies, or opinion pieces were reviewed. The results were used to generate a model for studying the cost-effectiveness implications of OSAS treatment options.

TREATMENT OPTIONS

Obesity is common in patients with OSAS, and weight loss reduces OSAS severity (22;29). However, many people cannot lose substantial weight, those who do rarely maintain their

reduction (51), and even significant weight loss often fails to control OSAS completely (44;58). Therefore, weight loss is rarely sufficient treatment (5). Positional therapy is another conservative treatment option: sleeping in a lateral rather than supine position sometimes treats OSAS effectively, with success rates between 40% and 70% (19). A third conservative approach requires avoidance of alcohol and sedatives, which worsen obstructive sleep apnea (5;19).

Nasal CPAP is an effective treatment for OSAS (5) and usually is recommended as the treatment of choice. The machine generates a pressure determined in a sleep laboratory, or in some cases automatically by the machine, to be most effective. For many patients who use it at home regularly, CPAP eliminates apneas, improves sleep architecture, and reduces daytime sleepiness. However, tolerance can be limited by discomfort, claustrophobic reactions to the nasal mask, nasal congestion, and conceptual distaste for long-term use of the apparatus. Compliance with CPAP has been reported to range between 46% and 90% (23;24;25;49). Several strategies have been proposed to increase CPAP compliance (42), including careful attention to mask selection (46), frequent telephone follow-up, brief written guidelines (9), active support during initial treatment (41), and weight reduction to allow lower CPAP pressures (47).

The most common type of oral appliance advances the jaw, and with it the tongue, to reduce upper airway obstruction during sleep. Oral appliances are more often effective in mild to moderate OSAS than in more severe OSAS (31;43;51), but can offer a relatively low-cost and low-risk alternative to CPAP. One randomized clinical trial has demonstrated effectiveness (33). Unfortunately, little is known about how to predict which patients will respond well. Patients whose sleep apnea occurs primarily while supine may benefit more than others. The American Sleep Disorders Association Standards of Practice Committee recommends the use of appliances in the following situations: snoring without OSAS, mild OSAS with poor response to behavioral treatments, and moderate to severe OSAS with intolerance or refusal of nasal CPAP and surgery (3).

Before surgery for OSAS, an evaluation to localize the sites of obstruction is recommended, though incomplete understanding of the pathophysiology of OSAS still makes formulation of surgical strategies challenging (60;62). The uvulopalatopharyngoplasty (UPPP) is the most common surgical procedure for treatment of adult OSAS (36). The soft palate, uvula, redundant pharyngeal tissues, and sometimes the tonsils are removed (51). Success rates vary widely between studies, by approximately 50% (4;7;8;17;27;34;35;61), and long-term outcomes have not been well studied (45). The UPPP is less effective when multiple craniofacial abnormalities are present (62), multiple sites of obstruction exist, or OSAS is severe. Some successfully treated patients later relapse, especially after weight gain (20;26;30). Addition of genioglossus advancement (GA) and hyoid suspension (HS) to relieve retroglossal obstruction may increase success rates in some cases (50;53;54).

Laser-assisted uvulopalatoplasty (LAUP) is a relatively new outpatient alternative to the more traditional UPPP (45). Efficacy diminishes as apnea severity increases, from 71% in mild OSAS to 37% in severe OSAS (28). Currently available evidence is considered inadequate to support routine use of LAUP in the treatment of OSAS (56). Radiofrequency volumetric reduction (heat-mediated scarring) of the tongue or soft palate may reduce OSAS, but insufficient efficacy data have been published.

In maxillary and mandibular advancement (MMA), the forward repositioning of the tongue enlarges the retrolingual airway (45), and high success rates (98% or 89/91) have been reported (50). The procedure is often a last resort for severe OSAS; in comparison to other available surgical procedures, MMA involves more complexity, length, recovery time, and cost (19). A final surgical treatment for OSAS is tracheostomy, which bypasses the upper airway obstruction and is nearly always successful (45). However, chronic maintenance

requires careful hygiene to avoid recurrent infections, and social consequences are often significant (59).

Combinations of treatment approaches are sometimes necessary. Multiple surgical procedures may be required, either simultaneously or in sequence (53). Many patients who have surgery still require CPAP, and an oral appliance also may be used after unsuccessful surgery (36). Postoperative patients require polysomnography to confirm that OSAS has resolved. Regardless of treatment approach, patients usually require some long-term clinical follow-up to ensure lasting adequacy of treatment.

CLINICAL APPROACH AND MODEL OF TREATMENT FOR OSAS

Management of OSAS varies based on outcome data and the background, expertise, and attitudes of treating physicians. However, the experience of most adults with OSAS is summarized by the decision tree shown in Figure 1. When OSAS is first suspected, several conservative behavioral recommendations can be given with low cost but limited benefit: gradual weight loss (for obese patients), avoidance of sedatives and alcohol late in the day, and avoidance of a supine sleeping position. The large majority of OSAS patients receive nasal CPAP as primary treatment. They must receive medical follow-up for the duration of their treatment, initially at short intervals and then at longer intervals once effective therapy and adequate compliance have been established. Initial problems with CPAP must be addressed as soon as possible, but if they persist, oral appliances or surgical procedures are the most common alternatives. Although LAUP, radiofrequency volumetric reduction of the tongue, and tracheostomy may be considered, their limitations often leave the following as main considerations: mandibular advancement device, UPPP, UPPP with GA and HS, and MMA (Figure 1). Oral appliances tend to be favored when OSAS is mild and the patient is averse to surgery. A surgical approach may be the best strategy for a potential "cure" when compliance with other treatments is unlikely, in the presence of tempero-mandibular joint pain or disease, or when dentition will not support an oral appliance.

If an oral appliance is used, patients who become asymptomatic may require polysomnography to ensure that OSAS is reduced sufficiently to eliminate long-term

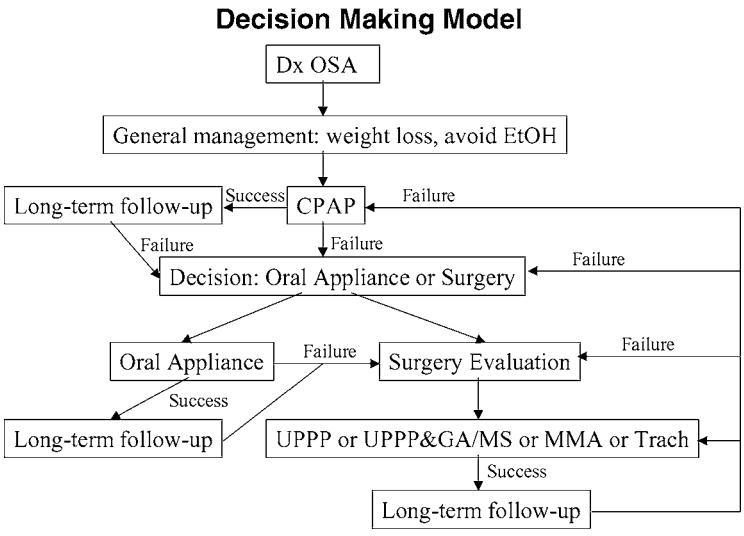

Figure 1. Decision-making model for management of obstructive sleep apnea.

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cardiovascular risk. Patients still symptomatic with use of oral appliances can consider repeat trials of CPAP, but in many cases surgery becomes an important option.

When preoperative evaluations reveal upper airway obstruction at the level of the soft palate, UPPP is frequently recommended. Some patients also have obstruction lower down, at the retrolingual level, and may be candidates for GA/HS. Patients with severe OSAS and retrolingual obstruction are candidates for MMA or tracheostomy. If postoperative assessment of symptoms and polysomnographic results do not indicate adequate control of OSAS, additional surgical procedures, oral appliances, or retrial of CPAP may be suitable options. In some cases, UPPP may be followed by GA/HS, and occasionally an initial UPPP with or without GA/HS may be followed by MMA. The optimal CPAP setting or oral appliance conformation may be different after surgery, and operative failures must be re-evaluated in a sleep laboratory or dentist's office if treatment with CPAP or an oral appliance is reconsidered.

CONCLUSIONS

Obstructive sleep apnea is a condition with high prevalence and morbidity, but most patients are not yet diagnosed or treated. Cost-effectiveness studies of treatment options are needed to help guide potentially enormous expenditures for this major public health challenge. However, standardized approaches to treatment of OSAS, and particularly OSAS refractory to CPAP therapy, do not exist. Although individuals' management must be determined on a case-by-case basis, this paper outlines a treatment model that has some evidence-based justification and reflects current medical practice. Relevant practice pattern studies are scant and will be needed to confirm the validity of this model. In the meantime, the schema outlined here may prove useful as the basis for initial outcome, cost, and cost-effectiveness analyses of treatments for OSAS.The following are important points to consider in treating OSAS:

1. OSAS is a common disorder with substantial morbidity but no widely accepted standardized management guidelines;
2. Treatment options include nasal CPAP, oral appliances, and several surgical procedures, and some patients must try more than one approach before effective control of sleep apnea is achieved; and
3. Although treatment must be individualized, the model outlined by the authors is supported by some published evidence, reflects their conception of current practice, and should allow initial studies of cost-effectiveness in the treatment of obstructive sleep apnea.

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