OHTAC

Recommendation

Oral Appliances for Obstructive Sleep Apnea

June 2009

OHTAC Ontario Health Technology Advisory Committee

Issue Background

The Ontario Health Technology Advisory Committee (OHTAC) met on June 26, 2009 to review the effectiveness and safety of oral appliances for the treatment of obstructive sleep apnea, based on an evidence based review produced by the Medical Advisory Secretariat.

Obstructive sleep apnea (OSA) is characterized by repeated occurrences of upper airway collapse and obstruction during sleep. OSA leads to excessive daytime sleepiness, diminished quality of life and increased risk of accidents, cardiovascular disease and death. In the general population, the prevalence of OSA estimated to be about 4% in men and 2% in women. Risk factors for OSA include obesity, male gender, increasing age, alcohol use, sedative use and a family history of OSA.

Oral appliances for OSA fall into 2 broad types: mandibular advancement splints (MAS) (also known as mandibular repositioning devices) and tongue repositioning (or retaining) devices. The aim of the MAS devices is to advance the mandible forward slightly to enlarge the upper airway, and prevent it from collapse. Similarly the tongue repositioning devices suction the tongue forward to prevent it from falling back and obstructing the airway during sleep.

The alternatives to oral appliances include continuous positive airway pressure devices (CPAP), surgery, drug therapy, positional devices and lifestyle modification. CPAP is the gold standard for the treatment of obstructive sleep apnea. Despite its effectiveness, CPAP has decreased compliance rates because the system is noisy and wearing the mask can be uncomfortable and cause claustrophobia in some users.

OHTAC Findings

Five systematic reviews and 16 randomized controlled trials were identified which met the inclusion criteria.

The systematic reviews consistently concluded that CPAP was more effective than oral appliances at improving sleep disordered breathing, although there may be opportunity for oral appliances, especially those with mild OSA, because CPAP is difficult to tolerate by some users.

Based on the results of the randomized controlled trials analyzed for this review, MAS devices are less effective than CPAP when AHI is used as the outcome of interest. MAS devices decrease AHI levels, however, whether this reduction is clinically meaningful is uncertain.

The Epworth Sleepiness Scale was not able to achieve statistical significance in comparisons between MAS and CPAP and MAS and placebo. Nonetheless, after treatment with either MAS or CPAP patients seem to be able to achieve normal ESS levels. The ESS has substantial limitations including the subjective nature of the scale and its low construct validity (i.e. it is unclear if the scale is an accurate measure of sleepiness).

The adverse events associated with the MAS devices in the randomized controlled trials were common, but mostly mild and transient. Jaw discomfort was the most commonly reported adverse event.

Based on the results of the RCTs included in this analysis, compliance does not seem to be better or worse with MAS or CPAP. Similarly, there is not a clear patient preference for MAS or CPAP in the studies that reported preference and satisfaction.

OHTAC Recommendations

- Since CPAP is more effective than oral appliances, the Ministry of Health and Long Term Care should continue funding CPAP through the Assistive Devices Program
- Patients should be informed that oral appliances are an option if they cannot tolerate CPAP. Potential adverse events of oral appliances should be discussed with patients.