## CPAP Alternatives Gaining Steam for Sleep Apnea

# Suboptimal CPAP compliance has led to growing use of oral appliances, maxillofacial surgery.

BY BRUCE JANCIN

From the annual meeting of the Associated Professional Sleep Societies

SAN ANTONIO — The days when continuous positive airway pressure was the only arrow in the quiver for physicians targeting obstructive sleep apnea are long gone.

The single most popular session at the annual meeting of the Associated Professional Sleep Societies—the one whose overflow crowds brought out the fire marshals in full force—was devoted to alternatives to CPAP that have come of age: oral appliances; maxillofacial surgery; and weight loss through diet and exercise, bariatric surgery, or drugs.

Session chair James K. Walsh, Ph.D., set the stage, citing studies showing that typically 50% of patients discontinue CPAP within 1 year.

Moreover, the percentage of nights patients use their CPAP drops after a couple of months from 50% to 40% and even 30%. An average of about 3 hours of use per night is the norm in clinical practice.

"The goal is to treat sleep apnea every night throughout the night. I'm not at all trying to suggest this therapy is totally in-



'I'm not at all trying to suggest [CPAP] therapy is totally ineffective, but I would term it highly suboptimal.'

DR. WALSH

effective, but I would term it highly suboptimal," declared Dr. Walsh, executive director of the sleep medicine and research center at St. Luke's Hospital in St. Louis.

While CPAP remains the guidelinerecommended gold standard therapy, many patients dislike sleeping while wearing a mask, and often their sleep partners aren't crazy about CPAP, either. Speakers at the session addressed the best-established alternatives.

#### **Oral Appliances**

This field has experienced phenomenal growth in recent years as a consequence of American Academy of Sleep Medicine guidelines declaring the devices are indicated for mild to moderate obstructive sleep apnea (OSA).

"For physicians, this is a particularly confusing field. There are more than 100 oral appliances on the market, and I've seen another four new ones introduced at this meeting. There's a lot of heavy marketing going on," said Dr. Alan A. Lowe, professor of oral health sciences and chair of the division of orthodontics at the University of British Columbia, Vancouver.

Not all of the devices have been approved by the Food and Drug Administration, and only seven are backed by clinical trials data. No single device is right for all patients. But as a general rule, the best results are achieved with devices that are adjustable in all planes in space, he stressed.

"The titration of an oral appliance is essential, and it takes weeks to months," Dr. Lowe said. "You don't just send patients home with a 'boil and bite' device



Oral appliances typically show an 80% success rate if the baseline apnea-hypopnea index is below 30 episodes/hour.

DR. LOWE

and say, 'Okay, off you go.' You need to go through the titration phase. So physicians who are prescribing oral appliances and just giving them to their patients might as well give them CPAP with a pressure of 7 mm Hg and send them home and tell them to wear it. It's absolutely useless to do that."

Oral appliances that have been subjected to formal trials typically show roughly an 80% success rate in patients with a baseline apnea-hypopnea index (AHI) below 30 episodes/hour, with the success rate dropping off to 60% in those with more severe OSA. Responders experience less daytime sleepiness, improved cognition, better results on simulated driving performance tests, and reductions in nighttime blood pressure and serum lipids.

When Dr. Lowe and his coinvestigators gave patients who were adherent to CPAP a trial period on an oral appliance, 55% subsequently switched over, while 30% maintained a clear preference for CPAP.

"Oxygenation improvement is always greater with CPAP because it forces air into the lungs. Oral appliances simply make the tube bigger and take away the obstruction," he explained.

Device titration needs to be done by a skilled dentist. The American Academy of Dental Sleep Medicine (www.aadsm. org/index.aspx) has roughly 1,600 dentist members, and is a useful resource for physicians seeking a local dentist experienced with oral appliances.

The main side effect associated with oral appliances is that they cause subtle tooth movement. In a series of 70 patients with full polysomnograms and dental records, Dr. Lowe found that only 10 had no change in dentition over time.

Of the other 60 patients, 29 had favorable changes in the fit and function of their teeth, whereas 31 had unfavorable changes.

"The issue is how we manage it. I have yet to stop a patient from wearing an oral appliance because of tooth movement that we couldn't manage somehow. It's not an issue of having to cease wear. When we weigh tooth movement against adequate oxygen to the heart, tooth movement loses.

"I'm trying to train the profession to think that way—panic less about tooth movement and think more about what the treatment is doing for the sleep-disordered breathing," continued Dr. Lowe.

Besides, his 3-year study of patients using classic CPAP masks showed that they, too, cause quantifiable changes in tooth position over time, he added.

#### **Maxillofacial Surgery**

Maxillomandibular advancement is a big operation, and it yields big results, said Dr. Kasey Li of Stanford (Calif.) University.

He cited a recent meta-analysis involving 627 patients who underwent maxillomandibular advancement (MMA). Their mean AHI dropped from 63.9 to 9.5 events/hour. Treatment success, defined as an AHI below 20, occurred in 86% of patients. A surgical cure, meaning an AHI below 5, was obtained in 43% of patients (Sleep Med. Rev. 2010 [doi:10. 1016/j.smrv.2009.11.003]).

This parallels Dr. Li's own experience,



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DR. LI

which includes 302 patients with pre- and post-MMA sleep data. The operation typically takes about 3 hours, with a 2-to 3-day hospital stay and return to work in 4-5 weeks.

As in the meta-analysis, there have been no postoperative deaths in Dr. Li's

The most common side effect is cranial nerve paresthesia, which typically resolves within 6-12 months. Four of Dr. Li's patients had severe malocclusion requiring revision surgery. Ninety percent of patients report being satisfied with their results.

A multivariate regression analysis performed as part of the meta-analysis identified four significant predictors of increased likelihood of MMA success: younger age, lower body mass index, less severe sleep apnea, and greater degree of maxillary advancement. This mirrors Dr. Li's experience as well.

"My enthusiasm for offering surgery to patients over age 60 goes down quite a bit. I'm fairly reluctant to offer surgery to patients with a BMI of 32-33 kg/m² or above, and you have to be able to advance the maxilla at least 10 mm in order to advance the airway. And the treat-

ment success rate is much higher in patients with an AHI in the 20s-40s than the 80s," the surgeon said.

Patients who have failed on oral appliances remain reasonable surgical candidates.

"The average advancement with an oral appliance is 4-7 mm, in comparison to 15-16 mm of maxillary advancement measured at the teeth level with surgery, in my experience," Dr. Li noted.

When asked if it makes sense to perform a less morbid soft tissue surgical procedure such as tonsillectomy or uvulopalatopharyngoplasty as a first-line operation for moderate to severe OSA, reserving MMA for the nonresponders, Dr. Li's answer was emphatically no.

"In the majority of patients, the entire airway is involved; the obstruction is at multiple levels. Surgical procedures that focus on one site often will not be successful," he said.

"The data over the past 10 years are very clear that patients with severe sleep apnea are not going to respond very well to soft tissue surgery, period. I tell patients that unless they're going to have MMA, they shouldn't bother with surgery. That's my personal bias, and I think it's supported by the data."

A prospective study comparing MMA to CPAP is in the planning stages at Stanford.

### **Weight Loss**

Too many physicians are jaded about this well-established but seriously underused treatment for OSA, according to Dr. Ronald R. Grunstein, professor of sleep medicine at the University of Sydney.

"I think we need to have a less nihilistic view about weight loss. We in sleep medicine are often still thinking very much in silos," he said.

Dr. Grunstein was first author of a large study with a 2-year follow-up period that demonstrated bariatric surgery to be a highly effective treatment for OSA in obese patients (Sleep 2007;30:703-10).

In addition, recent studies conducted in Finland (Am. J. Respir. Crit. Care Med. 2009;179:320-7) and Sweden (BMJ 2009; 339:b4609) have shown substantial improvement in OSA with weight loss achieved through a very-low-calorie diet plus exercise followed by a maintenance diet.

The bigger the weight loss, the greater the improvement in OSA as reflected in the reduction in AHI.

Promising pharmacologic alternatives to CPAP are also in development, and not all are weight-loss drugs.

Dr. Lowe disclosed that he is the inventor of the Klearway oral appliance, the royalties for which are assigned to the University of British Columbia, where they pay for much of his research. Dr. Walsh is a consultant to Ventus Medical Inc., which markets the Provent sleep apnea therapy device, which uses nasal expiratory positive airway pressure. Dr. Li and Dr. Grunstein reported no financial conflicts.