

Correspondence

Objective Measurement of the Therapeutic Effectiveness of Continuous Positive Airway Pressure versus Oral Appliance Therapy for the Treatment of Obstructive Sleep Apnea



To the Editor:

We read with great interest the article by Dr. Phillips and colleagues that reported on the 1-month results of a randomized crossover trial comparing the health effects of two treatment modalities for the management of patients with moderate-to-severe obstructive sleep apnea (OSA): continuous positive airway pressure (CPAP) treatment versus therapy with an oral appliance that reduces upper airway collapse by advancing the mandible (OA_m) (1). The results showed that health outcomes were similar after treatment with OA_m as compared with CPAP. These important findings are indeed likely to be explained by the greater efficacy of CPAP, in terms of a lower residual apnea-hypopnea index as compared with OA_m, being offset by inferior CPAP compliance relative to OA_m compliance, possibly resulting in equal overall effectiveness. In their conclusion, the authors advocate the need for long-term comparative effectiveness studies between CPAP and OA_m that include objectively measured compliance to better define treatment strategies for patients with OSA.

In Dr. White's accompanying editorial (2), he attributes the lack of objective compliance data for the OA_m therapy in the trial by Dr. Phillips and colleagues to the difficulty in obtaining objective usage data for the OA_m. In addition, Dr. White contends that a method to quantify OA_m effectiveness is needed on the basis of the well-documented experience that not all patients responded similarly to OA_m therapy, resulting in a residual apnea-hypopnea index greater than 20 or 30 per hour of sleep in a subset of the participants (1, 2). This method should allow physicians to determine the efficacy of OA_m before fabrication of the device for each individual patient.

We would like to emphasize the following: first, as the authors rightly point out (1, 2), objective assessment of compliance with both CPAP and OA_m is mandatory to assess the true night-to-night residual disease. Recently, we were able to report on the safety and feasibility of accurate, objective measurement of OA_m compliance in a 3-month prospective clinical trial using an embedded microsensor thermometer in the OA_m of 51 consecutive patients with OSA (3). Our one-year results confirm the safety and feasibility of this method to obtain long-term data regarding objective compliance during oral appliance therapy for OSA (4). Indeed, measurement of objective OA_m compliance allows for calculation of the mean disease alleviation, which is the product of objective compliance and therapeutic efficacy, as a measure of the overall therapeutic effectiveness (3).

Second, we underline the need for prospective identification of favorable candidates for OA_m therapy in the treatment of OSA. As mentioned by Dr. White (2), one should avoid fabricating and testing the OA_m in each patient before confirming that OA_m therapy is appropriate for a particular patient. Some of the many possible techniques for mimicking OA_m wear are to perform a mandibular titration sleep study with a remotely controlled mandibular positioner (5) or to use a simulation bite approach during drug-induced sleep endoscopy (6). Both the remotely controlled mandibular positioner and the simulation bite approach have the clear advantage of providing a reproducible mandibular advancement maneuver and adequately

accounting for the given vertical opening of a particular OA_m. Both devices can be applied during awake endoscopy or imaging studies as well as during drug-induced sleep endoscopy or overnight sleep studies (5–7).

In conclusion, we would like to join Dr. Phillips and colleagues in recommending long-term research on the comparative effectiveness of different treatment modalities for the management of OSA. We particularly emphasize the necessity to obtain objective measurement of OA_m use for all future clinical trials evaluating OA_m therapy. Improving the ability to predict OA_m outcome prospectively in the individual patient should be another important goal of the research agenda.

Author disclosures are available with the text of this letter at www.atsjournals.org.

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Reply

From the Authors:



We thank Dr. Vanderveken and colleagues for their insightful comments about our recent comparative effectiveness study exploring health outcomes with continuous positive airway pressure (CPAP) and oral appliance (OA_m) treatment for obstructive sleep apnea (OSA) (1).



It was unfortunate that compliance technology for oral appliance devices was not available at the time of our study. Accordingly, in our article, we acknowledged the limitations of subjective measures of OA_m compliance but argued that self-reported nightly use may well be similar to objectively determined use on the basis that the study by Dr. Vanderveken and colleagues found no difference between objective and subjective compliance over the first 3 months of use (2). This important study by Dr. Vanderveken was able to derive a measure of overall therapeutic effectiveness by combining measures of OA_m efficacy and compliance adjusted for self-reported total sleep time (2). The ability to derive a measure of overall therapeutic effectiveness (reflecting disease alleviation) is a crucial component in being able to conduct long-term comparative effectiveness trials between CPAP and oral appliance therapies. In this regard, we endorse the work of Dr. Vanderveken and colleagues and eagerly await the results of their 1-year follow-up study. It is important, however, to appreciate that measures of long-term therapeutic effectiveness will still be reliant on accurate reporting of total sleep time.

We fully agree that there is a great need for prospective identification of favorable candidates for OA_m in the treatment of OSA. A major barrier to the widespread prescription of oral appliance therapy for OSA has been the inability to reliably predict treatment outcome prior to fabrication of an expensive custom-fitted device. Unlike those considering CPAP devices, which patients can “try before they buy,” those considering OA_m treatment must rely on the expertise of their physician in being able to predict treatment success and be willing to pay without certainty about the outcome. It is therefore encouraging to see the significant progress being made in the development of tools to prospectively identify favorable OA_m candidates by a number of international groups.

Finally, we echo the call for long-term research on the comparative effectiveness of these and other treatments for the management of OSA. Such studies will be greatly enhanced by the incorporation of objective measures of compliance and by prospective identification of candidates for both CPAP and OA_m . However, we should not lose sight of the fact that although improving the therapeutic effectiveness of treatments is important, it is the improvement in important health outcomes that matters the most.

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Reply

From the Editor:

The letter by Dr. Vanderveken and colleagues in response to the article by Dr. Phillips and colleagues (1) and my accompanying editorial (2) nicely addresses both the problems encountered in predicting which patients are likely to respond to an oral appliance in the treatment of their obstructive sleep apnea (OSA) and the assessment of compliance with the device once it has been fabricated. I have only two comments in response to this letter.

First, several of the approaches proposed by Vanderveken and colleagues are not broadly available at this time:

- The embedded microsensor thermometer to measure oral appliance use is, to the best of my knowledge, not currently available in the United States, nor is the associated software to assess compliance. In addition, the device is certainly not provided on the commercially available oral appliances. Vanderveken and colleagues (3) have convincingly demonstrated the accuracy of this device in the clinical trial setting in Belgium and it is being used in several other current clinical trials. However, it needs to be more widely available before its true effectiveness can be determined.
- The “remotely controlled mandibular positioner” for oral appliance titration in the sleep laboratory developed by Remmers and colleagues (4) also has credible data supporting the accuracy of the device in determining who will ultimately respond to an oral appliance. However, few sleep laboratories currently have this technology available. It is also unclear whether such titrations would be readily reimbursed by payers.

Second, the use of drug-induced sleep endoscopy to assess the ability of an oral appliance to treat OSA in a given patient is arguably not sufficiently sensitive and specific to completely rule in or out the use of an oral appliance in that patient (5). In addition, the procedure itself may be more expensive (particularly in the United States) than fabricating the device and determining its efficacy with a home sleep test.

That being said, several of the approaches proposed by Vanderveken and colleagues need to become both more broadly available and more commonly used as oral appliances are a viable method of treating OSA. Despite their being available for decades, use of oral appliances remains modest, and this needs to change.

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