A tailor made approach to obstructive sleep apnea
Ravesloot, M.J.L.

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Treatment Adherence Should be Taken into Account when Reporting Treatment Outcomes in Obstructive Sleep Apnea.

M.J.L. Ravesloot
N. de Vries
B.A. Stuck

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ABSTRACT

INTRODUCTION:

An apnea hypopnea index (AHI) below 5 is the bar for continuous positive airway pressure (CPAP) adjustment in patients with obstructive sleep apnea (OSA). It is however common knowledge, that a majority of patients are not adherent to the treatment during 100% of the total sleep time under everyday, non-laboratory conditions.

CLINICAL PROBLEM:

Although the AHI is only a surrogate marker for this disease, it remains the most frequently reported outcome measure in OSA. The effectiveness of conservative treatment regarding the reduction of AHI depends both on its impact on airway obstruction and compliance. Momentarily, the second aspect is often overlooked. Currently, when reporting on treatment effectiveness of conservative treatment, the reduction in AHI whilst using CPAP in laboratory situations is documented. An artificial compliance of 100% is assumed.

EVIDENCE FOR CHANGE:

In line with the theory that limited adherence leads to periods of sleep without effective treatment, recent studies have shown a positive relation between hours of CPAP use and a favourable outcome.

CONCLUSION:

We suggest that OSA treatment effects on the AHI should no longer be reported under conditions of artificial compliance only, but in consideration of the individual compliance to the treatment. This is of particular importance when different treatment options are compared.
THE CLINICAL PROBLEM

Current treatment of obstructive sleep apnea (OSA) consists of a number of conservative approaches including weight loss, intraoral devices and continuous positive airway pressure (CPAP), the latter being considered the gold standard. CPAP and intraoral devices are regarded as successful if the apnea hypopnea index (AHI) drops below 5 while the devices are used; an AHI below 5 is the bar for CPAP adjustment. It is however common knowledge, that a majority of patients are not adherent to the treatment during 100% of the total sleep time under everyday, non-laboratory conditions.\(^1\) Current arbitrary trends define compliance as 4/ hours/night as an average over all nights observed.\(^2\)

In line with the theory that limited adherence leads to periods of sleep without effective treatment, studies have shown a positive relation between hours of CPAP use and a favourable outcome.\(^3\)

Although the AHI is only a surrogate marker for this disease, it remains the most frequently reported outcome measure in OSA. The effectiveness of conservative treatment regarding the reduction of AHI depends both on its impact on airway obstruction and compliance. Presently the second aspect is often overlooked. Currently, when reporting on treatment effectiveness of conservative treatment, the reduction in AHI whilst using CPAP in laboratory situations is documented. An artificial compliance of 100% is assumed.

Therefore, we propose that treatment adherence should be taken into account when reporting outcomes of treatment of OSA with regard to the AHI and comparing effects of different treatment options.

THE EVIDENCE FOR CHANGE

In a double-blind, placebo-controlled cross-over trial by Sharma \textit{et al}. 86 patients with OSA were randomly assigned to therapeutic CPAP or sham CPAP for a period of three months with a washout period of 1 month in between.\(^4\) A statistically significant greater mean reduction in systolic and diastolic blood pressure (BP), glycated haemoglobin, triglycerides,
LDL cholesterol and total cholesterol was observed in a subgroup of patients who used CPAP \( \geq 5 \) hours (\( n = 51 \)). Similar results were found in a prospective long-term follow-up study and a randomized controlled trial: a significant decrease in the 24 hour mean arterial pressure (MAP) was achieved in patients who used CPAP > 5.3 hours/day (\( n = 27 \)) and a statistically significant decrease in systolic BP was observed in patients who use CPAP \( \geq 5.6 \) hours/night.\(^5,6\) Hours of CPAP use was an independent predictor of reduction in BP.\(^5\)

Campos-Rodriguez et al\(^7\) reported in a retrospective cohort study, that the 5-year cumulative survival rate was significantly higher in patients with sleep apnea and hypertension who used CPAP \( \geq 6 \) hours/night.

Weaver et al\(^8\) reported a linear-dose relationship between hours of CPAP use and improvement in daytime sleepiness after 3 months of therapy in a recent follow-up cohort study of patients with severe OSA.

This current evidence demonstrates that clinical outcome is dependent on compliance to treatment in a dose dependent manner.

As cardiovascular effects and long term survival are relatively hard to assess, the AHI is mostly used as a surrogate outcome measure. The current evidence however demonstrates that compliance also needs to be taken into account when reporting treatment outcome in terms of AHI reduction.

Two current publications have suggested methods to include compliance into the calculation of the AHI under conservative treatment. Ravesloot and de Vries proposed mathematical formulas to assess mean AHI with regard to treatment compliance based on the hours of CPAP use as documented by the built-in counters of the CPAP devices.\(^9\) They suggest that a mean AHI in CPAP therapy is more realistic than using arbitrary compliance rates which in fact hide insufficient reductions in AHI. Almost simultaneously, Stuck et al\(^10\) published data on treatment effects of CPAP on the AHI in a cohort of patients with OSA. Mean AHI could also be calculated based on the treatment period and the hours of use of the device.
Treatment outcome based on individual compliance in conservative treatment can currently most reliably be reported in patients with CPAP. Built-in counters have become a standard feature in CPAP devices and hours of use can easily be assessed by every physician. Until recently accurate assessment of compliance for other conservative interventions was limited to subjective self-report.

Reporting on the efficacy of OA in a 3-month prospective clinical trial, Vanderveken et al took objective OA compliance into consideration through an embedded microsensor thermometer with on-chip integrated readout electronics. The mean AHI was calculated based on the objective OA use and treatment period. Their results support the hypothesis that higher compliance with OA therapy translates into a similar adjusted effectiveness as compared with CPAP. Despite not being common practice as yet, compliance to OA devices can be measured objectively with the introduction of this new device.

**HOW SHOULD WE CHANGE OUR PRACTICE**

We suggest that OSA treatment effects on the AHI should no longer be reported under conditions of artificial compliance only, but in consideration of the individual compliance to the treatment. This is of particular importance when different treatment options are compared.

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