

# Outcome Measures in Obstructive Sleep Apnea

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## Introduction

Obstructive Sleep Apnea (OSA) is characterized by recurrent episodes of complete upper airway obstruction resulting in oxygen desaturation and arousal from sleep<sup>1</sup>. The symptoms that these patients may experience are excessive day time sleepiness, morning headaches, unrefreshed sleep, tiredness and fatigue, poor cognitive skills, impairment of memory, depression, and impotence<sup>1</sup>.

Untreated OSA has numerous cardiovascular and systemic manifestations such as cardiac arrhythmias, ischemic heart disease, heart failure, poorly controlled hypertension and stroke.

Successful treatment of OSA is defined as a reduction in the number of apneas and hypopneas occurring during every hour of sleep. However, this correlates weakly with the quality of life and daytime symptoms as experienced by patients<sup>3</sup>. To determine as a parameter to assess the outcomes of treatment, PROMs (Patient-Reported Outcome Measures) should be included to measure patient's health and quality of life<sup>1,3</sup>.

## Outcome Measurement Parameters

Polysomnography measures variables such as apnea-hypopnea index (AHI), respiratory disturbance index (RDI), minimum O<sub>2</sub> saturation, arousal, time in REM sleep, total apnea time, and total sleep time below 90% saturation. In addition, cardiovascular morbidity, cognitive function and history of events like motor vehicle

accidents can be recorded. Questionnaires such as Epworth sleepiness scale (Johns 1991), the Functional outcome of sleep questionnaire (Weavers 1997), Calgary Sleep Apnea Quality of Life index (Flemons 1997) and Stanford Sleepiness scale (Hoddes 1973) are a few that can be used as outcome measures in OSA. Initially, PROMs were developed only for use in clinical research but in recent years their use has been extended to clinical practice. They can be used to assess if treatment given by health care providers improves the quality of life and health of patients<sup>4</sup>.

The focus of the physician is on the clinical parameters such as better control of blood pressure, decreased cardiovascular morbidity, and reduced AHI. However, from the patient point of view, the outcome measures can be strikingly different. Examples of patient's response could be 'I sleep better', 'I am less irritable', 'my wife says, I don't snore', 'I lost weight!' 'I have more energy' and 'we have a better sex life'. Clearly, more instruments of measurement are needed.

Inger Labma et al conducted a systematic review of all studies related to the development of methods to measure outcome in OSA (Fig 1). Eighty potential studies were reviewed and 22 PROMs that can be used as measures were identified. It was observed that there was a lack of evidence for the quality of measurement properties in case of most of the PROMs, including those validated for OSA. Four such OSA-related quality of life, PROMs that had thorough patient involvement in their development, were identified. They included OSAPOSI (obstructive sleep apnea patient-oriented severity index), MOSAS (Maugeri obstructive sleep apnea syndrome questionnaire), QSQ (Quebec sleep questionnaire), and SAQLI (sleep apnea quality of life index). Currently, aforementioned instruments are best suited as instruments of assessment of health status in patients with OSA<sup>1</sup>.

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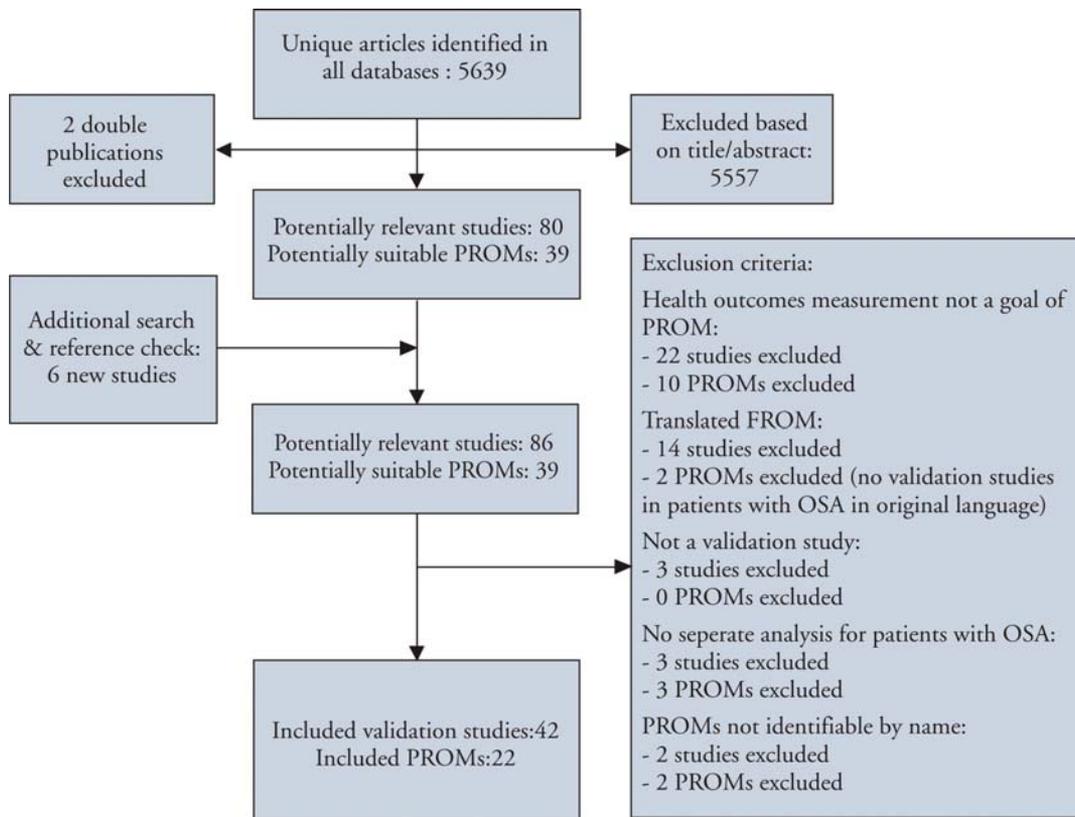


Figure 1: Algorithmic approach to analysis of all studies related to development of methods to measure outcome in OSA

Quality of measurement properties per PROM.<sup>a,b</sup>

| Instrument/patient group                            | Internal consistency | Reliability (test-retest) | Content validity | Structural validity | Hypothesis testing (construct validity) |                       |                       | Criterion validity | Responsiveness |
|---|----------------------|---------------------------|------------------|---------------------|---|-----------------------|-----------------------|--------------------|----------------|
|   |                      |                           |                  |                     | Convergent validity                     | Known-groups validity | Discriminant validity |                    |                |
| <b>OSA-related quality of life PROMs</b>            |                      |                           |                  |                     |   |                       |                       |                    |                |
| FOSQ  | +                    | na                        | ?                | +                   | ±                                       | ?                     | na                    | <sup>c</sup>       | +              |
| FOSQ-10   | ?                    | na                        | na               | na                  | na                                      | +                     | na                    | ?                  | ?              |
| MOSAS questionnaire                                 | -                    | na                        | +++              | -                   | +                                       | ?                     | na                    | <sup>c</sup>       | na             |
| OSAPOS1   | ?                    | na                        | +++              | na                  | ?                                       | na                    | na                    | <sup>c</sup>       | ?              |
| QSQ   | ?                    | ?                         | +++              | na                  | -                                       | na                    | na                    | <sup>c</sup>       | ?              |
| SAQLI   | ?                    | +                         | +++              | na                  | +                                       | na                    | na                    | <sup>c</sup>       | +              |
| SNORE25   | na                   | na                        | na               | na                  | ?                                       | na                    | na                    | <sup>c</sup>       | ?              |
| VAWS  | <sup>d</sup>         | ++                        | ?                | <sup>d</sup>        | +                                       | ?                     | na                    | <sup>c</sup>       | +              |
| <b>PROMs on single OSA-related symptoms</b>         |                      |                           |                  |                     |   |                       |                       |                    |                |
| BAI   | +                    | na                        | na               | +                   | +                                       | na                    | +                     | <sup>c</sup>       | na             |
| ESS   | ± <sup>e</sup>       | na                        | ?                | ±                   | +                                       | ±                     | na                    | <sup>c</sup>       | na             |
| HADS  | ?                    | na                        | na               | na                  | -                                       | na                    | na                    | <sup>c</sup>       | na             |
| Rotterdam sleepiness scale                          | na                   | na                        | ?                | na                  | -                                       | na                    | na                    | <sup>c</sup>       | na             |
| SQS   | ?                    | na                        | na               | na                  | ?                                       | +                     | na                    | <sup>c</sup>       | na             |
| SWIFT   | na                   | na                        | na               | na                  | ?                                       | +                     | na                    | <sup>c</sup>       | ?              |
| SOS   | ?                    | ?                         | ?                | na                  | -                                       | na                    | na                    | <sup>c</sup>       | ?              |
| ToDSS   | -                    | na                        | ?                | -                   | ?                                       | ?                     | na                    | <sup>c</sup>       | ?              |
| <b>Generic health-related quality of life PROMs</b> |                      |                           |                  |                     |   |                       |                       |                    |                |
| EQ-5D   | na                   | na                        | na               | na                  | na                                      | na                    | na                    | <sup>b</sup>       | -              |
| FLP   | na                   | na                        | na               | na                  | na                                      | na                    | na                    | <sup>b</sup>       | ?              |
| NHP part II   | na                   | na                        | na               | na                  | ?                                       | na                    | na                    | <sup>b</sup>       | na             |
| PGI   | na                   | na                        | na               | na                  | na                                      | na                    | na                    | <sup>b</sup>       | -              |
| SF-12   | na                   | na                        | na               | na                  | na                                      | na                    | na                    | ?                  | ?              |
| SF-36   | ?                    | na                        | na               | na                  | <sup>f</sup>                            | +                     | na                    | <sup>b</sup>       | -              |

Figure 2: Quality measurement properties of PROMs

Nisha et al<sup>5</sup> reviewed 136 articles and, described 10 processes and 3 outcomes that may be utilized as candidate PROMs. The various processes and outcomes are outlined in Table-1

**Table 1: Outcomes and processes related to PROMs**

| Processes   | Outcomes  |
|---|---|
| <ul style="list-style-type: none"> <li>• Baseline assessment of OSA symptoms</li> <li>• Severity assessment at initial diagnosis</li> <li>• Evidence-based therapy prescribed</li> <li>• Assessment of adherence to OSA therapy</li> <li>• Assessment of sleepiness</li> <li>• Assessment of motor vehicle accidents</li> <li>• Assessment of weight</li> <li>• Weight management discussion</li> <li>• Assessment of blood pressure</li> <li>• Elevated blood pressure discussion</li> </ul> | <ul style="list-style-type: none"> <li>• Improve disease detection and categorization</li> <li>• Improve quality of life</li> <li>• Reduce Cardiovascular risk</li> </ul> |

## Discussion

An ideal metric (measurement) to measure OSA and guide treatment of OSA is unclear. Polysomnography (PSG) alone does not appear to fully describe the disease. It is likely that physiological measures (fatigue, cardiovascular morbidities, and serology) are what we should ultimately treat and not a number as depicted by the PSG. Metrics should include what is important to the physician (cardiovascular morbidity, motor vehicle accidents (MVA), and the patient response (How do I feel?). We should strive to define the physiology more completely and develop more robust metrics to define sleep disordered breathing<sup>6</sup>.

As research methodologies advance, the quality measures will need to be updated to reflect the most recent disease management paradigms. Integration of these outcome measures into sleep medicine practice will require provider education and acknowledgment that measuring patient outcomes equates with the shared goal of providing excellent patient care<sup>5</sup>.

There are several challenges that sleep physicians in India and other countries with a similar socio-economic profile may have to face in day to day clinical practice. Sleep specialists have a high workload. They may also be practicing other diseases in medicine. There is a need for a tight control over follow-up visits. Outcome measures are expensive to perform. Sleep questionnaires are time-consuming. At times extra manpower is needed. There are several logistic issues with regard to multiple visits.

## Conclusion

Flemons had concluded (2002), “In the majority of patients without coexisting conditions ..... the primary reason to test for and treat sleep apnea is the potential to improve the quality of life”<sup>7</sup>.

Future studies should focus on the quality of information provided by PROMs that may help in providing direction towards personalized care in patients suffering from OSA.

## References

1. Measurement properties of patient-reported outcome measures (PROMs) in adults with obstructive sleep apnea (OSA): A systematic review  
Inger L. Abma, Philip J. van der Wees, Vik Veer, Gert P. Westert, Maroeska Rovers
2. **Bradley TD**, Floras JS. Obstructive sleep apnoea and its cardiovascular consequences. *Lancet* 2009;373:82e93
3. **Pang KP**, Rotenberg BW. Redefining successful therapy in obstructive sleep apnea: a call to arms. *Laryngoscope* 2014;124:1051e2
4. **Black N**. Patient reported outcome measures could help transform healthcare. *BMJ* 2013; 346:f167.
5. Quality Measures for the Care of Adult Patients with Obstructive Sleep Apnea R. Nisha Aurora, MD ; Nancy A. Collop, MD; OferJacobowitz, MD, Ph.D.; Sherene M. Thomas, Ph.D. ; Stuart F. Quan, MD5; Amy J. Aronsky, DO
6. **Goldberg**, University of California, San Francisco
7. **Flemons**, Obstructive Sleep Apnea, Clinical Practice. *New Engl J of Med* 2002; 347: 498-504