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Consensus & Evidence-Based INOSA GUIDELINES

(INDian initiative on Obstructive Sleep Apnea Guidelines)
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Under the auspices of
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Convener

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Multi-speciality disciplines across India- Public and Private Sectors

Stake Holders



INOSA Guidelines

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INOSA Guidelines 2014

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1 Executive Summary

1.1 Epidemiology and risk factors of OSA

What is sleep-disordered breathing?

Sleep-disordered breathing includes abnormal respiratory pattern (apnea, hypopnea, or respiratory effort related arousals) or central sleep apnea-hypopnea syndrome including Cheyne-Stokes breathing syndrome or central hypoventilation leading to an altered gas exchange.

What are Obstructive Sleep Apnea and Obstructive Sleep Apnea Syndrome?

OSA and OSAS are subsets of sleep-disordered breathing. OSA is the occurrence of an average 5 or more episodes of obstructive respiratory events (apneas, hypopneas, or RERAs) per hour of sleep with either sleep related symptoms or comorbidities or ≥ 15 such episodes without any sleep related symptoms or comorbidities. OSAS is defined as OSA associated with daytime symptoms, most often excessive sleepiness.

What are overlap syndrome, obesity-hypoventilation and Pickwickian syndromes?

Overlap syndrome is defined as the co-occurrence of both chronic obstructive pulmonary disease and OSA in the same individual. Both are common diseases affecting the adult population, mostly over 40 years of age. Obesity-hypoventilation syndrome consists of obesity, sleep-disordered breathing, hypoxia and chronic hypercapnia during wakefulness in the absence of other known causes of hypercapnia. Historically, OHS was first described as Pickwickian syndrome in a case report in 1956. This patient resembled a character depicted by Charles Dickens in “The Posthumous Papers of the Pickwick Club as he was obese and had hyper-somnolence.

What is the epidemiology of obstructive sleep apnea in India and is it different from the rest of the world?

Community based epidemiological studies from India have shown that the prevalence of OSAS is 2.4% to 5 % in males and 1 to 2% in females. There is no considerable variation in the prevalence of OSAS compared to rest of the world where it is 4% in males and 2% in females (**Evidence Quality B**).

What are the risk factors for obstructive sleep apnea?

The demographic characteristics that predispose to development of OSA include older age (**Evidence Quality B**), male gender (**Evidence Quality B**), pregnancy (**Evidence Quality C**) and post-menopausal state (**Evidence Quality C**). Risk factors that are linked by strong published evidence include obesity (**Evidence Quality A**), central body fat distribution (**Evidence Quality B**), increased neck circumference (**Evidence Quality B**) and several anatomical abnormalities of the craniofacial region and upper airway (**Evidence Quality B**). Other potential risk factors include genetic predisposition (**Evidence Quality C**), familial aggregation (**Evidence Quality C**), tobacco smoking (**Evidence Quality C**), alcohol use (**Evidence Quality C**), night-time nasal congestion (**Evidence Quality C**), endocrine abnormalities (hypothyroidism, acromegaly) (**Evidence Quality B**), polycystic ovarian syndrome (**Evidence Quality C**), Down’s syndrome and drugs (benzodiazepines, muscle relaxants, testosterone therapy) (**Evidence Quality C**).

1.2 Consequences of OSA

Is OSA associated with increased morbidity and mortality?

Yes, it is usually associated with several co-morbidities such as insulin resistance, diabetes mellitus, hypertension, stroke and coronary artery disease. OSA increases mortality either due to apnea *per se*, increased risk of vehicular accidents or associated co-morbidities (**Evidence Quality B**).

What is the relationship of OSA with hypertension? Is hypertension reversible after treatment of OSA?

OSA is causally related to hypertension. Treatment of OSA with PAP therapy or oral appliances has been shown to modestly improve the blood pressure control (**Evidence Quality B**). However, anti-hypertensive therapy may still be required to control the blood pressure. All patients with resistant hypertension should be screened for OSA (**Evidence Quality B: Recommended**).

What is the relationship between OSA and coronary artery disease? Should all patients with CAD screened for OSA?

OSA has been found to be associated with coronary artery disease especially in men (**Evidence Quality B**). All patients with coronary artery disease should be clinically screened for OSA (**Evidence quality B, Recommended**).

What is the relationship of OSA and congestive heart failure? Should all patients with CAD screened for OSA?

OSA and congestive heart failure are associated with each other independent of confounding factors (**Evidence Quality B**). All patients with heart failure should be screened for OSA (**Evidence Quality B, Recommended**).

Is OSA associated with increased prevalence of arrhythmias? Should all patients with arrhythmia be screened for OSA?

Yes, OSA is associated with increased prevalence of arrhythmias (**Evidence Quality B**). All patients with arrhythmias, particularly those with atrial fibrillation, should be screened for OSA (**Evidence Quality B, Recommended**).

What is the relationship between OSA and stroke? Should all patients with stroke be screened for OSA?

OSA is an independent risk factor for stroke. In turn, stroke can result in OSA (**Evidence Quality B**). All patients who suffer from stroke should be screened for OSA (**Evidence Quality B, Recommended**).

Does OSA affect neuro-cognitive function and quality of life?

Yes, OSA impairs neuro-cognitive function and decreases the quality of life (**Evidence Quality B**).

What is the relationship between OSA and psychiatric disorders?

OSA is associated with various psychiatric disorders like depression, bipolar disorder, delirium, anxiety and erectile dysfunction. All patients with psychiatric disorders especially erectile dysfunction (**Evidence Quality B: Recommended**) should be screened for OSA.

Is OSA associated with an increased prevalence of metabolic syndrome? What is syndrome Z?

Yes, OSA is associated with an increased prevalence of metabolic syndrome (**Evidence Quality C**). Metabolic syndrome is a constellation of various cardiovascular risk factors. Syndrome Z refers to the co-occurrence of OSA and metabolic syndrome and these patients are at a higher risk of cardiovascular and cerebrovascular complications.

1.3 Diagnosis of OSA

Who should be evaluated for OSA?

Patients undergoing routine health check-up with snoring, daytime sleepiness, obesity, hypertension, motor vehicular accidents (**Evidence Quality A, Strong Recommendation**) and high risk cases such as congestive heart failure, diabetes mellitus, coronary artery disease, stroke, metabolic syndrome, nocturnal dysrhythmias (**Evidence Quality B, Recommended**) should undergo a comprehensive sleep evaluation. Additionally, patients with pulmonary hypertension and preoperative cases should also have a comprehensive sleep evaluation. Those suspected to have OSA on comprehensive sleep evaluation should be referred for a sleep study. High risk cases, even if asymptomatic, can be referred for a sleep study. Further, medical examiners evaluating drivers, air pilots, railway drivers and heavy machinery workers should be educated about OSA and should comprehensively evaluate applicants for OSA, if snoring, daytime sleepiness or obesity irrespective of the presence or absence of co morbidities are noted (**Evidence Quality B, Strong Recommendation**).

What is the role of ESS and pre-test screening questionnaires in the diagnosis of OSA?

ESS can be used as a tool to measure the quality of life with regard to EDS, likelihood of long-term compliance to continuous positive airway pressure (CPAP) and to evaluate the treatment response rather than to screen for OSA (**Evidence Quality C, Recommended**). Both Berlin questionnaire and modified Berlin questionnaire are moderately accurate to screen for OSA (**Evidence Quality C, Recommended**). Although, other questionnaires have not been adequately studied, they can be used to screen the patients for OSA. STOP Bang questionnaire (**Evidence Quality C, Recommended**) is the most appropriate questionnaire for screening preoperative cases. It may also be used for pre-test probability assessment before portable monitoring because of ease of administration and high sensitivity.

What are various types of sleep studies?

Type 1: Fully attended polysomnography (≥ 7 channels) in a laboratory setting

Type 2: Unattended polysomnography (≥ 7 channels)

Type 3: Limited channel study (using 4–7 channels)

Type 4: One or two channels usually using oximetry as one of the parameters

What is the “Gold standard” for diagnosis for OSA?

Type 1 study or in-hospital, in-laboratory, technician-attended, overnight polysomnography (PSG) is the “Gold standard” for evaluation of sleep-disordered breathing (**Evidence Quality A, Strong Recommendation**).

What is the role of portable monitoring (PM)/ out of center sleep testing(OCST)/ home sleep testing (HST)/ unattended limited channel testing (ULCT) in diagnosis of OSA?

Laboratory attended PSG is not necessary in all patients suspected to have OSA. Portable monitoring or OCST with type 3 or type 4 devices (which should at least include airflow, oxygen saturation and respiratory effort) is adequate for diagnosis when used in conjunction with comprehensive sleep evaluation and in patients with high pre-test probability of moderate to severe OSA without co-morbid sleep disorders or medical disorders like pulmonary disease, neuromuscular disease, or congestive heart failure (**Evidence Quality A, Strong Recommendation**).

Is sleep study necessary in preoperative evaluation or can be bypassed?

The incidence of postoperative desaturation, respiratory failure, postoperative cardiac events and intensive care unit transfers is higher in patients with OSA (**Evidence Quality A, Strong Recommendation**). Portable monitoring is preferable as it reduces the likelihood of delay in surgery, inconvenience and high cost of in-laboratory PSG. Alternatively, in a case with high likelihood of OSA, sleep study may be deferred if it is not feasible or causes delay in surgery. Instead, a standby CPAP with a close monitoring may be advised. Patients with known OSA must be advised to use CPAP in the perioperative period.

What are the diagnostic criteria for OSA?

The diagnostic criteria for OSA as recommended in International Classification of Sleep Disorders, 3rd Edition, 2014 are the presence of (A and B) or C

A. Presence of one or more of the following:

- a. Complains of sleepiness, nonrestorative sleep, fatigue, or symptoms of insomnia.
- b. Waking up with breath holding, gasping, or choking.
- c. Habitual snoring, interruptions in breathing, or both during sleep as reported by patient's bed partner or other observer.
- d. Co-existing morbidities such as hypertension, type 2 diabetes mellitus, coronary artery disease, congestive heart failure,atrial fibrillation, stroke,mood disorder, or cognitive dysfunction.

B. PSG or OCST demonstrates

- a. Five or more obstructive respiratory events (apneas, hypopneas, or RERAs) per hour of sleep during a PSG or per hour of monitoring with OCST.

OR

C. PSG or OCST demonstrates

- a. Fifteen or more obstructive respiratory events (apneas, hypopneas, or RERAs) per hour of sleep during a PSG or per hour of monitoring with OSCT, even in the absence of symptoms.

OSA severity, based on the frequency of abnormal respiratory events during sleep is graded as a) mild: ≥ 5 to <15 events/hr of sleep, b) moderate: $\geq 15-30$ events/hr of sleep and c) severe: > 30 events/hr of sleep.

What is the role of MSLT and MWT in diagnosis of OSA?

MSLT is considered to be an objective measure of reported daytime sleepiness. However, MSLT is not routinely indicated in the initial evaluation, diagnosis or treatment response for OSA (**Evidence Quality A, Strong Recommendation**). It may be indicated when EDS persists despite optimal treatment with good compliance. MWT is mainly used to assess improved alertness following therapeutic intervention (**Evidence Quality D, Optional Recommendation**).

What are the various methods to prescribe PAP therapy?

Full-night PSG with attended manual CPAP titration is regarded as the gold standard for prescription of CPAP (**Evidence Quality A, Strong Recommendation**). However, split-night study, i.e., initial PSG followed by 3 hours of continuous positive airway pressure (CPAP) titration may be performed if AHI is >40 events/hr during first 2 hours or between 20-40 events/hr with clinical judgment regarding definitiveness of prescribing CPAP therapy (**Evidence Quality A, Strong Recommendation**). The process of BPAP titration in OSA management is initiated in two situations, i.e., after maximal CPAP has not resolved the respiratory events or less commonly as a primary PAP strategy (**Evidence Quality C, Recommended**). Certain autoPAP devices can be tried during attended titration with PSG (**Evidence Quality B, Recommended**) or in an unattended way to determine a fixed PAP level in patients with moderate to severe OSA without significant co-morbid illness such as CHF, COPD, central sleep apnea or hypoventilation syndromes (**Evidence Quality B, Recommended**).

1.4 Medical management of OSA

What is the role of behavioural therapy in OSA?

The following measures have shown modest improvement in OSA and should be considered as adjuncts to PAP therapy:

Smoking cessation (**Evidence Quality B, Strong Recommendation**)

Avoidance of alcohol, sedatives and nicotine (**Evidence Quality D, Optional Recommendation**)

Treatment of nasal obstruction (**Evidence Quality B, Strong Recommendation**)

Weight loss (**Evidence Quality B, Strong Recommendation**)

Positional therapy during sleep (**Evidence Quality C, Recommended**)

Sleep hygiene, avoidance of sleep deprivation (**Evidence Quality D, Optional Recommendation**)

What is the role of pharmacotherapy in OSA?

There is no role of pharmacotherapy in OSA, however, modafinil and armodafinil are the only agents approved for EDS despite adequate PAP therapy (**Evidence Quality A, Strong Recommendation**). Intranasal fluticasone may result in mild improvement in AHI in OSA patients with rhinitis (**Evidence Quality C, Optional Recommendation**).

What is PAP therapy and what is its role in OSA?

PAP therapy is the mainstay of treatment of OSA, however, patient compliance is a major issue. Therefore, proper patient counselling is necessary to ensure adequate compliance. PAP creates a pneumatic splint in the upper airway which prevents collapse of the pharyngeal airway, acting at all potential levels of obstruction. PAP therapy improves quality of life in terms of significant reduction in daytime sleepiness, improvement in quality of life, driving performance, neuro-cognitive performance and cardiovascular outcomes including overall mortality (**Evidence Quality A**).

What are the indications for PAP therapy?

PAP is indicated based on PSG results showing: (**Evidence Quality A, Strong Recommendation**)

1. AHI or RDI ≥ 15 events/hour

Or

2. AHI or RDI ≥ 5 but < 15 events/hour with any one of the following symptoms:
 - Excessive daytime sleepiness
 - Neurocognitive impairment
 - Hypertension
 - Coronary artery disease
 - Cardiac arrhythmias
 - Pulmonary hypertension
 - History of stroke

Are there other versions of PAP therapy other than CPAP, and what are their roles?

PAP can also be given as Bi-level PAP (BPAP) or Auto titrating PAP (APAP). BPAP is considered better in OSA with OHS (**Evidence quality D, Optional Recommendation**). APAP adjusts PAP level based on patient's variable needs and hence, at least theoretically, enhances tolerability and compliance. Data on its added usefulness in OSA patients with co-morbid illnesses are lacking, but it is a promising modality for near future. Other modalities are still investigational.

Is there any role of oral appliances in OSA?

Yes, OAs are indicated for use in patients with mild to moderate OSA who prefer oral appliances to CPAP, or who do not respond to CPAP or who fail treatment attempts with CPAP or behavioural measures (**Evidence Quality B, Recommended**). Two types of oral appliances are available- mandibular repositioning appliance (MRA) and tongue retaining appliances (TRA). These have defined indications and contra-indications with modest efficacy.

1.5 Surgical treatment of OSA

Who should undergo surgical treatment for OSA?

Surgical treatment is recommended in patients who have failed or are intolerant to PAP therapy. Patients with BMI $\geq 35\text{kg/m}^2$ should undergo bariatric surgery rather than site directed surgery (**Evidence Quality B, Recommended**).

How is the level of obstruction evaluated preoperatively?

Of the various methods available, fibre-optic nasopharyngoscopy with Müller's manoeuvre (FNMM) is found to predict response to UPPP. Other investigations like cephalometry, acoustic analysis, somnofluoroscopy are outdated. CT and MRI do not predict level of obstruction consistently and hence are not recommended for routine use (**Evidence Quality C, Optional Recommendation**).

What is the role of nasal and nasopharyngeal surgery?

Nasal surgery (correction of anatomical defects) alone is not a useful method of treatment of moderate to severe sleep apnea (**Evidence Quality B, Not recommended**). Nasal surgery improves the compliance with PAP and also enhances its effectiveness in patients who have nasal obstruction (**Evidence Quality B, Recommended**).

When is maxillo-mandibular surgery indicated?

Maxillo-mandibular surgeries which include maxillo-mandibular advancement, genioglossus advancement, distraction osteogenesis are recommended only in the subset of patients with the specific anatomical abnormalities and intolerance to PAP therapy (**Evidence Quality C, Optional Recommendation**).

When is uvulopalatopharyngoplasty (UPPP) indicated?

It is recommended in patients with retropalatal obstruction and PAP therapy intolerance (**Evidence Quality C, Recommended**).

When is multi-level surgery done?

Multi-level surgery is done in patients who have failed PAP therapy and other conservative measures with documented multi-level obstruction (**Evidence Quality C, Optional Recommendation**).

When is bariatric surgery indicated in patients with OSA?

Bariatric surgery is indicated in patients with BMI $\geq 35\text{kg/m}^2$. Gastric bypass is the most successful procedure and gastric banding is the least effective procedure for treating OSA (**Evidence Quality B, Strongly Recommended**).