Ambulatory Sleep Study

for diagnosing obstructive sleep apnoea

Technology Guidance from the MOH Medical Technology Advisory Committee (MTAC)

Guidance recommendations

The Ministry of Health's MTAC has recommended:

- ✓ Ambulatory sleep study or home sleep test (HST) with a type 2 or type 3 device for diagnosing obstructive sleep apnoea (OSA) in adults aged ≥18 years who fulfil **both (A) and (B).**

  A. High pre-test probability for moderate-severe OSA, where signs and symptoms indicating a high pre-test probability for moderate-severe OSA include:
     - Excessive daytime sleepiness; and
     - At least two of the following three criteria: (i) habitual loud snoring; (ii) witnessed apnoea, gasping, or choking; and (iii) diagnosed hypertension

  B. No complicated conditions that include:
     - Awake hypoventilation or high risk of sleep-related hypoventilation;
     - Significant cardiopulmonary disease;
     - Long-term home oxygen therapy;
     - Chronic opiate medication use;
     - Parasomnias (such as REM behavioural disorder);
     - Severe insomnia;
     - Sleep-related movement disorders (such as periodic limp movement disorder);
     - Potential respiratory muscle weakness caused by neuromuscular conditions;
     - History of stroke;
     - Disorders of central hypersomnolence;
     - Nocturnal seizure; and
     - Environmental or personal factors precluding adequate acquisition and data interpretation from HST

- ✓ The patient should be assessed, and raw HST data should be reviewed and interpreted by a trained sleep specialist able to interpret a polysomnogram, according to the institution-based clinical privileging criteria.

- ✓ Quality assurance procedures should have been established for data acquisition from HST.

Subsidy status

Subsidy for HST is recommended for the abovementioned indications only.

Published on 2 May 2019

Factors considered to inform the recommendations for subsidy

Technology evaluation

1.1 The MOH Medical Technology Advisory Committee ("the Committee") considered evidence presented for the technology evaluation of ambulatory sleep study or home sleep test (HST) for diagnosing obstructive sleep apnoea (OSA) among adults. The evaluation was conducted in consultation with clinical experts from the public healthcare institutions (PHIs). Available clinical and economic evidence for HST was considered in line with the registered indication.

1.2 The evidence was used to inform the Committee's deliberations around five core decision-making criteria:

- Clinical need of patients and nature of the condition;
- Clinical effectiveness and safety of the technology;
- Cost-effectiveness (value for money) – the incremental benefit and cost of the technology when compared with existing alternatives;
- Estimated annual technology cost and the number of patients likely to benefit from the technology; and
- Organisational feasibility, which covers the potential impact of adopting technology, especially barriers for diffusion

1.3 Additional considerations, such as ethical or social issues related to adopting the technology, may also be part of the Committee's deliberations.

Clinical need

2.1 The Committee noted the currently subsidised lab-based polysomnography (PSG) is the gold standard for diagnosing OSA.

2.2 The Committee further noted using PSG may result in long waiting times for diagnostic testing because of high OSA prevalence in Singapore.

2.3 The Committee acknowledged diagnosing OSA using PSG may significantly burden the healthcare system because of resources required for in-lab testing.

Clinical effectiveness and safety

3.1 In line with local clinical practice, the main comparator used in the evaluation was overnight lab-based PSG. The Committee noted HST is likely to be a safe technology, with some minor adverse events occurring in a proportion of patients (skin redness: 38%, mild itching: 12%). Technical failure rate of up to 16% for HST is a concern, and there are long-term safety data gaps associated with false positive and negative HST results.

3.2 The Committee noted that performance of HST varies by different types of test and apnoea-hypopnoea index (AHI) cut-offs. When compared with PSG, type 2 and type 3 HSTs appear to be accurate alternatives with comparable health outcomes such as quality of life, respiratory events, and symptom control.

3.3 Time from referral to diagnosis was significantly shorter with HST than PSG while no difference in time to commencement of treatment was observed between the two groups.

3.4 The Committee acknowledged variations in device models used; and heterogeneity in study population, follow-up period, and patient education on using HST devices properly; which may lead to uncertainties in the generalisability of reported effectiveness findings.

Cost-effectiveness

4.1 The cost-effectiveness of HST compared with PSG for diagnosing OSA was based on published literature. The Committee noted that HST is likely to lead to cost avoidance in the short-term when compared with PSG. Long-term cost-effectiveness is uncertain because of the downstream costs of false negative or false positive HST results, and device failure rates.

Estimated annual technology cost

5.1 An estimated 4,500 people with OSA who are currently managed in PHIs would benefit from HST subsidy. Considering only direct testing costs, the Committee noted providing HST services could lead to an estimated five-year cost-avoidance of >S$5 million.

5.2 The Committee acknowledged this is likely to be an overestimation given the uncertainties of downstream costs, such as PSG following device failure, negative or inconclusive HST results, and unnecessary treatment following a false-positive HST result.

Organisational feasibility

6.1 The Committee noted the HST device can be prescribed in the outpatient setting, and the HST can be administered by the patient after appropriate training. This can improve patient access to this technology and increase the efficiency of the healthcare system. Patients do need to learn how to use the HST device correctly.

6.2 The Committee considered the importance of reviewing and interpreting data from the HST device, by a physician trained in sleep medicine or overseen by one with appropriate credentials. In the local context, the Committee agreed to define sleep specialists as trained specialists able to interpret PSG, according to the institution-based clinical privileging criteria.

6.3 The Committee acknowledged that with a potentially increased uptake of HST, more trained staff may be needed to manage the potentially increased post-subsidy caseload.

Additional considerations

7.1 The Committee noted that the 2017 American Academy of Sleep Medicine (AASM) position statement does not recommend HST as a screening tool for OSA and there is limited evidence supporting its effectiveness in reassessing treatment efficiency in people with OSA.

Recommendation

8.1 Based on available evidence, the Committee recommended HST with a type 2 or type 3 device for diagnosing OSA among adults (aged ≥18 years) who fulfil both (A) and (B).

A. High pre-test probability for moderate-severe OSA, where signs and symptoms indicating a high pre-test probability for moderate-severe OSA include:
   - Presence of excessive daytime sleepiness; and
   - Presence of at least two of the following three criteria:
     (i) Habitual loud snoring;
     (ii) Witnessed apnoea, gasping, or choking; and
     (iii) Diagnosed hypertension

B. No complicated conditions that include:
   - Awake hypoventilation or high risk of sleep-related hypoventilation;
   - Significant cardiopulmonary disease;
   - Long-term home oxygen therapy;
   - Chronic opiate medication use;
   - Parasomnias (such as REM behavioural disorder);

- Severe insomnia;
- Sleep-related movement disorders (such as periodic limp movement disorder);
- Potential respiratory muscle weakness due to neuromuscular conditions;
- History of stroke;
- Disorders of central hypersomnolence;
- Nocturnal seizure; and
- Environmental or personal factors precluding adequate acquisition and interpretation of data from HST

8.2 The Committee emphasised a sleep specialist should first assess the patient before reviewing and interpreting raw HST data.

8.3 The Committee also recommended that quality assurance procedures should be established for any HST data acquisition.