SPECIAL ARTICLE

Canadian Sleep Society/Canadian Thoracic Society position paper on the use of portable monitoring for the diagnosis of obstructive sleep apnea/hypopnea in adults

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The present position paper on the use of portable monitoring (PM) as a diagnostic tool for obstructive sleep apnea/hypopnea (OSAH) in adults was based on consensus and expert opinion regarding best practice standards from stakeholders across Canada. These recommendations were prepared to guide appropriate clinical use of this new technology and to ensure that quality assurance standards are adhered to. Clinical guidelines for the use of PM for the diagnosis and management of OSAH as an alternative to in-laboratory polysomnography published by the American Academy of Sleep Medicine Portable Monitoring Task Force were used to tailor our recommendations to address the following: indications; methodology including physician involvement, physician and technical staff qualifications, and follow-up requirements; technical considerations; quality assurance; and conflict of interest guidelines. When used appropriately under the supervision of a physician with training in sleep medicine, and in conjunction with a comprehensive sleep evaluation, PM may expedite treatment when there is a high clinical suspicion of OSAH.

Key Words: *Guidelines; Home sleep testing; Obstructive sleep apnea; Portable monitoring*

Le document de principes de la Société canadienne du sommeil et de la Société canadienne de thoracologie sur l'utilisation de la surveillance portable pour diagnostiquer l'apnée obstructive du sommeil ou l'hypopnée chez les adultes

Le présent document de principes sur l'utilisation de la surveillance portable (SP) comme outil diagnostique de l'apnée obstructive du sommeil ou de l'hypopnée (AOSH) chez les adultes se fonde sur le consensus et l'avis d'experts au sujet des normes de pratique exemplaires d'intervenants de l'ensemble du Canada. Ces recommandations ont été préparées pour orienter l'utilisation clinique de cette nouvelle technologie et garantir que les normes d'assurance-qualité soient respectées. Les lignes directrices cliniques sur l'utilisation de la SP pour diagnostiquer et prendre en charge l'AOSH en remplacement de la polysomnographie en laboratoire publiées par le groupe de travail sur la surveillance portable de l'*American Academy of Sleep Medicine* ont permis de personnaliser nos recommandations en vue de tenir compte des éléments suivants : les indications, la méthodologie y compris la participation des médecins, les compétences des médecins et du personnel technique et les exigences de suivi, les considérations techniques, l'assurance-qualité et les directives sur les conflits d'intérêts. Lorsqu'elle est utilisée convenablement, sous la supervision d'un médecin formé en médecine du sommeil et conjointement avec une évaluation complète du sommeil, la SP peut accélérer le traitement dans les situations où la présomption clinique d'AOSH est élevée.

Recent studies confirm the utility of unattended portable monitoring (PM) as a diagnostic option for suspected obstructive sleep apnea/hypopnea (OSAH) that is uncomplicated (ie, without other sleep or medical comorbidities) (1-6). Practice standards are required to guide appropriate clinical use of this new technology and to ensure that quality assurance standards are adhered to.

Recommendations for the use of unattended PM devices are predicated on the understanding that PM should be performed in conjunction with a comprehensive sleep evaluation and supervised by a physician trained in sleep medicine. When used appropriately, PM may expedite treatment when there is a high clinical suspicion of OSAH (1-3).

The three general settings for the use of PM in Canada are as follows:

1. Areas with acceptable wait times for a sleep medicine consultation and Level 1 sleep study.
2. Areas where the prevalence of Level 1 laboratory and sleep specialists are limited and waiting times are excessive.
3. Primarily rural areas, where sleep medicine specialists and Level 1 testing are not available, and where general practitioners (including nurse practitioners under the signing name of a physician) are the primary caregivers.

The guiding principles for use of PM sleep testing are the following:

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1. A physician prescription is required to order PM testing for OSAH (see section 2.1).
2. The PM set-up is performed by a qualified individual.
3. All tests require review of raw data and scoring by appropriately trained staff (see section 4.2) and must be interpreted by a qualified physician (see section 4.1).
4. The results are acted on by the ordering physician or designate, who understands the investigation's results and limitations.
5. The recommendations in the present Canadian Sleep Society/Canadian Thoracic Society position paper should be implemented according to the practical needs and regulations of the local community. Ideally, however, any modification of the recommendations should be made in consultation with the local or regional sleep medicine specialists.

TABLE 1
Summary of evaluations used in sleep testing

Level 1: In-laboratory, technologist attended, polysomnography
Level 2: Full (unattended) polysomnography
Level 3: Portable monitoring with three or more channels, including pulse oximetry and heart rate
Level 4: Portable monitoring with only one or two channels including pulse oximetry

1.0 INDICATIONS

Complete laboratory polysomnography (Level 1) remains the gold standard for the evaluation of sleep-disordered breathing and is the test of choice when readily available. A summary of the levels of evaluations used for sleep testing depending on the types of monitoring devices are presented in Table 1 (1-3).

PM studies can be used to confirm the diagnosis of OSAH in patients with a moderate to high pretest probability of this disorder based on clinical evaluation when integrated into a package of care that includes a comprehensive sleep evaluation by a qualified sleep physician and the back-up availability of polysomnography.

A PM device should not be used for screening of asymptomatic patients, for the evaluation of individuals with comorbid medical conditions (eg, pulmonary disease, neuromuscular disease or congestive heart failure) or those suspected of having other sleep disorders (eg, insomnia, periodic limb movement disorder or central sleep apnea).

2.0 A MEDICAL EVALUATION AND REFERRAL ARE OF PRIMARY IMPORTANCE TO THE DIAGNOSTIC PROCESS WHEN PM IS USED FOR CASE SELECTION IN OSAH

2.1 The evaluation before ordering the PM includes a complete history and examination sufficient to determine the following:

A. A best estimate of the probability of OSAH (7,8);
B. The presence of any significant cardiopulmonary, vascular or neurological comorbidities;
C. The presence of any significant comorbid sleep disorders (eg, periodic limb movement disorder, central apnea or insomnia); and
D. Triage information including identification of patients working in safety-critical occupations.

Portable monitoring as case selection for OSAH is not recommended for the pediatric population (children younger than 12 years of age).

2.2 Post-test follow-up must include the following:

A. A review of test results and all treatment options with the patient (including, where appropriate, positive airway pressure [PAP] and non-PAP therapies);
B. Provision of a mechanism for treatment initiation, if indicated, which may include the following:
   i. Referral to a sleep specialist if findings suggest a diagnosis other than uncomplicated OSAH;
   ii. Home titration with an auto titration unit (which assumes the presence of appropriate expertise and/or the availability of consultative guidance by a sleep specialist); and
   iii. Level 1 PAP titration.
C. Follow-up care to ensure adequacy of treatment and compliance; and
D. Referral to a sleep medicine specialist if there are persistent abnormalities and/or complications.

3.0 A PM PROGRAM REQUIRES OVERSIGHT BY AN ACCREDITED SLEEP MEDICINE CLINIC OR HOSPITAL SLEEP MEDICINE PROGRAM

A PM program is defined by the inclusion of all steps from patient selection to completion of the PM report.

A. Any individual or group performing PM should do so in a partnership with or under the supervision of an accredited community or hospital Level 1 facility and sleep medicine specialist physician, or a specialist physician with recognized training in sleep medicine. (Accreditation is a relevant term in some provinces including Alberta, British Columbia, Ontario [and soon Quebec], as well as facilities with accreditation through the American Academy of Sleep Medicine. Guiding principle 4 [above] makes it clear that these guidelines need to be used in the context of the local community and in consultation with the local sleep medicine specialists.)
B. The PM program should have access (within the same facility or by formal agreement with another facility) to refer to a Level 1 sleep laboratory so that the specific PM technologies can be validated in the context of the local population, and so patients with equivocal results from PM studies can be referred expeditiously for Level 1 testing as clinically indicated (7).
C. When access to a Level 1 facility is not available, PM may be performed within the context of what is available in the local community; provided that all policies and procedures as per section 5.2 (below) are met.

4.0 PHYSICIAN AND TECHNICAL STAFF REQUIREMENTS

4.1 Minimum physician requirements to interpret portable tests

The ability to interpret PM studies is not limited by physician speciality, provided that the appropriate training and experience has been obtained and the physician is associated with an accredited sleep facility. Where there is no regional Level 1 sleep facility, interpreting physician collaboration with the nearest sleep centre is strongly recommended.

Recommended physician training for PM interpretation includes training in sleep medicine and Level 1 sleep study interpretation (certification by American Board of Medical Specialties – Sleep Medicine, or equivalent training) or a specialist physician with recognized training in sleep medicine.

4.2 Technical staff

A. The testing and analysis should be performed under the general supervision of a qualified physician with training in sleep medicine (see section 4.1).

B. A sleep technologist, respiratory therapist or appropriately trained individual (there is currently no recognized technical qualification and training for PM; consequently, training through sleep centres and experience in Level 1 studies are recommended) can set up the PM, while it is preferred that a trained and qualified sleep technologist with Registered Polysomnographic Technologist certification by the Board of Registered Polysomnographic Technologists, analyzes the PM data.

5.0 TECHNICAL CONSIDERATIONS

5.1 Equipment

At minimum, the PM must record airflow (preferably via pressure transducer), respiratory movement and blood oxygenation (1-3).

Level 3 monitoring devices that use a minimum of four channels including one respiratory movement, one airflow and one electrocardiogram/heart rate and one oxygen saturation channel are preferred over devices that monitor fewer variables (ie, Type 4, peripheral arterial tone or oximetry alone).

The use of Level 4 studies, or using oximetry alone, has significant limitations in distinguishing between different types of sleep-disordered breathing, which must be fully appreciated before they are used to make diagnostic decisions.

Level 3 studies (with three or more channels including oximetry and heart rate) are recommended over Level 4 studies or oximetry alone. Many Type 3 devices are commercially available and it is recommended that validated and reliable (data loss of less than 10%) PM equipment be used.

A post-test questionnaire should include time of lights off and lights on, the patient's estimated total sleep time, any unusual occurrences and whether the night with the PM was representative.

5.2 Performing the test

Application (or instruction of the correct application) of PM sensors must be provided by an appropriately trained individual (see section 4.2) with verified and documented quality appraisal.

Policies and procedures: Written policies and procedures must be available for the following:

- A description of the proper methods for performing the PM offered by the facility, including criteria to ensure that the results obtained are reliable;
- The normative values for each test and the references, where available in the literature;
- Instructions regarding the routine preparation of patients;
- Job descriptions;
- Delegated acts;
- Documentation of and method for receiving referrals for testing;
- Quality control activities (see section 6.0);
- Procedures to be followed to maintain proper infection control;
- A scoring manual that includes definitions of sleep-respiratory parameters, criteria and events;
- Routine maintenance procedures to be followed to ensure the reliability and accuracy of testing equipment;
- Patient triage procedures post-PM (see section 5.3);
- The policies and procedures manual is reviewed annually, revised as necessary, and dated to indicate the date of the most recent renewal or revision; and
- All facility staff involved in PM testing must review and acknowledge any changes of the policies and procedures manual.

Scoring and interpretation of PM testing: PM devices must allow for the display of raw data for manual scoring by trained and qualified technical staff (See section 4.2). There should be documented training and quality assurance with inter-rater reliability checks (see item 6) for all scoring staff.

- Scoring criteria should be consistent with current published American Academy of Sleep Medicine standards for the scoring of apneas and hypopneas (9).
- Apnea and hypopnea definition: Where other definitions are used for scoring hypopneas (eg, [10]), these criteria should be identified in the report with the relevant reference.
- A qualified physician (see section 4.1) must report the study results after reviewing the raw and scored data from the PM together with the accompanying clinical data.
- The Physician report should include comment on and/or confirm the following:
  - i. Pre- and post-test sleep questionnaires and their impact on test validity;
  - ii. Pre-test probability estimate of OSAH;
  - iii. Potential confounding effect of medical comorbidities and medications;
  - iv. Technical quality of study;
  - v. Presence of snoring (if available on recording);
  - vi. Heart rate abnormalities;
  - vii. Severity of the OSAH, if present;
  - viii. The severity of desaturations and the validity of these parameters if they are in question;
  - ix. Presence and potential significance, or lack thereof, of central and mixed respiratory events;
  - x. Respiratory patterns that may be artifactual, or suggest a complicated sleep apnea syndrome and/or hypoventilation;
  - xi. Possible differential diagnosis for nonspecific oximetry patterns;
  - xii. Suggestions for further investigations and management;
  - xiii. Highlight critically abnormal test results or results that may need further diagnostic clarification (see section 5.3).

5.3 Test follow-up

Appropriate follow-up or continuity of care must be coordinated by the testing facility/program:

A. Testing is performed by physician order. The ordering physician is responsible for acting on the test results. A request for a diagnostic test is not a sleep medicine consultation

request. However, any facility performing Level 3 testing should ensure that policies are in place or patterns of practice are well understood such that it is clear which physicians are expected to act on the test results.

B. Interpreting physicians may not necessarily be involved in actual patient management; however, they should extend their comments to advise when the test suggests the need for further urgent action, physician assessment, testing (eg, severe symptoms and a normal test) and/or referral to a sleep specialist.

6.0 QUALITY MANAGEMENT PROGRAM

Facilities performing PM require a quality management program that includes – but is not limited to – the following:

- Establishing routine inter-rater reliability checks of the technologist scoring of records;
- Establishing routine inter-rater reliability checks of the physicians' interpretation of records;
- Establishing a mechanism for a minimum of quarterly reviews of 10 randomly selected records of original data from PM tests performed by the facility to establish whether the tests were properly performed and that the test results are reliable;
- Surveying patients periodically to determine their satisfaction with the PM services provided by the facility and to seek their suggestions for improvements; and
- Surveying referring physicians periodically to determine their satisfaction with the PM services provided by the facility.

7.0 CONFLICT OF INTEREST GUIDELINES

Ideally, no aspect of PM for the purposes of diagnostic testing and/or treatment including, but not limited to, the delivery and/or pick-up of the device should be performed by a vendor of CPAP units, durable medical equipment supplier or other goods that may be sold based on results of the PM test.

However, given the limitation in available medical and facility resources, some communities may have to rely on third-party home care suppliers for a variable degree of PM testing. In these circumstances, the standard of care presented in the current guidelines should be maintained, and full disclosure of any conflict of interest must be made clear to the patients and referring physician by written public disclosure.

CONCLUSION

PM provides a useful additional diagnostic tool for the management of patients with uncomplicated OSAH when used with the appropriate practice standards as described above.

DISCLOSURE/CONFLICTS OF INTEREST: A Blackman is the President of MedSleep (Toronto, Ontario), the former chair of the Ontario Medical Association Sleep Disorders Section, and a member of the Independent Health Facilities Sleep Studies Task Force, College of Physicians and Surgeons of Ontario. **C McGregor** uses portable monitoring devices, but does not receive free equipment or sundries from any company manufacturing or involved with portable monitoring. **HS Driver** has used portable monitors from Braebon Medical Corporation (Kanata, Ontario). Her laboratory has received eight units over the course of three years, but no funding support from the company. She has no financial or other interests in the company. **K Fraser** is a consultant with the Railways Association of Canada. **A Khullar** is on the Advisory Boards of Pfizer, Biovail, AstraZeneca and Lundbeck. He serves on the Speaker's Bureau of Eli-Lily, AstraZeneca, Pfizer, Shire, Lundbeck, sanofi aventis and Janssen-Ortho. He has received research grants from AstraZeneca, sanofi aventis, Merck and Pfizer. **GE Sullivan** interprets sleep studies and oximetry tests for various hospitals, extramural hospitals and home care companies with which there is no financial relationship – service is billed as part of a fee-for-service medical practice. He works primarily as a salaried consultant in sleep medicine at the Saint John Regional Hospital (Saint John, New Brunswick). **N Ayas** has received a research grant from Respironics (Pennsylvania, USA). **J Kimoff** has received speaker's fees from GlaxoSmithKline Inc and VitalAire Inc (Mississauga, Ontario) for clinical presentations. **D Morrison** has previously reported portable monitoring on an ad hoc basis for VitalAire Inc (Mississauga, Ontario). **R Skomro** has received honoraria for speaking engagements for GlaxoSmithKline Inc and AstraZeneca. **W Tsai** performs level III testing and interpretation for Homecare Solutions (Tennessee, USA), VitalAire Inc (Mississauga, Ontario) and Medigas (a division of Praxair Canada Inc, Hamilton, Ontario). The remaining authors have no financial disclosures or conflicts of interest to declare.

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