TITLE: Portable Monitoring Devices for Diagnosis of Obstructive Sleep Apnea at Home: Review of Accuracy, Cost-Effectiveness, Guidelines, and Coverage in Canada

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EXECUTIVE SUMMARY

Context and Policy Issues

Obstructive sleep apnea (OSA) is a syndrome that is characterized by recurrent episodes of partial (hypopnea) or complete (apnea) upper airway obstruction during sleep despite ongoing respiratory efforts. The symptoms include excessive daytime sleepiness, impaired concentration, and snoring. OSA has been linked to an increased risk of motor vehicle accidents, hypertension, cardiovascular disease, neurocognitive changes, and stroke. Approximately 4% of men and 2% of women have OSA. Polysomnography (PSG) is the gold-standard investigation used in the diagnosis of OSA. The costs of using PSG in a sleep laboratory are high because of the cost of the examination time, the need for a qualified technician and sleep specialist, and equipment costs. Furthermore, OSA is often undiagnosed because of long wait times to see a sleep physician and receive a diagnosis. As a result, the requirement of using laboratory PSG to obtain an accurate diagnosis of OSA has been debated for years, and the use of portable monitoring devices has been proposed. This report reviews the evidence on the accuracy and cost-effectiveness of using portable monitoring devices for the diagnosis of OSA at home and in the laboratory when compared with laboratory PSG. Current guidelines, information on the portable monitoring devices available in Canada, coverage of devices by private and public health plans in Canada, and the level of patient compliance with continuous positive airway pressure (CPAP) treatment when OSA is diagnosed are reviewed.

Research Questions

1. Which portable monitoring devices for the diagnosis of obstructive sleep apnea at home are available in Canada?
2. What is the accuracy of using portable monitoring devices for the diagnosis of obstructive sleep apnea at home compared with laboratory-based testing? Which patient populations are most suitable for home diagnosis using portable monitoring devices? Is there evidence for the use of portable monitoring devices in a supervised setting?
3. What is the cost-effectiveness of using portable monitoring devices compared with laboratory-based testing for the diagnosis of obstructive sleep apnea?
4. What are the guidelines for using portable monitoring devices for the diagnosis of obstructive sleep apnea at home?
5. What is the level of patient compliance with continuous positive airway pressure treatment of obstructive sleep apnea?
6. What jurisdictions provide coverage for devices that are used for the diagnosis and treatment of obstructive sleep apnea at home? How much coverage is provided and under what conditions?

Methods

Published literature was obtained by searching databases between 2003 and October 2008. Filters were applied to limit the retrieval to health technology assessments (HTAs), systematic reviews, meta-analyses, economic analyses, and guidelines. A randomized controlled trial (RCT) filter was applied to retrieve RCTs from 2007 to January 2009. The websites of regulatory agencies, HTA organizations, and related agencies were also searched. The Google search engine was used to search for information on the Internet. These searches were supplemented by hand-searching the bibliographies of selected papers. Two reviewers screened and selected articles for inclusion in this report.

Summary of Findings

Several portable monitoring devices are available in Canada for use in the diagnosis of OSA. Most machines measure respiration and oxygenation directly. Several evolving technologies measure these variables indirectly through peripheral arterial tone and actigraphy.

Two HTAs published in 2007 were retrieved in the search. One of the key findings of the first HTA report was that for those with a high pretest probability of moderate-to-severe OSA (based on medical history, reported daytime sleepiness, and other measures), initial management using laboratory PSG does not result in better outcomes than an ambulatory approach in terms of diagnosis, CPAP titration, or response to CPAP therapy. Level 2 and 3 portable monitors produced accurate results in the diagnostic assessment of OSA when laboratory PSG was used as the reference. Accurate results were also achieved using level 4 portable monitors measuring at least three parameters. Diagnostic accuracy decreased for level 4 monitors measuring two or fewer parameters. The accuracy of portable monitors seemed to be better in studies that were conducted in sleep laboratories compared with studies that were conducted at home. In the second HTA report, results obtained from modelling different strategies showed a trade-off for time to diagnosis and CPAP therapy versus test accuracy. After the release of these assessments, the US Centers for Medicare & Medicaid Services (CMS) decided to cover CPAP therapy for adults who were diagnosed using PSG or home testing.

Two systematic reviews and one meta-analysis not included in the identified HTAs were reviewed. The results from a 2007 systematic review showed that diagnostic accuracy increases with manual scoring compared with automatic scoring. The low sensitivity that was demonstrated with the use of pulse oximetry alone indicated that it is insufficient for the diagnostic assessment of OSA. Findings from a 2006 meta-analysis suggested that home sleep studies provided similar diagnostic information when compared with laboratory PSG but may underestimate the severity of OSA. Portable sleep studies were also significantly more likely to give a poor recording when compared with laboratory PSG. A 2003 systematic review found that sensitivities and specificities were generally higher for level 2 and level 3 portable monitors than for level 4 portable monitors. The percentage of portable monitoring studies that did not collect adequate data was generally higher when not attended by a sleep technician. There was limited evidence on the use of portable monitors in an unattended setting. Based on these findings, the research group recommended against the use of portable monitoring devices for the diagnosis of OSA at home.

Two RCTs not included in the identified HTAs or systematic reviews were retrieved. One RCT (n = 106) assessed whether CPAP compliance and clinical outcomes differed between patients who were randomly assigned to home diagnosis and CPAP autotitration or conventional laboratory PSG. At a six-week follow-up clinic visit, CPAP compliance and the clinical outcomes evaluated did not differ between the two groups. Another RCT (n = 62) compared the utility and reliability of a portable monitoring device in patients who were randomly assigned to receive portable monitoring simultaneously with PSG or portable monitoring at home. The results indicated that portable monitoring at home is less sensitive for the diagnosis of OSA when compared with portable monitoring conducted in the laboratory. The use of wrist actigraphy tended to overestimate sleep time and did not significantly improve the accuracy of portable monitoring at home.

One cost-utility analysis and one informal cost comparison were identified. The cost-utility analysis indicated that portable monitoring followed by CPAP autotitration or split-night PSG may be cost-effective alternatives to full-night PSG for diagnosis and treatment initiation for OSA. The informal cost comparison showed that in the USA, Spain, UK, and France, portable sleep studies were 35% to 88% less costly than laboratory sleep studies.

Four clinical practice guidelines outlining the use of portable monitoring devices for the diagnosis of OSA were retrieved. Three of these guidelines recommend limiting the use of portable monitoring devices to those patients with a high pretest probability of moderate-to-severe OSA and without other potentially confounding medical conditions or sleep disorders. In addition, they recommend the maintenance of the same high technical standards during home testing as those that would be found in an accredited sleep centre. A fourth guideline recommends the use of actigraphy as a method to estimate total sleep time when PSG is unavailable.

Limitations

Most studies evaluating portable monitoring devices have been conducted on Caucasian male patients with no comorbidities and a high pretest probability of OSA. Consequently, the results of these studies may not be generalizable to other groups of patients. Most studies assessing portable monitors for diagnostic accuracy were conducted simultaneously with the use of PSG in a laboratory. Hence, it is difficult to assess the utility of portable monitoring devices for use at home. Studies examining long-term, clinically important outcomes in patients who receive a diagnosis after the use of portable monitoring devices are yet to be performed.

CPAP Compliance

Although CPAP is the cornerstone of therapy for OSA, compliance is often poor. Several factors may influence treatment initiation and compliance with CPAP, including severity of symptoms, cost to the patient, frequency of follow-up, satisfaction with mode of therapy, education about the health consequences of OSA, and level of discomfort including claustrophobia and upper airway side effects.

Coverage

A survey was conducted to assess which Canadian jurisdictions provide coverage for devices that are used in the diagnosis and treatment of OSA at home. Responses were received from all jurisdictions except Quebec, Northwest Territories, and Nunavut. Public funding of CPAP equipment is available in Ontario, Alberta, Manitoba, New Brunswick, Saskatchewan, Newfoundland, and the Yukon. The only jurisdiction that funds private testing at home using a portable monitoring device for oximetry is the Yukon. British Columbia, Prince Edward Island, and Nova Scotia do not provide coverage for devices that are used at home for the diagnosis or treatment of OSA. Several private medical insurance policies cover CPAP equipment, but the amount of aid varies between insurers, and there may be variations in benefits between individual and group policies at the same firm.

Conclusions and Implications for Decision- or Policy-Making

Although laboratory PSG is the standard test used in the diagnosis of OSA, there is evidence that among patients with a high pretest probability of moderate-to-severe OSA with no comorbidities, portable monitoring devices may be useful for the diagnostic evaluation of patients when there is limited access to laboratory sleep studies and sleep specialists. Pulse oximetry that is used alone is not recommended for the diagnostic evaluation of OSA. Canadian jurisdictions should take local needs and resources into account when considering reimbursement of portable monitoring at home.