Validation of the MediByte® type 3 portable monitor compared with polysomnography for screening of obstructive sleep apnea

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BACKGROUND: Portable monitors are increasingly being used as a diagnostic screening tool for obstructive sleep apnea (OSA), and in-laboratory validation of these devices with polysomnography (PSG) is required.

OBJECTIVE: To assess the reliability of the MediByte (Braebon Medical Corporation, Canada) type 3 screening device compared with overnight PSG.

METHODS: To cover a range of OSA severity, a consecutive series of patients wore the screening device while simultaneously undergoing PSG. Data acquired from the screener and PSG were blinded and scored separately. The number of apneas and hypopneas per hour were calculated using recording time (respiratory disturbance index [RDI]) for the MediByte device, and sleep time (apnea-hypopnea index [AHI]) for PSG.

RESULTS: Data from 73 patients with a mean age of 53 years and body mass index of 32.2 kg/m^2 showed high measurement association between the RDI and AHI, with a Pearson correlation of 0.92, accounting for 85% of the variance. Based on Bland-Altman measurement agreement, the mean difference between the RDI and AHI (−5.9±11.2 events/h) indicated screener under-reporting. For an AHI of greater than 15 events/h, the sensitivity and specificity of the screener was 80% and 97%, respectively; for an AHI of greater than 30 events/h, the positive predictive value was 100%, while the negative predictive value was 88%.

CONCLUSION: The MediByte device accurately identified patients without OSA and had a high sensitivity for moderate-to-severe OSA.

Key Words: *Diagnostic screening; Home sleep testing; Obstructive sleep apnea; OSA screener; PM studies; Portable monitor*

Prompt diagnosis and treatment of obstructive sleep apnea (OSA) can effectively reduce the risk of developing health consequences and improve general quality of life. However, access to the 'gold standard' of sleep apnea diagnosis – overnight polysomnography (PSG) in a sleep laboratory while monitored by a sleep technologist – is limited in many areas by long wait times at sleep clinics and sleep laboratories, and by the substantial cost of the in-laboratory studies (1-3). The prevalence of OSA syndrome in adults is approximately 5% (4,5); however, it is also estimated that 82% of men and 93% of women experiencing moderate-to-severe sleep apnea are currently enduring this condition undiagnosed and untreated (6). This is of particular concern because the morbidity and mortality rates associated with untreated OSA have been clearly delineated in the medical literature, as has the cost effectiveness of treatment with continuous positive airway pressure (CPAP) (7,8). In addition, the ever-increasing prevalence rates of obesity in the western hemisphere suggests that the prevalence of OSA will continue to increase, posing an even greater challenge to health care services to provide timely access to diagnosis and treatment (8).

With advances in technology, small portable monitors (PMs) that include oximetry, airflow measurements via a nasal cannula pressure transducer, respiratory movements (chest and abdomen) and a body position sensor, are available as home screening recorders for OSA (2,3,9-21). To address the backlog of patients awaiting diagnostic evaluation, the use of PMs to screen patients in whom there is a high clinical suspicion for OSA may provide an alternative to in-laboratory PSG. Several of these devices have recently been validated against in-laboratory PSG for use in an adult population; some simultaneously recorded with in-laboratory PSG (9-12), or conducted recordings on different nights (13) or had both concurrent and separate recordings (14-15). High-quality studies of patients with a high clinical suspicion of OSA using similar scoring definitions for apneas and hypopneas have been shown to have high specificity (greater than 90%), sensitivity and likelihood ratios when attended in the laboratory (2,14-16,20). Others using limited channels, ie, only airflow and/or snoring or performed in an unattended setting, have shown more variability (10,13,17). Similar clinical outcomes have been reported using PM devices compared with PSG (18). Furthermore, as recently reported by Ayas et al (19), the potential for economic benefit of using PMs within a clinical setting in patients with a high pretest score for OSA may be an additional advantage.

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