

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/m² 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

La validation du moniteur portable MediByte[®] de type 3 par rapport à la polysomnographie pour dépister l'apnée obstructive du sommeil

HISTORIQUE : Les moniteurs portables sont de plus en plus utilisés comme outil de dépistage de l'apnée obstructive du sommeil (AOS). Il faut valider ces appareils en laboratoire au moyen de la polysomnographie (PSG).

OBJECTIF : Évaluer la fiabilité de l'appareil de dépistage MediByte (Braebon Medical Corporation, Canada) de type 3 par rapport à la PSG de nuit.

MÉTHODOLOGIE : Pour couvrir une plage de gravité d'AOS, une série consécutive de patients ont porté l'appareil de dépistage tout en subissant une PSG. Les données acquises par l'évaluateur et le PSG étaient en insu et évaluées séparément. Le nombre d'occurrences d'apnée et d'hypopnée à l'heure était calculé au moyen de l'heure d'inscription (indice de perturbation respiratoire [IPR]) pour l'appareil MediByte, et du temps de sommeil (indice d'apnée-hypopnée [IAH]) pour la PSG.

RÉSULTATS : Les données recueillies auprès de 73 patients dont l'âge moyen était de 53 ans et l'indice de masse corporelle, de 32,2 kg/m², ont révélé une forte association de mesures entre l'IPR et l'IAH, la corrélation de Pearson étant de 0,92, laquelle représentait 85 % de la variance. D'après l'entente de mesure Bland-Altman, la différence moyenne entre l'IPR et l'IAH (-5,9±11,2 événements/h) indiquait une sous-déclaration de l'évaluateur. En présence d'un IAH supérieur à 15 événements/h, la sensibilité et la spécificité de l'évaluateur s'élevaient à 80 % et à 97 %, respectivement. Lorsque l'IAH était supérieur à 30 événements/h, la valeur prédictive positive était de 100 %, et la valeur prédictive négative, de 88 %.

CONCLUSION : L'appareil MediByte permet de dépister avec exactitude les patients sans AOS et avait une sensibilité élevée pour ce qui est de l'AOS modérée à grave.

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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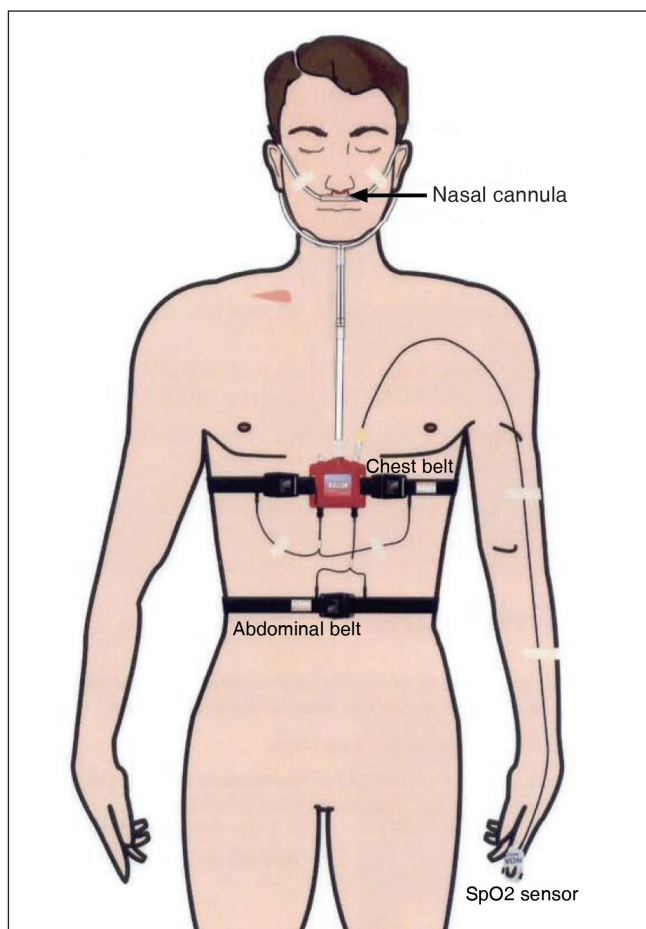


Figure 1) Full setup for the portable MediByte (Braebon Medical Corporation, Canada) home screening device. SpO₂ Oxygen saturation

The use of unattended PMs for patients with a high risk of OSA, and without other sleep or medical comorbidities, was recently recognized by the American Academy of Sleep Medicine (AASM) as an alternative diagnostic tool to in-laboratory, technologist-attended PSG (16). Recommendations to use unattended portable monitoring devices are predicated on the understanding that portable monitoring should be performed in conjunction with a comprehensive sleep evaluation and supervised by a physician with training in sleep medicine. When used appropriately, and properly interpreted, these PMs could serve as invaluable tools in helping to identify individuals with severe OSA, to expedite treatment, and improve the cost effectiveness of the diagnostic algorithm.

There are several PMs with a variety of technical and design capabilities available for OSA screening. These PM devices are classified into different levels according to specifications that were listed by the American Sleep Disorders Association in 1994 (21). Ideally, commercially available devices used for home screening for OSA should be validated and compared with in-laboratory, technologist-attended PSG, which is a level 1 study. A level 2 study is an unattended full overnight PSG, typically recorded at the patient's home. Devices for a level 3 study include three or more respiratory channels, pulse oximetry and heart rate, usually without electroencephalography (EEG). Their use in the outpatient setting was reviewed by the Portable Monitoring Task Force of the AASM in 2007, and guidelines were established (16).

The aim of the present study was to assess the viability of a portable screening device (MediByte [Braebon Medical Corporation, Canada]) for OSA in adults by simultaneously collecting data using the in-laboratory, technologist-attended PSG (level 1) and the PM (level 3).

METHODS

Participants

Patients referred to the sleep laboratory for a diagnostic overnight study, a possible split-night study or an assessment of positional therapy from January to March 2007, and October 2008 to March 2009, were invited to participate. For evaluation of a random sample of patients, including those without OSA, there was no pretest screening for OSA. An opportunistic sample of 80 patients was recruited depending on the availability of the PM device. Patients with high-care needs, known hypercapnia or hypoventilation were excluded. The refusal rate was negligible, including three individuals who were sleepy and did not want the start of their study to be delayed. All patients were informed that their participation was completely voluntary; they received no financial compensation for participation. The study was approved by Queen's University Health Sciences (Kingston, Ontario) and the affiliated teaching hospitals' research ethics boards.

Design

The protocol for the present study involved the patient wearing the usual equipment for overnight PSG simultaneously with the equipment for the MediByte device. Patients attended the Sleep Disorders Laboratory at Kingston General Hospital (Kingston, Ontario) for full overnight PSG. Recordings using the Sandman Elite SD 32+ digital sleep recording system (Embla [Mallinckrodt/Nellcor Puritan Bennett (Melville) Ltd, Canada]) included four EEG channels (C4-A1, C3-A2, O2-A1, O1-A2), two electrooculogram channels (ROC-A1, LOC-A2), submental electromyography (EMG), intercostal EMG, bilateral anterior tibialis EMG, electrocardiography, respiratory bands (chest and abdomen), finger pulse oximetry, a vibration snore sensor, and an oral/nasal cannula pressure transducer (Ultima Pressure Sensor, Braebon Medical Corporation, Canada) along with an oral and nasal thermistor (ProTech, USA). Patients were also monitored continuously throughout the night by an infrared video camera to document body position changes during sleep.

Once patients were equipped for PSG, sensors for the MediByte PM device were applied by the research assistant. Therefore, they wore an additional finger-pulse oximeter probe and two extra respiratory bands. Patients wore one oral/nasal cannula. The tubing from the cannula was attached via a Y connector to the two pressure transducers – one for PSG and the other for the MediByte PM device, enabling simultaneous recording of the airflow signal via the two different pressure transducers.

Device description

The MediByte device is a type 3 classification PM for OSA. It consists of two respiratory effort bands (chest and abdomen), a nasal cannula pressure transducer for airflow, a finger pulse oximetry sensor (oxygen saturation and heart rate) and a body position sensor. Typical patient setup is shown in Figure 1. The device is held in place via the chest effort band, and placed midsternum for comfort and for body position detection. The MediByte PM provides an additional auxiliary channel (with the option to use it as a snore sensor, electrocardiogram, EEG, EMG-periodic leg movement or EMG-bruxism), which was not included in the present analysis.

The device operates on battery power (3.6 V) and has a sampling rate of 2000 Hz. An internal memory of 128 Mb allows for up to 24 h of continuous data recording, and it can be configured to record two consecutive nights of data.

Data from the MediByte PM were downloaded into a chronologically readable format by using Pursuit software (Braebon Medical Corporation, Canada) for review and manual scoring.

Analysis

PSGs were manually scored using standard criteria (22-24) by registered polysomnographic technologists who were blinded to the results from the PM. Raw data from the MediByte PM were manually reviewed and scored while the PSG results were blinded; any respiratory events that were clearly associated with movement were not included. For both

TABLE 1
Demographic characteristics and sleep measurements for patients who underwent overnight polysomnography (PSG) combined with a portable monitor (PM) (n=73)

	Mean±SD
Age, years	
Men (n=30)	52.9±12.2
Women (n=43)	52.9±12.7
PSG: Total recording time, min	382±118
PM: Total recording time, min	381±119
PSG: Total sleep time, min	285±110
PSG: Sleep efficiency, %	74.2±14.6
PSG: REM sleep (%TST) (8 patients had no REM)	14.0±8.3
PSG: AHI, events/h	26.0±25.9
PM: RDI, events/h	20.1±18.8
Difference between RDI and AHI (RDI-AHI), events/h	-5.9±11.2

AHI Apnea-hypopnea index; RDI Respiratory disturbance index; REM Rapid eye movement; TST Total sleep time

PSG and PM data, apneas were scored when there was a cessation (with a reduction of more than 90%) of airflow for at least 10 s. Hypopneas were scored using criteria established by the AASM in 1999 (23) and adopted as the alternative AASM criteria in 2007 (24): these events, lasting at least 10 s, were scored for both the PM and PSG based on airflow reduction measured by nasal pressure of 50% to 90% from baseline followed by oxygen desaturation of at least 3% and, for PSG-scored events, in association with arousals (25).

Statistical analysis

Based on the manually scored number of apneas and hypopneas, the primary measure for the PSG data was the apnea-hypopnea index (AHI), which was defined as the number of apneas and hypopneas per hour of sleep time. The primary measure for the MediByte PM data was the respiratory disturbance index (RDI), which was defined as the number of apneas and hypopneas per hour of recording time. To assess the measurement agreement of the screening device for an accurate diagnosis of OSA, the mean difference and limits of agreement (Bland-Altman) between the RDI was compared with various AHI cut-off points (9,16). An AHI of 5 events/h was considered as the threshold below which was normal, an AHI of 15 events/h was used as the cut-off point for moderately severe OSA, while a cut-off point of 30 events/h was defined as the AHI for severe OSA. Based on these AHI cut-off points and, compared with the RDI, studies were rated as true positive (TP), false positive (FP), true negative (TN) or false negative (FN). The sensitivity and specificity of the device was calculated for the various AHI categories: Sensitivity refers to the proportion of patients with OSA (based on the AHI) who had a positive test result (ie, TP) calculated as $(TP \times 100 / TP + FN)$, whereas specificity refers to the proportion of patients without OSA who had a negative test result (ie, TN) calculated as $(TN \times 100 / TN + FP)$ (26).

ROC curve analysis uses sensitivity and specificity comparisons according to different thresholds – here AHI category – to graphically represent the trade-off between FNs and FPs (26). The ROC curve is a plot of sensitivity versus $(1 - \text{specificity})$ for various AHI values. Calculating the area under the curve (AUC) provides a measure in which the better the instrument, the greater the AUC, with an area of 1 representing a perfect instrument.

Multilevel, mixed-effects Poisson regression analysis was used to investigate possible sources of difference between the recording methods, including sex and obesity (body mass index [BMI] of 30 kg/m² or greater), while accounting for recording time differences among patients. The outcome was the observed number of respiratory events, with the observations nested in individuals – individuals were considered random effects, while recording method, sex, obesity and their interactions were considered to be fixed effects.

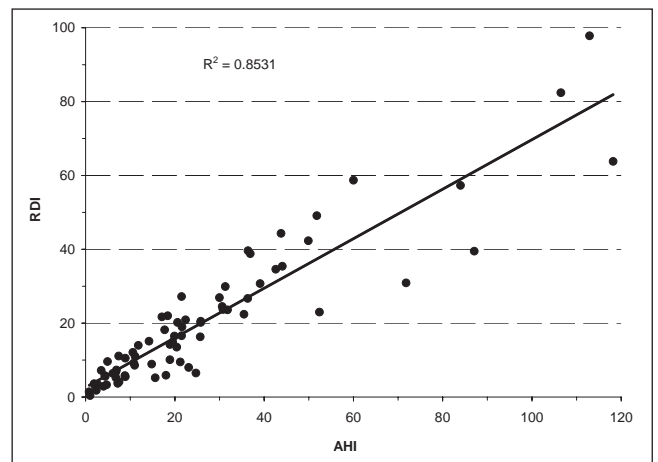


Figure 2) The correlation between the number of apneas and hypopneas from the MediByte (Braebon Medical Corporation, Canada) screener based on recording time (respiratory disturbance index [RDI]) and the polysomnography study based on sleep time (apnea-hypopnea index [AHI]) for 73 patients

RESULTS

Of the 80 studies collected, data were lost on the PM for seven patients. In two of the initial cases, this loss was due to low battery power, which resulted in the recording being automatically stopped once the battery had completely lost power. Of the other five cases, a faulty pressure transducer or a kink in the Y connector tubing to the PM resulted in a poor airflow signal, affecting the MediByte recording. No data loss occurred for the PSG recordings given the back-up thermocouple for airflow and technologist intervention when there was loss of airflow on the pressure signal. Data were compared for 73 patients who completed both the PSG and PM recording: they were 20 to 73 years of age with a mean (\pm SD) age of 53±12 years and a mean BMI of 32.2±6.8 kg/m². Demographic characteristics and sleep recording data for the 73 patients are shown in Table 1. The mean BMI for the 30 men was 32.1±6.6 kg/m² (range 20.4 kg/m² to 48.4 kg/m²), and for the 43 women was 32.2±7.0 kg/m² (range 21.4 kg/m² to 52.7 kg/m²). Fifteen of the studies (eight women and seven men) were split-night studies (initial diagnostic period followed by introduction of CPAP therapy partway through the night when the AHI was greater than 20 events/h); in these cases, the MediByte PM recording time was truncated to the time of lights on, ending the diagnostic study to initiate CPAP therapy. There was no difference in the total recording time for PM and PSG analysis, with a mean total sleep time of 4.75 h. Eight of the patients (six in the split-night protocol) did not experience rapid eye movement (REM) sleep in the diagnostic study.

A correlation analysis comparing the RDI recorded with the MediByte PM and the AHI recorded by PSG is presented in Figure 2. There was a strong positive association between the two measurements, with a Pearson correlation of 0.92 accounting for 85% of the variance.

The measurement agreement between the RDI and the AHI was calculated based on a Bland-Altman approach using the difference between the two measurements and the mean of the two measurements (Figure 3). The mean difference between the RDI and the AHI showed an under-reporting with the MediByte device by -5.9 ± 11.2 events/h, with limits of agreement (mean \pm 2 SD) at +16 and -28, as shown in Figure 3. For the Bland-Altman plot (Figure 4), each data point represents the percentage difference between the two measurements for each patient (ie, $(RDI - AHI) / \text{mean}$) plotted against the mean for each patient (ie, $(RDI + AHI) / 2$). The mean percentage difference was -19%, with limits of agreement of 61% and -99%, illustrating the systematic bias of under-reporting by the MediByte PM. Over-reporting by the PM occurred for three cases in which the AHI

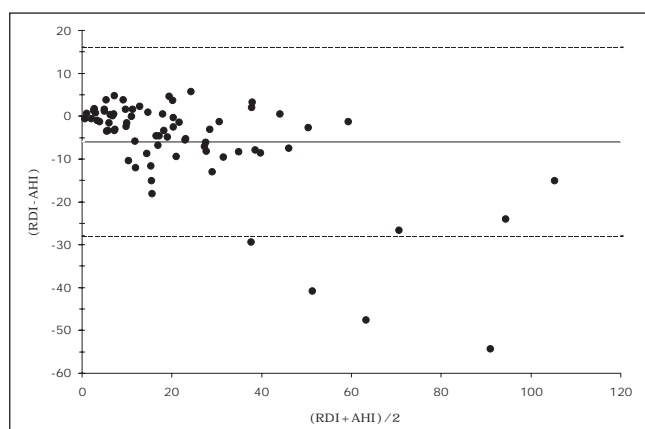


Figure 3) Bland-Altman plot. Difference between the MediByte (Braebon Medical Corporation, Canada) portable monitor and polysomnography, plotted against the mean of the respiratory disturbance index (RDI) and apnea hypopnea index (AHI) (n=73) during in-laboratory study. The solid line represents the mean difference, while the dashed lines represent the limits of agreement (± 2 SDs)

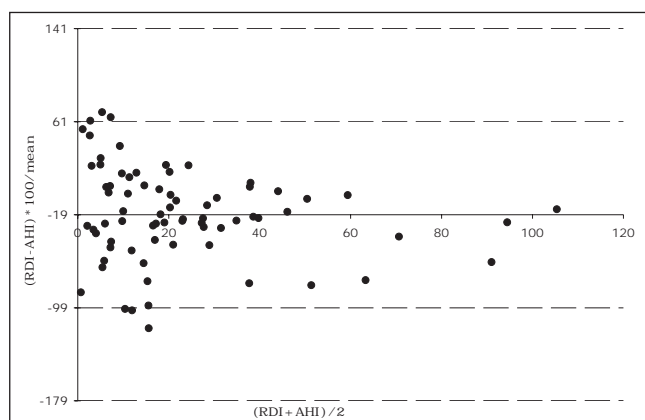


Figure 4) Bland-Altman plot. Percentage difference between the MediByte (Braebon Medical Corporation, Canada) and polysomnography (respiratory disturbance index [RDI] - apnea hypopnea index [AHI]) plotted against the mean of the RDI and AHI for all patients. The solid line at -19 represents the mean percentage difference, while the dashed lines represent the limits of agreement (± 2 SDs) at 61 and -99 (n=73)

was normal and the total sleep time was above the mean – for example, one outlier had an AHI of 1.9 events/h, an RDI of 3.6 events/h and total sleep time of 341 min.

Sensitivity and specificity were used to infer the utility of a diagnostic test to exclude or confirm the presence of OSA (9,16). The AHI cut-off points used to indicate severity of OSA were categories of AHI of less than 5 events/h rated as normal, 5 events/h to 15 events/h as mild, 15 events/h to 30 events/h as moderate, and greater than 30 events/h as severe (23). Table 2 displays these values for the MediByte PM at various AHI cut-off points. The MediByte PM had a high degree of specificity for identifying severe OSA (AHI of greater than 30), as well as a high-degree of sensitivity for the presence of OSA (AHI of less than 5 events/h). Indeed, 97% of the patients (59 of 61) with a higher than normal AHI were correctly identified (ie, TP). Overall, 100% of the PM studies correctly identified the presence (ie, TP) and 88% the absence (ie, TN) of severe OSA.

The ROC curves in Figure 5 show that the best results were obtained for an AHI cut-off value of 10 events/h. The AUC for an AHI of 5 events/h, 10 events/h and 15 events/h were similar at 0.940, 0.944 and 0.926, respectively, and indicated excellent agreement.

TABLE 2
Sensitivity, specificity, positive predictive value and negative predictive value of the MediByte* device according to apnea-hypopnea index cut-off points including the number of patients for various levels of obstructive sleep apnea severity (n=73)

	Apnea-hypopnea index, events/h				
	>5	>10	>15	>20	>30
n	61	51	44	35	23
Sensitivity	97	84	80	80	70
Specificity	67	91	97	95	100
Positive predictive value	94	96	97	93	100
Negative predictive value	80	71	76	84	88

*Braebon Medical Corporation, Canada

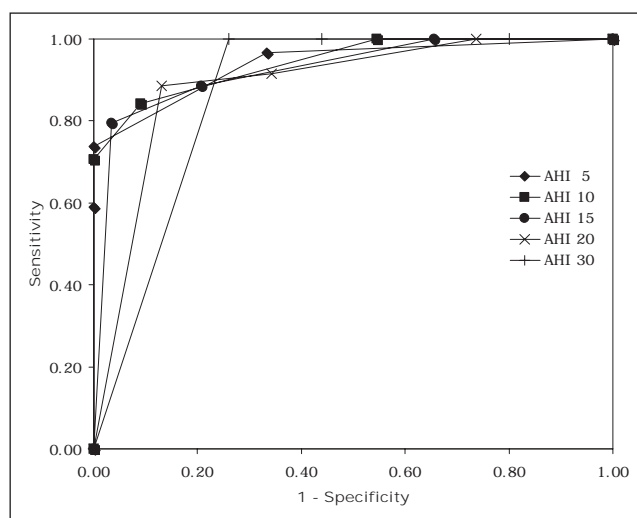


Figure 5) ROC curve according to apnea-hypopnea index (AHI) category for the MediByte (Braebon Medical Corporation, Canada) respiratory disturbance index. AHI 5: Area under the curve (AUC) = 0.940 (95% CI 0.866 to 0.985); AHI 10: AUC = 0.944 (95% CI 0.866 to 0.985); AHI 15: AUC = 0.926 (95% CI 0.847 to 0.977); AHI 20: AUC = 0.889 (95% CI 0.795 to 0.951); AHI 30: AUC = 0.870 (95% CI 0.779 to 0.942)

As an indication of clinical sensitivity based on an AHI of 15 events/h, the proportion of patients in the four possible comparison groups – namely, TP, FP, TN and FN, is shown in Table 3. Thirty-five of 44 patients had a positive PM result for moderately severe OSA. For the nine FN studies, the mean difference between the RDI and AHI was -10.3 ± 4.6 events/h, while the one FP result only had a difference of 0.9 across the cut-off value of 15. Thus, 86% of patients (63 of 73) would have been accurately identified for the presence or absence of moderately severe OSA from the MediByte study data when compared with PSG. The positive predictive value of the PM at the AHI cut-off point of 15 events/h was 97% (35 of 36), while the negative predictive value was 76% (28 of 37).

A low recording time, for example, in the split-night studies compared with full overnight diagnostic studies, lowered the measurement agreement. Excluding the 15 split-night studies improved the measurement agreement, with the mean difference between the PM and PSG reduced to -3.7 ± 8 events/h (compared with -5.9 ± 11.2 events/h), with limits of agreement of +12 and -20. However, sensitivity decreased to 72% (from 80%, due to the smaller number of patients with severe OSA), while specificity remained at 97% for an AHI of 15 events/h or higher.

TABLE 3
Diagnostic accuracy of the MediByte* device respiratory disturbance index (RDI) measured over the total recording time for a polysomnographically determined apnea-hypopnea index of 15 events/h based on total sleep time in a consecutive series of 73 patients

Portable monitor	Apnea-hypopnea index, events/h		Total
	Positive (>15/h)	Negative (<15/h)	
Positive, RDI >15	35	1	36
Negative, RDI <15	9	28	37
Total	44	29	73

Data presented as number of patients per category. *Braebon Medical Corporation, Canada

The rate of respiratory events (RDI and AHI) was twice as great for patients who were obese as it was for those who were not (incidence-rate ratio [IRR] = 2.01 [95% CI 1.28 to 3.16]; $P=0.002$). The rate among women was 59% of the rate for men (IRR = 0.59 [95% CI 0.38 to 0.91]; $P=0.017$). Compared with the PSG-based AHI, the PM-based RDI under-reported the rate of respiratory events for those who were obese compared with those who were not (IRR = 0.79 [95% CI 0.74 to 0.85]; $P<0.0001$). The PM-based RDI also under-reported the rate of respiratory events for women more than men (IRR = 0.91 [95% CI 0.85 to 0.97]; $P=0.005$). A sex distribution was evident for OSA severity. Although more women than men participated in the present study, more men had severe OSA – of 22 patients with severe OSA, eight were women and 14 were men, whereas of 51 patients with an AHI of 30 events/h or less, there were 35 women and 16 men; for an AHI of 15 events/h or less, 20 of 29 patients were women.

The accuracy of the position sensor for the time spent supine was compared between the PM and technologist-noted position based on the video camera for 71 studies. Two studies were excluded – one due to not having video for the PSG and the other due to excessive movements causing a shift in the position sensor. The Pearson correlation for the percentage of recording time spent supine was high ($r=0.94$), accounting for 89% of the variance, as shown in Figure 6.

DISCUSSION

Based on the present study and standard thresholds commonly used for the diagnosis of OSA for in-laboratory PSG (23,24), the MediByte PM had a high sensitivity for identifying moderate-to-severe OSA, and a high specificity in the exclusion of severe OSA. While sensitivity is one of the most important accuracy criteria when screening for OSA, specificity is important because of the potential costs associated with following up FP cases. The MediByte PM was a viable tool for screening for the absence or presence of severe OSA in 88% and 100% of patients, respectively.

Data loss in the present study was low at 6.25% (five of 80 studies) or 9% when including the loss of battery power for two patients in the initial trials. After these trials, as recommended by the manufacturers, we adopted a strategy of replacing the battery after two overnight studies and downloads. Other data loss was due to a poor airflow signal, sometimes due to a kink in the Y connector between the PSG and MediByte nasal cannula pressure transducer recorder. No real-time feedback of the signal quality during collection on the MediByte PM is available to correct signals on setup or during a study. This level of data loss may be reflective of that in the field because technologist intervention was minimal. No studies were excluded due to loss of the oximeter signal. As reported in previous studies (27), oral breathing contributed to airflow signal loss with the nasal cannula pressure transducer. However, this loss of sensitivity during oral breathing was an issue for both types of studies, with the caveat of having the additional thermal sensor for airflow on PSG that provided a measure of oral flow and as advised by the AASM guidelines (24).

Based on the Bland-Altman measurement agreement calculations between the MediByte PM and the PSG, there were four outliers with

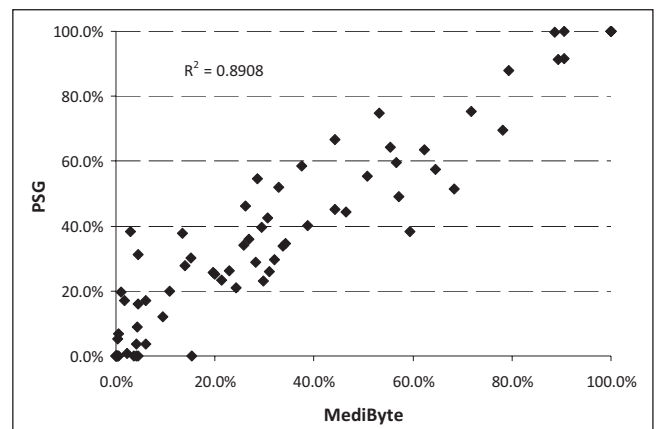


Figure 6 The correlation between the percentage of recording time spent supine detected by the MediByte (Braebon Medical Corporation, Canada) portable monitor screener position sensor compared with technologist-tagged body position monitored by video camera on polysomnography (PSG) ($n=71$)

severe OSA. Although the actual number of events recorded by the two devices in these patients was similar (the mean difference between the number of respiratory events detected was only -0.5 events/h), the difference between the RDI and AHI for the outliers was -43 . This difference was attributed to the short length of sleep time versus recording time, and the high number of apneic events. A shorter recording time than the average of 285 min and lower sleep efficiency were also noted for the patients with large differences in measurement agreement. Thus, their average recording time was nearly one-half that of the entire group (217 min versus 382 min). Furthermore, it is reasonable that for home screening of OSA, in which there is no objective measure of sleep, a subjective estimate of sleep time is valuable information to have, particularly when the severity of symptoms is not consistent with the PM assessment.

One possible explanation for the under-reporting bias of the MediByte device comes from the recognition of arousals, which is provided for with a full PSG. Scoring arousals following increasing respiratory effort, specifically when oxygen desaturation does not attain the cut-off of 3%, contributed to the higher number of hypopneas scored on the PSG studies. An AHI based on including events causing arousals would contribute to a lower sensitivity, especially when compared with some other studies in which desaturation was not a criterion for scoring apneas or hypopneas (9), when 4% and 1% desaturations were considered (14) or, indeed, in which the measurement is only based on a decrease in airflow (10,11). Recognition of respiratory events through associated arousals, rather than 3% or higher desaturation on oximetry, may have contributed to the sex bias for under-reporting in women (28,29) as reported here for the first time. This sex bias of under-reporting female RDI will be investigated further in our subsequent studies of the at-home PM versus in-laboratory PSG.

Other factors compounding the under-reporting of OSA severity over the total recording time include the clustering of events according to body position, REM sleep-related OSA and high BMI. Under-reporting associated with high BMI was due to a high respiratory disturbance. Obese patients experienced twice the rate of respiratory events and under-reporting was greater. However, the presence of severe OSA in these cases was unequivocal. Review of the raw data by experienced personnel would reveal the oximetry pattern and clustering of events coinciding with either body position or likely REM sleep periods; although this protocol was not used in the current algorithm, more importance should be placed on an analysis of the results according to body position (30,31), which is also provided by the MediByte report. Indeed, the PM screener showed good accuracy for supine detection.

The larger number of women than men recruited into the study was in contrast to the sex bias in favour of men having OSA. In the middle-age workforce, 4% of men and 2% of women are likely to fulfill the minimal diagnostic criteria for sleep apnea syndrome (32). We are confident that there was no selection bias in recruitment. The female to male ratio of 1:0.70 in the present study reflects the sex ratio of 1:0.74 for diagnostic and split-night studies in our laboratory over the data collection period, whereas for all studies over this period, more studies were performed for men (1:1.8). The sex bias toward more severe OSA in men compared with women was evident in our cohort, with a female to male ratio of 1:1.75.

Reviews and consensus reports on studies conducted on home screening devices for OSA provide convincing evidence that these devices are viable alternatives for the diagnosis of severe OSA when properly administered and interpreted (2,3,16-21). Results of the current study suggest that the MediByte device is particularly useful for screening patients for severe OSA, and a negative study with this device could be used to exclude severe OSA – a potentially important function in asymptomatic patients with suspected OSA (7). Furthermore, a MediByte study positively identified 80% of patients found to have moderately severe OSA on PSG, and can be undertaken successfully without the additional expense and effort of full PSG.

Given the results of the current study comparing the PM with the gold-standard on the same night, this particular type 3 PM has the potential to be used as a first path for patients in whom severe OSA is suspected. Further validation of the device should be in the patient's

home setting compared, in close proximity, with an additional night of in-laboratory PSG. A recommendation for the use of all home screening devices comes from the AASM – that physicians using PM should always combine it with a clinical assessment, and that decisions on therapy should be based on both the results of the study and knowledge of the individual patient's symptoms (16). Using this combined method could prove highly useful for future studies on the efficiency of the MediByte device.

To directly assess the utility of this PM in the home environment and address the under-reporting by female sex and obesity, our laboratory is currently conducting further investigations comparing at-home PM with in-laboratory PSG.

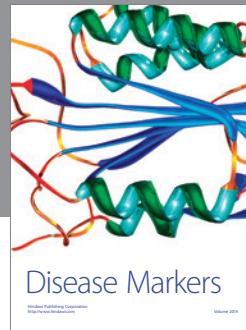
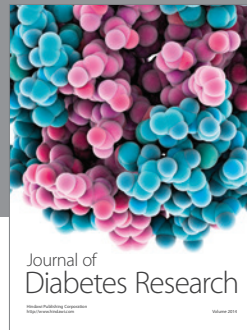
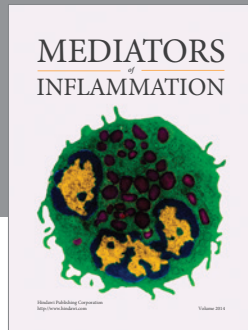
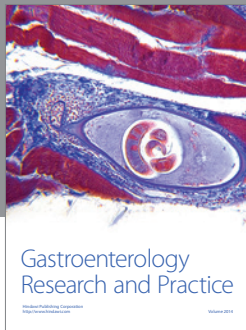
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