

# Comparing a Combination of Validated Questionnaires and Level III Portable Monitor with Polysomnography to Diagnose and Exclude Sleep Apnea

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SCIENTIFIC INVESTIGATIONS

**Study Objectives:** Questionnaires have been validated as screening tools in adult populations at risk for obstructive sleep apnea (OSA). Portable monitors (PM) have gained acceptance for confirmation of OSA in some patients with a high pretest probability of the disorder. We evaluated the combined diagnostic utility of 3 validated questionnaires and a Level III PM in the diagnosis and exclusion of OSA, as compared with in-laboratory polysomnography (PSG) derived apnea hypopnea index (AHI).

**Methods:** Consecutive patients referred to the Sleep Disorders Clinic completed 3 testing components: (1) 3 questionnaires (Berlin, STOP-Bang, and Sleep Apnea Clinical Score [SACS]); (2) Level III at-home PM (MediByte) study; and (3) Level I in-laboratory PSG. The utility of individual questionnaires, the Level III device alone, and the combination of questionnaires and the Level III device were compared with the PSG.

**Results:** One hundred twenty-eight patients participated in the study (84M, 44F), mean  $\pm$  SD age  $50 \pm 12.3$  years, BMI

$31 \pm 6.6$  kg/m<sup>2</sup>. At a PSG threshold AHI = 10, the PM derived respiratory disturbance index (RDI) had a sensitivity and specificity of 79% and 86%, respectively. The sensitivity and specificity for the other screening tools were: Berlin 88%, 25%; STOP-Bang 90%, 25%; SACS 33%, 75%. The sensitivity and specificity at a PSG AHI = 15 were: PM 77%, 95%; Berlin 91%, 28%; STOP-Bang 93%, 28%; SACS 35%, 78%.

**Conclusions:** Questionnaires alone, possibly given a reliance on sleepiness as a symptom, cannot reliably rule out the presence of OSA. Objective physiological measurement is critical for the diagnosis and exclusion of OSA.

**Keywords:** Screening tools, obstructive sleep apnea, questionnaires, portable monitoring, home sleep testing

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Obstructive sleep apnea (OSA) affects 24% of adult men and 9% adult women in North America.<sup>1-3</sup> A questionnaire-based survey in 2009 by the Public Health Agency of Canada (PHAC) estimated that 22% (5.4 million) of adult Canadians report either being diagnosed with sleep apnea (3%) or are at high risk for OSA (19%).<sup>4</sup> Untreated OSA has been associated with serious long-term medical and neurocognitive complications, including premature death.<sup>5-7</sup>

The recommended diagnostic test for OSA includes an overnight in-laboratory technologist-attended sleep study (Level I polysomnography [PSG]).<sup>8</sup> In addition to monitoring sleep stage by electroencephalography, electro-oculography, and chin electromyography, PSG includes monitoring of electrocardiography, respiratory effort, airflow (nasal pressure and oronasal thermal sensor) and snoring, oxygen saturation, leg movements via electromyography on the anterior tibialis muscles, and body position. This procedure is time- and labor-intensive, and costly. Given the large number of individuals in the population likely to be suffering from OSA, it is not surprising that a great majority remain undiagnosed.<sup>9</sup> It is clear that the challenge of providing a diagnosis of OSA to those suffering from the disorder cannot rely on in-laboratory polysomnography alone, and that simpler and less expensive

## BRIEF SUMMARY

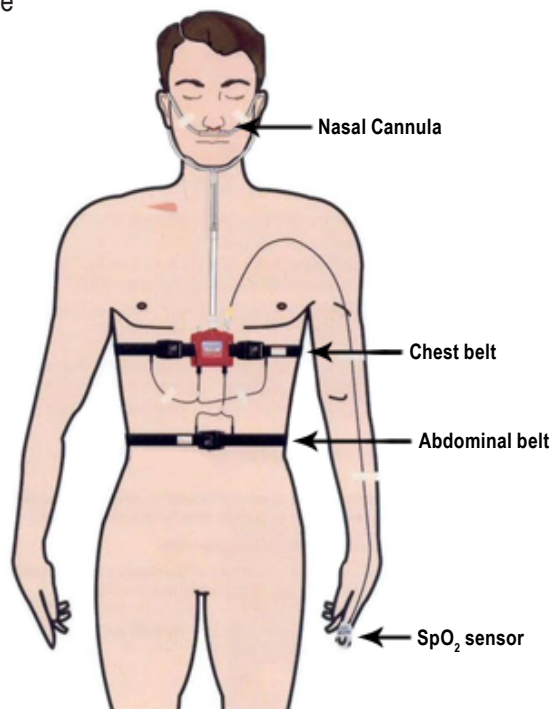
**Current Knowledge/Study Rationale:** Several validated questionnaires are available for screening for obstructive sleep apnea but none has sufficient sensitivity or specificity to mitigate the need for further clinical assessment and testing. Level III portable monitors, while tending to underestimate sleep apnea severity, provide an objective assessment of sleep apnea severity that is often adequate for clinical decision-making. This study evaluated whether one or more previously validated questionnaires, or a combination of these questionnaires with the results from a Level III study, could mitigate the need for polysomnography in patients referred to a sleep disorders clinic.

**Study Impact:** The results demonstrate that the questionnaires were inferior to the Level III study in determining the presence or absence of sleep apnea, and when combined with the information from the Level III study, did not enhance its discriminant ability. These findings strongly suggest that objective physiological monitoring is critically important in the diagnosis and exclusion of obstructive sleep apnea, and cannot be supplanted by questionnaire data.

diagnostic tests are needed. Several such tests for diagnosing OSA, including questionnaires and at-home portable sleep monitors (PM), have been investigated.<sup>10-13</sup>

Several questionnaires have been validated to assist in the stratification of patients as high risk or low risk for OSA based

**Figure 1**—Full set-up for the at-home portable monitoring device



on clinical symptoms and anthropomorphic risk factors.<sup>12-17</sup> Portable monitors that include the recording of oximetry, respiration, heart rate and rhythm, and body position have gained increasing acceptance as a diagnostic tool for sleep apnea. The complexity of physiological measures included range from the equivalent of a full PSG at home without the continuous attendance of a technologist (Level II polysomnography) to overnight pulse oximetry alone (Level IV).<sup>18-20</sup> In a previous report, we demonstrated a high level of agreement for OSA between a Level III portable device and in-laboratory PSG for the diagnosis of OSA, particularly at a threshold AHI of 15 (moderate OSA).<sup>19</sup> Hence, we were curious whether we could harness the screening power of validated questionnaires and the objective physiological measures provided by a Level III device to optimize out-of-laboratory diagnosis of OSA, and potentially obviate the need for PSGs in non-selected referrals to the sleep clinic. We evaluated the combined use of three previously validated questionnaires and a home-based Level III portable monitoring study compared with in-laboratory PSG, for the diagnosis of OSA in consecutive referrals to the sleep clinic.

## METHODS

### Study Participants

Consecutive referrals to the Sleep Disorders Clinic at Kingston General Hospital, Kingston, ON, were invited to participate in the study. All patients were informed that their participation was completely voluntary, and they received nominal compensation for incurred expenses only. The study was approved by Queen's University Health Sciences and the affiliated teaching hospital's research ethics board. Inclusion

criteria included the ability to apply the Level III monitoring equipment without supervision (after brief initial training) and a primary residence within 100 miles of the sleep clinic (for returning the PM equipment). Exclusion criteria included known COPD, congestive heart failure, or uncontrolled asthma.

### Study Design

The study was prospective, involving patients referred to the Kingston General Hospital Sleep Clinic. Study participants were recruited and interviewed by the Research Assistant (EJP), and consenting individuals completed 3 questionnaires: (1) Berlin Questionnaire,<sup>13</sup> (2) Sleep Apnea Clinical Score (SACS),<sup>14</sup> and (3) STOP-Bang.<sup>12</sup> Common features of the questionnaires include physical symptoms of snoring, witnessed episodes of apnea, and hypertension. Based on the Berlin and STOP-Bang questionnaires, respondents were categorized as low or high probability for OSA, while the SACS categorized low (likelihood ratio of  $AHI < 5 = 0.25$ ), intermediate (ratio of  $AHI < 15 = 2.03$ ), or high probability (ratio of  $AHI > 15 = 5.17$ ) of having the disorder.

Upon completion of the questionnaires, participants were shown how to set up the portable monitor. They were asked to wear the Level III portable monitoring device (MediByte; Braebon Medical Corporation, Ottawa, ON) for 2 consecutive nights at home. The first night of recording was used in the analysis, with the second night as a back-up if recording from the first night did not provide sufficient data. The PM device consists of 2 inductance bands for thoracic and abdomen measurement, a nasal cannula pressure transducer airflow signal, finger pulse oximetry, and a body position sensor. The typical at-home set-up is shown in **Figure 1**. Patients were given the option to either manually turn on the device before switching off the lights at night and turn off the device once awake in the morning, or to have the device start and stop automatically at predetermined times.

Following completion of home testing, patients attended the Sleep Disorders Laboratory at Kingston General Hospital for a full overnight PSG. Recordings were conducted using Sandman Elite SD32+ digital sleep recording system (Natus [Embla]; Ottawa, ON), and included 4 EEG channels (C4-A1, C3-A2, O2-A1, F3-A2), 2 EOG channels (ROC-A1, LOC-A2), submental EMG, intercostal (diaphragmatic surface) EMG, bilateral anterior tibialis EMG, ECG, respiratory piezo bands (chest and abdomen), finger pulse oximetry, a vibration snore sensor, nasal pressure airflow, and oronasal thermocouple. PSG recordings were conducted as either a diagnostic study or, in the event of severe OSA, a split-night study. For split-night studies, the initial diagnostic period was followed by the introduction of treatment during the night, and only the diagnostic part of the recording was used for comparison.

Data from the questionnaires and portable monitoring device were manually scored by an experienced scorer (EJP) who was blinded to the results of the in-lab polysomnography. The PSGs were manually scored using standard criteria by registered polysomnographic technologists, who in turn were blinded to results of the questionnaires and the PM device.<sup>20-23</sup> Sixty-four percent of the scored PM data were reviewed by an experienced technologist (HSD) (the concordance between the 2 scorers, EJP and HSD, was 99.2%), and all the PSG studies were reviewed by a sleep specialist. For both PSG and PM data,

**Table 1**—Apnea-hypopnea index (AHI) based on polysomnography (PSG) for questionnaire data for 128 patients

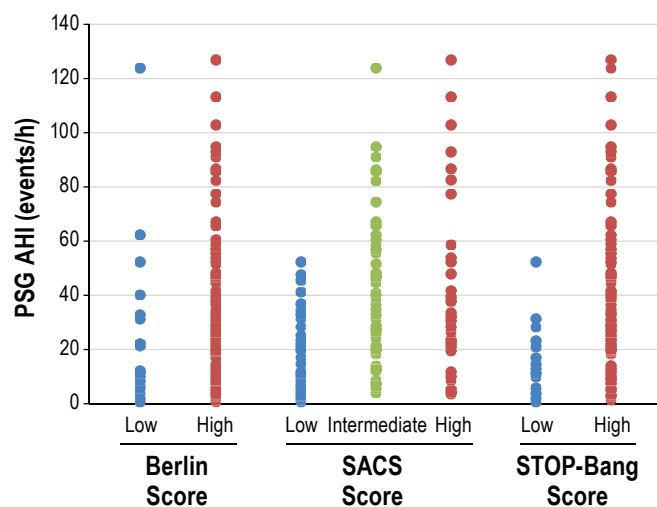
	Mean PSG AHI	SD
<b>Berlin Questionnaire</b>		
Low (n = 19)	24.6	29.7
High (n = 109)	34.6	27.0
<b>SACS Questionnaire</b>		
Low (n = 36)	18.5	15.6
Intermediate (n = 52)	38.8	27.5
High (n = 40)	38.9	31.3
<b>STOP-Bang Questionnaire</b>		
Low (n = 17)	14.5	13.7
High (n = 111)	36.0	28.0

apneas were scored as a cessation of airflow  $\geq 50\%$  for  $\geq 10$  sec, and hypopneas were scored as a reduction in pressure-derived airflow of 50% to 90% from baseline for  $\geq 10$  sec followed by  $\geq 3\%$  oxygen desaturation.<sup>20,22</sup> For the PSG, the definition of hypopnea also included  $\geq 50\%$  reduction in pressure-derived airflow amplitude associated with arousal, in the absence of a desaturation  $\geq 3\%$  (alternative criteria).<sup>22</sup> The outcome 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, and the outcome measure for the PM data was the respiratory-disturbance index (RDI), defined as the number of apneas and hypopneas per hour of recording time.

### Data Analysis

A dot plot comparison was conducted for the probability rating of sleep apnea based on each questionnaire (Berlin and STOP-Bang as low-high; SACS as low-intermediate-high) as compared to the PSG derived AHI (events/h). Measurement agreement and correlation analysis of the RDI and AHI values based on the PM and PSG, respectively, were obtained and a Bland-Altman plot of agreement was constructed.<sup>24</sup> Multilevel, mixed-effects Poisson regression analysis was used to investigate possible sources of differences between the recording methods, including gender and obesity ( $BMI \geq 30$  kg/m<sup>2</sup>), while accounting for differences in recording time. The outcome measurement was the observed counts of respiratory events, with the observations nested in individuals—individuals were considered random effects, while recording method, gender, obesity, and their interactions were considered to be fixed effects.

The agreement of each of the 4 screening tools was assessed, compared with PSG, at different threshold AHI threshold values (5, 10, 15, and 30). For each AHI threshold, PM and questionnaire data were rated as true-positive (TP), false-positive (FP), true-negative (TN), or false-negative (FN), allowing for a measure of the sensitivity and specificity for each of the diagnostic screening methods.<sup>25</sup> Receiver operating characteristic (ROC) curves were also plotted to assess the trade-off between false-negatives and false-positives in order to evaluate the area under the curve (AUC), which provides a measure of the diagnostic utility of the screening tools. Likelihood ratios (LR) were calculated to determine the practical significance of the screening measures.

**Figure 2**—Dot plots for each questionnaire rating compared to the polysomnographically (PSG) derived apnea-hypopnea index (AHI) for 128 patients

To evaluate the effectiveness of a combination of questionnaires and PM, 2 separate analyses were conducted: (i) the presence of OSA was defined as scoring high on  $\geq 2$  questionnaires along with a PM RDI  $\geq 10$  events/h, and (ii) the absence of OSA was defined as scoring low on  $\geq 2$  questionnaires along with a PM RDI  $< 10$  events/h. ROC curves, AUC, and LR were also calculated for the combination of screening measures by severity groups based on AHI thresholds 5, 10, 15, and 30 to assess for significance. A stepwise multiple linear regression was used to model the relationship between the various screening tools and the PSG AHI in order to determine the best combination of questionnaires and PM at each AHI threshold value; the PSG AHI was used as the dependent variable, and the questionnaire scores (Berlin and STOP-Bang scored as 0, 1, and SACS scored as 0, 1, 2) and RDI based on the PM as the independent variables.

## RESULTS

One hundred twenty-eight patients were recruited into the study (84 M, 44 F; mean  $\pm$  SD: age  $50 \pm 12.3$  years, BMI  $31 \pm 6.6$  kg/m<sup>2</sup>, neck circumference  $41 \pm 4.4$  cm). On average, patients reported that they snored (3-5 times a week), felt fatigued (3-4 times a week), and had witnessed apnea (1-2 times a month). The PM data for 13 participants (10%) were analyzed from the second night rather than the first due to unusable or lost data resulting in insufficient ( $< 2$  h) recording time on the first night.

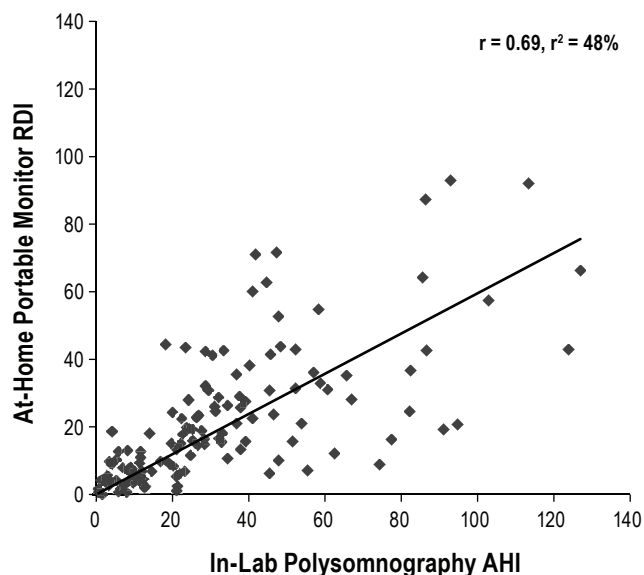
The mean AHI, derived from PSG, for the OSA risk categories determined by the questionnaires is shown in **Table 1**. Dot plots for each questionnaire compared to the PSG AHI are displayed in **Figure 2**; they illustrate a significant overlap and a wide range in the AHI between the different categorical probability ratings for each questionnaire. The mean PSG AHI for each of the questionnaire ratings are provided in **Table 1**.

Objectively recorded data for the PM and PSG are summarized in **Table 2**. The total recording time on PM was longer by

**Table 2**—Portable monitoring (PM) screening measures and polysomnography (PSG) data for 128 patients

	PM	PSG	p-value
Respiratory-Disturbance Index (RDI) (events/h) / Apnea-Hypopnea Index (AHI) (events/h)	21.9 ± 19.9	33.1 ± 27.5	< 0.001
Total Recording Time (TRT) (min)	438.4 ± 89.0	404.8 ± 103.0	0.003
Total Sleep Time (TST) (min)	N/A	304.4 ± 106.6	—

**Figure 3**—Correlation plot for the PM respiratory-disturbance index (RDI) and the PSG apnea-hypopnea index (AHI) for 128 patients

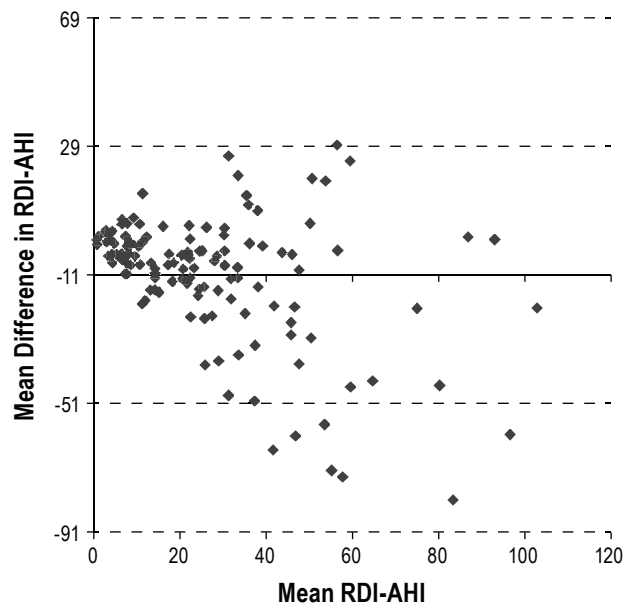


approximately 30 min (438 ± 89 min) as compared to the PSG (405 ± 103 min). There was a positive correlation between the PM derived RDI and PSG derived AHI ( $r = 0.69$ ,  $r^2 = 48\%$ ; **Figure 3**).

The Bland-Altman plot (**Figure 4**) shows the mean difference between the PM-RDI and the PSG-AHI, with an under-reporting by the PM of  $-11.2 \pm 19.2$  events/h, with limits of agreement ( $\pm 2$  SD) at +29 and -51. The mean percent difference between the 2 measures was -40%, with limits of agreement at +90% and -170%. The PM-based RDI under-reported the rate of respiratory events for women and non-obese men by 27% (women:  $p < 0.001$ , IRR = 0.73, 95% CI: 0.70, 0.75; non-obese men:  $p < 0.001$ , IRR = 0.73, 95% CI: 0.70, 0.76), and for obese men by 38% ( $p < 0.001$ , IRR = 0.62, 95% CI: 0.60, 0.64).

The sensitivity and specificity of each screening tool at various PSG-AHI thresholds is displayed in **Table 3**. For a threshold AHI of 10 events/h, the Berlin, SACS, and STOP-Bang questionnaires had sensitivities of 88%, 33%, and 90%, respectively, and specificity of 25%, 75%, and 25%, respectively. The positive (PPV) and negative (NPV) predictive values were 81%-83% and 24%-41%, respectively. In comparison, the PM had a sensitivity of 79% and specificity of 86% (PPV 95%, NPV 53%). Based on the ROC curve for an AHI threshold of

**Figure 4**—Bland-Altman plot examining the difference between the PM RDI and PSG AHI against the mean of the RDI and AHI for 128 patients



The solid line delimits the mean difference (-11), and the dotted lines represent the limits of agreement  $\pm 2$  SDs (29 and -51).

10 (**Figure 5**), the AUC for the PM at 0.82 was higher than that for any of the 3 questionnaires ( $\leq 0.58$ ). For a PSG-derived AHI diagnostic threshold of 15 events/h (moderate OSA), the sensitivity and specificity for each measure was: Berlin 91%, 28%; SACS 35%, 78%; STOP-Bang 93%, 28%; PM 77%, 95% (**Table 3**).

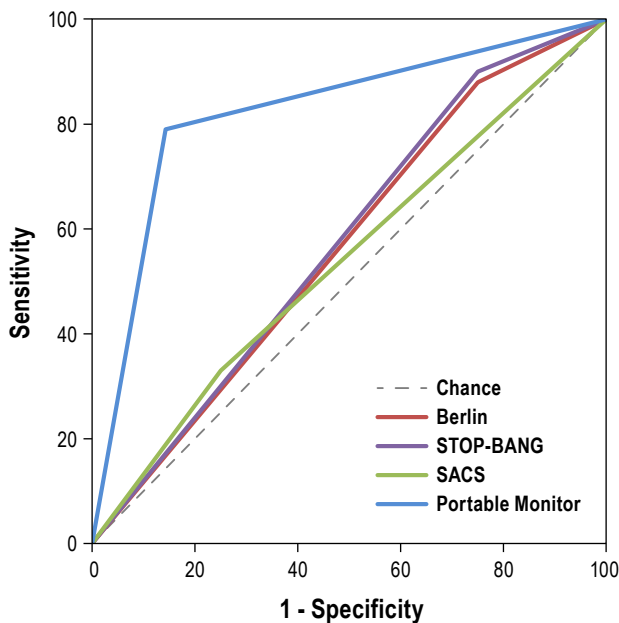
Sensitivity and specificity were also calculated for a combination of the screening tools (presence of OSA = high risk for  $\geq 2$  questionnaires and PM RDI  $\geq 10$  events/h; absence of OSA = low risk for  $\geq 2$  questionnaires and PM RDI  $< 10$  events/h) and are provided in **Table 3**. For an AHI threshold of 10 events/h, the combination of questionnaires and PM had a sensitivity of 71% and specificity of 89% for the presence of OSA (PPV = 96%, NPV = 46%), and a sensitivity of 94% and specificity of 25% for excluding OSA (PPV = 82%, NPV = 54%). The AUC for the combination of questionnaires and portable monitor was 0.80 (**Figure 6**) for the presence of OSA and 0.59 (**Figure 7**) for the absence of OSA. Positive and negative likelihood ratios for each individual screening tool along with the combination of the questionnaires and portable monitor are displayed in **Table 4**.

Stepwise multiple regression analyses were used to examine the relationship between the PSG AHI and the various screening tools. A model using all 3 questionnaires and the portable monitor produced an  $R^2 = 0.487$ ,  $F_{4,123} = 29.22$ ,  $p < 0.001$ . Of all 4 screening tools, the portable monitor was the only screening device with a statistically significant regression coefficient,  $b = 0.91$ ,  $\beta = 0.658$ ,  $p < 0.001$ . In fact, none of the questionnaires contributed significantly to the multiple regression model,  $p$ -values  $> 0.35$ ; combined, the questionnaires accounted for less than 1% of the variation of the regression.

**Table 3**—Sensitivity (Sen; %), specificity (Spec; %), positive predictive value (PPV; %), and negative predictive value (NPV; %) for the individual and combination of questionnaires and portable monitoring device based on the polysomnography (PSG) apnea-hypopnea index (AHI) threshold points for 128 patients

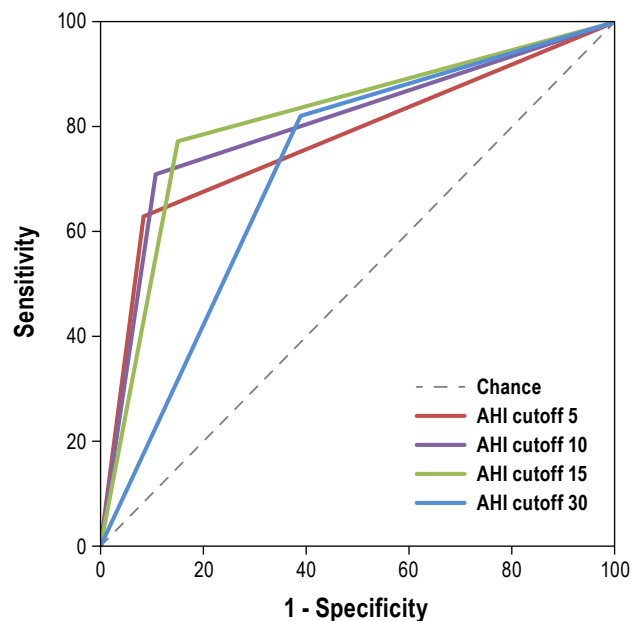
	AHI ≥ 5 (N = 116)				AHI ≥ 10 (N = 100)				AHI ≥ 15 (N = 88)				AHI ≥ 30 (N = 56)			
	Sen	Spec	PPV	NPV	Sen	Spec	PPV	NPV	Sen	Spec	PPV	NPV	Sen	Spec	PPV	NPV
<b>Individual</b>																
Berlin	86	25	91.7	15.8	88	25	80.7	36.8	91	28	73.4	57.9	89	18	45.9	68.4
SACS	33	83	95.0	11.4	33	75	82.5	23.9	35	78	77.5	35.2	36	72	50.0	59.1
STOP-Bang	90	42	93.7	29.4	90	25	81.1	41.2	93	28	73.9	64.7	96	21	48.6	88.2
Portable Monitor	87	67	96.2	34.8	79	86	95.1	53.3	77	95	97.1	65.5	50	93	84.8	70.5
<b>Combination</b>																
Presence of OSA: high ≥ 2 Qs & PM ≥ 10 events/h	63	92	98.6	20.3	71	89	95.9	46.3	77	85	91.9	63.0	82	61	62.2	81.5
Absence of OSA: low ≥ 2 Qs & PM < 10 events/h	93	42	93.9	38.5	94	25	81.7	53.8	97	25	73.9	76.9	100	18	48.7	100

**Figure 5**—Receiver operating characteristic (ROC) curves for each of the three questionnaires and the PM at a PSG AHI cutoff of 10 events/h



Area under the curve (AUC): Berlin = 0.565; SACS = 0.540; STOP-Bang = 0.575; PM = 0.824.

**Figure 6**—Receiver operating characteristic (ROC) curves for identifying OSA at various PSG AHI cutoffs based on the combination of ≥ 2 high-scoring questionnaires and a PM RDI ≥ 10 events/h



Area under the curve (AUC): AHI 5 = 0.773; AHI 10 = 0.801; AHI 15 = 0.811; AHI 30 = 0.716.

Our analysis is estimated to have had 90% power ( $1 - \beta$  error probability) of detecting a Cohen’s effect size  $f^2$  of 0.1 (medium effect size), given a sample size of 128 patients and  $\alpha$  error probability of 0.05.

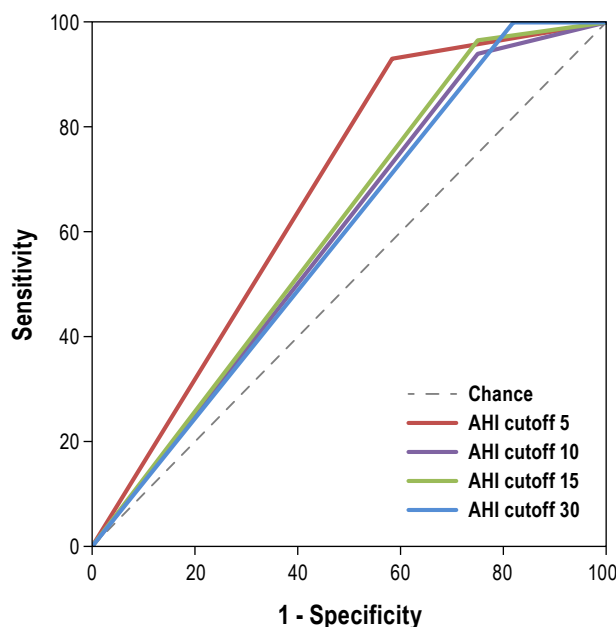
## DISCUSSION

This study demonstrated that in a consecutive series of patients referred to a hospital-based sleep clinic, questionnaires that have been previously well-validated in other populations were not accurate in determining the presence or

absence of OSA. None of the three questionnaires used had adequate sensitivity (proportion of patients with OSA who screen positive) and specificity (proportion without OSA who screen negative) to render them sufficiently reliable in a clinical setting to rule in or to rule out OSA—two of the questionnaires (Berlin and STOP-Bang) were found to have a high sensitivity for OSA but low specificity, while the SACS had higher specificity but low sensitivity for OSA. Overall, the portable monitor was found to perform significantly better in the identification as well as the exclusion of OSA than any

**Table 4**—Likelihood ratio positive (LR+) and likelihood ratio negative (LR-) for the individual and combination of questionnaires and portable monitoring device based on the polysomnography (PSG) apnea-hypopnea index (AHI) threshold points for 128 patients

	AHI $\geq 5$ (N = 116)		AHI $\geq 10$ (N = 100)		AHI $\geq 15$ (N = 88)		AHI $\geq 30$ (N = 56)	
	LR+	LR-	LR+	LR-	LR+	LR-	LR+	LR-
<b>Individual</b>								
Berlin	1.1	0.6	1.2	0.5	1.3	0.3	1.1	0.6
SACS	2.0	0.8	1.3	0.9	1.6	0.8	1.3	0.9
STOP-Bang	1.5	0.2	1.2	0.4	1.3	0.2	1.2	0.2
Portable Monitor	2.6	0.2	5.5	0.2	15.5	0.2	7.2	0.5
<b>Combination</b>								
Presence of OSA: high $\geq 2$ Qs & PM $\geq 10$ events/h	7.6	0.4	6.6	0.3	5.2	0.3	2.1	0.3
Absence of OSA: low $\geq 2$ Qs & PM $< 10$ events/h	1.6	0.2	1.3	0.2	1.3	0.1	1.2	0.0

**Figure 7**—Receiver operating characteristic (ROC) curves for **excluding OSA** at various PSG AHI cutoffs based on the combination of  $\geq 2$  low-scoring questionnaires and a PM RDI  $< 10$  events/h

Area under the curve (AUC): AHI 5 = 0.674; AHI 10 = 0.595; AHI 15 = 0.608; AHI 30 = 0.590.

of the individual questionnaires or combination of questionnaires with portable monitoring.

The accuracy and reliability of questionnaires used to screen for OSA appears to vary depending on the patient population studied and the diagnostic AHI threshold used.<sup>14,16,27</sup> In contrast to the present study of patients referred to a sleep clinic, in community screening the Berlin questionnaire had a high sensitivity (85%) and specificity (95%) at an AHI threshold of 5 events/h.<sup>27</sup> However, Netzer reported that when the AHI threshold for the diagnosis of OSA was raised to 15 events/h, sensitivity levels were reduced to 54%.<sup>13</sup> A decrease in specificity with increasing AHI was mirrored in the STOP-Bang

questionnaire, where specificity dropped from 56% to 43% with a change in AHI from 5 to 15 events/h, respectively.<sup>12</sup> Compared to questionnaire responses, portable monitors have shown a consistently high degree of sensitivity and specificity even at higher AHI thresholds with a bias of underreporting the OSA severity.<sup>19,28,29</sup> Our findings also showed a low negative predictive value for the portable monitor, both with and without the addition of the questionnaires, suggesting that the monitor may be able to establish a diagnosis of OSA with a high degree of certainty, but that it may not be able to conclusively rule out OSA. Guidelines from the Canadian Thoracic Society and Canadian Sleep Society have suggested that portable monitors be used in patients with a high pretest probability of OSA, and previous research has shown these devices to have a moderately high negative predictive value (71% to 100%) for patients with a high likelihood of having the disorder.<sup>20,29,31</sup> It had been our belief that the NPV of this objective diagnostic method would be increased with the addition of subjective questionnaires, but it appears that the portable monitor alone still outperformed the combination of the portable monitor and questionnaires in negative predictive value.

A potential contributing factor to the underreporting of OSA severity with the PM as compared with PSG is that the denominator is total sleep time for PSG and total recording time for the PM. By recalculating the PSG scored apnea and hypopnea index in the present study using total recording time rather than total sleep time as the denominator, there was an improvement in the performance of the PM such that the PM underreported the rate of respiratory events for women by only 5% ( $p = 0.001$ , IRR = 0.95, 95% CI: 0.91, 0.98), for obese men by 14% ( $p < 0.001$ , IRR = 0.86, 95% CI: 0.83, 0.88), and did not underestimate the AHI for non-obese men ( $p = 0.42$ , IRR = 0.99, 95% CI: 0.95, 1.02).

Different scoring rules for hypopneas have been found to affect the resultant AHI.<sup>32</sup> The highest AHI was based on 1999 (“Chicago”) scoring criteria (hypopnea based on  $\geq 50\%$  decrease in airflow or  $< 50\%$  reduction in airflow associated with a 3% oxygen desaturation and/or arousal), followed by the alternative criteria that was used in this study ( $\geq 50\%$  pressure-derived airflow reduction and  $\geq 3\%$  desaturation or arousal) and lowest using recommended criteria for hypopneas ( $\geq 30\%$

pressure-derived airflow reduction and  $\geq 4\%$  desaturation).<sup>21,22</sup> The authors suggested that the AHI cutoff of 5 events/h using AASM recommended criteria is approximately equivalent to an AHI of 15 events/h using the 1999 hypopnea definition and 10 events/h using the alternative AASM definition.<sup>32</sup> Scoring of hypopneas in our study was based on the AASM alternative criteria, but without the option of identifying arousals on the PM, which contributed to underreporting by this screening tool.

We have demonstrated that objective data from a portable monitor was superior to questionnaires in the identification and exclusion of OSA. Recently the Centers for Medicare and Medicaid Services and a position statement from the Canadian Thoracic Society and Canadian Sleep Society have endorsed the use of portable monitors as a means of providing sufficient evidence for the diagnosis of OSA, under defined circumstances and with specific patient populations.<sup>31</sup> These rulings, and the results of the current study, support the judicious use of portable monitors in the diagnosis of OSA, in association with appropriate clinical assessment.

Many patients with OSA are only minimally symptomatic. In the Sleep Heart Health Study, the average Epworth Sleepiness Scale (ESS) score of patients with severe OSA (AHI > 30) was within normal limits.<sup>32</sup> Indeed two-thirds of patients with severe OSA had an ESS within normal limits, while 21% with an AHI < 5 (normal) had an ESS score that was higher than normal.<sup>32</sup> Hence, the reliance of sleepiness as a symptom to determine the presence or absence of OSA is fraught with uncertainty. In addition, although obesity increases the propensity to OSA for simple anatomical reasons, many patients with OSA are not overweight.<sup>33</sup> It is our belief that the overlap in symptom profile and anthropomorphic features between individuals with OSA and those without underpins the weak discriminant ability of screening questionnaires for OSA (as demonstrated in the current study), even when anthropomorphic data is added. A critical factor here is the current uncertainty as to whether asymptomatic or minimally symptomatic OSA carries similar cardiovascular consequences to symptomatic patients with the OSA syndrome; if not, then the detection of clinically important OSA—based on symptoms—may prove to be adequate.<sup>34</sup>

It is important to acknowledge the limitations of the current study. Although our patient group was recruited from a series of consecutive referrals to the sleep clinic, our data did not come from a community-based random sample, and as such, our results may not be generalizable to the general population. Further research would be required to determine whether or not the sensitivity and specificity of the portable monitor would be maintained when testing more heterogeneous groups. It is also possible that our findings are specific to the particular brand of portable monitor used for the study (MediByte; Braebon Medical Corporation) and may not be as generalizable to other Level III devices. As such, it would be important to test patients without a high pretest probability of OSA on other portable monitors to further validate our findings. In addition, although the portable monitor and PSG had a moderately positive correlation for AHI, there were significant outliers in our data—which could potentially relate to the presence of other sleep disorders, particularly movement disorders and periodic limb movements. There are potential advantages of the use of at-home PM studies over in-lab PSG; for example, home sleep

testing may better represent habitual sleep habits, including posture, as compared to in-laboratory testing, where patients are likely to spend more time sleeping supine.<sup>35</sup> In-laboratory testing may also underrepresent habitual alcohol consumption at night, because of the need to drive to the sleep laboratory. Hence, the systematic underestimation of the RDI by PM, that does not include instrumentation for measurement of the sleep-wake state, may be balanced to some extent by the less than perfect reflection of true sleep-related habits provided by the “gold standard” PSG.

In conclusion, the current study demonstrated poor discriminant ability for OSA among previously validated questionnaires, and emphasizes the need for objective physiological monitoring in the identification and exclusion of OSA. Furthermore, in the current study, the use of questionnaire data did not further enhance the diagnostic utility of a Level III portable monitor for the diagnosis and exclusion of OSA.

## REFERENCES

- Young T, Evans L, Finn L, Palta M. Estimation of the clinically diagnosed proportion of sleep apnea syndrome in middle-aged men and women. *Sleep* 1997;20:705-6.
- Young T, Palta M, Dempsey J, Skatrud J, Wever S, Badr S. The occurrence of sleep-disordered breathing among middle-aged adults. *N Eng J Med* 1993;328:1230-15.
- Young T, Peppard PE, Gottlieb DJ. Epidemiology of obstructive sleep apnea: a population health perspective. *Am J Respir Crit Care Med* 2002;165:1217-39.
- Sleep Apnea Rapid Response Survey, The Canadian Community Health Survey. Statistics Canada. Centre for Chronic Disease Prevention and Control, Public Health Agency of Canada, 2009. <http://www.statcan.gc.ca/daily-quotidien/091208/dq091208d-eng.htm>.
- Lee W, Nagubadi S, Kryger MH, Mokhlesi B. Epidemiology of obstructive sleep apnea: a population-based perspective. *Expert Rev Respir Med* 2008;2:349-64.
- Shahar E, Whitney CW, Redline S, et al. Sleep-disordered breathing and cardiovascular disease: cross-sectional results of the Sleep Heart Health Study. *Am J Respir Crit Care Med* 2001;163:19-25.
- Turkington PM, Sircar M, Allgar V, Elliott MW. Relationship between obstructive sleep apnoea, driving simulator performance, and risk of road traffic accidents. *Thorax* 2001;56:800-5.
- Fleetham J, Ayas N, Bradley D, et al. Canadian Thoracic Society 2011 guideline update: Diagnosis and treatment of sleep disordered breathing. *Can Respir J* 2011;18:25-47.
- Pack AI. Advances in sleep-disordered breathing. *Am J Respir Crit Care Med* 2006;173:7-15.
- Banno K, Kryger MH. Factors limiting access to services for sleep apnea patients. *Sleep Med Rev* 2004;8:253-5.
- Pang KP, Terris DJ. Screening for obstructive sleep apnea: An evidence-based analysis. *Am J Otolaryngol* 2006;27:112-8.
- Chung F, Yegneswaran B, Liao P, et al. STOP questionnaire: a tool to screen patients for obstructive sleep apnea. *Anesthesiology* 2008;108:812-21.
- Netzer NC, Stoohs RA, Netzer CM, Clark K, Strohl KP. Using the Berlin Questionnaire to identify patients at risk for the sleep apnea syndrome. *Ann Intern Med* 1999;131:485-91.
- Flemons WW, Whitelaw WA, Brant R, Remmers JE. Likelihood ratios for a sleep apnea clinical prediction rule. *Am J Respir Crit Care Med* 1994;150:1279-85.
- Harding SM. Prediction formulae for sleep-disordered breathing. *Curr Opin Pulm Med* 2001;7:381-5.
- Ahmadi N, Chung SA, Gibbs A, Shapiro CM. The Berlin questionnaire for sleep apnea in a sleep clinic population: relationship to polysomnographic measurement of respiratory disturbance. *Sleep Breath* 2008;12:39-45.
- Chung F, Yegneswaran B, Liao P, et al. Validation of the Berlin questionnaire and American Society of Anesthesiologists checklist as screening tools for obstructive sleep apnea in surgical patients. *Anesthesiology* 2008;108:822-30.
- Collop NA, Anderson WM, Boehlecke B, et al. Clinical guideline for the use of unattended portable monitors in the diagnosis of obstructive sleep apnea in adult patients. *J Clin Sleep Med* 2007;3:737-47.

19. Driver HS, Pereira EJ, Bjerring K, et al. Validation of the MediByte® type 3 portable monitor compared with polysomnography for screening of obstructive sleep apnea. *Can Respir J* 2011;18:137-43.
20. Collop NA, Tracy SL, Kapur V, et al. Obstructive sleep apnea devices for out-of-center (OOC) testing: technology evaluation. *J Clin Sleep Med* 2011;7:531-48.
21. American Academy of Sleep Medicine Task Force. Sleep-related breathing disorders in adults: recommendations for syndrome definition and measurement techniques in clinical research. *Sleep* 1999;22:667-89.
22. Iber C, Ancoli-Israel S, Chesson A, Quan SF for the American Academy of Sleep Medicine. The AASM manual for the scoring of sleep and associated events: rules, terminology and technical specifications, 1<sup>st</sup> ed. Westchester, IL: American Academy of Sleep Medicine, 2007.
23. Rechtschaffen A, Kales A. Manual of standardized terminology, techniques and scoring system for sleep stages of human subjects. Bethesda, MD: National Institutes of Health (NIH Publ. No. 204), 1968.
24. Altman DG, Bland JM. Measurement in medicine: the analysis of method comparison studies. *Statistician* 1983;32:307-17.
25. Flemons WW, Littner MR. Measuring agreement between diagnostic devices. *Chest* 2003;124:1535-42.
26. Gafsou B, Marsac L, Fournier JL, Beloucif S, Baillard C. Validation of the STOP-Bang questionnaire as screening tools for obstructive sleep apnea in patients scheduled for bariatric surgery. *Eur J Anesthesiology* 2010;27;13.
27. Sharma SK, Vasudev C, Sinha S, Banga A, Pandey RM, Handa KK. Validation of the modified Berlin questionnaire to identify patients at risk for the obstructive sleep apnoea syndrome. *Indian J Med Res* 2006;124:281-90.
28. Ng SS, Chan TO, To KW, et al. Validation of Embletta portable diagnostic system for identifying patients with suspected obstructive sleep apnoea syndrome (OSAS). *Respirology* 2010;15:336-42.
29. Verse T, Pirsig W, Junge-Hulsing B. Validation of the POLY-MESAM seven-channel ambulatory recording unit. *Chest* 2000;117:1613-8.
30. Blackman A, McGregor C, Dales R, et al. Canadian Sleep Society / Canadian Thoracic Society position paper on the use of portable monitoring for the diagnosis of obstructive sleep apnea/ hypopnea in adults. *Can Respir J* 2010;17:229-32.
31. Gottlieb DJ, Whitney CW, Bonekat WH, et al. Relation of sleepiness to respiratory disturbance index: the Sleep Heart Health Study. *Am J Respir Crit Care Med* 1999;159:502-7.
32. Ruehland WR, Rochford PD, O'Donoghue FJ, Pierce RJ, Singh P, Thornton AT. The new AASM criteria for scoring hypopneas: Impact on the apnea hypopnea index. *Sleep* 2009;32:150-7.
33. White DP. Pathogenesis of obstructive and central sleep apnea. *Am J Respir Crit Care Med* 2005;172:1363-70.
34. Comondore VR, Cheema R, Fox J, et al. The impact of CPAP on cardiovascular biomarkers in minimally symptomatic patients with obstructive sleep apnea: a pilot feasibility randomized crossover trial. *Lung* 2009;187:17-22.
35. Iber C, Redline S, Kaplan Gilpin AM, et al. Polysomnography performed in the unattended home versus the attended laboratory setting - Sleep Heart Health Study methodology. *Sleep* 2004;27:536-40.

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