

Home set-up polysomnography in the assessment of suspected obstructive sleep apnea

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SUMMARY Home set-up polysomnography (PSG) has advantages over other portable monitoring devices, but remains unendorsed by professional bodies despite excellent utility in the Sleep Heart Health Study (SHHS). The study aims to determine technical reliability and diagnostic accuracy of unattended, home set-up versus attended laboratory-based PSG in patients with suspected obstructive sleep apnea (OSA). Thirty patients with suspected OSA without significant co-morbidity were recruited. After initial lab-PSG (Compumedics S series), patients underwent home set-up PSG (Compumedics Siesta) and lab-based PSG in random order. Studies were compared for study success, signal loss and likelihood ratio for OSA diagnosis [apnea–hypopnea index (AHI) > 10]. Thirty subjects (mean age 49 ± 13.8 years, body mass index 31 ± 6.1 kg m⁻²) completed investigations. SHHS technical acceptability criteria were met by all lab-based PSGs and 90% of home-based PSGs (93% clinically acceptable). Signal loss was higher at home ($P = 0.008$). Sleep efficiency was similar between sites, but more preferred home-based PSG (50%). ANCOVA revealed AHI was significantly different if initial AHI > 26 per h ($P = 0.006$), with an average underestimate of 5.1 per h at home. In technically acceptable studies the likelihood ratios to ‘rule in’ and ‘rule out’ OSA were 8.1 and 0.1, respectively. Unattended, home set-up PSG is technically reliable and achieves excellent diagnostic utility. Signal loss was higher at home but mitigated by multi-channel redundancy. Success rate was similar to SHHS and superior to laboratory set-up home studies. Home set-up PSG is a valid alternative to laboratory-based PSG for suspected OSA.

KEYWORDS diagnosis, obstructive sleep apnea, polysomnography

INTRODUCTION

Obstructive sleep apnea (OSA) is a growing health concern and with the increase in demand for diagnosis and treatment, alternate methodologies for diagnosis have been considered. Attended in-laboratory polysomnography (PSG) is considered the ‘gold standard’ diagnostic test for diagnosis of OSA. It enables comprehensive assessment of respiration, sleep architecture, arousals, position and heart rate, but it is costly, complex and in many countries difficult to access (Flemons *et al.*, 2004). Technological advances in portable monitoring

devices have made it possible to record complex physiological signals in an unattended setting. Potential advantages of unattended overnight sleep studies include the ability to record in a natural sleep environment and reduced costs.

A review of the use of unattended portable monitors in the diagnosis of OSA in 2007 notes the ability of portable monitors (type II or III) to rule in OSA in patients with a high pretest probability and no co-morbid conditions (Collop *et al.*, 2007). A large evidence-based review (Flemons *et al.*, 2003) of portable monitoring highlights a number of deficiencies in the literature and recommends that future studies of portable technology be compared with attended laboratory PSG, allow for night to night variability of apnea–hypopnea index (AHI) and have a randomized order of study. Studies should be scored blinded and compared by measuring

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agreement between two devices using the Bland Altman calculation of mean differences and limits of agreement and sensitivity, specificity and likelihood ratios (Flemons and Littner, 2003).

Portable sleep monitoring offers the potential to be able address the high unmet burden of disease; however, studies of home PSG set-up at a central monitoring site report high failure rates and signal loss (Fry *et al.*, 1998; Golpe *et al.*, 2002; Portier *et al.*, 2000; Whittle *et al.*, 1997). The Sleep Heart Health Study (SHHS) reported high technical diagnostic reliability of unattended home PSG when set-up at home by an experienced research technician and analyzed at a reference laboratory (Iber *et al.*, 2004; Kapur *et al.*, 2000). The aim of this study was to determine, relative to laboratory PSG, the reliability and diagnostic accuracy of unattended PSG set-up in the home for the diagnosis of OSA in the clinical setting.

MATERIALS AND METHODS

Study population

Consecutively referred patients were recruited. Inclusion criteria included adults (> 18 years) referred for possible OSA and residing within the home PSG catchment. We excluded patients with significant psychiatric or cardiovascular morbidity, limited mobility or referred for an alternate sleep disorder.

The study was approved by the local ethics committee and participants gave written informed consent.

Protocol

Patients underwent three separate nights of study within a 2-week period. After completing informed consent, closed urn randomization was used to allocate patients to an initial laboratory-based PSG followed in random order by home set-up PSG and lab-based PSG.

Overnight PSG

Laboratory studies utilized the S-series sleep system (Compumedics, Melbourne, Australia) and home studies used the Siesta sleep system (Compumedics).

All studies recorded: C3/A1 and C4/A2 electroencephalograms, right and left electrooculograms, a bipolar mental electromyogram, nasal pressure, oro-nasal flow (thermistor; Compumedics), chest and abdominal movement (piezo-electric bands; Sleepmate, Glen Burnie, MA, USA), arterial oxygen saturation (Home PSG: nonin sensor attached to inbuilt oximeter – 1 sample s^{-1} ; Laboratory PSG: Datex oximeter 1 sample s^{-1} (Datex Ohmeda; GE Healthcare, Chalfont St Giles, UK), electrocardiogram (bipolar lead), body position (Compumedics), leg movements (piezo-electric sensors; Compumedics) and sound (Home PSG: vibration sensor; Compumedics; Lab PSG: sound channel built into S series headbox).

Techniques were standardized for the study. Patients were set up at home for the home studies and in the sleep laboratory

for the laboratory studies. For all studies sensors were attached using-water soluble adhesives and gels with tape. Once the patient was set up, all signals were visualized and impedance values checked. All technicians were experienced. All home set-up PSGs were performed by a single technician who also collected monitoring equipment and removed sensors the following morning.

Study quality

All studies were reviewed by an experienced sleep technologist (AC) for signal quality using SHHS criteria (Kapur *et al.*, 2000). Studies were considered failed if they lacked one or more of the following: 4 h of oximetry data, one EEG signal of sufficient quality to distinguish sleep from wake or 4 h of contiguous data from either abdominal, chest or nasal sensors (Kapur *et al.*, 2000).

For analysis the duration of interpretable signal to the nearest quarter hour was assigned to channels and was used as an ordinal categorical measure of signal quality.

Scoring of PSGs

All studies were scored by a single experienced sleep technologist blinded to study subject, at the completion of data collection using the same software for each study at both sites (Profusion PSG2; Compumedics). It was not possible to blind the scorer to home or laboratory PSG due to the difference in the way sound was recorded.

Sleep stages were scored according to Rechtschaffen and Kales (1968). Arousals were scored according to ASDA Task Force criteria (American Sleep Disorders Association, 1992). Apnea was defined as a complete or almost complete (< 25%) cessation of airflow from the nasal pressure channel. A hypopnea was defined as a visible decrease in a measure of breathing that did not meet the apnea criteria and was associated with either an arousal or desaturation of 3% or more (AASM Task Force, 1999); each must be a minimum of 10 s in length.

Ten studies were randomly selected for rescoring by the one technologist to obtain intra-scorer variability.

Patient preference

At the conclusion of the three studies, patients were asked which site they preferred and why.

Statistical analysis

Analysis of covariance was used to determine differences in AHI between the two study sites, allowing for the AHI on the initial laboratory night. Bland Altman plots were constructed to look at agreement of AHI between sites. Sensitivity and specificity at AHI cutoff values of 5, 10 and 15 events h^{-1} were calculated and ROC curves constructed. Likelihood ratios were computed for AHI levels at 5, 10 and 15 h^{-1} . Likelihood

ratios give the utility of a test to both exclude and confirm a disorder in a single number. Primary analysis was performed using data collected on laboratory night II and the home study night to allow for first night effects. Signal quality and duration were compared using Wilcoxon signed rank test.

RESULTS

Subjects

Eighty-six subjects were screened for inclusion criteria: 22 were not asked by the physician about taking part, 10 lived outside the home PSG zone, nine had co-morbid conditions, five were considered urgent for continuous positive airway pressure, four refused to participate, two worked shifts and two had a poor understanding of English and in one the home environment was not thought to be suitable for study. Thirty-one subjects took part in the study. One subject was removed following the discovery of type 2 respiratory failure and hospital admission. No subjects were lost to follow-up. Thirty patients therefore completed the study. Their demographics are detailed in Table 1. New Zealand Europeans are slightly over-represented in this research subset compared with the usual clinical population (76% research subset, 66% clinical population) and Māori and Pacific peoples are under-represented (3.3% research subset, 27% clinical population).

Study quality

Five home studies had technical problems, of which two were considered diagnostically unacceptable [28/30 acceptable (93.3%)]. A single home study completely failed to record and one was considered technically unsatisfactory due to only 180 min of sleep being recorded in a 4-h period, after which the unit stopped recording. In one home study the oximeter failed for the entire night, but this study was considered clinically acceptable as all other signals were recorded for the entire sleep period. One study had intermittent loss of oximetry and one no position data, but both were deemed clinically acceptable as other signals were interpretable.

Table 2 presents the percentage of study from sleep onset each individual signal was interpretable for home- and laboratory-based studies. The signal most likely to fail at home was the respiratory effort band and in the laboratory the

Table 2 Duration of adequate signal (sleep onset to study end, %)

Signal	% Study duration lab II	% Study duration home	P
Oximetry	99.9	92.8	0.14
Nasal pressure	98.9	91.1	0.05
Chest effort	99.8	89.9	0.012
Abdominal effort	99.8	89.9	0.13
EEG	100	95.5	0.11
EOG	100	95.8	0.11
EMG	100	95.2	0.11
ECG	100	95.2	0.11
Sound	100	90	0.08
Position	96	95.1	0.86
Leg movements	100	96.7	0.32

ECG, electrocardiogram; EEG, electroencephalogram; EMG, electromyogram; EOG, electrooculogram.

position signal was the signal most likely to fail. The position signal, however, could be manually changed at the end of the recording according to technician notes, hence this signal was available for 100% of the time for scoring. All laboratory-based studies were considered technically satisfactory. For each study the total number of 15-min signal losses was added. There were significantly more signal losses during the home-based studies ($P = 0.008$; Fig. 1).

Sleep quality

Sleep efficiency ($P = 0.43$), percent time supine ($P = 0.19$, $n = 29$), rapid eye movement (REM) sleep time ($P = 0.14$) and arousal index ($P = 0.06$) did not differ between locations (Table 3). Intra-scorer staging concordance was $94 \pm 2.7\%$.

Respiratory parameters

Analysis of covariance was performed on AHI data using the AHI obtained on laboratory night I as a continuous covariate (Table 4). This resulted in an area of significance (Fig. 2), when the initial AHI was >26 events h^{-1} , the home and lab study AHIs differed significantly ($P = 0.006$). There were three patients (10%) where the severity of OSA was changed from severe on laboratory night II to mild ($n = 1$) or moderate ($n = 2$) at home.

AHI by sleep state

There was a significant difference in non-REM (NREM) sleep AHI between home and laboratory II; home median AHI 16.7 (IQR 2.0, 38.2), Lab II median AHI 27.7 (IQR 3.1, 51.5), $P = 0.015$. There was no difference in REM sleep AHI ($P = 0.37$).

The sensitivity and specificity were calculated for an AHI of 5, 10 and 15. For an AHI >10 , sensitivity was 90.5% and specificity was 88.9%, with 70% prevalence (Table 5). ROC curves were constructed for AHI 5, 10 and 15. Comparing

Table 1 Patient demographics (mean \pm SD, $n = 30$)

Age, years	49.1 \pm 13.8 (range: 23–78)
Sex	24 male, 6 female
Ethnicity	23/30 NZE
BMI, $kg\ m^{-2}$	31.0 \pm 6.1 (range: 18.9–48.4)
ESS (/24)	10.8 \pm 4.9 (range: 0–20)
AHI (laboratory night I median, events h^{-1})	23.6 (range: 1.9–95.8)

AHI, apnea-hypopnea index; BMI, body mass index; ESS, Epworth sleepiness scale; NZE, New Zealand European.

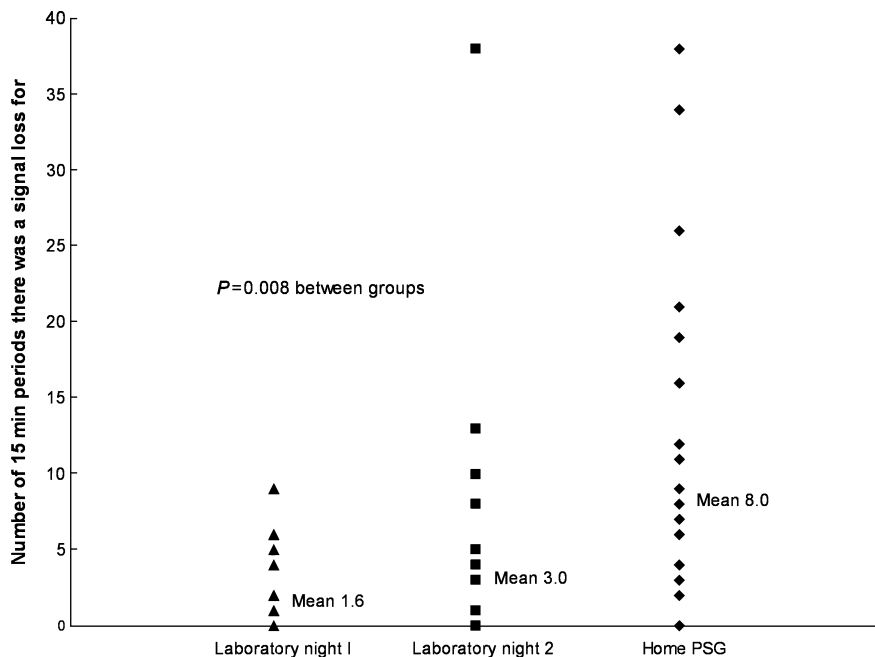


Figure 1. Signal loss: laboratory versus home PSG. For each study the number of 15-min intervals a signal was lost for is plotted.

Table 3 Sleep parameters from home PSG and laboratory-based PSG [median (inter-quartile ranges 25–75%)]

	Home	Laboratory (night II)	Mean difference	P
Arousal index events h ⁻¹	26.2 (20.7, 40.4)	32.3 (24.2, 50.1)	-3.3 (-9.8, 4.7)	0.11
Sleep efficiency	87.4 (77.2, 90.1)	83.7 (73.1, 87.1)	3.5 (-5.7, 8.8)	0.43
% REM sleep	16.2 (12.0, 21.0)	16.95 (11.8, 20.6)	-1.6 (-4.5, 2.5)	0.28
% Supine	41.4 (13.4–54.7%)	36 (16.2–65%)	-6.8 (-22.5 to 5.6%)	0.19

REM, rapid eye movement.

Table 4 Comparison of respiratory parameters observed during laboratory night II and home PSG recordings (mean ± sd)

	Laboratory night II	Home PSG	Mean difference	P
AHI	34.5 ± 29.0	26.9 ± 24.3	-5.1 ± 10.5	0.006*
AHI NREM	31.5 ± 28.4	22.5 ± 23.9	-5.3 ± 10.8	0.015
AHI REM	32.0 ± 28.5	26.9 ± 17.9	-4.1 ± 21.3	0.37
Average desaturation (%)	5.1 ± 5.1	5.3 ± 3.9	0.48 ± 2.15	0.21
Nadir SpO ₂	78.8 ± 10.3	83.7 ± 9.4	4.00 ± 5.99	0.0004

P values result from non-parametric tests. *Significant using ANCOVA at AHI > 26 h⁻¹. AHI apnea-hypopnea index; NREM, non-rapid eye movement; PSG, polysomnography; REM, rapid eye movement.

night to night variability, AUC ranged from 0.915 (AHI 10) to 0.991 (AHI 15). A comparison of laboratory PSG and home PSG, AUC ranged from 0.900 (AHI 5) to 0.942 (AHI 15).

The mean difference in AHI between home and laboratory II was -5.1 h⁻¹, 95% CI (-9.1 to -1.1). A Bland Altman plot (Fig. 3b) showed limits of agreement of 20.5, -25.5.

There was no evidence of a ‘first night effect’ or significant night to night variability in AHI (Fig. 3a) when comparing laboratory night I and laboratory night II by Bland Altman plots. The mean difference in AHI was -1.3 (25 and 75%;

CI: -5.7 to 0.4, P = 0.40). The Bland Altman plot shows limits of agreement at +15.5 and -17.5 for 1.96 × SD; the correlation coefficient was 0.958 (P < 0.01).

Intra-scorer variability in AHI was an average of -0.8 events h⁻¹, with a range of -11.9 to +5.0.

Patient preference

Fifteen (50%) patients preferred to have the study done at home, with 25% preferring the laboratory environment and

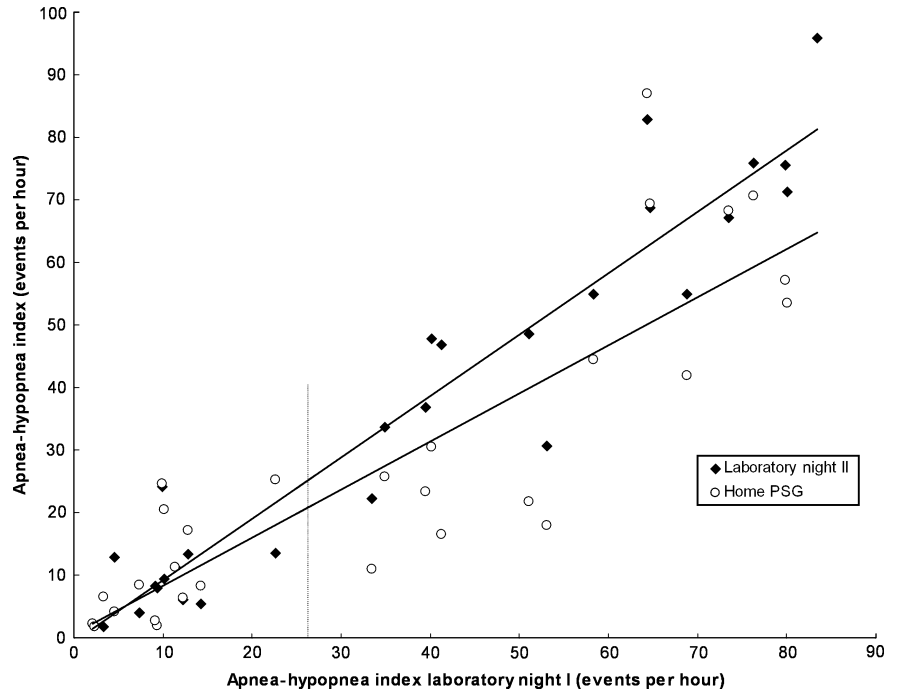


Figure 2. AHI: laboratory versus home PSG. The regression lines for home and laboratory night II are plotted. The vertical line represents the start of the area of significance, AHI > 26 events h⁻¹.

Table 5 Sensitivity, specificity and likelihood ratios for different cut-offs of AHI from laboratory night II for home PSG recordings

	<i>Sensitivity</i>	<i>Specificity</i>	<i>+ve LHR</i>	<i>-ve LHR</i>	<i>AUC</i>
AHI > 5	88.0	50.0	1.76	0.24	0.900
AHI > 10	90.5	88.9	8.14	0.11	0.921
AHI > 15	93.7	76.9	4.06	0.081	0.942

AHI, apnea-hypopnea index; AUC, area under the curve; LHR, likelihood ratio.

Cost effectiveness

Using the current study failure rate, for 100 home-based PSG studies, 6.7 would require a repeat night of diagnostic data collection (106.7 home studies per 100 laboratory diagnostic studies). A home-based PSG costs 70% of that of an attended laboratory study. For 100 attended studies at 100% cost, we would perform 106.7 level II studies equaling 75% of the attended PSG cost, this equals a saving of 25%.

DISCUSSION

The present study concludes that home set-up unattended PSG is a technically reliable and diagnostically accurate study protocol when compared with laboratory-attended PSG for the diagnosis of OSA. Signal loss was higher at home but this was mitigated by multi-channel redundancy.

25% having no preference. The most common reason for preferring a home-based study was the ability to sleep in their own bed. Those preferring the laboratory set-up and overnight stay cited less distractions and trained staff as their reason for this preference.

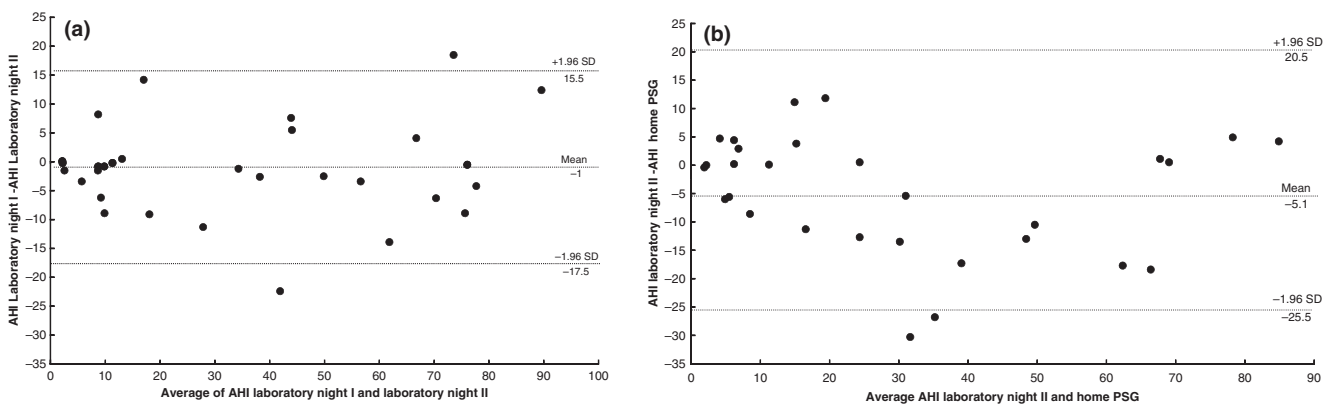


Figure 3. Bland Altman plot of apnea-hypopnea index (AHI). (a) Laboratory I versus laboratory II. (b) Laboratory II versus home PSG.

The overall success rate was similar to SHHS (Kapur *et al.*, 2000) and superior to laboratory set-up home studies (Portier *et al.*, 2000) or patient set-up home studies (Golpe *et al.*, 2002; Whittle *et al.*, 1997). Home PSG slightly underestimated AHI and this affected final OSA diagnosis in three patients, but treatment advice did not change (AHIs home/lab II: 1.9/7.9, 4.2/12.8, 6.5/1.8). The loss of the respiratory effort signal was more common at home and this might account for some of the difference seen in AHI. A home set-up PSG protocol was well accepted by patients.

This study confirms in a clinical population what has been previously reported in a research population, that home set-up PSG is technically reliable and accurate (Kapur *et al.*, 2000). A similar protocol to the SHHS was used involving home set-ups with an experienced technologist using standard procedures. Unlike those subjects in the SHHS, patients enrolled in this study had been seen by a sleep physician for evaluation and were referred for clinical suspicion of OSA.

The use of an adaptation night was to adapt patients to the sensors and equipment and secondly to provide information regarding the natural night to night variability in AHI of this patient group. AHI varied very little between the two laboratory nights and results were significantly correlated.

Weaknesses of the study include lack of a control night at home and clinical outcomes not reported, i.e. recommendations regarding treatment. The study is of a relatively small sample who were selected for lack of co-morbidity and who had been reviewed by a sleep physician, therefore the generalizability of results from this group is limited. It should be noted that patients routinely selected for home-based PSG undergo specific review where the suburb of residence (there are a small number of 'no-go' areas in the region), home environment (who lives at the residence, e.g. family, flatmates, lives alone) and social parameters (history of drug abuse, psychiatric illness) of each patient are assessed by the referring physician prior to referral. Staff attending patients' homes carry mobile phones and are able to terminate the study if at any point they feel threatened or unsafe. Thorough review of these patients has resulted in no incident in over 10 years of providing this service. All ethnic groups are eligible for home studies if they meet the criteria.

A recent meta-analysis of laboratory versus portable sleep studies (Ghegan *et al.*, 2006) concludes that they both provide similar diagnostic information but may underestimate severity of AHI by about 10%, which is consistent with the current study. For the current study, in both environments patients spent a similar amount of time in a supine position and sleep efficiency was also similar. The NREM AHI was, however, different between sites, with the NREM AHI at home being significantly less than in the laboratory. Failure rates of home-based sleep studies in the meta-analysis ranged from 2 to 23% (average 14%). The failure rate in this study was 6.6%. A recent study in Spain reports a sensitivity of 89% and specificity of 80% for home versus laboratory monitoring (Jurado-Gamez *et al.*, 2007), which is slightly less than that of the current study at 90.5 and 89%.

The AASM has published indications for the use of unattended portable recordings to diagnose sleep-related breathing disorders (Collop *et al.*, 2007). The conclusion of this paper is that unattended, home set-up portable monitoring may be effective for the diagnosis of severe sleep-related breathing disorders when used by a qualified sleep specialist as part of a comprehensive sleep consultation. We suggest that home set-up PSG can be used to rule in and rule out sleep-related breathing disorders providing the study meets technical acceptability criteria (Kapur *et al.*, 2000).

The burden of disease from untreated sleep apnea is thought to be large. Given the increased risk in patients with untreated sleep apnea of cardiovascular events and accidents, the ability to provide timely investigation and treatment is paramount. However, this must be considered against the ability of the test to provide the information required. Determination for a particular investigation strategy should be made on the basis of several key items: (i) probability of sleep apnea; (ii) co-morbidity; and (iii) knowledge of the limitations of the test proposed in the population it is being applied to. Laboratory PSG still has its place but should be reserved for high pretest probabilities where home studies are negative, complex sleep apnea, sleep hypoventilation and patients unsuitable for home studies, e.g. the elderly and anxious.

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