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Home studies for the diagnosis of sleep disorders

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PRIORITISING SUMMARY

REGISTER ID: 000237: REFERRAL FROM HEALTHPACT

NAME OF TECHNOLOGY: HOME STUDIES FOR THE DIAGNOSIS OF SLEEP DISORDERS

PURPOSE AND TARGET GROUP: DIAGNOSIS OF SLEEP DISORDERS

STAGE OF DEVELOPMENT (IN AUSTRALIA):

- | | |
|---|---|
| <input type="checkbox"/> Yet to emerge | <input checked="" type="checkbox"/> Established |
| <input type="checkbox"/> Experimental | <input type="checkbox"/> Established <i>but</i> changed indication or modification of technique |
| <input type="checkbox"/> Investigational | <input type="checkbox"/> Should be taken out of use |
| <input type="checkbox"/> Nearly established | |

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- | | |
|---|-------------|
| <input checked="" type="checkbox"/> Yes | ARTG number |
| <input type="checkbox"/> No | |
| <input type="checkbox"/> Not applicable | |

Numerous devices have received TGA approval.

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
United States			✓
Europe			✓
Australia			✓

IMPACT SUMMARY:

The prohibitive cost and limited availability of laboratory polysomnography, the gold standard for diagnosing sleep-disordered breathing, has led to the development of simpler and less expensive home methods. This prioritising summary investigates the effectiveness and value of home sleep studies in the diagnosis of obstructive sleep apnoea and other sleep disorders.

BACKGROUND

Obstructive sleep apnoea (OSA) is a common disorder caused by repeated obstruction of the upper airway during sleep. The disorder is characterised by periods of breathing cessation (apnoea) and reduced breathing (hypopnoea). OSA has been associated with a variety of negative health outcomes, including snoring, nocturnal choking and gasping, excessive daytime sleepiness, moderate obesity, hypertension and cardiovascular disease (Young et al 2002). Nasal continuous positive airway pressure (CPAP), a technique that prevents the airway from collapsing, is a cost effective and

commonly prescribed treatment option for OSA (Ayas et al 2006). Although the outcome of CPAP is generally beneficial, the technique relies on the accurate diagnosis of OSA in patients referred for investigation.

The diagnosis of OSA and other sleep-related disorders has typically been based on overnight studies performed in sleep laboratories. The most widely accepted diagnostic test for the investigation of OSA is polysomnography (PSG), a detailed sleep study in which the following channels of information are obtained: electroencephalography (EEG), electrooculography (EOG), electromyography (EMG), electrocardiography (ECG), oronasal airflow, bilateral anterior tibial muscle activity, arterial oxygen saturation (oximetry) and esophageal pressure monitoring (Hensley et al 2005). One of the primary quantities of interest estimated through PSG is the apnoea/hypopnoea index (AHI), a measure defined as the average number of apnoeas and hypopnoeas that occur per hour of sleep. Similarly the respiratory disturbance index (RDI) is often calculated, a quantity defined as the average number of apnoeas, hypopnoeas and oxygen desaturation events per hour of sleep. A diagnosis of mild OSA is confirmed when PSG reveals an AHI of greater than 5 events per hour of sleep. An AHI of 5 or less is deemed to be within normal limits and confers a negative diagnosis for OSA (Chesson et al 1997). In addition to OSA, PSG allows physicians to diagnose a variety of other sleep disorders, including central apnoea, periodic limb movement, chronic obstructive pulmonary disease and narcolepsy (Hensley et al 2005).

Due in part to an increased awareness of OSA, the demand for overnight sleep studies in Australia and New Zealand has risen dramatically over the last decade (Hensley et al 2005). The long waiting lists for overnight laboratory PSG, together with the high costs of the procedure, have led to the development of less expensive home diagnostic methods. Although earlier home sleeping studies were based on oximetry alone, a variety of portable devices are now available, capable of performing up to and including full PSG. The American Sleep Disorders Association (ASDA) has classified sleep study systems into four categories according to their level of complexity. Laboratory PSG defines a type 1 study and is considered the reference standard against which other studies are evaluated. Trained personnel should be available at all times during laboratory PSG and able to intervene when required. Home PSG defines a type 2 study and involves most if not all of the same measures used in laboratory PSG. Type 3 study systems are portable devices capable of measuring at least four channels of information. Finally, type 4 systems are devices that measure one or two channels of information, typically oxygen saturation and/or airflow (Ferber 1994). For type 2 to type 4 studies, trained personnel are required only in the preparation stage of the study.

CLINICAL NEED AND BURDEN OF DISEASE

In Western countries, mild OSA (defined as an AHI ≥ 5) has been estimated to affect approximately 20 per cent of the population, with prevalence two to three times higher in males than in females (Strohl & Redline 1996; Young et al 2002). In addition to gender, established risk factors for OSA include advanced age, menopause and obesity (Young et al 2002). OSA and the presence of daytime sleepiness, often referred to as OSA syndrome, has been estimated to affect between 2-4 per cent of men and 1-2 per cent of women in Western countries (Stradling & Davies 2004; Young et al 2002). Given the current Australian population of 20.7 million (ABS 2006), it is likely that OSA syndrome affects between 414,000 and 828,000 Australian males, and between 207,000 and 414,000 Australian females. Although the condition is widely recognised, the majority of affected individuals remain undiagnosed. In a community survey of 4,925 adults in the United States, it was found that as many as 82 and 92 per cent of the men and women with OSA syndrome respectively were likely to be undiagnosed (Young et al 1997).

In 2001, an informal listing by the patient support group 'Sleep Disorders Australia' identified a total of 79 adult (non-paediatric) clinical sleep laboratories across the country. Of these laboratories, 56 were in the private sector, 19 were in the public sector, while the remaining 4 contained a mixture of public and private beds (Pack 2006). During 2005, a total of 65,295 polysomnograms were performed by the combined sectors (HCP 2006).

DIFFUSION

Home sleep studies are readily available in Australia. Sleep Services Australia, a large diagnostic company that specialises in sleep disorders, offers home sleep studies in Victoria, NSW, ACT, Tasmania and Queensland. In South Australia, home sleep studies are available through Mycroft Sleep Diagnostics.

A variety of sleep study devices have received TGA approval for use in Australia. Many of these devices are compatible for use both in a laboratory and a home setting.

COMPARATORS

The main comparator for home sleep study systems is overnight laboratory PSG. At present, laboratory PSG is considered to be the gold standard for diagnosing sleep disorders. Advantages of laboratory PSG include the wealth of information obtained, the overall quality of this information, and the ability to verify that the patient has slept (Douglas 2003). Unlike most home sleep studies, laboratory PSG is also capable of diagnosing less common sleep disorders, including central apnoea, periodic limb movement, chronic obstructive pulmonary disease and narcolepsy (Hensley et al 2005). Unfortunately laboratory PSG is relatively expensive, is associated with long waiting periods and a lack of access in rural communities. Other disadvantages of

laboratory PSG include the artificial sleep environment (which may affect how the patient sleeps) and the high rate of variability in measurements between different sleep laboratories (Ghegan et al 2006).

Home sleep studies offer considerable benefits in terms of their cost, availability and centralisation of data analysis. In comparison to laboratory PSG however, fewer channels of information are recorded, and therefore less diagnostic information is generally available. As home sleep studies are performed in unattended surroundings, they are also more susceptible to data loss (for example due to sensor failure), which may result in a large number of sleep studies needing to be repeated (Douglas 2003).

EFFECTIVENESS AND SAFETY ISSUES

A systematic review conducted in 2003 by the American Academy of Sleep Medicine, the American College of Chest Physicians, and the American Thoracic Society investigated the diagnostic accuracy of portable sleep study systems in detecting OSA (level III-1 intervention evidence) (Flemons et al 2003). The research group identified a total of 46 studies published after 1997 that satisfied relevant inclusion criteria, of which 13 were performed in a home setting. Using a threshold value of AHI as estimated by laboratory PSG as the gold standard for diagnosing OSA, home sleep studies reported variable sensitivities ranging from 31 to 100 per cent, and specificities ranging from 48 to 100 per cent. In general, sensitivities and specificities were higher for type 2 and type 3 sleep study systems than for type 4 study systems. The research group recommended against the use of home sleep studies in clinical practice however due to the limited amount of evidence available at the time outlining accuracy and cost effectiveness.

In a recent meta-analysis, Ghegan et al (2006) compared the diagnostic accuracy of portable sleep study systems to laboratory PSG using a total of 18 previously published studies (level III-1 intervention evidence). The authors included studies that were published after 1996 and where participants were monitored by both portable sleep study systems and full laboratory polysomnography. Of the 18 studies included, the portable sleep study was performed in the home setting on 14 occasions. After pooling data from the 12 studies that included RDI¹ as an outcome measure, RDI values were found to be significantly lower on portable sleep studies when compared with laboratory PSG (OR = 0.90; 95% CI, 0.87 – 0.92). This trend was unchanged when studies performed only in a laboratory setting were excluded from the analysis. Using data from three studies that measured average low oxygen saturation (a commonly reported measure of sleep apnoea severity), there was no difference between laboratory PSG and portable sleep studies (OR = 1.0; 95% CI, 0.94 – 1.10). Across a total of eight studies, recorded sleep time was found to be higher for laboratory PSG compared with portable sleep studies (OR = 0.87; 95% CI, 0.86 –

¹ RDI = respiratory disturbance index

0.89). Finally, the authors found that while portable sleep studies were between 35 and 88 per cent less expensive than laboratory PSG, they were significantly more likely to give an inadequate recording ($p < 0.001$).

In another recent study, Whitelaw et al (2005) randomised 288 patients referred for a sleep study to receive either home oximetry (Snoresat, Sagatech, Canada; a type 4 sleep study system) or laboratory PSG (level II intervention evidence). Rather than comparing AHI² or RDI values, the authors investigated how results from PSG and home-based sleep studies might influence clinical decision-making and patient outcomes. Sleep specialists were required to estimate the likelihood of successful treatment as either greater than 50 per cent (defined as a predicted success) or less than 50 per cent (defined as a predicted failure) based on clinical data and results from the sleep studies. In the trial, success was defined as a one unit or greater increase in the Sleep Apnoea Quality of Life Index (SAQLI) following four weeks of treatment with auto adjusting CPAP. The correct prediction rate was 61 per cent with laboratory PSG and 64 per cent with home oximetry (no significant difference). That is, home oximetry was no worse than full laboratory PSG for correctly predicting patient outcomes following treatment for sleep apnoea.

COST IMPACT

Overnight laboratory PSG is available on the Medical Benefits Schedule (MBS) under item numbers 12003 and 12007. Both of these item numbers attract a fee of \$508.90. At present, home sleeping studies are not rebated through the MBS.

As home sleep studies do not incur the costs associated with the use of hospital rooms or the need for continuous technician attendance, it is generally held that they are a cost-effective approach to diagnosing sleep disorders (see for example Douglas 2003). However, due to the poorer quality of data obtained, the use of home sleep studies may result in poorer patient management or the need to repeat studies. Chervin et al (1999) performed a sensitivity analysis of five-year costs associated with laboratory PSG, home sleep studies and no diagnostic testing. Under a majority of modelling conditions, laboratory PSG was found to be the most cost effective approach for diagnosing OSA. Compared to a home sleeping study, the incremental charge for laboratory PSG per quality-adjusted life-year gained was estimated to be US \$13,400.

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified/raised in the sources examined.

OTHER ISSUES

A number of sleeping laboratories now offer split-night studies. In these studies, patients who report a significant number of apnoeas or hypopnoeas in the initial portion

² AHI = apnoea/hypopnoea index

of the study are given a therapeutic intervention later that night, typically CPAP titration and implementation. In unattended home sleep studies, the diagnosis of sleep-disordered breathing occurs only after the study has been completed. As a result, CPAP titration and implementation cannot be performed on the same night. With the emergence of automated self-titrating CPAP machines however, CPAP titration and implementation may still be effectively performed in the home setting following the diagnosis from an unattended sleep study (Masa et al 2004).

CONCLUSION

There are some uncertainties regarding both the diagnostic accuracy and cost-effectiveness of home sleep study systems. According to the guidelines presented by Australian Sleep Association and the Thoracic Society of Australia and New Zealand in 2005, there is only limited evidence to support the use of home sleep studies to “rule in” but not “rule out” OSA. Furthermore, the guidelines recommend that home sleep studies should only be conducted under the supervision of an accredited sleep physician.

HEALTHPACT ACTION

Given the significant morbidity and mortality associated with untreated OSA, there is a need for clinically validated diagnostic tests to supplement laboratory PSG. Home sleep studies offer considerable promise in this regard, therefore HealthPACT recommended that this technology be monitored and assessed again in 12 months time.

SOURCES OF FURTHER INFORMATION:

ABS (2006). *Population Clock* [Internet]. Australian Bureau of Statistics. Available from: <http://www.abs.gov.au> [Accessed 25th October 2006].

Ayas, N. T., FitzGerald, J. M. et al (2006). 'Cost-effectiveness of continuous positive airway pressure therapy for moderate to severe obstructive sleep apnea/hypopnea', *Arch Intern Med*, 166 (9), 977-984.

Chervin, R. D., Murman, D. L. et al (1999). 'Cost-utility of three approaches to the diagnosis of sleep apnea: polysomnography, home testing, and empirical therapy', *Ann Intern Med*, 130 (6), 496-505.

Chesson, A. L., Jr., Ferber, R. A. et al (1997). 'The indications for polysomnography and related procedures', *Sleep*, 20 (6), 423-487.

Douglas, N. J. (2003). 'Home diagnosis of the obstructive sleep apnoea/hypopnoea syndrome', *Sleep Med Rev*, 7 (1), 53-59.

Ferber, R., Millman, R. et al (1994). 'Portable recording in the assessment of obstructive sleep apnea. ASDA standards of practice', *Sleep*, 17 (4), 378-392.

Flemons, W. W., Littner, M. R. et al (2003). 'Home diagnosis of sleep apnea: a systematic review of the literature. An evidence review cosponsored by the American Academy of Sleep Medicine, the American College of Chest Physicians, and the American Thoracic Society', *Chest*, 124 (4), 1543-1579.

Ghegan, M. D., Angelos, P. C. et al (2006). 'Laboratory versus portable sleep studies: a meta-analysis', *Laryngoscope*, 116 (6), 859-864.

HCP (2006). *Health Care Providers: Medicare Benefits Schedule (MBS) Item Statistics Reports* [Internet]. Available from: http://www.medicareaustralia.gov.au/providers/health_statistics/statistical_reporting.htm [Accessed 6th June].

Hensley, M. J., Hillman, D. R. et al (2005). *Guidelines for sleep studies in adults* [Internet]. Australasian Sleep Association and Thoracic Society of Australia and New Zealand. Available from: <http://www.sleepaus.on.net/guidelinesforadultsleepstudies.pdf> [Accessed 8th June].

Masa, J. F., Jimenez, A. et al (2004). 'Alternative methods of titrating continuous positive airway pressure: a large multicenter study', *Am J Respir Crit Care Med*, 170 (11), 1218-1224.

Pack, A. I. (2006). 'Advances in sleep-disordered breathing', *Am J Respir Crit Care Med*, 173 (1), 7-15.

Stradling, J. R. & Davies, R. J. (2004). 'Sleep. 1: Obstructive sleep apnoea/hypopnoea syndrome: definitions, epidemiology, and natural history', *Thorax*, 59 (1), 73-78.

Strohl, K. P. & Redline, S. (1996). 'Recognition of obstructive sleep apnea', *Am J Respir Crit Care Med*, 154 (2 Pt 1), 279-289.

Whitelaw, W. A., Brant, R. F. & Flemons, W. W. (2005). 'Clinical usefulness of home oximetry compared with polysomnography for assessment of sleep apnea', *Am J Respir Crit Care Med*, 171 (2), 188-193.

Young, T., Evans, L. et al (1997). 'Estimation of the clinically diagnosed proportion of sleep apnea syndrome in middle-aged men and women', *Sleep*, 20 (9), 705-706.

Young, T., Peppard, P. E. & Gottlieb, D. J. (2002). 'Epidemiology of obstructive sleep apnea: a population health perspective', *Am J Respir Crit Care Med*, 165 (9), 1217-1239.

LIST OF STUDIES INCLUDED

Total number of studies

Level II evidence 1

Level III evidence 2