

21 August 2020

Mr Ryan Fernando
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Medical Services Advisory Committee and
Health Technology Assessment Group

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Dear Mr Fernando,

Re: MSAC application 1631 – home sleep apnoea test utilising peripheral arterial tone

The Royal Australian College of General Practitioners (RACGP) welcomes the opportunity to comment on the public consultation on MSAC application 1631 – home sleep apnoea test utilising peripheral arterial tone to assess its inclusion under the MBS item 12250.

The RACGP recommends studies of how the device performs in actual practice i.e. in the homes of general practice patients, should be conducted before its inclusion under the MBS item 12250, due to the concerns provided below.

The WatchPAT device

This device is a relatively unique and sophisticated sleep apnoea monitor which does not specifically measure respiration. Instead, it infers the presence of an apnoea or hypopnea event from the presence of a dip in oxygen saturation and brief arteriolar vasoconstriction in the finger (by plethysmography) – the latter being interpreted to be due to a brief arousal from sleep. The device makes an assessment of sleep versus wake time using a finger motion sensor; and claims also to be able detect random eye movement (REM) versus non-REM from a combination of the behaviour of the peripheral vascular activity (pulse rate, plethysmography etc).

The reviewed studies

Clinical outcomes are described in the meta-analysis¹ paper provided in the evidence summary (p.7). The reported correlation between WatchPAT respiratory disturbance index (RDI) and polysomnography (PSG) apnoea-hypopnea index (AHI) is impressively high but, for the reasons outlined below, caution is needed when interpreting the results of sleep studies:

- a. Almost all the reviewed studies have compared WatchPAT vs PSG in a carefully controlled environment (sleep lab) in highly selected patient populations. Signal loss tends to be less and the quality is higher in the laboratory than at home. This is an important point, as the WatchPAT is designed to be used at home.
- b. The reliability and usefulness of WatchPAT need to be tested in a general primary care population, particularly among older age patients with comorbidities such as diabetes, and cardiac disease. These groups were excluded from the validation studies.
- c. The study of diagnostic accuracy² on (p.9) included 200 'unselected' patients. It is assumed that this cohort was from a sleep clinic. The correlation coefficient for the automated WatchPAT RDI with PSG AHI was considerably lower (0.65) than found in the studies included in the meta-analysis¹, and it improved with manual review (0.81); and it was reportedly more of a problem in older patients.

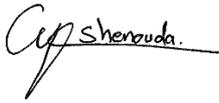
While there are potential benefits of to having general practitioners and practice nurses use an apnoea screening device in terms of access for patients, particularly those in regional and rural areas where specialised sleep laboratories are not available, there are some unresolved issues with the WatchPAT device as described above. Whilst there is the potential benefits of improved access, this must be balanced against its reliability in real world settings.

Overdiagnosis

There is risk of overdiagnosis of obstructive sleep apnoea, as measured by polysomnography or other sleep study devices. Treatment benefits do not correlate well with sleep study results. There are strong commercial interests in promoting sleep studies and in providing treatment with Continuous Positive Airway Pressure (CPAP) machines. Direct to consumer advertising of sleep studies is common and this puts pressure on general practitioners to provide a referral if requested by patients.

Thank you again for the opportunity to provide feedback on consultation. Please contact Mr Stephan Groombridge, Manager, eHealth and Quality Care on (03) 8669 0544 or at stephan.groombridge@racgp.org.au if you have any further queries.

Yours sincerely



Dr Ayman Shenouda
Acting president

References

1. Yalamanchali et al. Diagnosis of Obstructive Sleep Apnoea by Peripheral Arterial Tonometry. JAMA Otolaryngology Head Neck Surg. 2013 Dec 139(12):1343-50
<https://jamanetwork.com/journals/jamaotolaryngology/fullarticle/1759186>
2. Zhang et al. A comparison of automated and manual sleep staging and respiratory event recognition in a portable sleep diagnostic device with in-lab sleep study. J Clin Sleep Med. 2020;16(4):563–573
<https://jcs.m.aasm.org/doi/abs/10.5664/jcsm.8278>