Title

A validation study of the limited channel single and multi-use NightOwl sleep testing systems compared to laboratory polysomnography in the diagnosis of obstructive sleep apnoea

Project Team Roles & Responsibilities

* Dr Christopher Lyne BBiomed MD, Monash Lung and Sleep, Principle Investigator
* A/Prof Darren Mansfield MBBS PhD. Monash Lung and Sleep, Monash University, Chief Investigator.
* Dr Durda Stupar BSc Bmed Honours PhD, Investigator
* Mr Anthony Turton BSc Honours, Investigator

Resources

Polysomnography (PSG) will be conducted in the sleep laboratory of Monash Lung and Sleep, performed as part of usual clinical care with set up by a sleep scientist. Additional monitoring with the single use and multiuse NightOwl (Ectosense NV, Leuven, Belgium) home sleep apnoea testing (HSAT) devices will occur concurrently. The disposable and re-usable NightOwl devices, as well as the software to operate them, will be supplied by the manufacturer Ectosense at no cost. No funding will be received from the manufacturer.

Background

Obstructive sleep apnoea (OSA) is associated with increased risk of cardiovascular disease including hypertension, and screening for this condition and treatment may help reduce those risks1,2. Furthermore, undiagnosed OSA is also linked to increased risk of postoperative complications in patients undergoing major surgery3,4. Opportunities to screen using simplified diagnostic devices may be an important approach to addressing this clinical burden. Conventionally, the diagnosis of OSA is conducted by laboratory polysomnography (PSG) . A number of simplified devices are emerging commercially including single use disposable single or dual channel home monitoring. Single use disposable devices may emerge as the most convenient method for screening for OSA, especially in the home setting, however formal validation against PSG has not been previosly performed. The NightOwl is a small dual channel device that acquires data from a single fingertip and is now TGA registered as a single-use device in addition to a previously validated reusable option6. The purpose of this study is to validate the single-use NightOwl compared to its reusable counterpart and the gold standard laboratory PSG for the diagnosis of OSA. Findings of this study will inform models of care that may include screening for OSA. This may be important in the clinical assessment of operative risk in those suspected of OSA undergoing major surgery.

* Research questions/aims/objectives/hypothesis
	+ Hypothesis: NightOwl single-use and reusable devices are equivalent and correlate with laboratory PSG for the diagnosis of OSA
	+ Objective: Compare the simplified single-use and reusable dual channel HSAT device with laboratory PSG for the detection of obstructive sleep apnoea.

Project Design

* Setting: Monash Lung and Sleep department, Monash Medical Centre, Monash Health
* Methodological approach:
	+ Prospective cohort study of consecutive eligible patients undergoing clinically indicated in-laboratory PSG. Observation is using a NightOwl device to record accelerometer and photoplethysmography data to compare with in-laboratory PSG on the same participant. Comparison with laboratory diagnostic PSG is chosen as this is the gold standard for diagnosis of obstructive sleep apnoea.
	+ On the night of a clinically indicated laboratory sleep study, eligible patients will be invited to participate in the project. Informed consent will be required on the night of the study
	+ Two versions of the NightOwl device will be tested concurrently – a recently developed unvalidated single-use disposable version and a previously validated reusable version.
	+ Each device attaches to one finger with use of a single-use biocompatible adhesive. (see Figure 1 below)
	+ Each NightOwl device records two signals:
		- Dual-wavelength photoplethysmography
		- 3-axis accelerometry
		- Data from the device is sent via Bluetooth to an App on a IPad or mobile phone provided by the study coordinators
	+ The NightOwl data is analysed by proprietary software to derive the apnoea hypopnoea index (AHI) and total sleep time. This data will be deidentified and stored on the proprietary cloud-based software system.
	+ Analysis of raw data obtained by the NightOwl will also be completed by the investigators to examine oxygen desaturation index (ODI) and confirm signal quality obtained by the sensor.
	+ PSG data will be analysed according to American Academy of Sleep Medicine manual 2017 by two sleep scientists. If the scores for AHI have a variance of greater than 10% then a third scientist will score the study to achieve a consensus
* Participants:
	+ Participant screening for study inclusion will be on consecutive patients undergoing clinically indicated laboratory PSG at Monash Lung and Sleep suspected of having OSA
	+ Inclusion criteria include participants aged between the ages of 18-85 undergoing diagnostic PSG being tested for the diagnosis of OSA
	+ Exclusion criteria include:
		- 1. Patients with a known diagnosis of OSA undergoing a treatment PSG.
		- 2. Unable to provide informed consent
		- 3. Total sleep time less than 4 hours
* Outcome measures:
	+ Primary outcome: correlation between AHI obtained from PSG and the AHI obtained from the NightOwl single-use and reusable Night Owl
	+ Secondary outcomes: agreement of the ODI, Agreement of the total sleep time, level of agreement between NightOwl derived and PSG derived OSA severity.
* Consent:
	+ Written informed consent obtained on the night when attending their laboratory PSG
	+ The attending sleep scientist will issue and obtain written consent.
	+ Participants will have approximately 30 minutes to consider participation
	+ Consent will be sought prior to being connected to the laboratory PSG to ensure the patient does not feel obligated to participate.
* Research Activities:
	+ Participant commitment will be minimal as the study device(s) will obtain data recordings while the patients are having their PSG
	+ Project duration – aim to recruit 2 participants per night.
	+ Participant follow-up – not required for this study
* Data Collection/Gathering:
	+ Data collection: Demographic data: age, gender, BMI. Laboratory PSG data will be collected using Compumedics Grael and Profusion 3 recording Software. The Night Owl single-use and reusable devices collect accelerometer and photoplethysmographic data to derive actigraphy, SpO2, pulse rate and peripheral arterial tone. This data is transmitted via Bluetooth to a mobile smart device (investigators will be supplying) using the NightOwl companion app and stored as de-identified cloud based data on the proprietary storage platform.
* Data Management:
	+ Study data will be de-identified using a unique code for each participant.
	+ Study data will be stored on a secure server at Monash Health and a cloud-based server by the manufacturer. The study investigators have access to the data.
	+ The manufacturer will not be able to re-identify participant data.
* Data Analysis:
	+ Analysis will be performed using standard statistical software.
	+ Analysis: PSG vs disposable NightOwl and PSG vs re-usable NightOwl
	+ The primary outcome, correlation of total sleep time and ODI will be assessed using the Spearman correlation coefficient, intraclass correlation coefficient and Bland-Altman plot. Agreement between characterisation of OSA severity will be assessed using a weighted kappa.
	+ Sample size estimation is based on the previous study by Massie et al6 and we will aim for a size of 100 participants. A sample size of 100 has been chosen to minimise heterogeneity between this study and the previous study by Massie et al.
* For research involving an investigational drug or device as part of a clinical trial: What is/are the drug(s) and/or device(s):
	+ Approved name: NightOwl
		- NightOwl Sensor Reusable
		- NightOwl Sensor Mini (single use version)
	+ Manufacturer: Ectosense
	+ Supplier of drug/device (e.g. manufacturer/pharmacy): Ectosense
	+ Approved therapeutic indication, dosage/duration in Australia: for detection of OSA
	+ Known adverse events: allergic reaction to adhesive
	+ Known contra-indications or warnings: manufacturer advises not to use the sensor on skin that is tattooed, heavily blemished or rough.

Results, Outcomes and Future Plans

* Plans for dissemination and publication of project outcomes:
	+ Project will be published in a medical journal
	+ Project will be presented at national conference
* Plans for sharing and/or future use of data and/or follow-up research
	+ The follow up project will be a larger trial using the NightOwl device to screen high risk surgical patients pre-operatively at home and to assess if this high risk cohort is at higher risk of post-operative complications if OSA is present.

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2. Marin JM, Carrizo SJ, Vicente E, Agusti AG. Long-term cardiovascular outcomes in men with obstructive sleep apnoea-hypopnoea with or without treatment with continuous positive airway pressure: an observational study. The Lancet. 2005 Mar 19;365(9464):1046–53.

3. Chan MTV, Wang CY, Seet E, Tam S, Lai HY, Chew EFF, et al. Association of Unrecognized Obstructive Sleep Apnea With Postoperative Cardiovascular Events in Patients Undergoing Major Noncardiac Surgery. JAMA. 2019 May 14;321(18):1788–98.

4. Abdelsattar ZM, Hendren S, Wong SL, Campbell DA, Ramachandran SK. The Impact of Untreated Obstructive Sleep Apnea on Cardiopulmonary Complications in General and Vascular Surgery: A Cohort Study. Sleep. 2015 Aug 1;38(8):1205–10.

5. Kapur VK, Auckley DH, Chowdhuri S, Kuhlmann DC, Mehra R, Ramar K, et al. Clinical Practice Guideline for Diagnostic Testing for Adult Obstructive Sleep Apnea: An American Academy of Sleep Medicine Clinical Practice Guideline. Journal of Clinical Sleep Medicine. 2017 Mar 15;13(03):479–504.

6. Massie F, Mendes de Almeida D, Dreesen P, Thijs I, Vranken J, Klerkx S. An Evaluation of the NightOwl Home Sleep Apnea Testing System. Journal of Clinical Sleep Medicine. 2018 Oct 15;14(10):1791–6.



Figure 1. *Left:* NightOwl Sensor Reusable and *Right:* NightOwl Sensor Mini (single use). Images courtesy of Ectosense