(Acta Anaesth. Belg., 2020, 71, 107-110)

Feasibility of novel smartphone app-based pulse oximetry system compared with proprietary level 4 home sleep testing device for obstructive sleep apnea detection

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Keywords : Obstructive sleep apnoea ; mobile phone application ; airway ; sleep study.

Obstructive sleep apnea (OSA) is a chronic condition of sleep disordered breathing, characterized by upper airway obstruction, and intermittent episodes of apnea and hypopnea during sleep. It affects approximately 17% of men and 9% of women between 50-70 years old. Currently, there are substantial numbers of elective surgical patients with unrecognized OSA (1). Unrecognized severe OSA and longer cumulative time during sleep with oxygen saturation (SpO_2) < 80% has been recently reported to predict an increased risk of postoperative myocardial injury, stroke and cardiac death in surgical patients (1).

Pre-operative sleep monitoring devices have traditionally been categorized into 4 Levels based on the type of monitoring and physiological parameters measured (2). Polysomnography (PSG) is a Level I sleep study which includes a minimum of seven parameters (electroencephalogram, airflow, respiratory effort and oxygen saturation) and requires trained personnel in constant attendance. Unlike Level I, patients are unattended for Level II to IV studies. Level II devices measure both respiratory and sleep variables, while Level III and IV devices measure cardiorespiratory variables only, and do not assess sleep stages. Level III sleep studies measure a minimum of four cardiorespiratory variables, which include ventilation, oxygen saturation and heart rate or electrocardiography. On the other hand, level IV sleep devices are continuous recordings of a minimum of one parameter, which allows it to be the simplest form of portable sleep monitoring available.

Currently, PSG remains the gold standard for diagnosis of OSA. However, this requires extensive usage of manpower and hospital resources. Costs to the patient would generally be more than 1,000 US dollars. Level III and IV home sleep apnea devices can capture data for the diagnosis of OSA and are potential alternatives to PSG for diagnosing OSA in patients at high clinical risk of moderate to severe OSA (3), and have been shown to be sensitive and specific to detect OSA in surgical patients (4). However, data from these devices needs to be downloaded using proprietary software (e.g. Profox Associates, Inc, www.profox.net) and the process of calculating sleep disorder parameters can be inflexible and cumbersome.

In modern times mobile smartphones are readily available and phone-based applications are versatile at low costs. Smartphones have been rapidly adopted and are becoming the technological lynchpin of our current healthcare revolution. They facilitate database management and allow real time data processing to be more convenient and cost effective. A novel mobile phone-based system was created, which is able to process and store oximetry data securely. The mobile phone is linked via an adaptor to a commercially available oximeter. A patent was filed with the Intellectual Property Office of Singapore for this technology (application number 10201500967S – "Telemedicine Oximetry System). We are not aware of the existence of such applications commercially.

We conducted a prospective observational feasibility study of surgical patients at risk of OSA to determine the utility of a novel smart phone

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ES, CS, LKM and CMK have made substantial contribution to the manuscript in drafting the article or revising it critically for important intellectual content, final approval of the version to be published. They agree to be accountable for all aspects of the work.

Paper submitted on July 30, 2020 and accepted on October 4, 2020
Conflict of interest : None

application for OSA detection and calculation of the cumulative time of oxyhemoglobin desaturation. Informed consent was obtained for all participants and institutional research board endorsement was given (DSRB reference 2017/00891) by the chairperson and members of Domain D (Anesthesia), National Healthcare Group Domain Specific Review Board, Nexus @One-North (South Tower), No. 3 Fusionopolis Link, #03-08, Singapore 138543. The inclusion of subjects into the study started on December 01, 2018 and ended on July 01, 2019.

A smart phone (Xiaomi Redmi 2, model number 2014817) with an Android operating system (5.1.1, LMY47V) was loaded with a novel application for OSA detection. This was connected to a commercially available oximetry finger probe (Masimo, iSpO_2) to create a novel phone application-based pulse oximetry system. Data from the pulse oximeter was directly transferred to the smart phone in real time, with processing and calculation of data conducted on the phone application itself. Data retrieval can either be conducted directly from the phone, or online via a secure connection. The mobile phone application is configured to upload data securely and wirelessly through the respective hospital intranet Wi-Fi, including but not limited to, WPA2 Enterprise or higher, to a backend system in a cloud or to a designated server in a secure hospital WLAN or LAN. For this study, all data was retrieved directly from the phone itself to protect patients' confidentiality and to avoid loss of data in the event of limited internet connection. The framework of this phone app-based pulse oximetry system was designed based on current literature on the use of nocturnal oxygen desaturation index for surgical patients with suspected OSA (4).

This phone application-based pulse oximetry system was compared with a commercially available proprietary Level IV pulse oximeter wristwatch (Pulsox-300i, Konica Minolta Sensing Inc, Osaka, Japan). The aim of the study was to determine the feasibility and accuracy of the novel smart phone application attached to a finger oximetry probe for OSA detection and calculation of cumulative time of oxyhemoglobin desaturation during sleep.

Patients planned for elective surgery were recruited if they were suspected to be at risk of OSA, by scoring at least 3 out of 8 or more (i.e. at risk of OSA) using the STOP-Bang screening tool (5). Seven male patients and 1 female patient were recruited between December 2018 and June 2019. The smartphone app-based oximetry system and the Pulsox-300i were applied to the same hand of study participants just before bedtime and were removed the next morning. Data compared from both devices included the heart rate, lowest O_2 saturation, cumulative time of oxyhemoglobin desaturation with SpO_2 < 80% (CT 80%) and 90% (CT 90%), and the number of episodes per hour of oxygen desaturation of ≥4% lasting for at least 10 seconds, defined as the oxygen desaturation index (ODI 4%). For the Pulsox-300i oximeter, the ODI 4% was calculated using a ≥4% decrease in average SpO_2 values for each patient in the preceding 120 seconds. The ODI 4% was automatically calculated via an in-built analysis tool in the phone app-based pulse oximeter (Figure 1). For both devices, the CT 80% and CT 90% were manually calculated from downloaded data.

The Pearson's correlation coefficient was used to assess the strength of data association between the Pulsox-300i and the novel smartphone

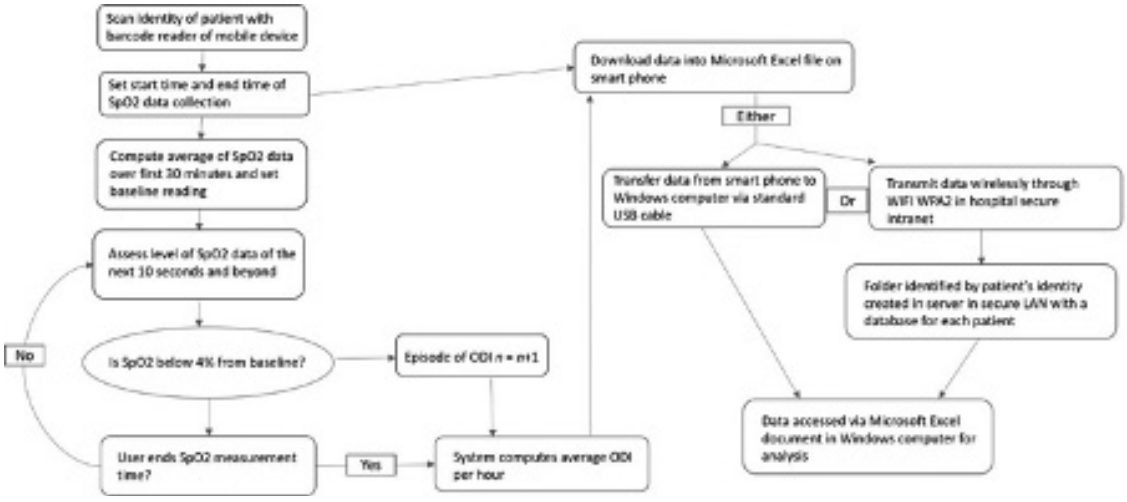

Fig. 1. – Novel mobile phone application-based pulse oximetry system.

Table 1

Parameters measured from the smartphone app-based oximetry system and the Pulsox-300i

	Masimo	Pulsox-300i
HR (beats/min)	74 ± 12	74 ± 12
Lowest SpO_2 (%)	81.5 ± 9.8	74.4 ± 8.2
CT 90% (% of sleep time)	1.1 ± 0.9	1.7 ± 1.8
CT 80% (% of sleep time)	0.4 ± 0.6	0.4 ± 0.3
ODI 4%(% of oximetry time)	7.1 ± 5.5	13.9 ± 10.4

HR = Heart rate, SpO_2 = Oxygen saturation, CT 90% = Cumulative time with SpO_2 < 90% expressed as percentage of sleep time, CT 80% = Cumulative time with SpO_2 < 80% expressed as percentage of sleep time, ODI 4% = number of episodes per hour of oxygen desaturation of ≥ 4% lasting for at least 10 seconds expressed as percentage of oximetry time.

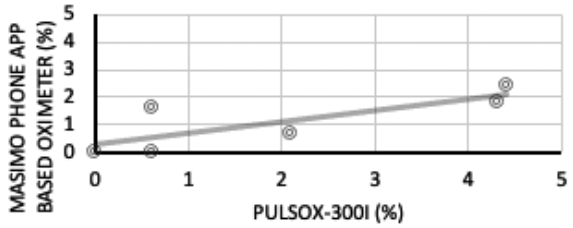

Fig. 2. – Percentage of overall sleep time with SpO_2 < 90% measured by the Pulsox-300i versus the smartphone app-based oximetry system.

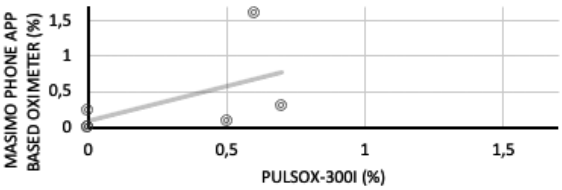

Fig. 3. – Percentage of overall sleep time with SpO_2 < 80% measured by the Pulsox-300i versus the smartphone app-based oximetry system.

oximetry system. The Bland-Altman method was also used to determine agreement of both devices. The limits of agreement were reported based on standard deviation. Data analysis was performed using GraphPad Prism (Version 8.4.2 for Windows, GraphPad Software, La Jolla California USA). As this was a feasibility study, no sample size calculation was done.

Of the 8 patients recruited, 2 patients had no OSA, 4 patients were found to have mild OSA and 2 patients found to have moderate OSA. The smartphone app-based finger probe was dislodged during sleep for 1 patient (no OSA), and the Pulsox-300i finger probe was dislodged during sleep for 1 patient (mild OSA). The age range of patients was between 40 to 72 years, with a mean age of 60 ± 10 years. The data obtained from both devices is summarised in Table 1.

Cumulative time of SpO_2 < 90% (in percentage of number of hours of recorded oximetry time) was 1.1 ± 0.9% for the smartphone group and 1.7 ± 1.8% for the Pulsox-300i group (Table 1). Cumulative time of SpO_2 < 80% (in percentage of number of hours of recorded oximetry time) was 0.4 ± 0.6% in the smart phone group and 0.4 ± 0.3% in the Pulsox-300i group (Table 1). The Pearson's correlation coefficient for CT 90% was 0.8 (Figure 2) and that of CT 80% was 0.6 (Figure **3**), indicating a high positive correlation for both devices in the calculation of CT 90% and a moderate positive correlation in the calculation of CT 80%.

The CT 90% and CT 80% was plotted using the Bland Altman method to measure agreement between both devices (Figure 4). The mean bias for the CT 90% as a percentage of recorded oximetry time was 0.9067% {Limit Of Agreement (LOA) : -1.625 to 3.438%} while the mean bias for CT 80% as a percentage of recorded oximetry time was 0.0917% (LOA : -0.4135 to 0.5968%).

There were several limitations to the study identified during the data collection process. Finger probe dislodgement was a common occurrence

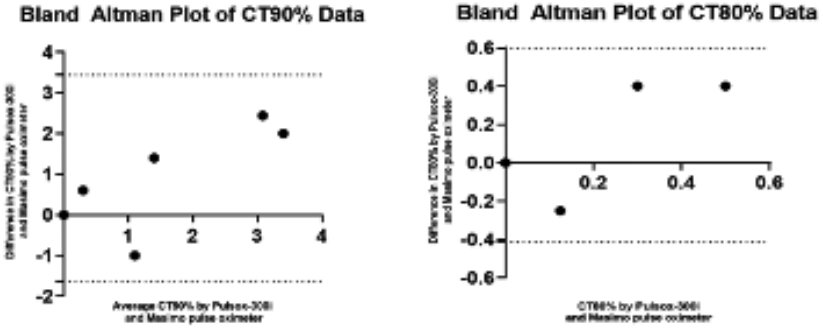

Fig. 4. – Bland-Altman plots for CT90% and CT80% data from the Pulsox-300i and Masimo pulse oximeter. The dotted lines represent the 95% limits of agreement calculated from the data obtained.

in 12.5% of patients and was shown to affect the accuracy of data collected. It was difficult to monitor compliance to finger oximetry overnight and dislodgement could only be identified during data retrieval the following day. Patients also needed to be educated on the use of these sleep tests to ensure compliance overnight, which may prove to be difficult in patients who lack capacity to do so, including patients with dementia or other neurological pathology.

Additionally, overall sleep time was not measured in this study as patients were not evaluated for onset and offset of sleep, or periods of wakefulness during the night. As such CT 90% and CT 80% values were interpreted based on the number of recorded oximetry hours rather than each patient's sleep time.

In this study, it was shown that 75% of the patient cohort had unrecognized OSA, in keeping with previous large sample size publications (1). Interclass correlation between both devices showed moderate agreement for measured cumulative time of $SpO_2 < 90\%$. Based on the Bland-Altman analysis, all patients were within the LOA for both devices with a low mean bias. As such, the novel smartphone application-based oximetry system may play a role in perioperative OSA screening and detection. We propose that this smartphone application to be used by medical professionals as a quick screening tool in conjunction with current scoring systems like the STOP-Bang score to assess a patient's risk of OSA prior to surgery. These patients can then be referred early for an eventual initiation of continuous positive airway pressure (CPAP) therapy in order to reduce the risk of post-operative respiratory complications. Data from the phone app-based pulse oximeter can also be more readily accessed as compared to current commercially available level IV sleep devices which require proprietary hardware for data accessibility. This easy accessibility also enables patients to use the phone oximeter to assess their risk of OSA and seek medical attention early if indicated. This may potentially be useful in reducing the burden placed on hospital resources for PSG studies and could also be a more convenient option for patients who may wish to reduce their number of hospital visits pre-operatively.

Acknowledgements

The authors would like to acknowledge the contributions by Dr Daniel Chia and Ms Audris Chia for the creation of the mobile phone application and data collection respectively. The authors declare they have no conflict of interest and no financial interest in the products included in this study. The mobile phone application creation and study was supported by the Alexandra Health Enabling Grant FY 2017 (AHEG1703) – limited from 2017-2019.

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