Study Title:
The Accuracy of Smartphone Pulse Oximetry in Patients Visiting an Outpatient Pulmonary Function Lab for a 6-Minute Walk Test

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Aim of the Study

The primary aim of this research is to determine the accuracy of smartphone pulse oximeters in detecting blood oxygen saturations, episodes of desaturations, and heart rate by comparing results to a Masimo© hospital-grade pulse oximeter.

Introduction

Digital innovations have made it possible for consumers to use mobile devices for medical purposes. They can be used to monitor physiological parameters such as blood pressure, heart rate, blood oxygen saturation, and body temperature. They can also be used to conduct diagnostic tests, request prescription refills, and relay medical information to physicians.[1] Consequently, the healthcare sector is being profoundly affected by this emerging technology.[1,2] A frequent reliance on mobile devices has been reported among healthcare practitioners (HCPs) and students, with 85% reporting the use of a mobile device at least once daily for clinical purposes. The most common use was for information, time management, or communication relating to education and patient care.[3] In 2010, approximately 50 percent of physicians used a mobile phone or a smart mobile device as a part of his or her practice. In 2015, that number increased to approximately 70 percent. The overall growth of applications (apps) was 38.1 percent, compounded annually over the past five years; in regards to medical apps, the growth was documented at 41.9 percent.[4]

Various cell phone companies have created and embedded pulse oximetry apps in smart phones that enable individuals to monitor their oxygen saturation and vital signs. Samsung, Apple, and various other companies have designed cellular devices that are capable of providing health-related apps. Other developers have created apps that are compatible with Android and iOS technologies. Some companies, including Lionsgate Technologies and Masimo, have developed external pulse oximeters that are compatible with smartphones. While these features seem promising for use of home monitoring of blood oxygen saturation levels, the accuracy of many of these features and devices have not yet been established.

Smartphone pulse oximeters and other mobile health (mHealth) apps are examples of new and evolving technology, which if developed accurately and used correctly, may make a difference in the lives of many individuals. A study conducted by Petersen et al suggests that if pulse oximeters could be available on mobile phones many global infectious diseases, such as pneumonia in children, could be treated faster and mortality rate would thus decrease due to prompt detection of changes in vital signs alongside quicker treatments.[5, 6] Studies from both Canada and Uganda regarding the Phone Oximeter prototype (a device interfacing pulse oximeters and smartphones) provide an overall usability scores of 82 percent and 78 percent respectively, indicative that a phone could be a functional oximeter interface.[7] A usability score of $> 75\%$ is considered appropriate as a functional interface. Additionally, a blinded randomized control trial in Australia, revealed that self-monitoring of oxygen saturation via a telehealth app Breathe-easy© reduced exacerbations of asthma in pregnant women.[8] Since the severity of asthma increases during pregnancy commonly, Zairaina et al studied monitoring in pregnant women and found that it improved quality of life, although it did not impact lung function.[8]

Alexander et al compared four different smartphone application-based monitors: Instant Blood Pressure, Instant Blood Pressure Pro, Pulse Oximeter, and Pulse Oximeter Pro. Three different parameters were measured using these four devices: heart rate, blood pressure, and SpO_2. The comparison revealed a large degree of variance in the values between the Instant Blood Pressure, the Instant Blood Pressure Pro, the Pulse Oximeter, and the Pulse Oximeter Pro.[9] Another study by Petersen and Dumont was conducted that compared the response of motion artifact of three different mobile pulse oximeter devices, all interfaced to Apple iPod Touch devices: the Nonin Xpod, the Masimo OEM inline module, and an Audio Phone Oximeter prototype. The study showed that there was more motion artifact at lower saturations for all three of the devices. The most valid measurements was found with Masimo's mobile device at readable values of approximately 85 to 87 percent.[10]

While the technology to detect SpO_2 and heartrates on smartphones is emerging and widely available, there is no evidence supporting its use in patients with lung disease. Smartphone pulse oximetry could be useful in individuals with acute or chronic lung disease; however, device inaccuracies could be harmful if desaturations are not detected immediately. It is not known how accurately these devices detect oxygen saturation/desaturation in patients with acute or chronic lung conditions. This study will be used to evaluate the accuracy of smartphone pulse oximeters in patients that will be undergoing a six-minute walk test in a pulmonary function lab.

Experimental Design and Methods

This is a prospective, observational study conducted at the pulmonary function laboratory at Rush University Medical Center. Subjects (n=48) will be selected if they are of 18 years of age or older, ambulatory, scheduled for a six-minute walk test, and agree to participate. The following information will be collected:

- First name
- Last name
- Date of Birth
- Age
- Height
- Gender
- Race/Ethnicity
- Oxygen use and frequency (if they are already on oxygen)
- Pulmonary Disorders
- Borg's Dyspnea Scale
- Heart rate (hospital-grade pulse oximeter and external and built-in smartphone pulse oximeter; pre- and post- test)
- SpO_2 (hospital-grade pulse oximeter and external and built-in smartphone pulse oximeter; pre- and post- test)

Procedures

For every patient that meets inclusion criteria, demographic information such as: age, race, and gender will be collected. Weight will be measured in the pulmonary function clinic by the designated respiratory therapist. Heart rate and SpO_2 measurements will be taken per normal routine during the six-minute walk test (before and after the test). Parameters will be measured

using an iPhone attached external pulse oximeter (Kenek Edge, LionsGate Technologies, Vancouver, Canada), a Samsung S8 (Samsung Electronics Co. Inc., Seoul, South Korea) built-in pulse oximeter, and a Masimo© (Masimo Corporation, Irvine, California) hospital-grade pulse oximeter. Readings will be obtained before and after the test. All three devices will be used to obtain readings from a single arm, consecutively. Each reading will be recorded manually by persons involved in the research. Each reading will be recorded using RedCap software and later transferred to SPSS software for data analysis. All data placed on the RedCap software and SPSS will only be accessible by the primary investigators.

Subject Population

Inclusion criteria

Ambulatory patients, 18 years and older, visiting the pulmonary function laboratory at Rush University Medical Center for a 6-minute walk test (n = 30) that agree to participate.

Exclusion criteria

Patients who are under the age of 18 years or patients with high blood pressure above 180/90 mm Hg or pressure below 70/50 mm Hg will be excluded. Patients who are dizzy, light-headed or have severe headaches, if SpO_2 at or below 85% on supplemental oxygen or if patients are on oxygen greater than 4 liters per minute will be excluded. Gait issues that may result in a fall or patient walks with a walker and did not bring the device to this visit will be excluded.

Consent and Recruitment Procedure

Recruitment will be based on inclusion and exclusion criterion. Study subjects will be recruited through convenience sampling of patients attending the pulmonary function lab for a 6-minute walk test at Rush University Medical Center. Verbal consent will be obtained during the time of subject interaction. Waiver of written consent will be requested since no invasive procedures are involved or procedures that would potentially be harmful to the participants.

Compensation

There is no compensation provided in this study. The participant is not required any other follow up after obtaining this initial data.

Special Precautions

There are no special precautions needed in this study. Standard disinfection policies apply. Personal protective equipment and standard protocol should be followed at all times. Patient safety and privacy will be addressed at all times.

Confidentiality

Persons who are primary investigators and secondary investigators, along with the IRB, will have access to patient records. To protect patient privacy and confidentiality, each patient will be assigned a subject identification number. Names will not be included in the data analysis. The investigators will strictly adhere to HIPAA and IRB guidelines to ensure that patient confidentiality is maintained.

Plans for Data Analysis

Data for each subject will be recorded in RedCap which will only be accessed by study investigators. Means and standard deviation will be calculated for age, gender, race, heart rate,

and pulse oximeter reading from hospital-grade and smartphone pulse oximeters. A t-test will be used to determine any significant association between age, gender, diagnosis, weight, and oxygen use ($p < .05$). Alpha will be used as 0.05 and beta will be used as 0.20. It can be predicted that these tests will be parametric. A scatter plot will be used to assess bias and validity.

Independent variables: Type of pulse oximeter

Dependent variables: SpO_2 and heart rate
Co-variables: body mass index, admitting diagnosis, age, site of measurement, oxygenation status, skin pigmentation, nail color, and pulmonary disorders.

References

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Appendix

Subject ID _____

Gender □Male □Female □Transgendered

Ethnicity □White/Caucasian
□Hispanic/Latino
□Black/African American
□Asian
□Other (specify) _____

Age _____

Weight (lbs) _____

Diagnosis □Asthma
□Congestive obstructive pulmonary disorder (COPD)
□Cystic Fibrosis
□Pulmonary Fibrosis
□Chronic Bronchitis
□Bronchiectasis
□Congestive Heart Failure
□Stroke
□Heart Attack/Failure
□Pulmonary Hypertension
□Cancer
□Renal Disease
□Other (specify)

Oxygen use? □Yes □No

If yes, indicate the amount of oxygen used

o < 2L/min flow o 2-6 L/min flow o 6-10 L/min flow o As needed o Only after physical activity

	Pre-test Vital Signs			Post-test Vital Signs		
	Masimo	Kenek/Apple	Samsung	Masimo	Kenek/Apple	Samsung
Heart Rate						
SpO_2						
Blood Pressure						
RR						
Borg Dyspnea Scale						