Clinical Interpretation of Peripheral Pulse Oximeters Labeled "Not for Medical Use"

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ABSTRACT

The purpose of our study was to clarify limitations of off-label use for low cost nonmedical use (NMU) pulse oximeters by primary care providers. These devices are widely marketed over the Internet and in drugstores but are not intended for medical use or reviewed by the Food and Drug Administration (FDA). Our study compared oxygen saturation (SpO_2) in patients from 1 medical use (MU) pulse oximeter to 8 NMU pulse oximeters. Measured arterial oxygenation (SaO_2) was compared with SpO_2 when available. In patients who were normoxic (SpO_2 ≥90%), all oximeters exhibited similar readings. This finding suggests that NMU pulse oximeters may be able to rule out hypoxemia in clinical settings.

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INTRODUCTION

Peripheral pulse oximeters are one of the most widely used medical monitoring technologies. Although the Food and Drug Administration (FDA) considers all pulse oximeters to be prescription medical devices, most sold in drugstores or on the Internet are specifically labeled "not for medical use" and were not reviewed by FDA for accuracy.[1,2] Their package inserts indicate the intended use is for "sports and aviation"[3] or "wellness."[4] In contrast, "medical use" (MU) pulse oximeters are only labeled as such after rigorous testing on human volunteers and review by FDA.[1] Laboratory-based research has found nonmedical use (NMU) pulse oximeters to be inaccurate when oxygen saturation is low.[5] Unfortunately, most consumers, even physicians, do not read the package insert and assume all pulse oximeters are intended for medical use and have been reviewed for accuracy.

METHODS

We conducted a cross-sectional, concurrent-controlled observational study with 60 consenting adult patients (aged 18-85 years) scheduled for elective cardiothoracic or neurosurgery who required continuous postoperative pulse oximetry and intermittent arterial blood gas monitoring. Our study designated 1 MU pulse oximeter (Nellcor MAXA, Medtronic PLC) as the reference standard and compared it with 8 different brands of NMU pulse oximeters purchased from retail stores to typify consumer use (Supplemental Table 1 available at http://www.annfammed.org/content/16/6/552/suppl/DC1). As skin pigmentation is known to affect readings, subjects were stratified by Fitzpatrick score[6] before randomization. Each enrolled study subject was randomized for concurrent placement of 1 MU pulse oximeter and 2 NMU pulse oximeters. To ensure the measurements were obtained simultaneously, only 3 pulse oximeters were placed on a patient at one time. The pulse oximeters were applied to adjacent fingertips of the hand contralateral to the location of arterial line for each patient. Multiple measurements were obtained on patients and all were obtained while patients' vital signs and clinical status were stable, as is directed for volunteer hypoxia

studies.[1] Only the MU pulse oximeter measurement was interpreted for clinical care decisions. Laboratory measurement of arterial oxygen saturation (ABL90 FLEX analyzer, Radiometer America Inc) was performed only when clinically indicated and was compared with the 3 pulse oximetry readings when available.

Our primary outcome measure was the statistical predictive value of spot oxygen saturation (SpO_2) from NMU pulse oximeters. We defined *true hypoxemia* as <90% oxygen saturation measured as either SpO_2 from the MU pulse oximeter or arterial oxygenation (SaO_2) from the laboratory.[7,8]

The secondary outcome measure was the calculated average differences between SpO_2 on a NMU pulse oximeter and the MU pulse oximeter (or SaO_2 when available) using a modified Bland Altman analysis over the entire range of SpO_2 encountered in our study. Our goal was not to evaluate accuracy of each brand of oximeter, but rather to determine if NMU pulse oximeters could safely rule out hypoxemia when they displayed an SpO_2 ≥90%.

Institutional Review Boards from Walter Reed National Military Medical Center and the Uniformed Services University of the Health Sciences, Bethesda, Maryland, approved this study. Written informed consent was obtained for each patient. Study registration was not required as no study intervention was performed.

Table 1. Predictive Value of NMU-PO

	MU-PO				
NMU-PO	Hypoxemia Present, n (Classification)	Hypoxemia Absent, n (Classification)	Totals	Predictive Vaue, %	95% CI, %
SpO_2 <90%	12 (true positive)	24 (false positive)	36	33[a]	24-44
SpO_2 ≥90%	3 (false negative)	630 (true negative)	633	99[b]	98-100
Totals	15	654	699		

Note: Hypoxemia present is defined as SpO_2 <90% and hypoxemia absent is defined as SpO_2 ≥90%.

MU-PO = medical use pulse oximeters; NMU-PO = nonmedical use pulse oximeters; SpO_2 = oxygen saturation.

[a] Positive predictive value.

[b] Negative predictive value.

RESULTS

A total of 60 adults (19 women and 41 men) were studied and 669 data points (69 to 104 per pulse oximeter model) were obtained.

The positive predictive value of the NMU pulse oximeter was 33% (12/36), indicating a low probability of correctly detecting hypoxemia compared with our reference standard MU pulse oximeter. In contrast, the negative predictive value of NMU pulse oximeter was 99% (630/633) (Table 1).

The secondary analysis of the average differences between SpO_2 on a NMU pulse oximeter and the MU pulse oximeter (or SaO_2 when available) over the range of SpO_2 from 90% to 99% revealed no clinically significant difference (Supplemental Figure 1 available at http://www.annfammed.org/content/16/6/552/suppl/DC1). Differences of >5% between spot measurements of SpO_2 and laboratory measurements of SaO_2 occurred with both the MU pulse oximeter and NMU pulse oximeters, but here were too few instances to evaluate statistically.

DISCUSSION

Our clinical study revealed no meaningful differences in the displayed oxygen saturations between the MU pulse oximeter and the NMU pulse oximeters in the range from 90% to 99%, and this is consistent with laboratory findings from a prior study.[5] Thus, when confirming normoxia or ruling out hypoxemia, spot measurement of SpO_2 by NMU pulse oximeters appeared satisfactory among patients in a population where hypoxemia was unlikely. Because pulse oximeter measurements of oxygen saturation are less accurate for measurements below 90%, patient management decisions regarding oxygenation should be verified using a device intended for medical use whenever possible.[5,9,10]

Since small quantitative differences in SpO_2 may not be clinically meaningful when oxygen saturation is nearly complete, NMU pulse oximeters may be helpful for family physicians and their patients to use when ruling out hypoxemia despite being labeled as not for medical use and sold without prescription. Moreover, the widespread availability of NMU pulse oximeters and their relatively low cost compared with MU pulse oximeter devices serves to improve access to rapid assessment of systemic oxygenation in many patients when it would otherwise be impractical.

Study Limitations

Our goal was to study device performance in a clinical environment, and therefore, few of our carefully managed patients were hypoxemic. It would be informative to conduct additional studies in cases when desaturation of hemoglobin is especially precipitous (SpO_2 85% to 90%). Furthermore, by pooling the NMU pulse oximeter data we did not distinguish between brands or models. Our study included more men than women,

reflecting military patient demographics. As our protocol was modeled on FDA guidance[1] for the study of pulse oximeters, multiple measurements were taken for each study subject. Within-subject correlation of oxygen measurements could not be excluded.

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Supplementary materials: Available at http://www.AnnFamMed.org/ content/16/6/552/suppl/DC1/.

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