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A Comparison of Wireless Pulse Oximetry Technologies during Sustained Shivering in Post-Operative Patients

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Abstract

Background: Pulse oximetry measures oxygen saturation in arterial blood non-invasively and is routinely practiced in many clinical settings. Technological advancements have expanded the performance capabilities of these devices to operate wirelessly, making pulse oximetry measures more convenient to obtain. Factors such as patient motion however can potentially complicate the ability to retrieve these measures. We examined the performance of two wireless pulse oximeters in patients who shiver postoperatively.

Methods: Two additional pulse oximeter sensors (Masimo and Nonin) were added to 30 patients who shivered post-operatively and met eligibility criteria. Dropout rates were calculated by dividing the number of times that each instrument displayed no SpO_2 or pulse rate value by the total time both sensors were in camera view for that subject. We used Wilcoxon matched pairs tests to compare the average time until the first reading displayed on the sensor for each device as well as dropout times. Dropout events were also compared using McNemar's test.

Results: Drops in signal occurred in thirteen subjects. The Masimo sensor had more dropouts and a longer average drop duration, which was found to be statistically significant (p=0.02). Masimo's sensor required more s on average than Nonin's (8.86>8.78) to display the first reading, but this was not found to be statistically significant (p=0.90). Masimo also had a higher percentage of drops however this was not statistically significant (p=0.07).

Conclusion: Overall incidence of shivering was low among patients in this setting (0.1%). More than 1/3 of subjects experienced drops during identical time intervals indicating that motion artifact may impact results regardless of technology. Additionally, Masimo's sensor is not meant for clinical use thereby raising questions regarding our statistically significant result in this particular setting. Combined with results from part I of this study, we cannot confidently detect a statistically significant difference between manufacturers.

Keywords: Pulse oximetry; Post-operative shivering; Oxygen saturation; General anesthesia; Pulse oximeter measures; post-operative care

Introduction

Pulse oximetry is a noninvasive method of measuring oxygen saturation (SpO_2) and is commonly accepted as "a fifth vital sign" (in conjunction with blood pressure, temperature, pulse and respiratory rate). This technology is utilized in a variety of clinical settings ranging from primary care to critical care and is largely relied upon to prevent certain dangerous conditions in patients, such as hypoxia [1]. Advancements in medical technology have made pulse oximeters affordable, easy to use and readily available to the general public [2]. For example, outside of healthcare facilities, athletes are using pulse oximeters during strenuous workouts and mountain climbers are able to check for early signs of high altitude sickness by being able to conveniently measure oxygen saturation [3].

This study compared the monitoring capabilities of 2 commercially available, wireless pulse oximeters from different manufacturers in patients who experience shivering as a side effect of anesthesia post-operatively. We tested the Masimo MightySat Fingertip Pulse Oximeter and the Nonin Onyx Vantage 9590 Finger Pulse Oximeter. The Masimo MightySat is intended for use by sports and aviation users who are interested in monitoring their oxygen saturation level, pulse rate and perfusion index. This device features Signal Extraction Technology[®] developed by Masimo to provide accurate measurements during low perfusion and motion. This technology uses adaptive filters to identify and block noise signals from the true arterial saturation value [4].

The Nonin Onyx is specifically designed for spot-checking measurements and is intended for use in addition to other clinical methods of monitoring and assessment [5]. The device uses a tricolor Light-Emitting Diode (LED) to visually report the quality of the pulse signal and blinks at the corresponding pulse rate. Nonin's PureSAT technology uses pulse-by-pulse filtering to obtain oxygen saturation measurements instead of reporting the average measure of numerous pulses [6].

Part I of this study examined the monitoring capabilities of two commercially available wired pulse oximeters in patients who experienced post-operative shivering [7]. Post-operative shivering can occur in anywhere from 5-65% of patients and can make vital sign monitoring difficult for clinicians [8]. The primary outcome of this study was to determine if there is a difference in the abilities of two different wireless pulse oximeters to obtain readings in SpO_2 and pulse rate data during sustained shivering episodes in post-operative patients.

Methods

This is the second part of a two-phased, comparative, single-center, non-randomized observational study that took place at an outpatient surgery center. It was conducted under local institutional review board monitoring from October 2016-January 2017. Patients undergoing non-cardiac, outpatient surgery with general or spinal anesthesia and presented with sustained shivering post-operatively were enrolled. Sustained shivering was defined as spontaneous muscle activity or shivering-like tremors in normothermic patients immediately upon arrival to the post anesthesia care unit (PACU) [9]. For this study, the shivering episode (s) had to occur either intermittently or consistently for at least 90 s or longer to ensure adequate timing for test sensor placement. Patients were 18 years of age or older and were both willing and able to comply with study procedures. Exclusion criteria were less than 18 years of age; had another condition, which in the opinion of the investigator would not be suitable for participation in the study; is unwilling or unable to provide written informed consent to participate in the study or is unwilling or unable to comply with the study procedures.

An a priori power analysis was performed to determine sample size. With an alpha=0.05, power=0.95 and effect size=0.75, a sample population of N=26 was adequate for this simple comparison between manufacturers [10]. Given the rarity and spontaneity of shivering occurrences, especially in the setting where this study was conducted, and accounting for possible missed shivering cases, a sample size of 30 subjects was reasonable for the main objective of this study.

Thirty healthy patients who experienced sustained shivering episodes post-operatively were enrolled and consented for participation for this study. Each subject had two additional pulse oximeter sensors placed on additional fingers. The sensors were placed on fingers that were readily available to the researcher and did not impede standard post-operative care for the patient. A small video camera was positioned above the subjects' hands so that both sensors were in view. The researcher documented shivering episodes by recording the start and stop times for each one. The additional sensors were removed, and video recording ended when the shivering subsided. The video recordings were reviewed to identify drops in signal as well as any other type of irregularity in sensor function.

Due to varying degrees of patient motion, there were times during the recordings that one or both sensors were moved out of camera view. Any amount of time where one or both sensors were not in view was subtracted from the total test time for that subject, resulting in the total adjusted time. Total adjusted time was calculated for each device in every subject. We calculated the dropout rate of each device by dividing the number of times that each instrument displayed no SpO_2 or pulse rate value by the total adjusted time of the test. Wilcoxon matched pairs tests were performed to compare the average time until the first reading for each device as well as dropout times. Occurrences of dropout events for each device were compared using McNemar's test.

Results

Thirty patients underwent the aforementioned protocol. Data from 29 of these subjects was used for analysis. Data from 1 subject was excluded due to a malfunction in the video recording software that occurred during the subject's monitoring period. The study population consisted of 16 males and 13 females between the ages of 18 and 67.

Additional demographic characteristics of our sample population are reported in Table 1.

Age	Mean	min, max
	41.1	18, 67
Sex	**n**	**%**
Male	16	53.3
Female	14	46.7
Ethnicity	**n**	**%**
Not Hispanic or Latino	29	96.7
Hispanic or Latino	1	3.3
Race	n	%
Black or African American	3	10
White	26	87.7
Unknown	1	3.3
Monitoring time (min)	mean	SD*
Nonin	5.51	1.84
Masimo	5.48	1.86
*Standard Deviation		

Table 1: Characteristics of sample Population.

The study sample consisted of patients who underwent an orthopedic surgical procedure. The average surgery duration was 48.9 min with the shortest and longest surgeries lasting 13 and 93 min, respectively. Specific surgical interventions and types of anesthesia used for our sample can be found in Table 2.

	Number of subjects
Anesthesia	
General	5
General with local	11
General with nerve block	13
Upper extremity	
Carpal and/or cubital tunnel release	2
Elbow/wrist/finger ORIF	4
Artroscopic shoulder repair	2
Other	3
Lower extremity	
Artroscopic ACL repair/revision	5
Artroscopic (partial) lateral/medial	5
menisectomy/ies	
Ankle ORIF	2

Artroscopic knee/ankle debridement	2
other	4
Note: ORIF refers to open reduction internal fixation	

Table2: Anesthesia and surgery details of study sample.

The rate of shivering among subjects enrolled for this study was calculated by dividing the total amount of time that shivering occurred

by the total adjusted time. The data indicate that shivering episodes accounted for 25.65% of the overall testing time. During the testing period, signal drops occurred in 13 subjects total. The Masimo sensor had more drops in signal as well as longer dropout times than Nonin, however this difference was not found to be statistically significant (Table 3).

	Masimo		Nonin		
Meaaured values	**Number ot dropouts**	**Mean dropout time (SD)**	**Number ot dropouts**	**Mean dropout time (SD)**	**p-value**
Overall	34	12.17 (18.14)	13	5.45 (12.81)	0.152
Spo$_2$	17	12.17 (18.14)	6	5.03 (12.79)	
HR	17	12.17 (18.14)	7	0.24 (0.51)	
Note: Mean dropout time is displayed in s; SD=standard deviation					

Table 3: Comparison of dropout times in masimo and Nonin sensors.

While 17.24% of subjects experienced dropouts in both Nonin and Masimo sensors, the percentage of subjects who only experienced drops in the Masimo sensor was higher than the percentage of subjects who only experienced drops in the Nonin sensor. Again, the difference

in these percentages was not found to be statistically significant. Table 4 shows signal drops as they occurred between manufacturers and among test subjects.

	Masimo (exclusively)	Nonin (exclusively)	Both	p-value
Number of subjects who experienced dropout(s)	7	1	5	0.07
% of dropout subjects	53.85	7.69	38.46	
% of sample population	17.95	3.45	17.24	

Table 4: Dropout events as they occurred within study sample.

Masimo had more drops on average than Nonin within this study sample resulting in a higher dropout rate of 0.22 compared to Nonin's of 0.08. We found this to be statistically significant with a p-value of 0.02. For 23 subjects, we were able to note the time between placing the Nonin sensor on the subject's finger and the first displayed reading. This was recorded for 22 subjects with the Masimo sensor and for 23 subjects with the Nonin sensor. The average times were 8.86 and 8.78 s for Masimo and Nonin, respectively, but were not found to be statistically significant.

Discussion

Post-operative shivering is not a common occurrence and was only observed in approximately 0.1% of all patients being treated at this location. Shivering only accounted for 25.6% of the total adjusted time that subjects were recorded. Masimo's sensor had a higher dropout rate within this study sample that was found to be statistically significant. While the other results were not found to be statistically significant, they do provide information about the overall performance of each sensor.

More than one-third of subjects who experienced drops in signal experienced drops in both sensors at the exact same time intervals. For

these subjects, neither technology outperformed the other and monitoring capabilities might have been limited by another factor such as motion artifact.

Dropout rates in this study are consistent with the failure rates of the lowest performing devices reported in a study by Shah. Neither study utilized a control device however their protocol designated a control and test hand for each subject [11]. This study is unique in that patient motion (shivering) was not generated by an outside force. Other studies have relied on the subject to perform specific motions and movements to simulate patient restlessness instead of observing it as it may occur [12].

This study is not without limitations. While this analysis is an acceptable general comparison, it cannot be generalized to the manufacturers because the intended use for each model is not the same. The Masimo MightySat is not intended for medical use therefore its performance in this setting is not representative of its performance overall [13]. While Masimo had more drops than Nonin, which was found to be statistically significant, this result is not an accurate reflection of performance. Lack of a control device also hindered comparison capabilities in that each sensor's performance was assessed based on that of the other.

Another limitation to this study was sample size. Data was only included for analysis if shivering was observed for at least 90 s. If the subject continued to shiver, the sensors were attached, and the video camera was arranged to ideally get and keep both sensors in view. If the subject stopped shivering during the time required to adjust and maneuver the camera and/or sensors so that readings for both sensors were in view, they were no longer included in the study. Given the varying lengths of shivering episodes as well as the low rate of occurrence within this sample, a large sample size was not realistically attainable.

Combined with part I of this study, it is the first to examine pulse oximetry during sustained shivering events. Post-operative shivering did present challenges in obtaining consistent readings for both manufacturers. While both sensors experienced drops in signals, Nonin had fewer and shorter dropouts in parts I and II of this study

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