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SpO_2 and Pulse Rate Data: A Comparison of Current Technologies during Sustained Shivering in Post-Operative Patients

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Abstract

Pulse oximetry is a noninvasive method of measuring the oxygen saturation (SpO_2) of the arterial blood and is considered standard-of-care in post-operative settings. Patient motion or low perfusion can present challenges in obtaining accurate readings. Postoperative shivering occurs in anywhere from 5-65% of patients who have received general anesthesia and can manifest as continuous tremors and/or sporadic muscle movements.

Objective: Compare the effect of post-operative shivering on functioning capabilities of two commercially available pulse oximeters.

Methods: Two additional pulse oximeter sensors (Nonin 7500 Pulse Oximeter with 8000AA Sensor and Masimo Rad-8 with Rainbow DCI SC-200 Adult Reusable Sensor) were added to 40 shivering patients who met eligibility criteria. Shivering episodes were documented by recording the start and stop times for each episode as it occurred. Dropout rates for each device were calculated by dividing the amount of time that each instrument displayed no SpO_2 or pulse rate value by the total time of the test. A 2-sample T-test was performed to compare dropout times of the devices and dropout rates were compared using a z-test for 2 proportions.

Results: Drops in signal occurred in fourteen subjects. The Masimo sensor dropped 21 times, for an average of 40 seconds per drop and Nonin's dropped 16 times averaging 29 seconds per drop. Nonin's dropout rate of 0.108 was less than that of Masimo's at 0.149, however this difference was not found to be statistically significant (p=0.87).

Conclusion: The incidence of shivering was very low among patients in this particular study setting (0.1%) For 5 different subjects, both sensors experienced drops during identical time intervals indicating that motion artifact may impact readings regardless of specific technology. Clinically significant shivering varied in duration among subjects therefore individual shiver rates varied as well. This preliminary analysis shows no significant difference between Nonin and Masimo sensors.

Keywords: Pulse oximetry; Shivering; Post-operative care

Introduction

Pulse oximetry is a noninvasive method of measuring the oxygen saturation (SpO_2) of the arterial blood. These devices are vital and commonplace in any healthcare setting where a patient's blood oxygenation monitoring is required. Surgical procedures performed under general anesthesia rely on pulse oximetry to provide accurate readings before, during and after a patient receives anesthesia in order to ensure adequate oxygenation throughout the operation and recovery period.

The pulse oximeter device consists of a sensor, which detects the oxygen saturation and pulse rate of the patient and a monitor that displays these measurements. The sensor is designed for use on a fingertip, toe or ear lobe. Through a series of LEDs and photo-detectors, beams of light are transmitted through the tissues from one side of the probe to the other. The monitor processes and displays a value for oxygen saturation based on how much light is absorbed by the blood and tissues. The technology uses multiple wavelengths within the visible light spectrum in order to determine the percent of oxygenated hemoglobin and deoxygenated hemoglobin through the differential absorption properties of deoxy and oxy-hemoglobin using the Beer-Lambert Law [1].

Certain post-operative conditions such as patient motion, low perfusion and arrhythmias can present challenges in obtaining pulse oximetry measures [2]. In order to ensure accurate measurements, pulse oximeters must be able to function without interruption despite any potential interference. Disruptions in proper function resulting in inaccurate SpO_2 measures could potentially result in dangerously low levels that may not be immediately detected.

This study aimed to examine the ability of two commercially available pulse oximeters to obtain readings during a potentially challenging clinical scenario. The rate of post-operative shivering has been reported to occur in anywhere from 5-65% of patients after general anesthesia [3]. The primary outcome of the study is to determine if there is a difference in the ability to obtain readings in SpO_2 and pulse rate data measured by two different models of wired pulse oximeters during sustained shivering episodes in post-operative patients.

Methods

This is the first 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 May 2016-October 2016. 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) [4]. For this study, the shivering episode(s) had to occur either intermittently or consistently for at least 90 seconds 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=0.99 and effect size=1.28, a sample population of N=40 [5] was adequate for this simple comparison between manufacturers. Given the rarity and spontaneity of shivering occurrences, especially in the particular setting where this study was conducted, and accounting for possible missed shivering cases, a sample size of 40 shiver subjects was reasonable for the main objective of this study.

Forty 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. The two additional sensors were Nonin 7500 Pulse Oximeter with 8000AA Sensor (Minneapolis, MN, USA) and Masimo Rad-8 with Rainbow DCI SC-200 Adult Reusable Sensor (Irvine, CA, USA). After the sensors had been placed and turned on, shivering episodes were documented by recording the start and stop times of each episode as they occurred. The two additional sensors were removed when the shivering subsided. We calculated the dropout rate of each device by dividing the amount of time that each instrument displayed no SpO_2 or pulse rate value by the total time of the test. Since shiver documentation did not begin until both sensors were secured to the patient, the total test time for each sensor is the same. A 2-sample T-test was performed to compare the dropout times of the two devices and dropout rates were compared using a z-test for two proportions.

Results

Forty patients underwent the aforementioned protocol. Data from 36 of these subjects was used for analysis. Data was excluded from four subjects due to spontaneous, temporary lapses of function in the computer software used to mark each shivering episode. The study population consisted of 18 males and 18 females between the ages of 20 and 76. Additional demographic characteristics are reported in Table 1. 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 amount of time subjects had the additional two sensors in place. The data indicate that shivering episodes accounted for 69.09% of the total time subjects were monitored.

Parameters			
Age		**Mean**	**Min, Max**
		42.5	20, 76
Sex		**n**	**%**
	Male	18	50
	Female	18	50
Race		**n**	**%**
	Black or Afrian	3	8.33
	American		
	White	33	91.67
Monitoring time		**mean**	**SD***
Minutes		4.47	3.37
*Standard Deviation			

Table 1: Characteristics of sample population.

During the testing period, signal drops occurred in 14 subject's total. The Masimo sensor had more drops in signal than the Nonin sensor, but this difference was not found to be statistically significant. While 35.7% 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. Tables 2 and 3 show signal drops as they occurred between manufacturers and among test subjects, respectively.

Anesthesia/Surgical Detials		Number of Subjects
Anesthesia		
	General	17
	General with nerve block	11
	General with local anesthetic	8
Upper extremity surgeries		
	Carpal/cubital tunnel release	4
	Wrist arthroscopy with debridement	3
	Other hand/wrist operations	3
Lower extremity surgeries		
	Should arthroscopy with debridement +additional repair	5
	Knee arthroscopy with debridement+ACL/MCL/etc. repair	12
	Other leg/Knee operations	2
	Ankle/foot/toe operations	7

Table 2: Anesthesia and operation details of sample population.

Measured values	Masimo		Nonin			
	No. of dropouts	Mean dropout time (SD)	No. of dropouts	Mean dropout time (SD)	t	P-value*
Overall	62	1.72 (4.62)	54	1.5 (4.55)	0.529	0.598
SpO2	30	0.84 (2.31)	27	0.75 (2.27)		
HR	32	0.89 (2.31)	27	0.75 (2.27)		
Note: Mean dropout time is displayed in minutes. *95% confidence interval for P-value						

Table 3: Comparison of dropout events in masimo and nonin sensors.

The dropout rate of each oximeter was calculated by dividing the total test time by the total dropout time. While the dropout rate was higher in Masimo than Nonin, the result was not statistically significant. Table 4 compares the overall dropout rate of each manufacturer as well as individual drops in SpO_2 and heart rate.

Measured values	Masimo	Nonin		
	dropout rate	dropout rate	z	P-value*
Total	0.385	0.335	1.96	0.67
SpO_2	0.186	0.168		
HR	0.199	0.168		
*95% confidence interval for P-value				

Table 4: Comparison of dropout rates.

The digit of sensor placement was noted for each manufacturer in every subject and dropout occurrences were recorded. The Nonin sensor had the least amount of dropouts in the middle and ring fingers while Masimo had the fewest when placed on the index finger. Table 4 shows the percentage of drops for each digit, however the differences between the Masimo and Nonin sensor were not found to be significant for any digit.

The Masimo sensor experienced the largest number of signal drops when placed on a subject's middle finger. Masimo had a greater dropout rate for every finger except for the index finger, where Nonin's dropout rate of 0.27 was just slightly greater than Masimo's of 0.25. The little finger proved to be the least reliable for maintaining signal in either sensor dropping 100% of the time in Masimo and 75% for Nonin. It is important to note however that the Masimo sensor was only placed on 1 subject's little finger compared to the Nonin sensor which was placed on 4 subjects' little fingers.

Discussion

Post-operative shivering is a fairly rare occurrence and was only observed in approximately 1% of patients throughout the duration of this study. Shivering accounted for 69% of the total time that enrolled subjects were recorded. While this study did not yield any statistically significant results, the data does provide some useful information about both sensors. Overall, more drops occurred in the Masimo sensor than in the Nonin sensor. This was also found to be true when comparing the number of subjects who experienced dropouts between the two sensors. It is important to point out that for 5 different subjects, both sensors experienced drops at the exact same time intervals. In these cases, the ability of pulse oximetry to obtain readings regardless of specific technologies may be limited due to motion artifact.

In 4 subjects, drops in Nonin's sensor occurred when the sensor was placed on the subject's small finger. This represented 37.5% of all drops for the Nonin device. While this was only the case for 1 subject with respect to the Masimo sensor (9.5% of all losses), 80% of all readings taken from a subject's small finger were lost. Overall the small finger accounted for 19.5% of all signal losses. In the difficult patients where shivering or other factors may make obtaining readings a challenge, avoiding the small finger for monitoring may maximize overall functionality and consistency of reliable recordings.

There are some areas where limitations to this study were encountered. The sample size was 36 subjects, which may have limited the power of the study and its ability to detect a difference between technologies. Differences in fingers, difficulties in the small finger, were not known prior to the study and a standardized finger rotation or avoidance of the small finger was not utilized. Without a control device to individually compare the performance of each sensor, the two test sensors were compared with each other, which did not offer a significant indication of overall performance. Clinically significant shivering varied in length; therefore, some subjects had more time shivering compared to others.

This study is the first study to examine pulse oximetry in the setting of sustained shivering. This clinical setting proved to offer some challenges in the ability of two commercially available pulse oximetry devices. In the majority of time, the readings could be obtained. However fewer and shorter dropouts occurred in the Nonin 7500 sensor.

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