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Accuracy of Pulse Oximeter and Abg Analysis in Measurement of Oxygen Saturation in Covid 19 Patients in Recovery Ward and In Silent Hypoxia- An Observational Study.

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Abstract

Need: A specific and accurate thorough clinical monitoring is crucial for observing patients' recovery status and further planning of treatment/management measures in COVID 19 pandemic. Fluctuations in blood oxygen saturation are particularly important in COVID 19 patients to prevent and early detect the unforeseen situations. Silent hypoxia is one of the threatening situations in such patients. Therefore the exact calibearation and accuracy testing of the oxygen is crucial. **Method:**. Out of 22 patients in COVID 19 recovery ward, 7 were encountered with silent hypoxia in sample collection process. The 30 paired samples of 15 patients and 14 paired samples of 7 patients with silent hypoxia (in a pair one sample was of SpO2 by pulse oximeter and another was of SaO2 by ABG analyzer) were analyzed seperately for accuracy by Bland and Altman's equations of limits of agreement. The mean difference and standard deviations were documented and the inferences were drawn. **Results:** For 15 patients, 30 paired samples were drawn for SpO2 and SaO2 respectively. The results obtained were with the bias of 0.6 % with LOA of 5.2 % to 3.6 %.For the patients with silent hypoxia (n=7, samples 14), the LOA was similar with mere changes i.e. 5.1% to 3.5%. **Conclusion:** The SpO2 measurements by pulse oximeter can be used routinely for monitoring purpose and to check for

silent hypoxia of COVID 19 patients in recovery wards. But for accurate measurements of oxygen saturations in critical situations also in silent hypoxia, SaO2 by arterial blood analyzer still should be considered as better choice.
Key words: - COVID 19, silent hypoxia, oxygen saturation, accuracy, SpO2, SaO2, pulse oximeter, arterial blood gas analysis, analyzer.

Introduction

The whole world and human population is shadowed under the threat of COVID 19 pandemic. The disease is not only having impact on the health but also on the psychological, economic and social health, which is witnessed globally. COVID 19 has presented multiple subsets of difficulties and challenges regarding clinical management. A specific and accurate thorough clinical monitoring is crucial for observing patients' recovery status and further planning of treatment/management measures. Out of the common symptoms and parameters like sneezes, coughs, malaise and temperature, fluctuations in blood oxygen saturation are particularly important.[1]

In clinical practice, the two most common methods are utilized to measure the oxygen saturation. They are arterial blood gas analysis (ABG) and pulse oximetry. With ABG analysis, we can take out the specific arterial blood oxyhaemoglobin saturation. (SaO2). This method is one of the accurate [2] one but it is an invasive process which requires either puncturing the artery or pulling the blood from arterial line. For the same, is associated with procedure-associated complications such as, damage to the blood vessel, pain due to puncture, and bleed. Also the risk of contamination is there due to unhygienic handling. This method requires expert staff and specific instrument which increases the healthcare cost and burden.

The pulse oximeter assesses peripheral oxygen saturation (SpO2) which is the percentage of haremoglobin binding sites occupied on red blood cells by oxygen. The estimation of blood oxygen level through this method is non-invasive, fast, and easy. It enables the continuous monitoring and sudden fluctuations can also be measured and documented swiftly. The UK based national health services (NHS) have emphasized the use of pulse oximetry for blood oxygen saturation by measuring it through peripheral artery i.e. SpO2 rather than that of SaO2 by ABG analysis for the patients with COVID 19. [3]

In general in the hospital set up, the handheld or pocket oximeter is used. The device works on the basis of light transmission of the cutaneous tissue. The oxygen saturation is estimated by emission of two different wavelengths of light from a diode to the sensor on the opposite side of finger (which is sandwiched in between two prongs of the device) through the cutaneous vascular bed. The lights are absorbed depending on the oxygen sites bound to the hemoglobin and the no absorbing structures. The remaining light is transferred to the sensor where the internal algorithmic conversion is done to covert the absorbance pattern to SpO2. There are certain deviations such as pigmentation, perfusion, motion etc. [4] which may alter the results by pulse oximeter.

Many studies have reported the suboptimal accuracy of pulse oximeter in detecting the SpO2 levels in varying set ups like ICUs and healthy populations. [5] Though the contribution of pulse oximeter in measuring SpO2 does not reflect accurate SaO2 levels as of with ABG analysis, its simplicity in use and ease with quick measurement prevails its use in ICUs, wards settings.

In few studies caution and limitations have been potentially inferred pulse oximeter use in COVID 19 patients. [4, 6] Paradoxically in some studies of patients with COVID 19 having specific co morbidities like sickle cell disease resulting in thromboembolism [7,8]; it was found that pulse oximeter was specific enough to identify silent hypoxia due to the potential complications [9]. Studies have also analyzed the

incidence of silent hypoxia in the relatively stable patients of COVID 19 in wards irrespective of the complaints of dyspnea.

Silent hypoxia is a serious threatening situation in COVID 19 patients. It may occur in severe, mild as well as asymptomatic patients. The term 'silent' refers to the dropping of oxygen saturation with no apparent shortness of breath. The possible reasons for silent hypoxia are the air-blood mismatch which is one of the hypotheses proposed. [9, 10]

The study to find out the accuracy and sensitivity of pulse oximeter in detecting SpO2 in patients who are shifted to recovery wards is lacking. So, to find and connect the missing loop in the chain of assessment and monitoring of COVID 19 patients; the study is is proposed.

Method

The study aimed at appropriateness and sensitivity of SpO2 levels by pulse oximetry to that of SaO2 by ABG analysis in detecting the fluctuations of blood oxygen levels and silent hypoxia in the patients of COVID 19 in recovery ward.

For the study, we included the patients admitted to/ shifted to COVID recovery ward during September-October 2020 in Shalinitai meghe hospital and research center, Nagpur. 30 patients fitting in the study criterion were informed taken consent and explained about the study.

The patients stable vitally, may or may not have arterial line for drug administration , not requiring ventilator support , not in need of o2 support were included. In the due course 5 patients died and hence they were excluded from the study. Further 3 patients were again shifted to ICU due to severe dyspnea, so those were excluded from the study.

Two paired measurements of the SpO2 and SaO2 were taken on alternate day from the first day of extraction of samples for 3 consecutive days. The three samples were collected for minimizing variations from the patients. To prevent bias of time frame, the measurements of SpO2 and the sample of SaO2 were taken within the same time with mere difference of few seconds with no change in the patient position or drug line of treatment throughout the process.

The ABG analysis was done for SaO2 by BGA 101 blood gas analyzer which was routinely calibrated and maintained. The SaO2 was calculated by analyzer using the formula: SaO2 = (FO_2Hb/ FO_2Hb+ FHHb) where FO_2Hb is oxyhaemoglobin and FHHb is deoxygenated reduced hemoglobin. SpO2 was calculated as per routine clinical monitoring by using BPL smart oxy lite pulse oxymeter. The probe was placed on patients index finger and the display measurements noted as per on the screen. This device is being routinely used in adult patient care. The procedure was routinely observed by the staff nurse and the resident medical officer posted in ward to prevent any delay in collecting the sample and any technical error encountered during the procedure.

The samples of patients having co morbid status like diabetes mellitus, hypertension or certain metabolic disorders were not considered as those wouldn't have interfered with the collection and result process. Further the patients (n=7) who abruptly landed up in transient /sudden hypoxia and stabilized conservatively with drug management later on were also included to assess the sensitivity of SpO2 and SaO2 levels in such patients. These patients data was excluded from the previous group and analyzed differently. The sensitivity was assessed by the Bland and Altman equation of limits of agreement. [11] The inferences were drawn by comparing SpO2 and SaO2 levels from pulse oximeter and

ABG analysis respectively. The mean difference (M.D.) and standard deviation (S.D.) were drawn and sensitivity was calculated.

Formula: limits of agreement (LOA) =(M.D.$^{+}_{-}$ 1.96 x S.D.)

Results:

For 15 patients admitted in the COVID 19 recovery ward, 30 paired samples were drawn for SpO2 and SaO2 respectively. The results obtained with the Bland Altman's limits of agreement equation. For which the mean difference drawn was of 0.6 % with standard deviation of 2.2 LOA obtained for this group is of 5.2 % to 3.6 % with 95% of confidence interval. The mean temperature of at the time of sample collection was 34.67^0 C with S.D. of 0.54. The mean pH of blood was 7.10 with S.D. of 0.02. The accuracy value of the measured data was 2.33%. THIS lays beyond the suggested manufacturer accuracy data. Still these values lie in the FDA approval level rate of <= 3.00% of UK which validates the results. [3] The level of agreement may vary from device to device, but the market readily available pulse oximeter are showing good correlation with SaO_2. [11]

Another comparison was done between the paired samples of patients with silent hypoxia encountered in the the patients with silent hypoxia (n=7, samples 14), the LOA was similar with mere changes i.e. 5.1% to 3.5%. With 95% CI this suggests again that in silent hypoxia the pulse oxymeter can be used as an initial indicator but one should not totally rely on it.

Discussion:-

The samples of patients admitted in COVID 19 ward on comparison revealed that they show similar sensitivity when calculated with pulse oximeter and ABG analyzer for oxygen saturation with LOA of 5.2 % to 3.6 %.Though the exact accuracy is not matched of SpO2 with that of SaO2 for previously mentioned considerable reasons. Similarly 14 paired samples were taken from patients encountered sudden and silent hypoxia with apparently non dyspneac symptoms, the LOA was similar with mere changes i.e. 5.1% to 3.5%.

Silent hypoxia is a serious threatening situation in COVID 19 patients. It may occur in severe, mild as well as asymptomatic patients. The term 'silent' refers to the dropping of oxygen saturation with no apparent shortness of breath.

The possible reasons for silent hypoxia are the air-blood mismatch which is one of the hypotheses proposed. The alveoli are collapsed as a consequence of infection in COVID 19, but the lungs normal ability to expel carbon dioxide is preserved. This creates the feedback to the respiratory centers to continue normal breathing and the situation does not prevail the system to land up in hypoxia. [12] Hence its detection is crucial in preventing the further deterioration. Hence quick and reliable measurements of oxygen saturations are needed in this condition. This study thus highlighted accuracy of pulse oximetry measures in silent hypoxia. [9, 10]

These inferences suggest that, saturated oxygen measurements by pulse oximeter are reliable in silent hypoxia when tested for sensitivity with that of ABG analysis.

Due to its easy, simple and quick measurement characteristics, pulse oximeter still remains a valuable tool to assess the SpO2 especially in emergency situations. The baseline deviations in the measures of SpO2 and SaO2 by oximeter and ABG analyzer respectively could be due to previously explained

technical and physiological factors. [4] Some additional factors could be the patient sensor interface, the algorhythms used to calculate the saturation of oxygen, the optical indices for calculation of saturation percent, precision, anaemia, sensors, vassopressors effect etc. [13] These factors may interfere with the accuracy of the pulse oximeter and the more creation of bias especially when the reading goes below 80%. Hence caution should be made to take repetitive measurements and one should not rely totally on one single value. In our study we tried to cover this by taking two samples of each device.

As the purpose of the study was to assess the sensitivity of SpO2 levels with SaO2; the gender, race, time of sample collection, temperature variations, effect of drug were not considered. For nullifying the time and temperature variations the samples were taken on different times of the day but in pairs. The extraction of samples was enabled on the same time for pairing due to effective support from nursing and laboratory technical staff.

In India, it is apparently observed that the FDA and Indian Certification for Medical Devices (ICMED) have established the drug, device safety and accuracy regulations. But the adherence to the same is a debatable point. In developing countries as we are, there is hardly any clearance needed to market devices like pulse oximeter. The real time clinical scenarios should be built or set up to check for the accuracy of such devices. [13]

The devices readily available in the Shalinitai meghe hospital and research center were taken for the study. Further the study could be carried out with the accuracy and sensitivity measurements of various market available devices. The sample size was relatively constrained; extensive studies should be carried out with larger samples.

Conclusion:

In the available clinical setting, it was evident that pulse oximeter stays a reliable and sensitive measure of monitoring SpO2 when tested for accuracy with that of arterial blood analysis.SpO2 fluctuations in silent hypoxia also can be similarly detected when tested for accuracy with that of SaO2. Finally, to conclude with, the SpO2 measurements by pulse oximeter can be used routinely for monitoring purpose and to check for silent hypoxia of COVID 19 patients in recovery wards. Repetitive documentation is needed by pulse oxymeter measures so as to prevent biases. But for accurate measurements of oxygen saturations in critical situations also in silent hypoxia, SaO2 by arterial blood analyzer still should be considered as better choice.

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