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ORIGINAL RESEARCH

The equivalence and reliability of point-of-care devices routinely used for haemoglobin measurement compared with the laboratory standard

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Background: Point-of-care (POC) technology aims to hasten diagnosis in the clinical setting. Reducing samples, especially invasive samples, for the same result will reduce the work volume, and potentially the cost. Faith in POC devices requires finding the most reliable POC device in the interest of cost and patient benefit, especially in an intensive care unit (ICU).

Methods: This study assessed the haemoglobin (Hb) correlation between invasive and non-invasive POC devices at a quaternary trauma ICU. A non-invasive, continuous Hb pulse oximeter was compared with two invasive POC devices, as well as the laboratory reference measurement. A 10% variance was considered a clinically significant difference.

Results: A total number of 48 arterial blood gas (ABG) measurements, 49 Mission haemoglobinometer measurements, 50 Masimo Radical-7 measurements, and 52 Inkosi Albert Luthuli Central Hospital (IALCH) laboratory Hb measurements were performed with a mean Hb of 8.8. The Masimo non-invasive haemoglobinometer failed to demonstrate interchangeability with the GEM blood gas analyser machine ($p < 0.004$), neither did it show interchangeability with the IALCH laboratory measurements ($p < 0.001$), or the Mission haemoglobinometer ($p < 0.0014$). Comparing the POC devices with the results from the laboratory revealed that the ABG machine (GEM 4000) was the closest to correlate with the laboratory measurements (mean device difference of 0.51, $p < 0.007$). The values for the Mission haemoglobinometer were the next closest, but both the devices slightly overestimate the Hb in the order of 6–7%.

Conclusion: This study compared the equivalence of the Hb level measured by two currently used POC devices (the Gem 4000 and Mission haemoglobinometer) against a novel, continuous, non-invasive device (the Masimo device) and the reference standard laboratory Hb level. The study found that the novel device did not perform equivalent or better than the existing devices.

Keywords: point-of-care, devices, haemoglobin measurement, laboratory standard

Introduction

The Inkosi Albert Luthuli Central Hospital's (IALCH) trauma intensive care unit (ICU) requires rapid clinical and laboratory results, with a dedicated multidisciplinary team focused on the management of the critically ill. Alongside this, point-of-care (POC) devices routinely aid decision-making and facilitate the need for further investigations, blood transfusions, correction of electrolytes, and trauma surgery.

Numerous blood samples are drawn and spread sparingly between available POC devices and the haematology laboratory at IALCH. Blood is always sent to a laboratory to support decision-making from POC devices. These methods are usually invasive, with the frequency of sampling guided by clinical decision-making. Because POC devices influence management so greatly, blood results sent to the Department of Health National Health Laboratory Service (NHLS) are used to confirm decisions made or to cater for human and machine error from POC devices.

The cost of laboratory tests and sample transportation places financial strain on the low-resource setting, with the further disadvantage of having to wait for results. POC devices can provide rapid results from a small sample with fewer financial implications, and staff can be easily trained in correct device usage. These POC devices can guide decision-making by delivering results at the POC; hopefully, these are reliable and repeatable.

Devices are used with the knowledge that there is potential for error, but they are still used because they meet the need of the clinical setting for reliable haemoglobin (Hb) measurements. Reducing redundancy in samples collected for the same result read on a POC device will reduce the volume of work experienced by laboratory personnel. Much faith has been placed in POC devices, with these devices influencing the management and outcome of surgical patients. Consequently, identifying the most reliable POC device is in the patient's best interest.

Aim and objectives

The study aims to determine the equivalence and reliability of the POC devices routinely used for Hb measurement compared with the laboratory standard.

Methods

Study setting

This study sought to assess the correlation in Hb between invasive and non-invasive POC devices. A recently developed,

non-invasive, continuous Hb pulse oximeter was compared with two invasive POC devices against laboratory Hb measurement. A 10% variance between the device mean and the NHLS was considered a clinically significant difference.

Sample population

The sample size calculation required 52 participants, drawn from the Biomedical Research Ethics Committee (BREC)-approved trauma registry (BCA207-09). The study is registered as a sub-study of the Class Approval, and a waiver of informed consent was granted since all the devices and the laboratory are used as routine care devices for all patients.

Inclusion criteria

The inclusion criteria were all male and female trauma or non-COVID-19 patients presenting to the IALCH trauma ICU (TICU), who were stabilised and post-transfusion, if indicated, following admission to the TICU. All cases were admitted to TICU and were included in the study, including some non-trauma COVID-19-negative patients during the COVID-19 pandemic when the unit was the "COVID-19-negative" ICU for the facility. Samples were collected at midnight on haemodynamically stable patients. All consumables were within the three-month expiration date and the devices were routinely calibrated by clinical technologists.

Devices under study

Masimo Radical-7 pulse oximetry probes (Masimo Corporation, Irvine, California, United States of America) with a rainbow sensor were used. A suitable size rainbow probe was chosen. The sensor is used preferably on the ring, middle, or index finger. All nail polish was removed, and nails were kept clean, dry, and short. For time correlation, a spot Hb measurement was taken from the continuous monitor at midnight, along with specimens for all other devices.

An aseptically placed arterial line and dried heparinised sampling syringes were used to draw the invasive samples for the Gem 4000 (ILEX South Africa, Sandton, Gauteng, South Africa) and the HemoCue Mission haemoglobinometer (Acon Laboratories Inc., San Diego, California, United States of America) samples at the time of drawing the arterial blood gas (ABG) and haematology routine specimens. The Masimo Radical-7 and the Mission haemoglobinometer were calibrated by clinical technologists before the commencement of the study. Blood gas analysers had automatic calibration functions.

For this study, the statistical sample size calculation was 52 participants, and the α was set at 0.05, with a power of 80%. Data were accrued using Microsoft Excel (Microsoft Corporation, Redmond, Washington) and analysed in Stata version 15 (StataCorp LLC, College Station, Texas, United States of America). Descriptive statistics, including frequencies and percentages, were used to summarise categorical variables. Central tendency and dispersion of data were measured using means and standard deviations (SD) for normally distributed variables, and medians and interquartile ranges for skewed variables. Bland-Altman plots were used to measure the agreement of Hb levels measured using the NHLS reference method and the POC device. A paired t-test or Wilcoxon signed-rank test was used to test the null hypothesis that Hb levels are equivalent.

Results

A total of 52 haemodynamically stable patients, not immediately requiring blood transfusion and with a mean Hb of 8 g/dl, were included in this study. Of these patients, 47 were Africans and five were Caucasians, with 46 males and six females outlined by admission diagnosis from December 2021 to January 2022 (Table I). Ages ranged from five to 67 years, as the unit manages adult and paediatric patients.

Table I: Total number of patients under admitting diagnosis

Admission diagnosis	Number of patients
Traumatic brain injury	24
Polytrauma	3
Pedestrian motor vehicle accident	4
Gunshot to abdomen	3
Burns	2
Squamous cell carcinoma	2
Stab to heart	2
Pelvic fractures	1
Renal failure (community assault)	1
Intra-abdominal sepsis	1
Stab to abdomen	1
Assault	1
Sinusitis	1
Appendicitis	1

A total of nine measurements were missing from the patient cohort: four ABG measurements, three Mission haemoglobinometer measurements, and two Masimo measurements. This resulted in a total number of 48 ABG measurements, 49 Mission haemoglobinometer measurements, 50 Masimo Radical-7 measurements, and 52 IALCH laboratory Hb measurements serving as the reference with a mean Hb of 8.8 g/dl.

Comparing the POC with the results from the laboratory revealed that the ABG machine (GEM 4000) was the closest to correlate with the laboratory measurements (mean device difference of 0.51, $p < 0.007$) (Figure 1). The 95% confidence interval (CI) was statistically significant for the closest device to show equivalence to the reference value. The values for the Mission haemoglobinometer were the next closest, but both the devices slightly overestimate the Hb in the order of 6–7%.

Unfortunately, the Masimo non-invasive haemoglobinometer (95% CI 0.82–1.75, $p < 0.001$) demonstrated statistical significance for non-equivalence to the reference value. Importantly, the Masimo overestimates the Hb by up to 17%, which may be the difference between a transfusion threshold and not transfusing the patient. Additionally, the Masimo non-invasive

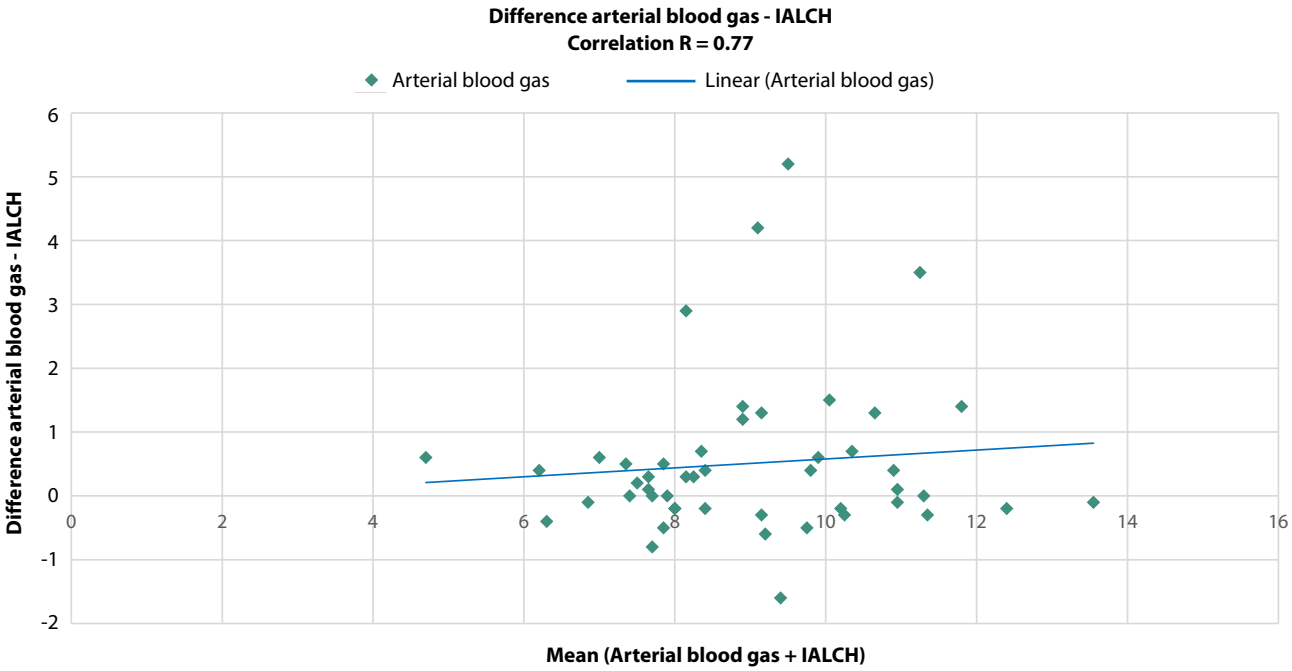

Figure 1: Bland-Altman demonstrating correlation in mean Hb difference between the arterial blood gas machine and IALCH laboratory

Table II: Comparing Hb measurements from POC devices with the NHLS reference standard

	ABG Hb measurements	Mission haemoglobinometer measurements	Masimo Radical-7 and Hb measurements
Sample size	48	49	50
Mean difference (device vs. laboratory)	0.51	0.41	1.28
SD	1.24	2.09	1.64
95% CI	0.15–0.87	-0.19 to 1.00	0.82–1.75
p-value	0.007	0.18	< 0.001
Mean percentage overestimated Hb	6.8	6.2	17.4

ABG – arterial blood gas, CI – confidence interval, Hb – haemoglobin, SD – standard deviation

haemoglobinometer failed to demonstrate interchangeability with the GEM ABG machine ($p < 0.004$), neither did it show interchangeability with the IALCH laboratory measurements ($p < 0.001$), or the Mission haemoglobinometer ($p < 0.0014$), since it had a variance of comparison to the laboratory value of more than 10% (Table II).

Discussion

This study compared the equivalence of the Hb level measured by two currently used POC devices (Gem 4000 and Mission haemoglobinometer) against a novel, continuous, non-invasive device (Masimo device) and against the reference standard laboratory Hb level in a cohort of 52 patients. The study found that the novel device did not perform as equivalent or better than the existing devices.

The study results support the current practice in trauma, where decision-making is based on the measurements obtained from an ABG sample. Therefore, it may be arguable whether a formal Hb measurement from a NHLS is required. It is clearly demonstrated that the ABG machine in our practice can be considered a gold standard due to its strong equivalence to the laboratory reference standard. The Mission haemoglobinometer for a newly introduced POC device, it was user-friendly despite not showing equivalence to the reference standard in terms of reliability of Hb measurement.

As an initial comment, it is important to note that the Masimo haemoglobinometer was designed to be used in its capacity to continuously monitor Hb trends rather than for a single Hb measurement. Therefore, it was not tested to its full capacity in the current study. However, it was not shown to be equivalent to the other three methods in terms of Hb correlation to the reference value of the formal laboratory in the context of having less than 10% variance from the reference standard at the same time point that the bloods were drawn.

Recklessness is the main driving force that leads to wounds, with the young, economically active members of the population dying and thousands ending up disabled. This results in behavioural, psychological, and functional consequences requiring rehabilitation and an ever-growing social burden. This recklessness constitutes a vicarious burden carried by KwaZulu-Natal's flagship IALCH trauma service.[1-4]

There are many different non-invasive and invasive haemoglobinometer models, all mostly working with spectrophotometry to determine the same measurement. All POC devices have advantages and disadvantages, which make the need for clinically guided decision-making even more important. However, certain devices show more promise than others. The Masimo, GEM 4000, and HemoCue 201+ all demonstrate the ability to provide unbiased, pooled estimates of laboratory Hb measurement as shown by Lee et al.,[5] Khanna et al.,[6] and Hiscock et al.[7] Contrary to the current study, Gamal et al.[8] found the Masimo SpHb to show excellent accuracy compared to a laboratory measurement.

Giraud et al.[9] reviewed 219 blood samples taken from 53 patients that directly compared Hb absolutes and trend accuracy values from the central laboratory (reference method). The results obtained demonstrated poor correlation, but in conclusion, none of the devices tested would have led to unnecessary or delayed transfusion according to the 2006 American Society of Anesthesiologists (ASA) transfusion criteria.[9] This is in keeping with the local study findings that regardless of any lack of correlation between devices, it did not, according to staff, influence a change in transfusion strategies. These findings are further supported by Campos et al.[10] when using non-invasive Hb measurements in their decision-making, with it changing transfusion in only 1.9% of transfusion cases. Gupta et al.[11] demonstrated a faster decision-making time around transfusions.

Miller et al.[12] demonstrated that HemoCue (a predecessor of the Misson machine) was more consistently accurate, but the non-invasive haemoglobinometer reading often correlated well with the laboratory; however, this may not be as accurate as clinically necessary in some patients. The current study agrees with the above findings, even though the Masimo does not always correlate for statistical significance in terms of reliability compared to the laboratory standard.

Gehring et al.[13] compared the HemoCue/ABG/automated haematology analyser, concluding a small systemic deviation. Despite this deviation, Oris et al.[14] validated the above devices for POC analysis. In comparing ABG and laboratory values, Carabini et al.[15] further supported the use of ABG to CO-oximetry. However, with a fair-to-moderate agreement between the central blood collection and ABG, their study did not demonstrate interchangeability.[15] Ray et al.[16] supported this by producing similar information that blood gas analysers overestimate Hb but provide a valid alternative.

Unfortunately, the Mission haemoglobinometer used in this study failed to demonstrate interchangeability, unlike the other POC haemoglobinometers, which are thought remarkably reliable according to multiple previous studies. These studies were from Pecoraro et al.,[17] Bond et al.,[18] Despotis et al.,[19] Sanchis-Gomar et al.,[20] Hudson-Thomas et al.,[21] Yadav et al.,[22] and Kim et al.[23] Only Hinnouho et al.[24] demonstrated some inaccuracy when used in children, and Mahajan et al.[25] demonstrated that the HemoCue device had a highly significant correlation with their laboratory compared to the GEM 4000 blood gas analyser. Marwick et al.[26] showed HemoCue devices to be more accurate than the blood gas devices and even concluded a reduction in transfusion error.

What makes the HemoCue and the ABG reliable when their equivalence is tested against a central laboratory measurement? One can only conclude that staff inaccuracies, despite adequate training, play a significant role when introducing new devices, especially ones that lack familiarity. Laney et al.[27] showed that if staff are trained, the device's accuracy improves, and Mashamba-Thompson et al.[28] emphasised the difficulties of implementing POC devices in rural areas. Salmond et al.[29] demonstrated the importance of testing new POC devices before introducing them into practice because several technical and physiological factors affect reliability, as further evidenced by Briggs et al.[30]

Gramz et al.[31] discussed eight components that manage many different aspects of POC devices and the need for a structured approach that involves collaboration among healthcare institutions, device manufacturers, and information technology vendors. Berkow et al.[32] reinforce this need for collaboration by expanding into different methodologies, technical aspects, and physiological factors that affect measurement.

POC testing had an early struggle regarding accuracy and reliability but has now developed into a reliable, rapid, and appropriate patient management tool. It is testing at the point of patient care, and there is much interest and effort in the continued development of POC devices. POC devices have diverse applications, including hospitals, clinics, and home health facilities. The benefits are the potential for reduced cost, quick staff training, ease of use, and minimal blood sample requirements.[33,34]

Limitations

The study was a single-centre study undertaken in a quaternary facility that functions as a training hospital. There was a risk of patient selection bias as the first 52 patients were consecutively included; however, the study had strength in that the devices were routinely used by experienced staff. Furthermore, the study was conducted in a dedicated trauma ICU, and most patients were trauma patients. Thus, the generalisability to other ward or general ICU settings may be reduced. All bloods were drawn from arterial or central venous access catheters, so they may not be comparable to peripheral venous or capillary samples.

Conclusion

POC devices may benefit South Africa as significant resource limitations remain, and laboratory Hb measurements are not immediately available. The speed of results obtained from POC devices is unparalleled by laboratory services and consequently aids in rapid decision-making, especially in trauma surgical ICU patients. This further reduces laboratory costs and labour in transporting specimens. POC devices, such as the Masimo, potentially offer greater versatility and a more comprehensive

range of applications than other haemoglobinometers due to their non-invasive functionality. Nonetheless, they must be proven comparable to the reference standard before routine adoption.

Conflict of interest

The authors declare no conflict of interest.

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None

Ethical approval

Ethical approval was obtained from the University of KwaZulu-Natal Biomedical Research Ethics Committee (Ref: BCA207/09).

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