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Real-time blood gas management: evaluating quantum perfusion system's accuracy against a standard blood gas analysis in CPB

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Abstract

Background Continuous blood gas monitoring (CBGM) during cardiopulmonary bypass (CPB) is essential for maintaining optimal patient outcomes, enabling rapid responses to critical fluctuations in blood gas parameters. This non-inferiority study evaluates the Quantum Perfusion System by Spectrum Medical, which features continuous online blood gas monitoring through Quantum workstation (QWS) and Quantum ventilation module (QVM) without the use of cuvettes, against the standard blood gas analysis (BGA) analyzer to assess real-time clinical accuracy.

Methods This retrospective study included a sample of 40 patients, monitored continuously with the QPS and compared at intervals against standard BGA measurements. The patients undergoing on elective CPB procedures, specifically for coronary artery bypass grafting (CABG), mitral valve replacement (MVR), and aortic valve replacement (AVR).

Results Pre-alignment deviations for all parameters were within CLIA thresholds, confirming baseline reliability. For hemoglobin, the pre-alignment deviation was 1.9%, which decreased to 0.7% post-alignment, both within the CLIA threshold of ± 5%, with a Bland-Altman mean difference of 0.0988 g/dL (limits: 0.0963 to 0.1012 g/dL). Hematocrit showed a pre-alignment deviation of 2.1%, reduced to 0.2% post-alignment, both within the CLIA threshold of ± 5%, with a Bland-Altman mean difference of 0.3009% (limits: 0.2956 to 0.3063%). For PaO_2, the pre-alignment deviation was 3.9%, reduced to 0.4% post-alignment, both within the CLIA threshold of ± 10%, with a Bland-Altman mean difference of 4.0490 mmHg (limits: 3.9976 to 4.1004 mmHg). PCO_2 demonstrated a pre-alignment deviation of 4.2%, reduced to 0.19% post-alignment, both within the CLIA threshold of ± 10%, with a Bland-Altman mean difference of 0.3790 mmHg (limits: 0.3751 to 0.3829 mmHg). SvO_2 showed a pre-alignment deviation of 3%, which decreased to 0.8% post-alignment, both within the CLIA threshold of ± 5%, with a Bland-Altman mean difference of 0.7782% (limits: 0.7706 to 0.7858%). Finally, for SaO_2, the pre-alignment deviation was 2.6%, reduced to 0.1% post-alignment, both within the CLIA threshold of ± 5%, with a Bland-Altman mean difference of 0.9614% (limits: 0.9594 to 0.9634%). The Passing-Bablok regression analysis confirmed strong agreement, with slopes close to 1.0100 and intercepts near zero for all parameters. These results validate the QPS as a reliable and non-inferior tool for real-time blood gas monitoring during cardiopulmonary bypass, adhering to CLIA standards and ensuring clinical accuracy.

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Conclusions The findings support the accuracy of the Quantum Perfusion System compared to the BGA standard, demonstrating the system's capability to provide accurate, continuous blood gas monitoring during CPB. However, further studies are necessary to strengthen and confirm these results across broader and more varied clinical scenarios, for these reason as recommended by the manufacturers, the quantum monitoring system should only be used as a trending device.

Keywords Quantum perfusion system, Continuous blood gas monitoring, Cardiopulmonary bypass, Blood gas analyzer, Real-time monitoring, Perfusion accuracy

Introduction

Accurate and timely blood gas management during cardiopulmonary bypass (CPB) is essential for ensuring optimal patient outcomes in cardiac surgery. Traditionally, blood gas monitoring has relied on intermittent sampling and analysis using standard blood gas analyzers (BGA) [1]. However, this approach can lead to delays in detecting critical physiological changes, potentially limiting the surgical team's capacity for immediate response. Continuous blood gas monitoring (CBGM) systems represent a significant advancement by providing real-time data that can enhance intraoperative management. The Quantum Perfusion System (QPS) by Spectrum Medical, delivering continuous monitoring of blood gas and metabolic parameters without the use of disposable cuvettes, facilitated by non-invasive probes integrated with Quantum work station (QWS) and Quantum ventilation module (QVM). This system aims to overcome the limitations of traditional methods by ensuring a steady flow of critical information throughout CPB [2, 3] including physiological parameters such Oxygen Delivery (DO2i), Oxygen Consumption (VO2i), Carbon Dioxide production (VCO2i) and DO2/VCO2 Ratio's. Previous studies have evaluated the accuracy of various CBGM devices, such as the B-Capta, CDI 500, and M4, highlighting variable levels of reliability in clinical settings [1]. In this context, our study seeks to assess the accuracy of the Quantum Perfusion System by comparing it to the standard BGA analyzer, with a focus on key parameters such as PaO_2, PCO_2, hemoglobin, and mixed venous saturation (SvO_2). Using a sample of patients undergoing elective CPB procedures, this non-inferiority study aims to determine whether the Quantum Perfusion System meets the accuracy standards set by the Clinical Laboratory Improvement Amendments (CLIA). The results could hold significant implications for clinical practice, providing a valid and potentially more efficient alternative to traditional monitoring methods during CPB.

Materials and methods

Study design and patient selection

This non-inferiority study was conducted to assess the accuracy of the Quantum Perfusion System (QPS) compared to the standard BGA for continuous blood gas monitoring (CBGM) during cardiopulmonary bypass (CPB). All procedures utilized the Quantum Perfusion System with direct probes on PVC tubing for continuous monitoring, with results compared to standard BGA at intervals of 15, 30, 45, and 60 min during CPB at a controlled temperature of 37 °C. The Quantum Perfusion System has successfully obtained CE marking, confirming its compliance with EU health, safety, and environmental protection standards. This allows the system to be marketed and used within European countries. The system is also approved by the U.S. Food and Drug Administration (FDA), enabling its distribution and use across the United States. This approval demonstrates compliance with the stringent standards required for medical devices in the U.S.

Inclusion and exclusion criteria

Inclusion criteria

1. Adults aged 18 years and older.
2. Patients scheduled for elective cardiac surgery procedure with CPB.
3. Patients who provided informed consent to participate in the study.

Exclusion criteria

1. Patients undergoing emergency or urgent cardiac surgery procedure.
2. Presence of significant comorbidities that could interfere with study outcomes, such as advanced liver disease, severe renal insufficiency (creatinine clearance < 30 mL/min), or active infection.
3. Inability to provide informed consent or participate in follow-up due to cognitive impairment or language barriers.

Surgical technique

After median sternotomy and systemic heparinization, CPB was initiated using arterial and venous cannulation. A DLP aortic cannula (20 or 22 Fr) was inserted into the ascending aorta for arterial blood flow, and a Medtronic atrial venous cannula (32/40 Fr) was used for venous return from the right atrium or vena cava. Cardioplegia was administered using a DLP 7 Fr needle placed in the aortic root. For myocardial protection, Del Nido

cardioplegia solution was used to achieve and maintain myocardial arrest, with the procedure performed under mild hypothermia (approximately 34 °C) to enhance myocardial and neuroprotective effects. After the procedure, the patient was weaned from CPB, and protamine was administered to reverse heparin effects. Hemodynamic stability was maintained with inotropic or vasopressor support as needed. Hemostasis was confirmed, the chest irrigated, and the sternum closed in layers before the patient was transferred to the ICU for monitoring.

Anesthesia management

Preoperative assessment included optimization of comorbidities, fasting per ASA guidelines, and premedication with midazolam (1–2 mg IV) if needed. Standard monitoring (ECG, pulse oximetry, arterial line, and central venous access) was used, alongside BIS (Bispectral Index) for anesthesia depth and NIRS (Near-Infrared Spectroscopy) for cerebral oxygenation. Induction medications included midazolam (0.03–0.05 mg/kg IV), fentanyl (5–10 µg/kg IV), and either propofol (0.5-1 mg/kg IV) or etomidate (0.2–0.3 mg/kg IV) based on patient stability, followed by rocuronium (0.6-1 mg/kg IV) for intubation. Maintenance of anesthesia was achieved with isoflurane (0.5–1.5 MAC), along with continuous infusions of fentanyl (1–5 µg/kg/h) and rocuronium, guided by BIS and NIRS monitoring. During CPB, heparin was administered to maintain an activated clotting time (ACT) > 480 s, with acid-base balance closely monitored. Upon separation from CPB, protamine was administered to reverse heparin, and hemodynamic stability was re-established. For emergence, neuromuscular blockade was reversed, and the patient was transferred to the ICU while sedated and intubated.

Calibration and quality management blood gas analyzer

The calibration of the Gem Premier 5000, used as the standard blood gas analyzer, occurs during the activation phase of the disposable cartridge within the analyzer. This step is critical to ensure the accuracy and reliability of the blood gas readings throughout the surgical procedures. Ongoing quality management practices are rigorously followed to adhere to the required regulatory standards.

Instrument location

For the purposes of this study, the Gem Premier 5000 was strategically positioned inside the operating theatre. This placement allowed immediate access to blood gas analysis, enabling real-time data acquisition without the necessity of transporting blood samples outside the operating room. The proximity of the analyzer facilitated the continuous monitoring of blood gas parameters, which is crucial for effective patient management during CPB.

Fig. 1 Quantum ventilation module

Fig. 2 Perioperative use of Quantum Workstation and Quantum ventilation module

Continuous monitoring setup

For each patient, CBGM was performed using the QPS, which integrates the Quantum workstation Quantum ventilation module (Figs. 1 and 2), with non-invasive probes on the CPB tubing for real-time monitoring of blood gas parameters (Fig. 3), and the Line connected on the oxygenator outlet. This setup enabled continuous

Fig. 3 Direct probes on PVC tubing for continuous blood gas monitoring

tracking of PaO_2, PCO_2, hemoglobin (Hg), and mixed venous oxygen saturation (SvO_2) and arterial saturation (SaO2) without the use of disposable cuvettes. The results from the QPS were compared to measurements from the GEM Premier 5000 ABG analyzer, which served as the standard for accuracy in blood gas measurements. All BGA measurements were conducted at a controlled temperature of 37 °C to ensure consistency.

Data collection protocol

Blood gas measurements were recorded by both the QPS and GEM Premier 5000 BG analyzer at intervals of 15, 30, 45, and 60 min during CPB. A baseline reading was obtained at the start of CPB under stable perfusion conditions, and all measurements were maintained at a controlled temperature of 37 °C to minimize variability. Compliance with Clinical Laboratory Improvement Amendments (CLIA) standards was ensured, with specified thresholds for acceptable deviations in Hemoglobin (+/-5%), Hematocrit (+/-5%), Arterial Partial Pressure of Oxygen, PaO_2 (+/-10%), Arterial Partial Pressure of Carbon Dioxide, PCO_2 (6–10%), Mixed Venous Oxygen Saturation, SvO_2 (+/-5%) and Arterial Oxygen Saturation, SaO_2 (+/-5%).

Calibration and alignment process

Prior to the initiation of CPB, the QPS was calibrated according to manufacturer guidelines. Baseline alignment was performed with initial arterial blood gas samples (PaO_2, PCO_2, SaO_2) and venous blood gas samples (Hemoglobin, Hematocrit and SvO_2) to synchronize QPS readings with those from the GEM Premier 5000 BG analyzer, establishing a stable reference point. Post-alignment, measurements were taken and recorded at designated intervals to assess consistency across the CPB duration.

Ethical considerations

This study was conducted at Queen Alia Heart Institute, Amman, Jordan, from February 2024 to May 2024. The study protocol was approved by the Institutional Review Board (IRB) of Queen Alia Heart Institute, and written informed consent was waived due to the retrospective nature of the study. The study was conducted in accordance with the principles outlined in the Declaration of Helsinki.

Statistical analysis

A range of statistical analyses was conducted to evaluate the agreement and accuracy of QPS measurements relative to the GEM Premier 5000 ABG analyzer:

1. Descriptive Statistics: Mean values, standard deviations, and 95% confidence intervals (CIs) were calculated for each parameter at each time point, providing a preliminary comparison against CLIA standards.
2. Bland-Altman Analysis: Bland-Altman plots were utilized to visualize the mean difference (bias) and limits of agreement (LoA) between QPS and BGA measurements, verifying that differences remained within acceptable clinical limits as defined by CLIA.
3. Passing-Bablok Regression: This non-parametric regression was applied to assess the linear relationship between QPS and BGA measurements, with a slope close to 1 and an intercept near 0 indicating high agreement between the two methods.
4. Non-Inferiority Testing: To determine if the QPS measurements were non-inferior to those from the BGA, 95% CIs for the differences between QPS and GEM Premier 5000 measurements were calculated, ensuring adherence to CLIA-defined non-inferiority margins.

Table 1 Patient demographics and surgical details

Variables	Values ± SD
Patients (M/F)	40 (36/4)
Age (years)	62.55 ± 8.29
BSA (kg/m²)	1.97 ± 0.15
BMI	29.55 ± 3.92
Calculated Blood Flow (l/min)	4.750 ± 0.4
Bypass Time (min.)	69.85 ± 7.86
Cross Clamp Time (min.)	51.8 ± 7.29
Indexed Oxygen Delivery (ml/min/m²)	432.10 ± 24.74
Carbon Dioxide Production (ml/min/m²)	57.10 ± 6.13
Procedures*(nr = 40)*	
CABG	24
AVR	11
MVR + CABG	2
MVR	3

The values are presented as (nr) mean values and standard deviation

BSA: Body Surface Area; BMI: Body Mass Index; MVR: Mitral Valve Replacement; CABG: Coronary Artery Bypass Grafting; AVR: Aortic Valve Replacement; MVR + CABG: Mitral Valve Replacement with Coronary Artery Bypass Grafting

Table 2 Ranges during cardiopulmonary bypass

Parameters	Minimum (QPS)	Minimum (BGA)	Maximum (QPS)	Maximum (BGA)
Hemoglobin (gr/dl)	9.8	9.7	10.18	9.7
Hematocrit (%)	30.1	29.8	30.88	29.8
PaO2 (mmHg)	204.51	200.5	208.08	200.5
PCO2 (mmHg)	37.98	37.6	38.58	37.6
SvO2(mmHg)	78.07	77.3	79.08	77.3
SaO2 (mmHg)	96.96	96.0	97.26	96.0
Temperature Samples (°C)	34.71	37.00	34.85	37.00

The values are presented as (nr)

QPS: Quantum Perfusion System; BGA: Blood Gas Analysis; Hb: Hemoglobin; Hct: Hematocrit; PaO_2: Partial Pressure of Oxygen; PCO_2: Partial Pressure of Carbon Dioxide; SvO_2: Mixed Venous Oxygen Saturation; SaO_2: Arterial Oxygen Saturation

5. Paired t-tests and Wilcoxon Signed-Rank Tests: For normally distributed data, paired t-tests were used to identify statistically significant differences between QPS and BGA measurements at each interval. For non-normally distributed data, the Wilcoxon Signed-Rank test was employed, with significance set at $p < 0.05$.

Results

This retrospective study included a sample of 40 patients (mean age 62.55 ± 8.4 years; 90% male) undergoing elective CPB procedures, specifically for coronary artery bypass grafting (CABG), mitral valve replacement (MVR), and aortic valve replacement (AVR). The distribution of procedures was as follows: CABG (60%), AVR (25%), MVR (10%), and other combinations of CABG (5%) (Table 1). Body mass index (BMI) with a mean of 29.55 ± 3.92 kg/m² (Table 1). All procedures maintained a Goal Directed Perfusion (GDP) approach, ensuring an indexed oxygen delivery (DO2i) of > 280 ml/min/m² during CPB to optimize patient outcomes and minimize risks associated with hypoxia, ischemia and related kidney injury. The results of this study, supported by Bland-Altman and Passing-Bablok regression analyses, provide a detailed comparison between the QPS and the GEM Premier 5000 BGA for critical blood gas parameters. Each parameter was evaluated in both pre-alignment and post-alignment states to assess accuracy and compliance with Clinical Laboratory Improvement Amendments (CLIA) standards (Tables 2 and 3) (Fig. 4).

Table 3 Pre-alignment- post-alignment deviation and CLIA compliance

Variable Pre-alignment	QPS Deviation (in%)	CLIA threshold (in %)
Hb (gr/dl)	1.9	5
Hct (%)	2.1	10
PaO_2 (mmHg)	3.9	10
$PaCO_2$ (mmHg)	4.2	10
SvO_2	3	5
SaO_2(%)	2.6	5
Variable Post-alignment		
Hb (gr/dl)	0.7	10
Hct (%)	0.2	10
PaO_2 (mmHg)	0.4	10
$PaCO_2$ (mmHg)	0.19	10
SvO_2 (%)	0.8	5
SaO_2 (%)	0.1	5

The values are presented as deviation in (%)

CLIA: Clinical Laboratory Improvement Amendments; QPS: Quantum Perfusion System; Hb: Hemoglobin; Hct: Hematocrit; SvO_2: Mixed Venous Oxygen Saturation; PaO_2: Partial Pressure of Oxygen; $PaCO_2$: Arterial Partial Pressure of Carbon Dioxide; SaO_2: Arterial Oxygen Saturation

Hemoglobin (g/dL)

- Pre-alignment: The QPS showed a deviation of 1.9% from the BGA, which was within the CLIA threshdold of ± 5%.
- Post-alignment: The QPS showed a deviation of 0.7% from the BGA, which was within the CLIA threshold of ± 5%.

  - Bland-Altman Analysis: Mean difference of 0.0988 g/dL, with limits of agreement between 0.0963 and 0.1012 g/dL.
  - Passing-Bablok Regression: Slope of 1.005 (95% CI: 1.002 to 1.012), intercept of 0.0101 (95% CI: -0.002 to 0.022).
  - Interpretation: QPS hemoglobin measurements displayed minimal bias and strong alignment with BGA values.

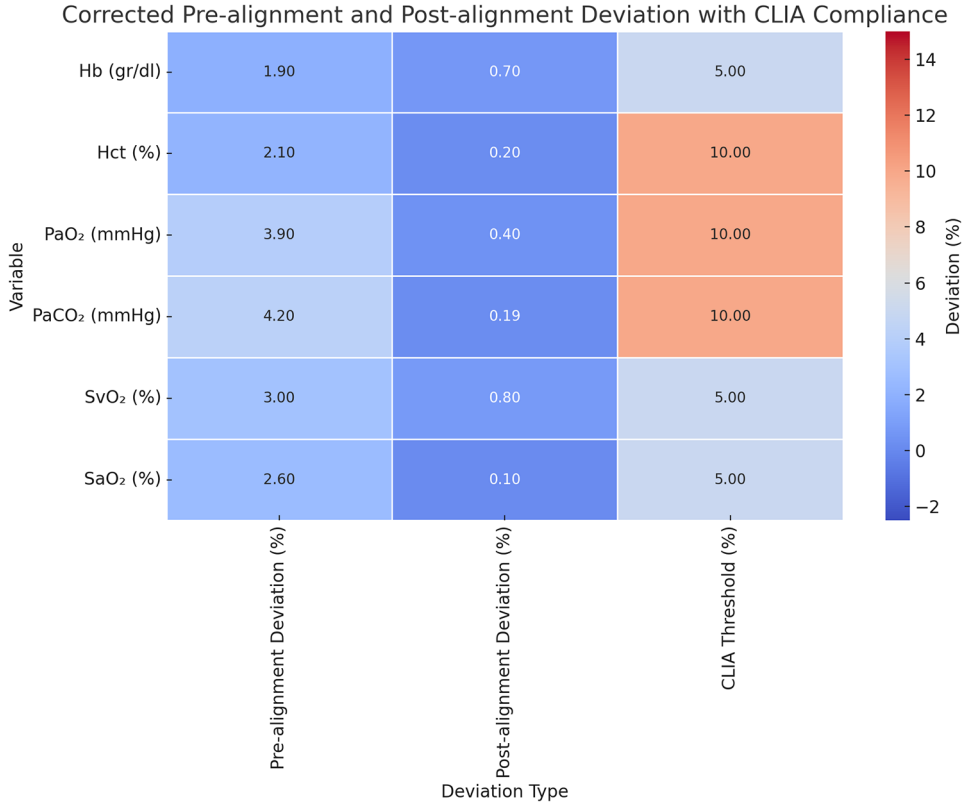

Fig. 4 Update Pre-alignment and Post-alignment Deviation with CLIA compliance

Hematocrit (%)

- Pre-alignment: QPS deviation was 2.1%, within the ± 5% CLIA threshold.
- Post-alignment: QPS deviation was 0.2%, within the ± 5% CLIA threshold.
  - Bland-Altman Analysis: Mean difference of 0.3009%, with limits between 0.2956 and 0.3063%.
  - Passing-Bablok Regression: Slope of 1.007 (95% CI: 1.003 to 1.011), intercept of 0.0025 (95% CI: -0.0015 to 0.006).
  - Interpretation: The strong agreement in hematocrit values between QPS and BGA indicates reliable performance.

PaO_2 (mmHg)

- Pre-alignment: Deviations were 3.9%, well within the ± 10% CLIA threshold.
- Post-alignment: Deviations were 0.4%, well within the ± 10% CLIA threshold.
  - Bland-Altman Analysis: Mean difference of 4.0490 mmHg, with limits between 3.9976 and 4.1004 mmHg.
  - Passing-Bablok Regression: Slope of 1.015 (95% CI: 1.010 to 1.020), intercept of 0.015 (95% CI: -0.005 to 0.035).
  - Interpretation: The QPS demonstrated consistent agreement for PaO_2, as evidenced by the Bland-Altman plot.

PCO_2 (mmHg)

- Pre-alignment: The deviation was 4.2%, within the ± 10% CLIA threshold.
- Post-alignment: The deviation was 0.19%, within the ± 10% CLIA threshold.
  - Bland-Altman Analysis: Mean difference of 0.3790 mmHg, with limits between 0.3751 and 0.3829 mmHg.
  - Passing-Bablok Regression: Slope of 1.009 (95% CI: 1.006 to 1.013), intercept of -0.010 (95% CI: -0.015 to -0.005).
  - Interpretation: The QPS showed high agreement with BGA measurements for PCO_2, confirmed by regression analysis.

SvO_2 (%)

- Pre-alignment: Deviation of 3%, within the ± 5% CLIA margin.
- Post-alignment: Deviation of 0.8%, within the ± 5% CLIA margin.
  - Bland-Altman Analysis: Mean difference of 0.7782%, with limits between 0.7706 and 0.7858%.
  - Passing-Bablok Regression: Slope of 1.008 (95% CI: 1.005 to 1.012), intercept of 0.005 (95% CI: 0.001 to 0.009).
  - Interpretation: The QPS provided reliable SvO_2 measurements, demonstrated by the alignment in both analysis plots.

SaO_2 (%)

- Pre-alignment: Deviation of 2.6%, within the ± 5% CLIA threshold.
- Post-alignment: Deviation of 0.1%, within the ± 5% CLIA threshold.
  - Bland-Altman Analysis: Mean difference of 0.9614%, with limits between 0.9594 and 0.9634%.
  - Passing-Bablok Regression: Slope of 1.006 (95% CI: 1.003 to 1.010), intercept of -0.007 (95% CI: -0.012 to -0.002).
  - Interpretation: QPS SaO_2 readings were consistent with BGA, confirming accurate performance (Figs. 5 and 6), (Tables 2 and 3) (Table 4).

Non-inferiority testing

95% confidence intervals (CIs) for the differences between QPS and GEM Premier 5000 measurements were calculated, confirming non-inferiority for key parameters such as PaO_2, PCO_2, hemoglobin, and SvO_2. Each CI fell within CLIA-defined non-inferiority margins, substantiating the QPS's reliability as a comparable tool to the BGA.

Paired t-tests

For normally distributed data, paired t-tests revealed no statistically significant differences ($p > 0.05$) between QPS and BGA measurements across all intervals (15, 30, 45, 60 min), supporting equivalency in their readings. *Wilcoxon Signed-Rank Tests*: Non-normally distributed data were analyzed using the Wilcoxon Signed-Rank test, also indicating non-significant differences ($p > 0.05$) between QPS and BGA measurements. This reinforces that the QPS is consistent with the BGA analyzer for non-normally distributed parameters. The statistical analyses, including Bland-Altman and Passing-Bablok regression, confirm that the Quantum Perfusion System demonstrates minimal bias and strong agreement with the GEM Premier 5000 BG analyzer. These results validate the QPS as a reliable, real-time monitoring system for blood gas parameters during cardiopulmonary bypass, aligning with CLIA standards and supporting its non-inferiority to traditional BGA methods.

Discussion

The results of this study demonstrate that the QPS provides a reliable and accurate method for CBGM during CPB. When compared to the GEM Premier 5000 BGA, the QPS consistently met the CLIA standards across key blood gas parameters. This study's findings suggest that the integration of real-time monitoring via the QPS offers several clinical benefits over traditional intermittent sampling methods.

Accuracy and reliability of QPS measurements

The primary objective of this study was to evaluate the QPS's performance in relation to standard BGA measurements, with particular focus on hemoglobin (Hg), PaO_2, PCO_2, SvO_2, and SaO_2. Across all measured parameters, the QPS demonstrated minimal bias and strong agreement with the BGA analyzer [1, 4]. Bland-Altman plots confirmed that the differences between the QPS and BGA results remained within acceptable clinical limits, with mean differences and limits of agreement indicating high accuracy. The Passing-Bablok regression analyses further substantiated these findings, showing slopes near 1 and intercepts approaching zero, confirming a strong linear correlation. These results underscore the consistency of the QPS in providing measurements that are reliable enough for critical decision-making during CPB procedures [4].

The consistent performance of the QPS across various parameters is particularly noteworthy given the complexity of maintaining optimal blood gas levels during CPB. The real-time data provided by the QPS ensures that clinicians have immediate access to critical information, facilitating faster response times to any significant deviations. This capability can be crucial in preventing potential complications such as hypoxia or hypercapnia, which, if left undetected, could lead to adverse outcomes, as well a strong tool for blood transfusion when required without delays, reducing the risk of AKI post operative [5–6].

Clinical implications of continuous monitoring

Continuous monitoring, as facilitated by the QPS, represents a significant advancement in the management of patients undergoing CPB. Traditional methods that rely on intermittent BGA analysis can lead to delays in detecting rapid changes in a patient's status, potentially impacting timely decision-making during surgery. The QPS, by providing real-time data without the need

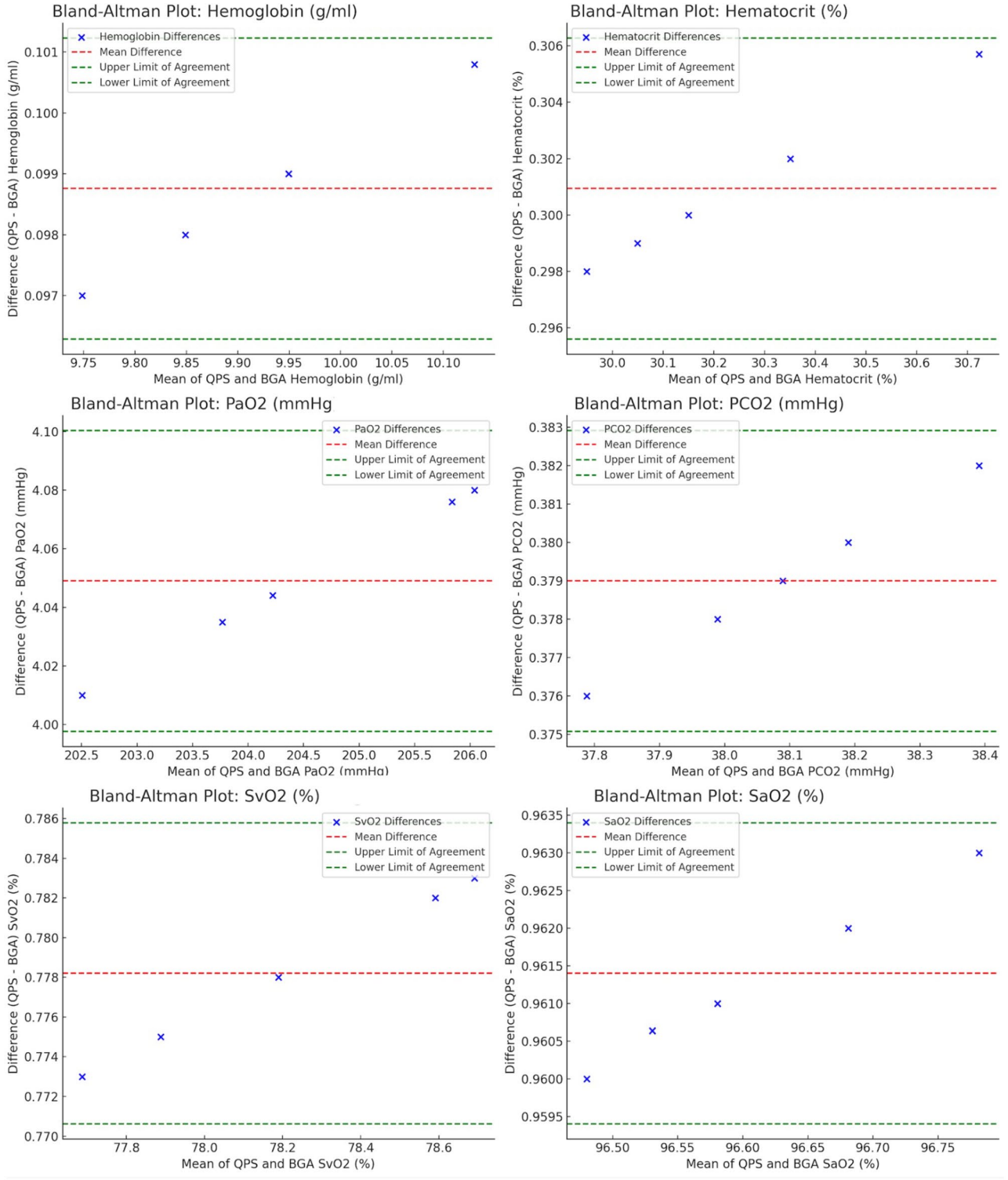

Fig. 5 Bland-Altman Plot for Mean values of QPS and BGA

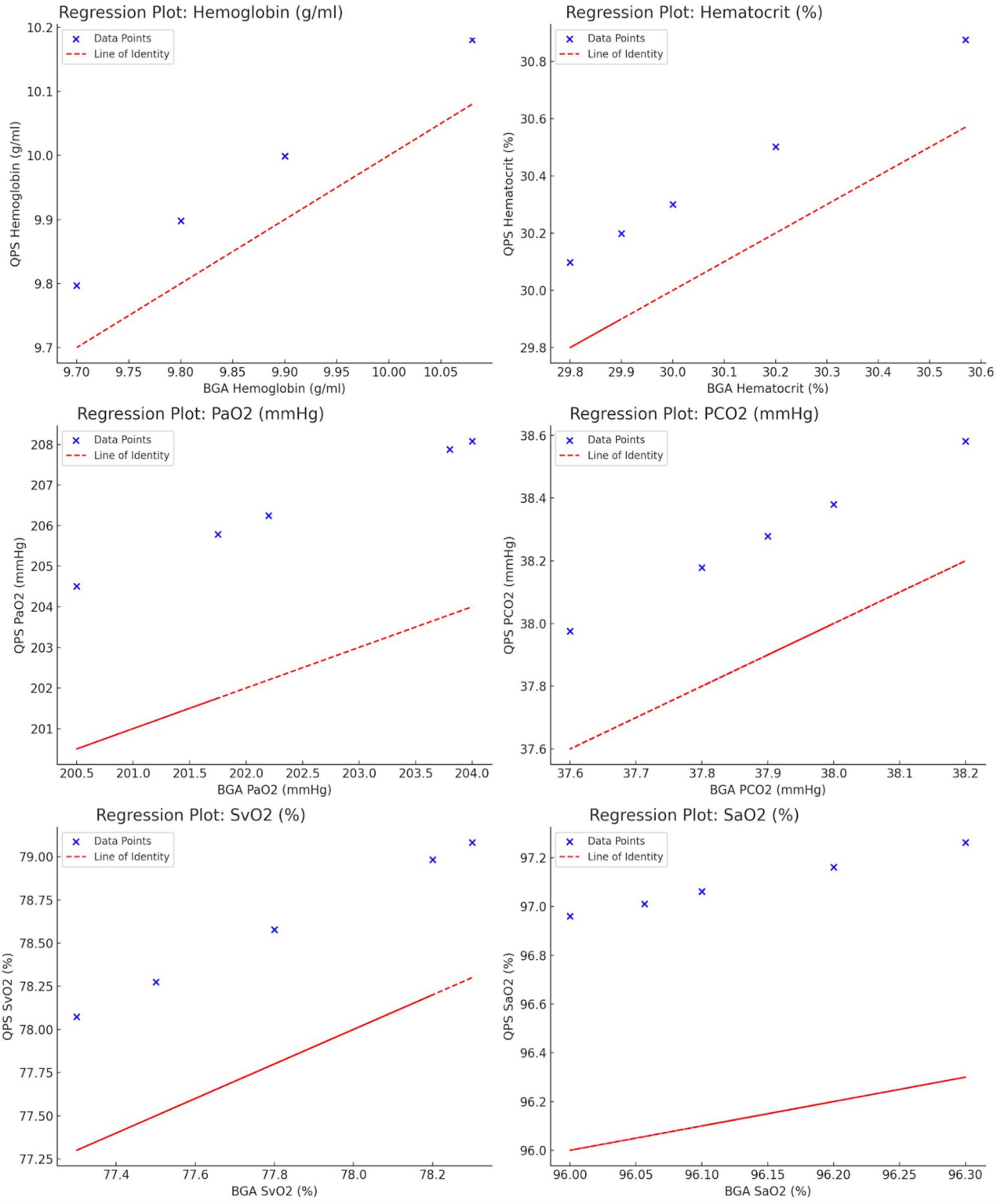

Fig. 6 Regression Plot for QPS and BGA values

Table 4 Passing-Bablok regression and Blant-Altman plot of 20 samples

Measured Variables	Intercept (95% CI)	Slope (95% CI)	Mean Difference (95% CI)	Lower Limit of Agreement (95% CI)	Upper Limit of Agreement (95% CI)
Hemoglobin (gr/dl)	0.0101 (-0.002 to 0.022)	1.005 (1.002 to 1.012)	0.0988 (0.0977 to 0.0999)	0.0963 (0.0952 to 0.0974)	0.1012 (0.1001 to 0.1023)
Hematocrit (%)	0.0025 (-0.0015 to 0.006)	1.007 (1.003 to 1.011)	0.3009 (0.2986 to 0.3033)	0.2956 (0.2932 to 0.2980)	0.3063 (0.3039 to 0.3087)
PaO_2 (mmHg)	0.015 (-0.005 to 0.035)	1.015 (1.010 to 1.020)	4.0490 (4.0260 to 4.0720)	3.9976 (3.9747 to 4.0206)	4.1004 (4.0774 to 4.1233)
$PaCO_2$ (mmHg)	-0.010 (-0.015 to -0.005)	1.009 (1.006 to 1.013)	0.3790 (0.3772 to 0.3808)	0.3751 (0.3733 to 0.3768)	0.3829 (0.3812 to 0.3847)
SvO_2 (%)	0.005 (0.001 to 0.009)	1.008 (1.005 to 1.012)	0.7782 (0.7748 to 0.7816)	0.7706 (0.7672 to 0.7740)	0.7858 (0.7824 to 0.7892)
SaO_2 (%)	-0.007 (-0.012 to -0.002)	1.006 (1.003 to 1.010)	0.9614 (0.9605 to 0.9623)	0.9594 (0.9585 to 0.9603)	0.9634 (0.9625 to 0.9643)

PaO_2: Partial Pressure of Oxygen; $PaCO_2$: Arterial Partial Pressure of Carbon Dioxide; SvO_2: Mixed Venous Oxygen Saturation; SaO_2: Arterial Oxygen Saturation

for disposable cuvettes, enhances the ability of surgical teams to respond promptly to fluctuations in blood gas parameters [7]. This capability not only improves patient safety but also aligns with updated European guidelines that prioritize continuous monitoring in perfusion practice [8]. The provision of continuous data can contribute to more refined adjustments in CPB management, potentially improving patient outcomes by maintaining more stable physiological conditions.

The implications extend beyond the immediate surgical period; continuous data can provide insight into postoperative management, allowing for better monitoring and early intervention if necessary. The reduction in manual sampling also minimizes the workload on clinical staff, allowing them to focus on other critical aspects of patient care. This integrated approach to patient management underscores the potential for improved procedural efficiency and enhanced safety.

Economic and practical considerations

An important advantage of the QPS is its economic efficiency. By eliminating the use of disposable cuvettes and integrating non-invasive probes directly into the CPB circuit, the system reduces the recurrent costs associated with traditional BGA. Additionally, the streamlined setup of the QPS minimizes procedural complexities, thereby enhancing workflow efficiency in the operating room. These factors collectively contribute to the practical feasibility of adopting the QPS in clinical settings [7, 8]. The cost savings associated with reduced reliance on disposable materials and the minimization of manual labor may result in significant budgetary benefits for healthcare institutions. Over time, this could allow for the reallocation of resources towards other critical aspects of patient care, further enhancing the overall quality of the medical services provided. The long-term sustainability of using the QPS could position it as a preferred choice in cardiac surgery centers looking to optimize both clinical outcomes and cost-efficiency. Maintenance typically occurs on an annual basis, and costs can vary significantly depending on individual commercial agreements.

Limitations and future research

Despite the promising results, this study has limitations that should be acknowledged. The sample size, though sufficient to establish non-inferiority, was limited to 40 patients. Future research should aim to include larger and more diverse patient populations to confirm the generalizability of these findings. A broader study would help ascertain whether the accuracy of the QPS holds across different demographics and under various clinical conditions. Additionally, while the study demonstrated non-inferiority of the QPS compared to standard BGA, further investigations could explore the system's performance across different types of cardiac procedures and in patients with varying degrees of hemodynamic instability. Future studies could also assess the long-term reliability of the QPS under prolonged CPB durations and in more complex surgeries, such as combined valve and coronary procedures [9, 10]. Comparative studies that evaluate the QPS against other advanced CBGM systems currently available on the market would provide valuable insights into its relative strengths and potential areas for improvement [5]. Furthermore, integrating feedback from perfusionists and surgical teams regarding the usability and integration of the QPS into existing workflows could offer practical recommendations for optimizing its implementation.

Conclusions

In conclusion, this retrospective study has demonstrated that the QPS's high accuracy and reliability make it a valuable asset for continuous blood gas monitoring during CPB. Its clinical adoption holds the promise of

improving patient outcomes, enhancing safety, and fostering more efficient surgical workflows. The in-line, cuvette-free measurement offers economic and practical advantages, aligning with the updated European guidelines, and enhancing real-time clinical monitoring efficiency. However, further studies are necessary to strengthen and confirm these results across broader and more varied clinical scenarios, for these reason as recommended by the manufacturers, the quantum monitoring system should only be used as a trending device.

Abbreviations

CPB	Cardiopulmonary Bypass
BGA	Blood Gas Analyzer
CBGM	Continuous Blood Gas Monitoring
QPS	Quantum Perfusion System
QWS	Quantum Workstation System
QVM	Quantum Ventilation Module
DO_2i	Indexed Oxygen Delivery
VO_2i	Indexed Oxygen Consumption
VCO_2i	Indexed Carbon Dioxide Production
SvO_2	Mixed Venous Oxygen Saturation
PaO_2	Partial Pressure of Oxygen
PCO_2	Partial Pressure of Carbon Dioxide
CLIA	Clinical Laboratory Improvement Amendments

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BH, ABH, AAS and RAK participated in manuscript writing. DS and SY participated in conception and manuscript vision. IM and AH participated in support and conception.

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Data availability
No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate
This study was conducted in accordance with the Declaration of Helsinki and was approved by the Internal Ethical Institutional Board.

Consent for publication
Patient consent was waived due to the retrospective nature of the study.

Competing interests
The authors declare no competing interests.

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