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Clinical validation of pulse contour analysis cardiac output: a systematic review and metanalysis

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ADMINISTRATIVE INFORMATION

Support - Anesthesiology Department.

Review stage at the time of initial registration - Data analysis.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 17 November 2026 and was last updated on 17 November 2026.

INTRODUCTION

Review question / Objective To evaluate the agreement between pulse contour analysis (PCA)-based cardiac output monitoring devices (PiCCO, LiDCO, and FloTrac) and the reference standard of intermittent bolus thermodilution via a pulmonary artery catheter (PAC) in adult perioperative and critical care patients, using pooled Bland–Altman parameters and percentage error derived from a parameter-based meta-analytic framework. Secondary objectives include exploring device-specific, generation-specific, and clinical context-specific performance.

Rationale Accurate cardiac output (CO) monitoring is essential in complex surgical and critically ill patients, guiding hemodynamic therapy and interpretation of hypotension. While bolus thermodilution via a pulmonary artery catheter (PAC) remains the reference standard, its invasiveness has driven adoption of minimally invasive pulse contour analysis (PCA)-based devices — including PiCCO, LiDCO, and FloTrac. However, clinical validation of these devices has been inconsistent, and adoption has often relied on industry-sponsored education rather than independent evidence.

Existing systematic reviews are outdated relative to the current volume of validation literature, the latest generations of device algorithms, and modern meta-analytic methods for method-comparison studies. This review will synthesize available validation data using a rigorous parameter-based framework that preserves the statistical structure of Bland–Altman analyses, providing pooled estimates of bias, precision, and percentage error across devices, generations, and clinical contexts. The goal is to offer clinicians the most comprehensive independent evidence to guide rational adoption of PCA-based CO monitoring.

Condition being studied Adults population in any peri-operative or critical care setting.

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METHODS

Search strategy A comprehensive electronic search was performed across MEDLINE, Embase, the Cochrane Central Register of Controlled Trials (CENTRAL), and Web of Science. The search combined descriptors for minimally invasive CO monitoring technologies (e.g., PiCCO, LiDCO, FloTrac, pulse contour analysis) and PAC-based thermodilution (e.g., pulmonary artery catheter, Swan-Ganz, thermodilution). Outcome terms were intentionally not be included to avoid narrowing results. The complete database-specific strategies will be provided in a Supplementary Material. Additional articles were identified through reference searching of included studies and relevant reviews.

Participant or population Eligible studies include adults (≥18 years) in any perioperative or critical care setting, evaluate at least one commercially available PCA-based device (PiCCO, LiDCO, or FloTrac/Vigileo), and use intermittent bolus thermodilution via a pulmonary artery catheter as the reference standard.

Intervention Monitoring of cardiac output using pulse contour analysis.

Comparator Monitoring of Cardiac Output using Pulmonary Artery catheter bolus thermodilution.

Study designs to be included Method comparison, diagnostic accuracy studies, randomized and non randomized control trials.

Eligibility criteria Inclusion Criteria: Studies Onclude adults (≥18 years) in any perioperative or critical care setting, evaluate at least one commercially available PCA-based device (PiCCO, LiDCO, or FloTrac/Vigileo), and use intermittent bolus thermodilution via a pulmonary artery catheter as the reference standard.
Exclusion Criteria: – Pediatric populations; animal studies; no cardiac assist devices (IABP, Impella)
– Other pulse contour analysis than PiCCO, LiDCO, FloTrac/Vigileo or other non-invasive technologies (e.g., esCCO, ModelFlow, PRAM, Hemac), experimental prototypes
– Other reference methods than intermittent thermodilution, such as transpulmonary thermodilution or continuous thermodilution PAC devices
– Studies not presenting absolute values for Bland–Altman agreement analysis between index device and PAC.
– Conference abstracts, case reports and series, narrative or systematic reviews, editorials, letters.

Information sources A comprehensive electronic search was performed, across MEDLINE, Embase, the Cochrane Central Register of Controlled Trials (CENTRAL), and Web of Science.

Main outcome(s) The primary endpoint of this review will be the pooled percentage error of the combined PCA- based devices (test) and the the intermittent bolus thermodilution via a Pulmonary Artery Catheter (PCA) (reference standard). Main metrics will include Percentage error (PE), bias and Limits of Agreement (LOA).

Additional outcome(s) Exploratory secondary outcomes will include device- specific performances, use of statistical correction for multiple measurements, and context-specific analyses across clinical environments suggested by current evidence: hyperdynamic state, high level of vascular resistance, and reduced left ventricular ejection fraction.Exploratory secondary outcomes will include device- specific performance, calibration-specific performance, device-generation comparisons, and context-specific analyses across clinical environments or patient phenotypes suggested by current literature, such as hyperdynamic state, high level of vascular resistance, and reduced left ventricular ejection fraction.

Data management All search results were imported into Covidence for deduplication and systematic screening. Title and abstract screening were performed independently by two reviewers who resolved disagreements through discussion. Full-text review was conducted independently by two other reviewers with discrepancies adjudicated by a third reviewer. Reasons for exclusion at the full-text stage will be recorded and are presented in the PRISMA flow diagram.
Data extraction was performed using a structured template and entered into a cloud-based spreadsheet. For each study, we recorded authorship, publication year, country, study period, and type of device studied, including device generation when available. Patient and sample characteristics were extracted, including the number of participants, total number of paired CO measurements, clinical setting (for example, cardiac surgery, liver transplantation, bariatric surgery, or septic shock). We also recorded available cardiac function markers, including left ventricular ejection fraction, and procedural information such as arterial catheter site and thermodilution procedures followed with PAC.

Quality assessment / Risk of bias analysis Quality assessment and risk of bias was assessed

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using the QUADAS-3 tool, which is widely recommended for diagnostic accuracy and method-comparison studies. This tool evaluated potential biases in patient selection, conduct and interpretation of the index test, conduct and interpretation of the reference standard, and the flow and timing of measurements. Applicability concerns in each domain were also assessed. Two reviewers independently evaluated the methodological quality of included studies, resolving any differences by consensus.

Strategy of data synthesis All statistical analyses will be conducted using R version 4.4.2 (The R Foundation, 2023). Data management and cleaning will be performed using the dplyr and tidyr packages, and meta-analysis will be conducted using metafor and meta. Heterogeneity across studies will be quantified using the between-study variance (τ2) and the I2 statistic. The primary analysis will follow a parameter-based meta-analytic framework described by Tipton and Shuster, which directly models study-level bias and variance using random-effects models. This method preserves the statistical structure of the Bland–Altman approach and avoids mathematical distortions inherent in pooling study-level percentage error values.

Subgroup analysis Subgroup analyses were performed to explore differences among device families (PiCCO, LiDCO, FloTrac), among device generations (such as third- versus fourth-generation FloTrac algorithms), among clinical contexts (e.g., cardiac versus hepatic surgery), and between populations with preserved versus impaired left ventricular function.

Sensitivity analysis When repeated measurements within the same patients cannot be fully resolved, or when a study reports only combined repeated-measure data, we will use sensitivity analyses based on the intraclass correlation coefficient to estimate the effective sample size. For the trending analyses, the exclusion zone is not always clearly defined. When a study does not explain how its zone was set, we will record the threshold used or flag it as unclear. Similarly, whenever assumptions or reconstructions were needed for trending data, we will document these choices and assess their effect in subsequent sensitivity analyses.

Language restriction Yes- English.

Country(ies) involved United States.

Keywords Pulmonary Artery Catheter; Cardiac Output; LIDCO; Flotrac; PICCO; Thermodilution; Pulse Contour Analysis; Validation.

Dissemination plans The findings of this systematic review will be published in a peer-reviewed, open-access journal to ensure broad accessibility, and reported in accordance with the PRISMA 2020 guidelines. Results will also be presented at relevant national and international conferences in anesthesiology, critical care, and perioperative medicine. To support translation into clinical practice, accessible summaries of the key findings will be shared with relevant professional societies and clinical networks.

Contributions of each author

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