

Comparison of two continuous non-invasive haemodynamic monitoring techniques in the perioperative setting

Jonė Jackevičiūtė¹,

Greta Kraujalytė²,

Inna Jaremko¹,

Vilija Stremaitytė¹,

Jūratė Gudaitytė^{1,2*}

¹Department of Anaesthesiology,
Medical Academy,
Lithuanian University of Health Sciences,
Lithuania

²Medical Academy,
Lithuanian University of Health Sciences,
Kaunas, Lithuania

Background. The aim of the study was to identify the accuracy of and agreement between two non-invasive haemodynamic monitoring techniques in the perioperative setting – thoracic electrical bioimpedance (TEB) and Edwards Lifesciences ClearSight system (CS).

Materials and methods. The study included ten patients. Parametric quantitative data were expressed as mean \pm SD. The Shapiro-Wilk test was used to test the normality of the distributions. A linear regression model was used to measure the strength of the linear relationship between TEB and CS. Bland-Altman analysis was performed to assess the mean difference, precision, and the limits of agreements (LOA). The Critchley and Critchley method was used to calculate the percentage error (PE), and if $<30\%$, it was considered clinically acceptable.

Results. Ten patients were involved in our study. The mean cardiac output (CO) with TEB was 6.15 ± 1.14 L/min vs. 4.78 ± 1.40 L/min with CS ($p < 0.01$). The relationship was significant ($n = 144$; $r^2 = 0.7$; $p < 0.01$). The mean bias, LOA, and PE were 1.37 ± 1.01 L/min, 3.35 L/min and -0.61 L/min and 36.22% , respectively. The mean stroke volume index (SVI) with TEB was 48.64 ± 9.8 ml/beat/m² vs. 37.12 ± 9.14 ml/beat/m² with CS ($p < 0.01$). The relationship was significant ($n = 144$; $r^2 = 0.65$; $p < 0.01$). The mean bias, LOA, and PE were 11.52 ± 7.92 ml/beat/m², 27.04 ml/beat/m² and -4 ml/beat/m² and 36.19% .

Conclusions. The two methods of non-invasive haemodynamic monitoring are not compatible in the perioperative setting. However, the CS system has more advantages in terms of continuity and simplicity of monitoring, while measurements of TEB are interrupted by electrocautery.

Keywords: haemodynamic monitoring, cardiac output, non-invasive, intraoperative, pulse wave analysis, bioimpedance

* Correspondence to: Jūratė Gudaitytė, Department of Anaesthesiology, Medical Academy, Lithuanian University of Health Sciences, Eivenių St. 2, Kaunas 50009, Lithuania.
Email: jurate.gudaityte@kaunoklinikos.lt

INTRODUCTION

Approximately 27% of high-risk surgical patients develop at least one of postoperative complications after elective surgery. Postoperative cardiovascular complications have a higher mortality rate in comparison with other types of complications (1). Standard anaesthesia monitoring provides core information about patient oxygenation, ventilation, circulation, and temperature (2). Conventional assessment of haemodynamics is of key importance; however, it is incapable of evaluating patients' volume status (3). For instance, normotension might present in patients with hypovolemia due to increased systemic vascular resistance. Moreover, the absence of tachycardia in mild to moderate hypovolemic patients suggests that basic haemodynamic monitoring lacks early sensitivity in the case of hypovolemia (4–5).

On the other hand, excessive fluid therapy increases the risk of pulmonary oedema and may cause acid-base derangements (6). Therefore, the Enhanced Recovery Partnership programme recommends optimal intraoperative fluid management to avoid hypovolemia or fluid excess (7). The main goal of optimal fluid management during surgery is adequate tissue oxygenation (6). Oxygen delivery depends on the cardiac output and arterial oxygen content rather than on the arterial blood pressure, therefore advanced haemodynamic monitoring takes a pivotal role in providing additional information about the patient (8).

Previously goal-directed fluid therapy was based on invasive haemodynamic monitoring, for example, transpulmonary thermodilution or pulmonary artery catheter (PAC) (9). Unfortunately, invasive monitoring techniques have serious complications associated with cannulation of the vessel, while non-invasive monitoring provides detailed tracking without such complications (10). Most of the non-invasive systems provide continuous measurements, however, each monitor has a different mechanism of action leading to advantages and disadvantages associated with it (11). The ClearSight system uses inflatable finger cuff around the middle phalanx to measure the finger arterial pressure, which is reconstructed into a brachial artery waveform (12). Bioelectrical impedance (TEB) relies on the application of a constant voltage high-frequency low-amplitude electrical current across the thorax and its comparison with the detected voltage. It is assumed that fluctuations in

the signal are based on the changes in intrathoracic blood volume (13). The aim of the study was to identify the accuracy and agreement of two non-invasive haemodynamic monitoring techniques in the perioperative setting: thoracic electrical bioimpedance and Edwards Lifesciences ClearSight system.

MATERIALS AND METHODS

Patients

After obtaining an approval from Kaunas Regional Biomedical Research Ethics Committee, the prospective observational study was conducted at the Department of Anaesthesiology, Kauno Klinikos Hospital of the Lithuanian University of Health Sciences from 1 December 2017 to 1 March 2018.

The inclusion criteria were as follows:

- high-risk surgical patients;
- >30 years of age;
- major elective colorectal surgery;
- the duration of surgery >120 min.

Exclusion criteria were:

- cardiac arrhythmias;
- the patient's weight <55 kg or >140 kg;
- the patient's refusal to participate in the study.

Anaesthesia

The basic monitoring was used for all of the patients: three-lead electrocardiogram, pulse oximetry, non-invasive arterial blood pressure taken every 5 min, and temperature monitoring. All of the patients were under general anaesthesia. The induction of anaesthesia was made using propofol (2–2.5 mg/kg), fentanyl (1–2 mcg/kg), and neuromuscular block was induced by atracurium (0.4–0.5 mg/kg). All patients were intubated, mechanically ventilated with adequate respiratory rate to maintain end-tidal carbon dioxide (ETCO₂) between 35 and 45 mmHg, and anaesthesia was maintained with inhalation of sevoflurane.

Haemodynamic measurements

Both non-invasive haemodynamic monitors were attached to the patient prior to the induction of anaesthesia. Anthropometric parameters were entered into both devices for the accuracy of measurements. The CS system was applied by wrapping an appropriate size disposable finger cuff with integrated photoplethysmogram around the middle phalanx. Simultaneously, eight TEB electrodes were placed according

to the manufacturer's instructions: four on the base of the neck, the rest of the electrodes in the midaxillary line at the xiphoid process level. CS and TEB parameters were recorded every 5 min during surgery. Time-specific points were collected: baseline values before the induction of anaesthesia, followed by 19 during surgery and one after the extubation.

During 21 measuring time points: 210 measurements were collected from the CS system and 164 from the TEB. Of TEB measurements, 46 were lost due to electrocautery and therefore 46 pairs of measurements from CS were excluded.

Statistical analysis

Data were analysed using SPSS software v.22.0. Parametric quantitative data were expressed as mean \pm standard deviation (SD). The Shapiro-Wilk's test was used to test the normality of the distributions. The linear regression model was used to measure the strength of a linear relationship between TEB and CS. Bland-Altman analysis was performed to assess the mean difference, precision, and limits of agreements (LOA). (The mean difference represents the accuracy of the devices, while the LOA represents their precision.) Limits of agreement were calculated using the formula: mean difference $\pm 1.96 \times$ standard deviation. Critchley and Critchley method was

used to calculate the percentage error (PE). PE was calculated using the formula: standard deviation of the mean difference multiplied by two and divided by the mean of the measurements, and if the result $< 30\%$, it was clinically acceptable.

RESULTS

After written informed consent was obtained, ten patients (sex ratio: five male, five female; mean age 65 ± 15 years; weight 76 ± 13 kg; height 172 ± 5 cm; BMI 25.5 ± 4.5 kg/m²) were involved in our study. Four patients were ASA II, five – ASA III, and one – ASA IV. Ten pairs of data were obtained before the induction of anaesthesia: the mean CO with TEB 6.12 ± 1.96 L/min vs 6.04 ± 2.48 L/min with CS ($p > 0.05$). No correlation was found between CO TEB and CO CS ($n = 10$; $r^2 = 0.33$; $p = 0.358$). One hundred and forty-four pairs of data were collected during the anaesthesia: the mean CO with TEB was 6.15 ± 1.14 L/min vs 4.78 ± 1.40 L/min with CS ($p < 0.01$). The relationship was significant ($n = 144$; $r^2 = 0.7$; $p < 0.01$). The mean bias, LOA and PE were 1.37 ± 1.01 L/min, 3.35 L/min and -0.61 L/min and 36.22%, respectively. The linear regression model and Bland-Altman analysis are shown in Figs. 1 and 2. The mean CI with TEB

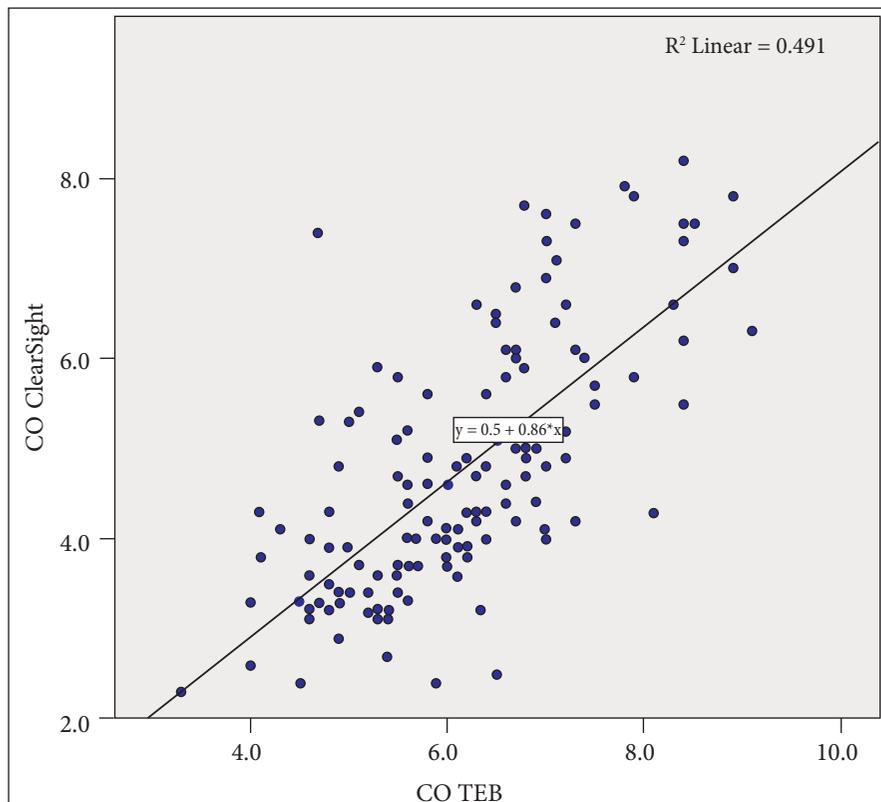


Fig. 1. Linear regression analysis during anaesthesia between CO TEB and CO ClearSight (L/min)

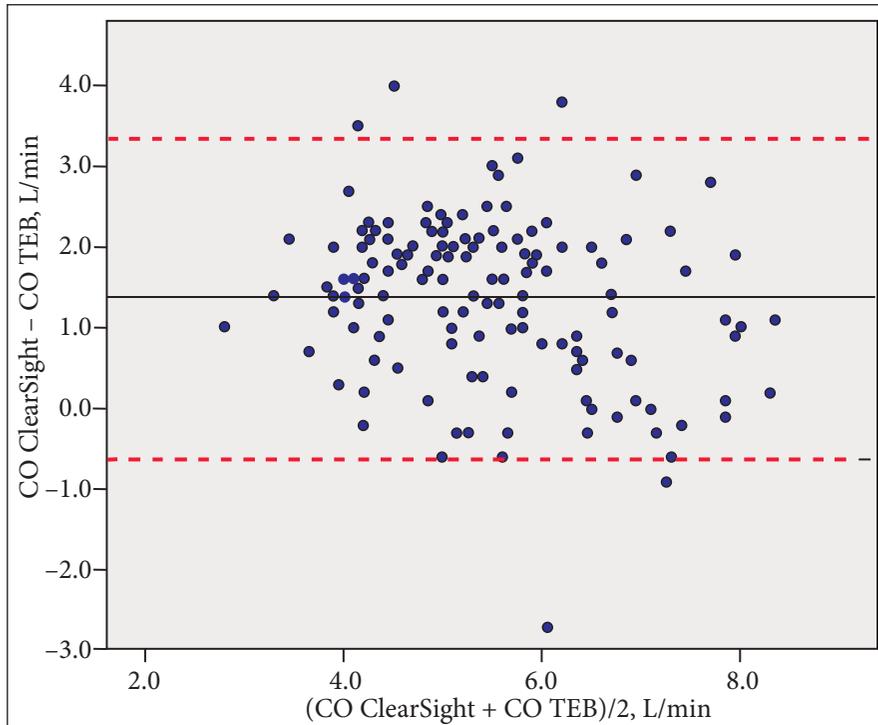


Fig. 2. Bland-Altman analysis during anaesthesia. The mean bias 1.37 L/min, LOA 3.35 L/min and -0.61 L/min. PE 36.22%

was 3.27 ± 0.68 L/min/m² vs 2.53 ± 0.79 L/min/m² with CS ($p < 0.01$). The relationship was significant ($n = 144$; $r^2 = 0.78$; $p < 0.01$). The mean bias, LOA and PE were 0.740 ± 0.50 L/min/m², 1.72 L/min/m² and -0.24 L/min/m² and 33.79%, respectively. The mean SV with TEB was

91.69 ± 15.91 ml/beat vs. 70.35 ± 15.83 ml/beat with CS ($p < 0.01$). The relationship was significant ($n = 144$; $r^2 = 0.54$; $p < 0.01$). The mean bias, LOA and PE were 21.34 ± 15.15 ml/beat, 51.03 ml/beat and -8.35 ml/beat and 36.65%, respectively (Figs. 3 and 4). The mean SVI with TEB was

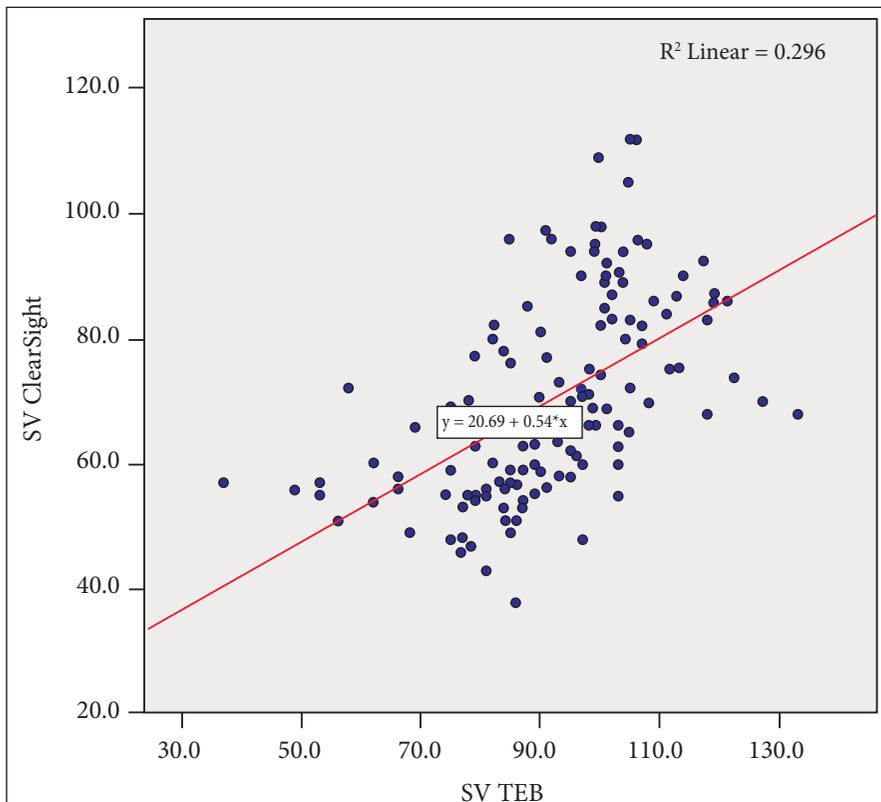


Fig. 3. Linear regression analysis during anaesthesia between SV TEB and SV ClearSight (ml/beat)

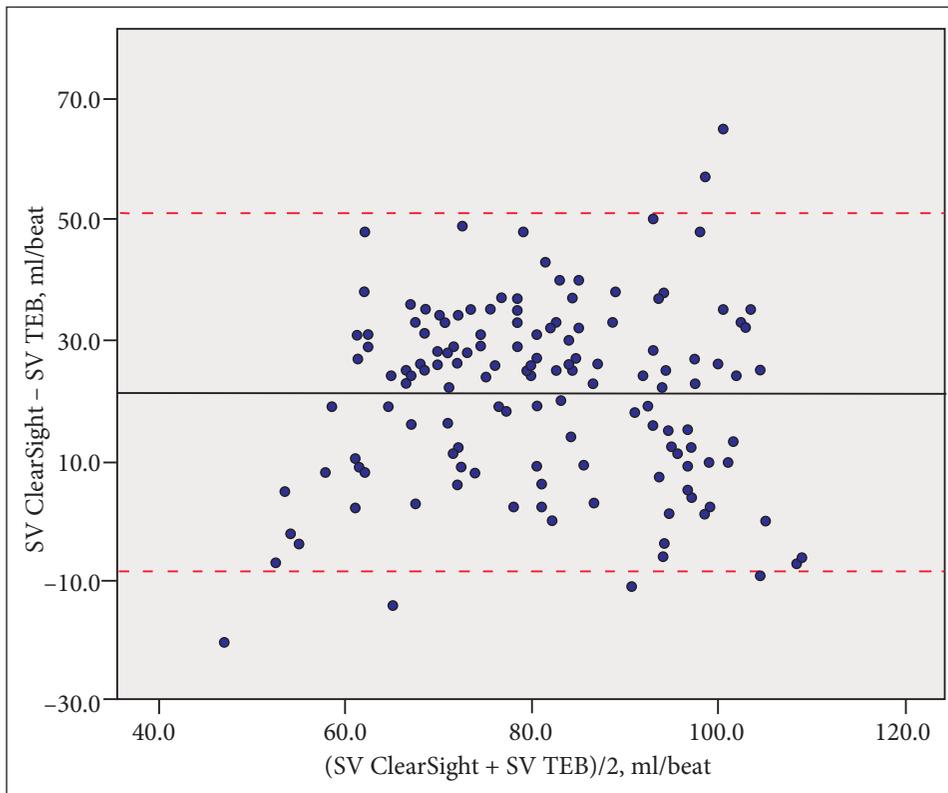


Fig. 4. Bland-Altman analysis during anaesthesia. The mean bias 21.34 ± 15.15 ml/beat, LOA 51.03 ml/beat, and -8.35 ml/beat. PE 36.65%

48.64 ± 9.8 ml/beat/ m^2 vs. 37.12 ± 9.14 ml/beat/ m^2 with CS ($p < 0.01$). The relationship was significant ($n = 144$; $r^2 = 0.65$; $p < 0.01$). The mean bias, LOA and PE were 11.52 ± 7.92 ml/beat/ m^2 , 27.04 ml/beat/ m^2 and -4 ml/beat/ m^2 and 36.19%, respectively.

DISCUSSION

No acceptable agreement was found between TEB and CS system throughout all parameters. The plausible cause of these results may be due to a different device reaction to identical clinical circumstances, for example, electrocautery. However, our results do not provide information that one device is superior to the other. Each technology gives specific value for the individual population of the patients. For example, the volume clamp method is easy to apply and use in the perioperative setting, however, peripheral oedema and severe vasoconstriction impair the quality of the received information (14). On the other hand, the accuracy of the TEB is highly determined by the position of the electrodes and fluid status in the thoracic compartment (15).

In addition, we did not use an invasive haemodynamic device, for example, PAC, as a reference

technology. However, recent literature suggests that PAC provides semi-continuous cardiac output monitoring combined with less accurate detection of the patients' volume status (16). Non-invasive haemodynamic devices cannot provide absolute cardiac output appraisal, but it can record the dynamic changes in CO (17). The ability of these devices to reveal the trends is especially convenient for goal-directed fluid therapy (18).

The place for the non-invasive haemodynamic monitoring in the clinical setting remains debatable. For instance, clinicians use basic haemodynamic monitoring for low-risk surgical patients, however, high-risk non-cardiac surgical patients with impaired vascular tone require invasive haemodynamic monitoring devices (19). Nevertheless, the new era of personalised care medicine will increase the requirements for monitoring patients' haemodynamic status and homeostasis, even of the healthier ones (20). The preoperative assessment of the volume status might provide additional information about the targets for perioperative patient management or can be used for haemodynamic optimisation of the patient before surgery (21).

Some limitations of our study should be taken into consideration. First of all, we studied only

ten patients during the perioperative period. Secondly, we did not have any invasive haemodynamic monitoring technique as a reference. Furthermore, we lost some of the data due to electrocautery, which may have affected our results. Therefore, the continuity of the measurement and the ability to track CO changes are the main preferable features of the haemodynamic monitoring device, even though the collected data is less accurate.

CONCLUSIONS

Neither of the methods of advanced non-invasive haemodynamic monitoring are compatible in the perioperative setting. However, the ClearSight system has more advantages in terms of continuity and simplicity of monitoring, while measurements of TEB are frequently interrupted by electrocautery.

Received 28 January 2019

Accepted 26 March 2019

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21. Non-Invasive Hemodynamic Monitoring for Hemodynamic Management in Perioperative Medicine.

Jonė Jackevičiūtė, Greta Kraujalytė, Inna Jaremko, Vilija Stremaitytė, Jūratė Gudaitytė

DVIEJŲ NEINVAZINIŲ TESTINĖS HEMODINAMIKOS STEBĖSENOS PRIETAISŲ PALYGINIMAS PERIOPERACINIŲ LAIKOTARPIU

Santrauka

Įvadas. Tyrimo tikslas – nustatyti dviejų neinvazinių hemodinamikos monitoravimo technikų tikslumą ir suderinamumą, lyginant bioimpedansą ir Edwards Lifesciences ClearSight sistemą.

Tyrimo medžiaga ir metodai. Tyrime dalyvavo 10 pacientų. Kiekybiniai duomenys pateikti kaip aritmetiniai vidurkiai su standartiniu nuokrypiu. Skirstinio normalumui patikrinti naudotas Šapiro-Vilko testas. Tarpusavio ryšio stiprumui tarp bioimpedanso ir

ClearSight įvertinti pasitelkta linijinė regresinė analizė. Bland-Altman analizė panaudota nustatant vidutinių skirtumą, tikslumą ir sutarties ribas. Critchley ir Critchley metodas buvo naudojamas apskaičiuojant procentinę paklaidą. Jei paklaida mažesnė nei 30 %, laikyta, kad ji kliniškai priimtina.

Rezultatai. Vidutinis širdies minutinis tūris išmatuotas bioimpedansu; $6,15 \pm 1,14$ l/min., CS $4,78 \pm 1,40$ l/min. ($p < 0,01$). Nustatytas vidutinio stiprumo ryšys tarp minutinio širdies tūrio matavimų ($n = 144$; $r^2 = 0,7$; $p < 0,01$). Vidutinis skirtumas – $1,37 \pm 1,01$ l/min., sutarties ribos nuo $3,35$ l/min. iki $-0,61$ l/min., paklaida – 36,22 %. Vidutinis sitolinio tūrio indeksas išmatuotas bioimpedansu: $48,64 \pm 9,8$ ml/susitraukimui/m² ir CS $7,12 \pm 9,14$ ml/susitraukimui/m² ($p < 0,01$). Nustatytas vidutinio stiprumo ryšys tarp sistolinio tūrio indekso matavimų ($n = 144$; $r^2 = 0,65$; $p < 0,01$). Vidutinis skirtumas – $11,52 \pm 7,92$ ml/susitraukimui/m², sutarties ribos: $27,04$ ml/susitraukimui/m² – 4 ml/susitraukimui/m² ir paklaida 36,19 %.

Išvados. Šie neinvaziniai hemodinamikos stebėjimo metodai perioperaciniu laikotarpiu yra nesuderinami. Tačiau ClearSight pranašesnis dėl metodo paprastumo ir tęstinumo, o bioimpedanso matavimams įtaką darė elektrinio peilio naudojimas.

Raktažodžiai: hemodinamikos stebėseną, minutinis širdies tūris, neinvazinis, intraoperacinis, pulso bangos analizė, bioimpedansas