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Accuracy, Precision and Trending Ability of Electrical Cardiometry *vs*. Esophageal Doppler in Major Abdominal Surgery: A Prospective, Observational Study

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Abstract

Background: This study was performed to evaluate the accuracy, precision and trending ability of Cardiac Output (CO) measurements using the Aesculon™ bioimpedance electrical cardiometry (Aesc) compared to the CardioQ™ (CardioQ) esophageal Doppler technique at different time points during the perioperative period in major abdominal surgery.

Methods: We performed a prospective observational study in 50 patients, physical status ASA 1-4, referred for major abdominal surgery. After induction of anesthesia the Esophageal Doppler probe was placed and the bioimpedance device was connected. At eight time points (T) before, during and after surgery measurements of Cardiac Index (CI), and standard hemodynamics were performed. CI was measured simultaneously by thoracic bioimpedance and esophageal Doppler. The primary objective was to assess agreement of the thoracic bioimpedance method compared to the transesophageal Doppler method for Cardiac Index (CI) and the secondary objective was to determine if the surgical incision would have effect on bioimpedance measurements. Main analysis was performed using Bland Altman analysis, polar plot methodology, and four-quadrant plot.

Results: Data of all 50 patients were suitable for analysis. CI obtained with the CardioQ™ and Aesculon™ ranged from 1.2 to 7.6 L min^{-1} and 0.8 and 5.6 L min^{-1} respectively.

Bland-Altman analysis showed a bias between CI_{bio} and $CI_{cardioQ}$ of - 1.0 liter min^{-1} m^{-2}, with LOA of [-3.02 to 0.89] liter min^{-1} m^{-2}. The percentage error between the two techniques was greater than 30% at every time point. Polar plot methodology and 4-quadrant analysis showed poor trending ability. Skin incision during surgery had no effect on the difference between the two measurement techniques.

Conclusion: Esophageal Doppler and bioimpedance technology for CO/CI measurements are not interchangeable in patients undergoing major abdominal surgery. The surgical incision has no effects on bioimpedance measurements.

Keywords: Cardiac output; Electrical impedance; Electrical cardiometry; Esophageal Doppler monitor; Accuracy; Precision

Abbreviations

CO: Cardiac Output; CI: Cardiac Index; T: Time point; CardioQ: CardioQ™; Aesc: Aesculon; SV: Stroke Volume; PE: Percentage Error; SPSS: Statistical Package for Social Science; LOA: Limits of Agreement

Background

Considering the increasing age of the surgical population with accompanying co-morbidity, it is likely that monitoring of CO and CI will be increasingly important or even mandatory for optimal clinical decision-making and good clinical practice during the peri-operative period [1,2]. The availability of additional patient data on blood flow, when used in a goal directed therapy concept, contributes to a reduction of complication rates and hospital length of stay according to evidence

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gathered during the last decade [1,3-7].

In the literature it is proven that discrepancies in predicting and estimating hemodynamics accurately, based on routine parameters and clinical evaluation exist [8]. Even if physicians were confident of their estimates, there was no correlation between confidence and accuracy [9].

Measuring CO by thermodilution using the pulmonary artery catheter is the most regularly used clinical reference technique up till now [10-12]. However, due to risks associated with the invasiveness and unproven outcome benefit, several less or even non-invasive methods have been developed [2,13]. The ideal technique should be reliable, noninvasive, continuous, cost-effective, user-independent, and should have fast response time enabling rapid detection of hemodynamic changes [14].

Hemodynamic optimalization using Doppler-derived CO measurements has a proven benefit to the patient and leads to a decrease in perioperative morbidity and in postoperative length of stay [1,7,15-17].

Thoracic bio impedance is one of the least invasive methods for the assessment of CO and is based on the theory that the thorax is a cylinder filled with blood. The technology has been described in detail elsewhere, briefly according to Ohm's law R=V/I, this model assumes that the impedance of thoracic tissue is parallel to that of blood. Blood related impedance changes repeat themselves with every heart beat and are linked to cardiac activity [29].

To improve the reliability of impedance measurements, the basic equation, was modified by Bernstein and Osypka, so that the maximum rate of change of impedance is related to the peak aortic blood acceleration [18]. This method, used in the Aesculon™ device, is initially described as electrical cardiography. The bioimpedance method performed well in clinical studies in young healthy volunteers. However, reliability in critically ill patients and in peri-operative use is not proven and the available literature contains inconsistencies [19-24].

Also, systematic reviews and meta-analysis stated that there is a problem with interchangeability, accuracy and precision of non-invasive cardiac output measurement techniques [25,26].

Most available studies concerning the clinical use of electrical cardiometry are within neonatal and pediatric populations [27,28]. In the present study, adult patients undergoing high risk surgery were included. Moreover, until now it is unclear whether interruption of the skins integrity by a surgical incision could be a source of error.

The aim of the present study is to assess agreement and precision between transesophageal Doppler and thoracic bioimpedance technique, measuring peri-operative hemodynamic performance in high risk surgical patients.

Materials and Methods

Study design

The study protocol was approved by the institutional review board of the Maastricht University Medical Centre+ (MEC 09-4-052.2) and written informed consent was obtained from every patient prior to surgery. A prospective observational study was performed to assess agreement of the thoracic bioimpedance method compared to the transesophageal Doppler method for CI measurement in 50 adult patients planned for elective major abdominal surgery. Exclusion criteria were nasal, pharyngeal, laryngeal or esophageal pathologies, bleeding disorders, cardiac arrhythmias, age <18 years, or no informed consent. All patients were treated according with institutional guidelines.

Measurements protocol

After arrival in the operating theatre, standard monitoring including heart rate, (invasive or non-invasive) blood pressure and O_2 saturation was installed. Anesthesia was induced according to local protocols. If indicated, patients received a Thoracic Epidural Catheter (TEC) for per- and post-operative pain relief. Effectiveness of the TEC was evaluated. Hereafter four standard electrocardiogram electrodes were placed according to the manual of the Aesculon™ (Osypka Medical, Berlin, Germany) on the left part of the neck and on the left part of the thorax at the level of the process us xyphoideus. The Aesculon™ monitor was connected to the electrodes for continuous display of bioimpedance Cardiac Index (CI_{BIO}). Subsequently the nasal probe (I_2C 72) of the CardioQ™ (Deltex Medical, Chichester, United Kingdom) was inserted through one of the nostrils and connected to the CardioQ™ monitor in order to continuously measure Doppler Based Cardiac Index (CI_{DOP}). The Doppler signal was optimized to reach the best possible signal and the curve was optimized before every measurement by an experienced user not involved in the clinical care of the individual patient. Both devices were installed and adjusted to the individual patients using weight, length, sex and age.

To exclude the possibility of incorrect measurements during rapid fluid infusions and hemodynamic instability, measurements of CI_{DOP} and CIBIO were performed only during hemodynamically stable conditions, and during normothermia.

We used the mean of two measurements of continuous CI. No correction for repeated measurements were applied as we analyzed the results per time point separately and assumed the measurements to be independent due to extensive fluctuations.

Measurements were performed at eight time points (T) during and after surgery: After induction (T1), after skin incision (T2), during surgery at random in a stable condition (T3, T4), after skin closure (T5), just before extubation (T6), 30 min (T7) and 60 min (T8) after arrival on the recovery ward. In addition to CI heart rate, arterial blood pressure and body temperature were registered simultaneously. Nasopharyngeal body temperature was measured during T1 to T6 and at the recovery temperature was taken by infrared ear measurement.

Statistical analysis

Based on preliminary results /pilot data, for the power calculation a standard deviation was established at 1.0 for the difference between the (paired) CI measurements by bioimpedance and Doppler respectively. If the true mean difference is 0.5, 44 patients are needed to be able to reject the null hypothesis that the difference is zero with probability (Power) 0.9. The Type I error probability associated with this test of this null hypothesis is 0.05. To correct for loss to follow up an additional 6 patients were included, resulting in 50 patients in total.

Data were checked for normality using the Shapiro-Wilk test histograms (visually), including the difference between CI_{BIO} and CI_{DOP}. Descriptive analysis was performed using number (%) or mean ± SD. Differences between the absolute CI measurements were assessed using the paired t-test. Accuracy and precision of CI_{BIO} against CI_{DOP} at the various time points was assessed using Bland-

Table 1: Patient and surgery characteristics.

	Mean (sd)	Range
Age (years)	63.08 (14.56)	32 to 85
Heigth (m)	1.70 (8.23)	1.54 to 1.86
Weight (kg)	76.78 (17.76)	48 to 150
BMI (kg/m²)	26.44 (5.93)	18.29 to 50.7
	N	
ASA 1	15	
ASA 2	26	
ASA 3	7	
ASA 4	2	
Sex m/f	21/29	
Gastro-intestinal	21	
Liver	6	
Gynaecology	14	
Whipple/pancreatic	9	

SD: Standard Deviation; BMI: Body Mass Index; ASA: American Society of Anesthesiologists Physical Status Classification System; m: male; f: female

Altman analysis and plots showing the bias, Limits of Agreement (LOA), and Percentage Error (PE) [30,31].

CI_{BIO} and CI_{DOP} were considered interchangeable if the percentage error (PE) was <30%. In the formulas for the LOA and PE, a t-statistic of 2.02 was used at the various time points (N=50) and 1.97 for pooled data (N=400). To evaluate trending ability, four-quadrant plot and polar plot methodology was applied to changes in CI_{BIO} and CI_{DOP} between the time points [32,33]. Concerning polar plot analysis central zone data (<10% change) were excluded because they introduce statistical noise [32]. Angular bias is defined as the mean polar angle to the 0° line. The radial LOA's refer to the radial sector that contains 95% of the data points. Polar concordance represents the percentage data points the lie between ± 30°. In case of good trending ability, most of the data points are positioned within this 30° sector [32,34]. Trending ability of CIBIO was considered interchangeable with CIDOP if angular bias was between -5° and +5°, with radial LOA between -30° and +30°.

A p-value <0.05 was considered statistically significant and Bonferroni correction for multiple testing of the absolute differences at the eight time points was applied (p<0.05/8 measurements =0.006).

Statistical analysis was carried out using SPSS software (SPSS Inc. Chicago, IL, USA) and Excel, (Microsoft Corporation, Redmond, WA, USA).

Results

Fifty patients undergoing major abdominal surgery were included. The baseline characteristics are presented in (Table 1). The hemodynamic variables and temperatures are presented in (Table 2). CI varied between 0.8 to 5.6 (CI_{BIO}) and 1.2 to 7.6 $Lmin^{-1}$ (CI_{DOP}). CI_{BIO} and CI_{DOP} were significantly different at each point (p<0.001).

Five patients (10%) asked for removal of the nasally inserted Doppler probe during their stay on the recovery ward because of inconvenience. The probe was removed in these patients before the last measurement (T8). In two patients the probe was removed during operation. Reasons were the necessity of introducing a nasal-gastric tube, which could not be introduced through the free nasal orifice.

Differences were present at open abdomen (T2,3,4) and closed abdomen (T1,5,6,7,8) respectively, indicating non-interchangeability between both techniques independent of skin incision.

Bias between CIBIO and CIDOP was -1.07 liter min^{-1} m^{-2}, with LOA of [-3.02; 0.89] liter min^{-1} m^{-2} (Table 3). Visual assessment of the Bland-Altman plots (Figure 1); however shows that some agreement might be present at CI values between approximately 1.6 and 2.7 liter/min/m^2. At higher CI values, the spread in the differences between CI_{BIO} and CI_{DOP} rapidly increases, especially at T1, T4 and T7 (Figures 1B-1D).

The percentage error between CI_{BIO} and CI_{DOP} was above the 30% agreement limit at every time point, including the lower limit of the 95% confidence interval (Table 3).

Trending ability was assessed in 311 pairs of changes in CI (Figure 2). Polar plot analysis in 211 data pairs outside 10% exclusion zone showed an angular bias of -9.0°.

The radial LOA were - 61° to 54°. All values were outside the boundaries for acceptable trending ability. Polar concordance at 30° was 62%. These results were outside the boundaries for acceptable trending ability. 4-quadrant plot analysis also showed poor trending ability. Data pairs outside the 15% exclusion zone showed a concordance of only 77.1% (Figure 3).

Concerning postoperative pain treatment 82% of patients received a thoracic epidural catheter which was successful in 78% of patients. Patient Controlled Intravenous Analgesia (PCIA) was given in 14% and 4% had neither.

Discussion

The present study investigated as primary objective the accuracy, precision, and trending ability of thoracic impedance CO monitor (Aesculon™) versus esophageal Doppler monitor (CardioQ™) in

Table 2: Haemodynamic data Cardio Q *vs*. Aesc.

	T1	T2	T3	T4	T5	T6	T7	T8
MAP (valid 48, missing 2)	66.4 (16)	68.4 (13)	70.8 (11)	70.0 (10)	71.1 (12)	74.9 (14)	81.1 (18)	84.7 (18)
HR (valid 48, missing 2)	65 (14)	63 (13)	67 (10)	67 (12)	69 (13)	73 (15)	80 (15)	77 (14)
CVP (valid 13, missing 37)	11 (4.8)	13 (5.7)	11 (4.9)	9 (5.3)	11 (5.6)	12 (5.5)	5 (2.8)	4 (3.5)
CI Aesculon™ (valid 48, missing 2)	2.2 (0.8)	2.1 (0.7)	2.3 (0.8)	2.3 (0.8)	2.4 (0.9)	2.6 (1.0)	2.8 (0.9)	2.7 (1.0)
CI CardioQ™ (valid 48, missing 2)	3.1 (0.9)	3.0 (0.8)	3.4 (0.9)	3.3 (0.9)	3.6 (1.0)	3.7 (1.2)	4.0 (0.9)	3.9 (0.9)
Temp (valid 48, missing 2)	35.7 (0.6)	35.7 (0.5)	35.8 (0.5)	36.0 (0.5)	36.2 (0.5)	36.2 (0.5)	36.2 (0.6)	36.2 (0.6)

Mean (sd). MAP mean arterial pressure (mmHG), HR heart rate (beats min-1), CVP central venous pressure (mmHG), CI cardiac index (liters min-1 m-2), Temp body temperature (°C). Time point 1 (T1) prior to surgery, after induction of anesthesia; T2 after skin incision; T3 during surgery; T4 during surgery; T5 directly after skin closure; T6 prior to extubation; T7 30 min after arrival at recovery ward, T8 30 min after arrival at recovery ward

Table 3: Agreement results.

	Pooled		T1	T2	T3	T4	T5	T6	T7	T8
N	381		50	50	50	50	48	47	44	44
Bias (L min^{-1})	-1.07		-0.88	-0.94	-1.04	-1.02	-1.17	-1.15	-1.22	-1.16
CI bias (L min^{-1})	-0.97 to -1.17		-1.13 to -0.63	-1.18 to -0.71	-1.32 to -0.76	-1.31 to -0.73	-1.47 to -0.87	-1.51 to -0.80	-1.53 to -0.91	-1.46 to -0.85
LOA (L min^{-1})	-3.02 to 0.89		-2.67 to 0.91	-2.60 to 0.71	-3.01 to 0.93	-3.06 to 1.03	-3.26 to 0.93	-3.58 to 1.27	-3.24 to 0.81	-3.16 to 0.85
CI lower LOA (L min^{-1})	-3.19 to -2.85		-3.10 to -2.24	-2.30 to -2.20	-3.49 to -2.53	-3.56 to -2.57	-3.78 to -2.74	-4.18 to -2.97	-3.77 to -2.72	-3.68 to -2.64
CI CI upper LOA (L mmin^{-1})	0.72 to 1.06		0.48 to 1.35	0.31 to 1.11	0.45 to 1.41	0.53 to 1.52	0.41 to 1.44	0.66 to 1.87	0.28 to 1.34	0.31 to 1.37
Percentage error (95% CI)		66 (61 to 72)	68 (52 to 84)	64(49 to 80)	69 (53 to 86)	73 (55 to 91)	70 (53 to 87)	77 (58 to 96)	60 (44 to 76)	61 (45 to 77)

Bias: Difference between cardiac index Aesculon™ cardiac index CardioQ™. 95% CI: 95% Confidence Interval. LOA limits of agreement. Time point 1 (T1) prior to surgery, after induction of anesthesia; T2 after skin incision; T3 during surgery; T4 during surgery; T5 directly after skin closure; T6 prior to extubation; T7 30 min after arrival at recovery ward, T8 30 min after arrival at recovery ward

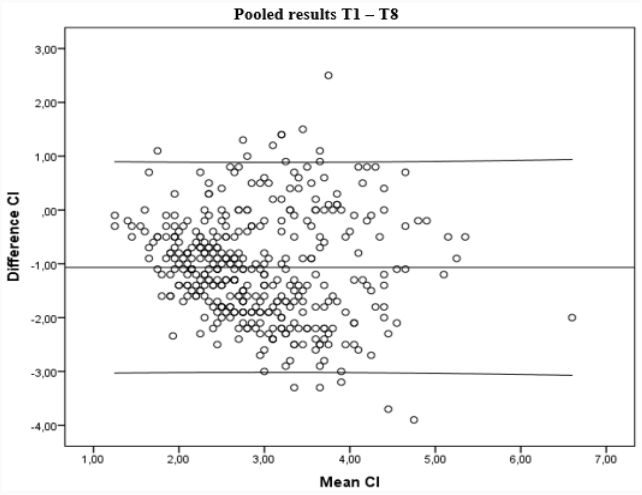

Figure 1A: Bland-Altman plot of pooled results. Lines indicate mean difference (Lit/min) with 95% prediction intervals.

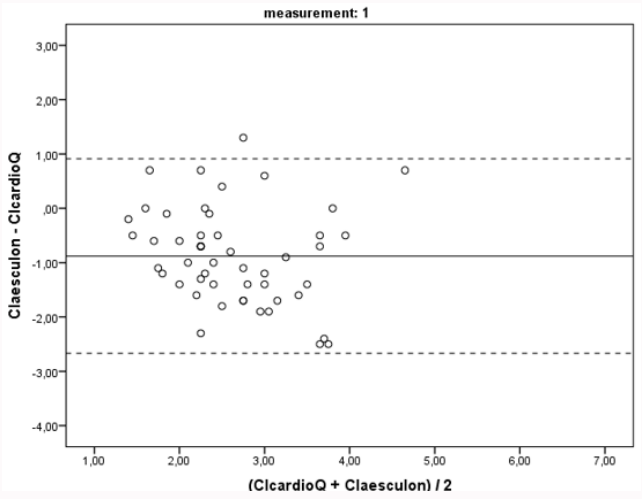

Figure 1B: Time point 1.

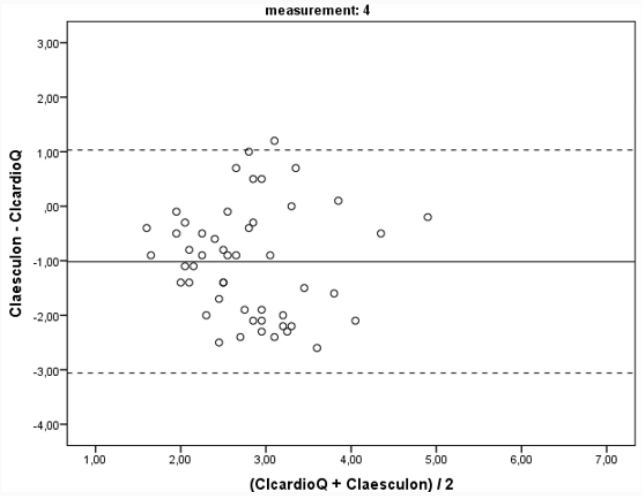

Figure 1C: Time point 4.

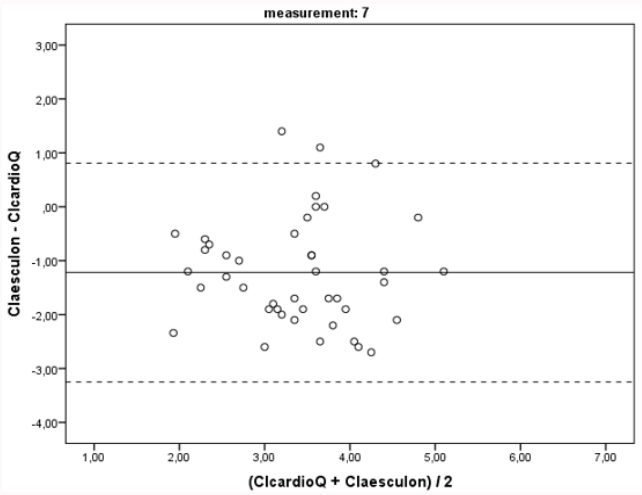

Figure 1D: Time point 7.

Figure 1A-1D: Bland Altman plot. Fixed lines indicates mean difference, dotted lines indicate limits of agreement.

1A pooled results, time point (T) 1 prior to surgery; T4 during surgery at stable condition; T7 thirty minutes after arrival at the recovery ward.

patients undergoing major abdominal surgery under thoracic epidural analgesia. Our results do not support interchangeability of both devices in this patient group during surgery as well as during the early postoperative period, as both PE and trending ability exceed the clinically acceptable, predefined limits [32,33].

There is an ongoing need for a non- or minimal-invasive method of cardiac output measurement combining high reliability with high usability. The present study reveals a significant difference between CI values measured by CardioQ™ and Aesculon™ at every time point.

This discrepancy is not affected by the surgical incision (secondary objective). During the whole measurement period, the CI measured with the Aesculon™ was lower than corresponding values

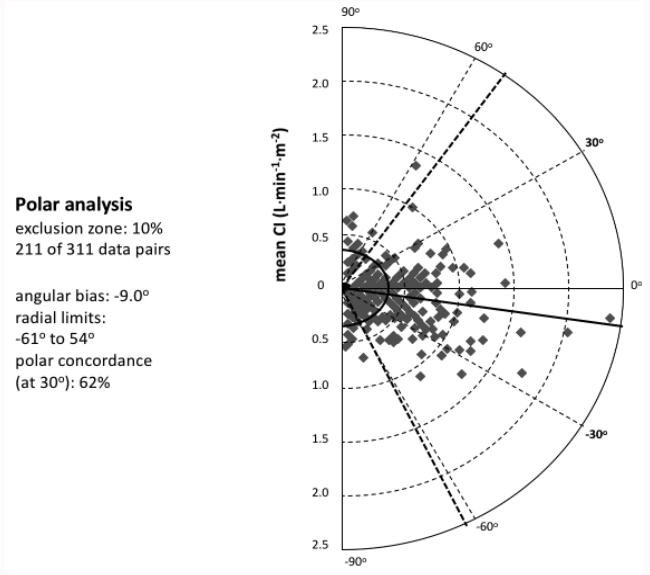

Figure 2: Polar plot analysis.

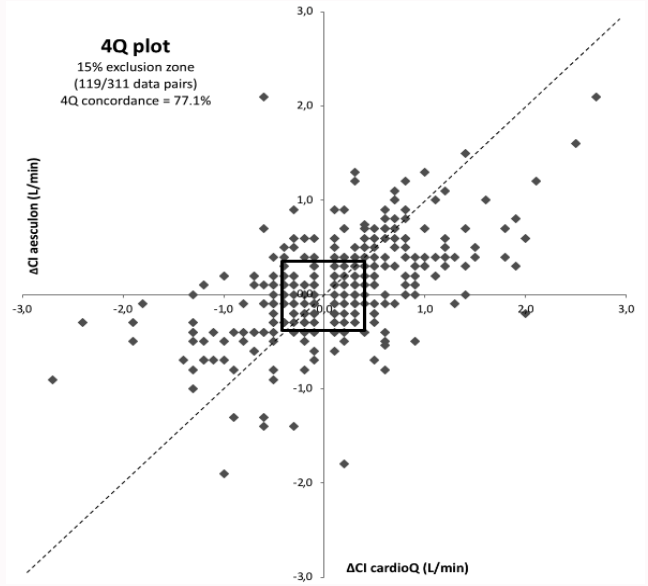

Figure 3: Four-quadrant plot.

measured by the CardioQ™. The more the CI values increased, the greater became the discrepancy between the two devices or so-called proportional bias [35]. Concerning the measurements performed with the Aesculon™, changes in CI occurred slowly and were more useful for trend monitoring than as a helpful instrument in clinical decision making in the OR for goal directed fluid management.

In our population the CI and CO measurements were relatively high. This may be due to the structural use of a thoracic epidural catheter and per-operative fluid management in our clinic.

Electrical bioimpedance is a potential accurate, non-invasive method to assess a variety of hemodynamic parameters e.g. stroke volume, cardiac index and cardiac output [27,36-38]. For several reasons the Aesculon™ could be preferred over the CardioQ™. The Aesculon™ is a continuous monitor, after installation there is no action required to obtain data. Using the CardioQ™ it requires more or less fine-tuning to obtain the most optimal signal. Also, the Aesculon™ is less expensive than the CardioQ™ because there is no need for additional probes. The surgical incision, and therefore the interruption of the continuity of the skin seem to be no important factor in the reported discrepancy between the two instruments. This is shown by the fact that the difference between both values during surgery is comparable to the difference between both values before and after surgery. However, an important intra-operative role is very unlikely for the Aesculon™ because it depends on an ECG registration which frequently is disturbed by diathermia. Moreover, in arrhythmia patient's wrong interpretation of the heart rate and therefore failure in calculating adequate CO and CI might occur. When using the CardioQ, measurements can also fluctuate due to probe dislocation or e.g. arrhythmia. But because these measurements are more a beat-to-beat registration, correction and quick re-calibration are possible, improving the usefulness in per-operative hemodynamic monitoring.

Besides CO and CI, Stroke Volumes (SV) and Stroke Volume Variation (SVV) are widely used parameters to compare different kinds of hemodynamic monitors [39]. We decided to focus on CO and CI because this parameter is claimed to be measured by the bioimpedance monitor accurately and were investigated already in former studies [21].

Although the effect of skin temperature and hydration status has been suggested as cause of variation in bioimpedance measurements, Cornish et al. found no significant effect of the above on whole body bioimpedance measurements [40].

MAP was stable during all procedures using goal directed therapy and low dose vasoconstrictors if indicated (Table 2).

Failure of epidural analgesia is widely reported with an incidence of 9% to 50% [41-43]. Almost all patients (82%) in our study received analgesic treatment using a thoracic epidural catheter with a failure rate of 4%. Relatively high CO findings may be explained by a reduction of vascular after load in patients with successful thoracic epidural analgesia.

Strengths and Limitations

One of the strengths of this study is that, compared to other studies in this field, we studied a relatively substantial population, resulting in adequate power of the present study. A number of studies published during the last years focus on neonatal, pediatric or critically ill populations [22,27,28], patient groups which are not necessarily comparable to those undergoing high risk surgery.

It was our aim to use only minimally or non-invasive monitoring to minimize the risk of side effects seen by invasive monitoring. Therefore, we decided to compare the transthoracic bioimpedance monitor (Aesculon™) with the esophageal Doppler monitor (CardioQ™). However, despite the fact that the CardioQ™ is validated versus thermodilution techniques, the accepted standard in clinical practice, Doppler derived CI does not represent the gold standard per se [44-48]. This is a limitation of the study. During perioperative data collection we had the impression that Stroke Volumes (SV) measured by the Aesculon™ didn't react on fluid boluses. However, this study was not designed to measure the hemodynamic effects of goal directed therapy; therefore we cannot report on these observations. As being the basis of any goal directed treatment this should be objectified in future studies.

Conclusion

According to Bland-Altman analysis the Aesculon™ cannot be used interchangeably with the CardioQ™ in the operation theatre. We found no effect of skin interruption on accuracy, precision, and trending ability of the investigated technique.

Key Message

The bioimpedance cannot be used interchangeably with the esophageal Doppler during major abdominal surgery.

Declarations

Ethical approval

The study protocol was approved by the institutional review board of the Maastricht University Medical Centre+ (MEC 09-4-052.2) and written informed consent was obtained from every patient prior to surgery.

"All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards."

Consent for Publication

Written informed consent was obtained from every patient prior to surgery.

Availability of Data and Material

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Author's Contribution

BC contributes to the design of the study, carried out the analyses, interpreted the data and wrote the manuscript. MT interpreted a part of the data and reviewed the manuscript. JO contributed in the initial manuscript and data collection. WFFAB reviewed the manuscript critically. LJM advised substantially in statistical analysis and data interpretation.

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