Original Article

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Agreement of a Non-Invasive Continuous Hemodynamic Monitoring System ClearSight™ during Anesthesia in Prone Position: Concordance Correlation with a Standard Minimally-Invasive Pulse Contour Method

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Objective: Recent clinical studies have suggested that non-invasive pulse wave analysis (PWA) devices can be an alternative to minimally invasive PWA devices for hemodynamic measurement during major or high-risk operations. However, the agreement of these two systems has not been previously characterized in operations that requires prone positioning.

Methods: This prospective case-based observational study recruited patients that underwent lumbar spine surgery in the prone kneeling position. All patients received minimally invasive Flotrac/EV1000 and non-invasive ClearSight systems for continuous intraoperative hemodynamic measurements. Bland-Altman plots and Lin's concordance correlation coefficient (CCC) were used to analyze the agreements between the two systems.

Results: A total of 30 patients were included in this study. Both systems showed considerably less bias in measuring mean pressure and high accuracy in measuring stroke volume variation (SVV) in the prone position (Cb 0.98 – 0.99). However, the agreements in cardiac output (CO) measurement using the ClearSight were relatively low (CCC < 0.65) and the overall 95% limit of agreement reached negative values, as 35.3% of low cardiac index (CI) (< 2.5 L/min/m^2) measured by the Flotrac was shown as normal-to-high CI (≥ 2.6 L/min/m^2) in the ClearSight.

Conclusion: Compared with minimally invasive PWA device, ClearSight provided clinically acceptable mean pressure and reasonably consistent SVV values for optimization of intravascular volume in non-critical patients in the prone position during lumbar spine surgery. However, perioperative data from patients in prone position should be interpreted with caution, as CO is likely to be overestimated by the ClearSight than the Flotrac.

Key words: lumbar spine surgery, prone position, finger cuff, cardiac index, stroke volume variation

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Introduction

Prone position anesthesia is necessary for surgeries of the posterior structures or retroperitoneum, such as spinal and urological surgery. Shifting from a supine to a prone position increases intra-thoracic and intra-abdominal pressures and reduces systemic venous return as well as left ventricular compliance and filling. This results in a rise in central venous pressure but decreases in stroke volume (SV), cardiac output (CO), and systemic blood pressure.[1,2] A combination with intraoperative precipitating conditions such as excessive blood loss, hypovolemia, fluid shift, hypothermia, electrolyte imbalance, venous air emboli sms, myocardial injury, and trigeminocardiac reflex may contribute to unexpected cardiovascular collapse and arrest in the prone position.[2,3] Therefore, routine arterial cannulation for continuous hemodynamic monitoring is recommended for high-risk patients undergoing operations in the prone position.[2] The introduction of pulse wave analysis (PWA) techniques allows left ventricular stroke volume/cardiac index (SV/CI) and stroke volume variation (SVV) to be estimated based on a continuous analysis of arterial blood pressure waveforms. This make PWA technique a non-invasive alternative to the minimally invasive hemodynamic monitoring system to be used during major operations or in high-risk patients undergoing anesthesia.[4] Using minimally invasive PWA devices (e.g., FloTrac™) for continuous hemodynamic monitoring during major spinal surgery, previous clinical studies have reported a high degree of agreement in patients' hemodynamic parameters when the patients were in supine and prone positions.[5,6]

In the past decade, the development of volume clamp methods for calculating CO using pulsation and pressure waveform analysis in digital arteries provides a non-invasive and accurate system for hemodynamic monitoring. One such system is the ClearSight system.[4,7] Previous studies have shown no significant difference in the measurement of absolute and changing SV/CO between ClearSight PWA and invasive pulse-contour device that requires arterial cannulation in patients undergoing major surgeries in the supine position.[8] Therefore, non-invasive PWA systems have been recommended as an alternative to arterial lines for hemodynamic monitoring in perioperative patients.[9] Nevertheless, whether the non-invasive PWA system could provide hemodynamic parameters comparable to those acquired through invasive means in patients receiving spinal surgery or other operations in a prone position remains unclear. Hence, this prospective observational study aimed at assessing the degree of agreement between the minimally invasive PWA Flotrac and non-invasive PWA ClearSight systems when the patients are in supine and prone positions.

Materials and Methods

This prospective case-based observational study was conducted at E-Da Hospital, a tertiary referral hospital in southern Taiwan,

	Baseline	Initial prone phase	Stable prone phase
	Supine (T1)	Prone (T2)	Prone (T3)
Duration of measurement (minutes)	5	10	10
Number of valid data collected*	12	28	23

Fig. 1 Change in positioning of patients during lumbar spinal surgery and the measuring timepoints of the study.

from April 2020 to August 2020 in accordance with the Declaration of Helsinki. The study protocol was approved by the Institutional Review Board of E-Da Hospital, Taiwan. Eligible participants included adults aged 20 – 65 years with American Society for Anesthesiologist physical statuses (ASA PS) ≤ III who were scheduled for posterior spine instrumentations. Patients with major cardiac risk factors (revised cardiac risk index ≥ 3), sustained arrhythmias, previous stroke, malignancy or hematologic disease, serum creatinine level > 2 mg/dL, liver cirrhosis with Child-Pugh class ≥ B, and those undergoing emergency surgeries were excluded from the study.

Anesthesia and Intraoperative Monitoring

All patients received endotracheal general anesthesia (ETGA) during spinal surgery. The anesthetized patients were paralyzed with intermittent administrations of muscle relaxants to maintain the train-of-four count < 2 throughout the operation. After orotracheal intubation, patients were mechanically ventilated using the volume-control mode with an expired tidal volume of 8 mL/kg ideal body weight and a positive end-expiratory pressure (PEEP) of 3 – 5 cmH_2O. An arterial line was positioned inside the radial artery and connected to a Flotrac/EV1000 system (Edwards Lifesciences, Irvine, CA). An appropriately sized finger cuff from the ClearSight™ system (Edwards Lifesciences, Irvine, CA) was placed on the intermediate phalanx of the middle finger of the hand ipsilateral to the arterial catheter. The setup and calibration of the hemodynamic monitoring systems were in accordance with the manufacturer's instructions and operating standards at the level of midaxillary line.

Measurements

The patients' hemodynamic parameters (CO, SV, SVV) independently measured by the Flotrac and ClearSight systems were recorded in the supine and prone positions, as (1) T1 supine: five minutes before positioning from supine to prone; (2) T2 prone: 15 minutes after positioning to prone; (3) T3 prone: 15 minutes before positioning back from prone to supine. Figure 1 illustrates the hemodynamic measurement protocol of the current study.

Statistics

A valid data entry was defined as the average of at least three consecutive measurements within five minutes at each study time point and only paired data measured simultaneously by the two systems at each study time point were included in the analysis. Since previous studies have confirmed the Flotrac system's precision in measuring hemodynamic parameters in the supine and prone positions,[5] hemodynamic values measured by Flotrac system were considered to be the standard values of measurement in our study. A Bland-Altman (BA) plot and scatter diagram were used to analyze the agreement between the corresponding hemodynamic parameters measured by the Flotrac and ClearSight methods at each study time point. The x-axis of the Bland-Altman plot (BA plot) represents the values measured by Flotrac (standard measurements) and the y-axis represents the differences between the FloTrac and ClearSight values. The 95% limits of agreement (LOA) of each BA plot were defined as mean of the differences (bias) ± 1.96 × SD, and the percentage error (PE) was defined as 1.96 × SD/FloTrac value. We defined a PE within ± 30% as the clinically acceptable agreement between the two measurement systems.[10] Lin's concordance correlation coefficient (ρc or ρCb, precision × accuracy), which is calculated from multiplying Pearson's correlation coefficient (ρ, precision) by the bias correction factor (Cb, accuracy), was used to estimate the concordance between the ClearSight measurements (y-axis, considered the new method) and Flotrac measurements (x-axis, considered the

standard method) at each time point of measurement. The strength of agreement between the values measured by the two systems was assessed by levels of ρc and were classified as unsatisfactory (ρc < 0.6), satisfactory (0.6 ≤ ρc ≤ 0.9), and excellent (ρc > 0.9).[11,12] For all statistical analyses, we used the MedCalc (Version 19.8, MedCalc Software, Ostend, Belgium) for descriptive statistics, BA plotting, PE, and ρc.

Results

Patient characteristics and collected data

A total of 30 patients who received posterior spinal operations (> 2 segment lesions) were included in this study. The numbers of paired datasets at each study time point are listed in Figure 1. The mean age of the patients was 57 ± 10 years and 73% of the patients received operations involving 2 – 3 lumbar intervertebral discs. Table 1 summaries the demographic characteristics and clinical variables of the patients recruited in this study.

Agreement of hemodynamic measurements between supine and prone positions

Heart Rate

Heart rates were detected by the presence of arterial pulse waves in the Flotrac and ClearSight systems. In comparison to the Flotrac system, the heart rate agreements measured by the ClearSight system were extremely high in the supine (T1) and prone (T2 and T3) positions, with extremely high CCC values (0.93 – 0.99) and a low PE (< 10%) (Table 2) (Fig. 2A).

Arterial blood pressures

The ClearSight system showed considerably less bias (< 6.4%) compared to the Flotrac system in systolic, diastolic, and mean arterial pressure measurements in the prone position (T2 and T3) with a PE ranging from 16.9% to 27.9% (Table 2) (Fig. 2B – D). The agreements of arterial pressures measured by the two systems with the patient in the prone position were satisfactory (CCC 0.66 – 0.85) (Table 2). The accuracy of measuring arterial blood pressures using the ClearSight system was generally high (Cb > 0.92), while the precision was relatively low (ρ < 0.86) (Table 2). Compared with systolic pressures, the mean arterial pressure determined by the ClearSight system showed a significantly higher accuracy (Cb = 0.99 – 1.00) with a satisfactory precision level (ρ = 0.70 – 0.86) (Table 2).

Cardiac index (CI)

Compared with the Flotrac system, the CI bias calculated by the ClearSight system in the T2 prone and T3 prone positions were -0.2% (95% LOA -1.3% to 0.9%; PE 46.8%) and -0.5% (95% LOA -1.4% to 0.5%; PE 41.6%), respectively (Table 2) (Fig. 3A). The CCCs in the CI measurements using ClearSight system were only satisfactory in the T2 and T3 positions (0.60 and 0.65 respectively) (Table 2). The concordance of the two methods in measuring CI was reanalyzed in subjects with low (≤ 2.5 L/min/m^2) or normal-to-high (> 2.5 L/min/m^2) CI (Table 3). The CCC between the

Table 1. Patient characteristics (n = 30).

Age (years)	57 (50 – 61)
Gender	
Male	16 (53%)
Female	14 (47%)
Height (cm)	161 (155 – 169)
Weight (kg)	63 (54 – 79)
Body mass index (kg/m^2)	25.1 (20.7 – 26.8)
Number of operation levels*	
2	8 (26%)
3	14 (47%)
4	6 (20%)
5	2 (7%)
ASA physical status	2 (2 – 2)
Duration of operation (min)	180 (145 – 200)

*Levels of operation in the lumbar to sacral vertebrae. ASA: American Society of Anesthesiologists. Data are presented as mean (interquartile range) or numbers (percentages).

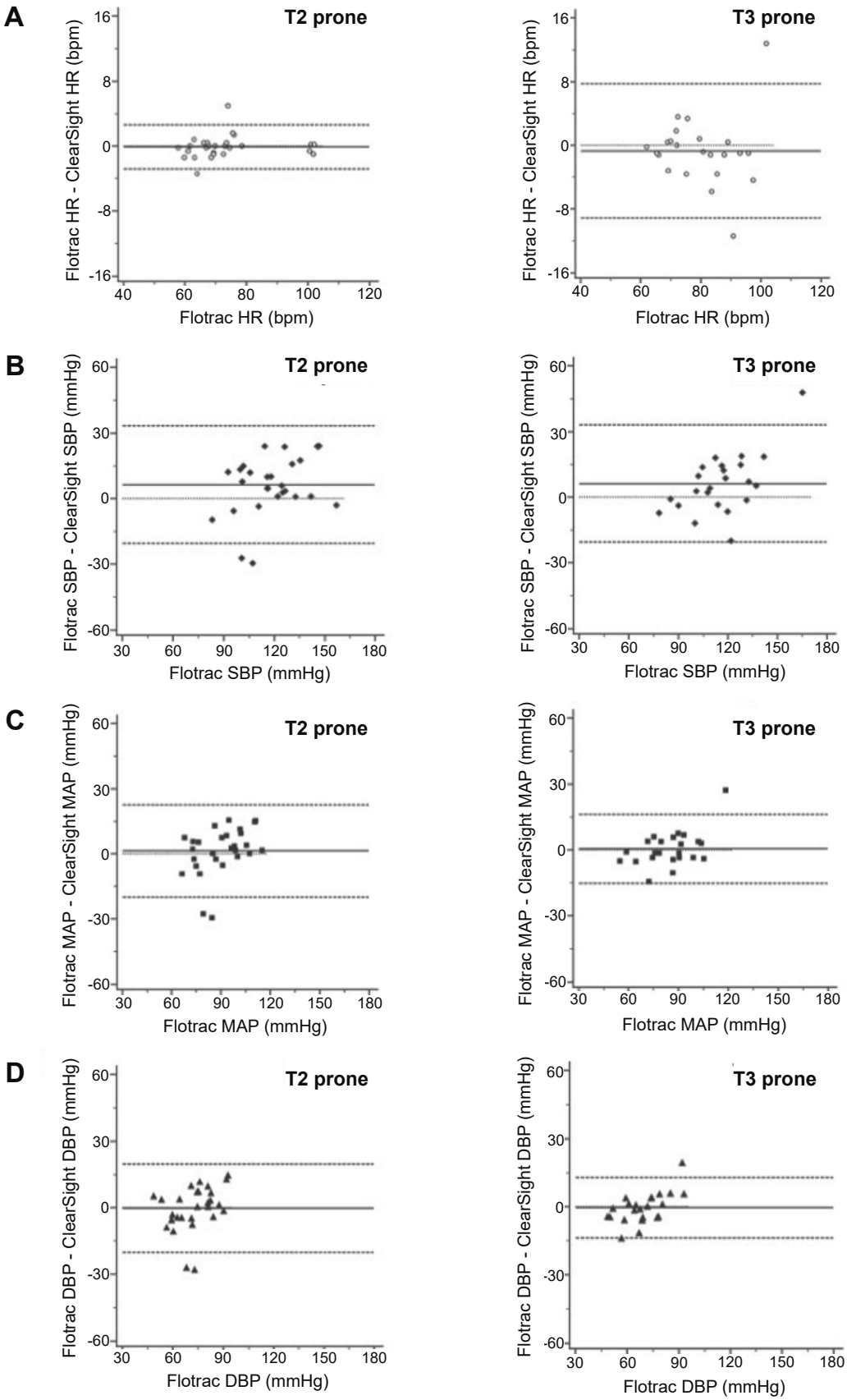

Fig. 2 Bland-Altman (BA) plotting for the corresponding hemodynamic parameters measured by the Flotrac and ClearSight methods at T2 and T3 prone positions. The x-axis of the BA plots represents the values measured by Flotrac, and the y-axis represents the difference between the Flotrac and ClearSight values. The course dotted lines indicate the 95% limits of agreement, and the solid line in between the course dotted line indicates the mean of bias. The fine dotted line represents no differences in measuring the hemodynamic parameter using the two methods. (A) HR: heart rate; (B) SBP: systolic blood pressure; (C) MAP: mean arterial pressure; (D) DBP: diastolic blood pressure.

Table 2. Correlation and Bland-Altman analyses of hemodynamic measurements.

	Bland-Altman analyses				Lin's concordance correlation coefficient			
	n	Bias	LOA	PE (%)	CCC (ρc)	95% CI	ρ (precision)	Cb (accuracy)
T1 supine	12							
HR (bpm)		-0.9	-8.3 to 6.4	7.9	0.94	0.83 to 0.98	0.95	0.99
SBP (mmHg)		10.7	-17.8 to 39.1	22.5	0.77	0.46 to 0.92	0.86	0.90
MAP (mmHg)		3.2	-15.2 to 21.5	20.3	0.86	0.61 to 0.96	0.88	0.98
DBP (mmHg)		0.7	-17.0 to 18.4	25.5	0.80	0.48 to 0.93	0.82	0.98
CI (L/min/m^2)		-0.3	-1.3 to 0.7	35.1	0.72	0.40 to 0.88	0.84	0.85
SVV (%)		1.1	-3.8 to 5.9	54.9	0.88	0.66 to 0.96	0.91	0.97
T2 prone	28							
HR (bpm)		-0.1	-2.8 to 2.6	3.9	0.99	0.99 to 1.00	0.99	1.00
SBP (mmHg)		6.4	-20.5 to 33.4	23.7	0.68	0.43 to 0.83	0.72	0.94
MAP (mmHg)		1.3	-20.0 to 22.6	24.9	0.70	0.44 to 0.85	0.70	1.00
DBP (mmHg)		-0.2	-20.2 to 19.8	27.9	0.66	0.39 to 0.83	0.66	1.00
CI (L/min/m^2)		-0.2	-1.3 to 0.9	46.8	0.60	0.32 to 0.79	0.64	0.95
SVV (%)		0.1	-5.0 to 5.1	45.6	0.86	0.74 to 0.93	0.88	0.98
T3 prone	23							
HR (bpm)		-0.7	-9.1 to 7.8	9.3	0.93	0.85 to 0.97	0.93	1.00
SBP (mmHg)		6.3	-20.6 to 33.1	20.3	0.66	0.38 to 0.83	0.72	0.92
MAP (mmHg)		0.5	-15.2 to 16.2	16.9	0.85	0.68 to 0.93	0.86	0.99
DBP (mmHg)		-0.4	-13.7 to 13.0	18.6	0.81	0.63 to 0.91	0.83	0.98
CI (L/min/m^2)		-0.5	-1.4 to 0.5	41.6	0.65	0.40 to 0.81	0.79	0.82
SVV (%)		0.2	-5.5 to 6.0	54.4	0.74	0.49 to 0.88	0.75	0.99

HR: heart rate; SBP: systolic blood pressure; MAP: mean arterial pressure; DBP: diastolic blood pressure; CI: cardiac index; SVV: stroke volume variation; Bias: mean of difference; LOA: limits of agreement; PE: percentage error; CCC: concordance correlation coefficient; 95% CI: 95% confidence interval; ρ: Pearson ρ; Cb: bias correction factor Cb.

two measurement methods improved significantly from 0.23 – 0.24 in patients with a low CI to 0.52 – 0.67 in those with a normal-to-high CI (Table 3). The precision and accuracy were also markedly increased in patients with CIs > 2.5 L/min/m^2 (Table 3) (Fig. 3B).

Of all CI measurements considered normal-to-high (i.e., > 2.5 L/min/m^2) when measured with the ClearSight system, up to 35% were found to be low (i.e., ≤ 2.5 L/min/m^2) if assessed with the Flotrac system (Fig. 4). Therefore, the finding highlighted the tendency of CI overestimation when using the ClearSight system.

Stroke volume variation

Although the values of PE were high in the measurement of SVV, the biases of using ClearSight system in measuring SVV were considerably low in the T2 prone (bias 0.1%, 95% LOA -5.0 – 5.1%, PE 45.6%) and T3 prone (bias 0.2%, 95% LOA -5.5 – 6.0%, PE 54.4%) positions (Table 2) (Fig. 5). The concordance of SVV measurement using the two systems in T2 and T3 positions were satisfactory (CCC = 0.74 – 0.86) with high accuracy (Cb 0.98 – 0.99) (Table 2).

Discussion

Although the pulmonary artery or transpulmonary thermodilution methods are considered the clinical reference standards for intraoperative hemodynamic measurement, the invasiveness of these methods has limited the popularity of their application in clinical anesthesia.[13,14] Vascular unloading (or the volume clamp method) is an innovative non-invasive finger cuff technique that enables continuous arterial blood pressure monitoring and CO

analysis based on PWA.[13] Arterial pulse wave signals are the results of a number of physiological factors, including left ventricular stroke volume, aortic compliance, vascular resistance, and wave reflection phenomena.[14] One major clinical limitation in the accurate estimation of PWA is the rapid changes in the peripheral vasomotor reactivity that may impair the accuracy of a PWA-based system in hemodynamic measurement. For instance, a prone position

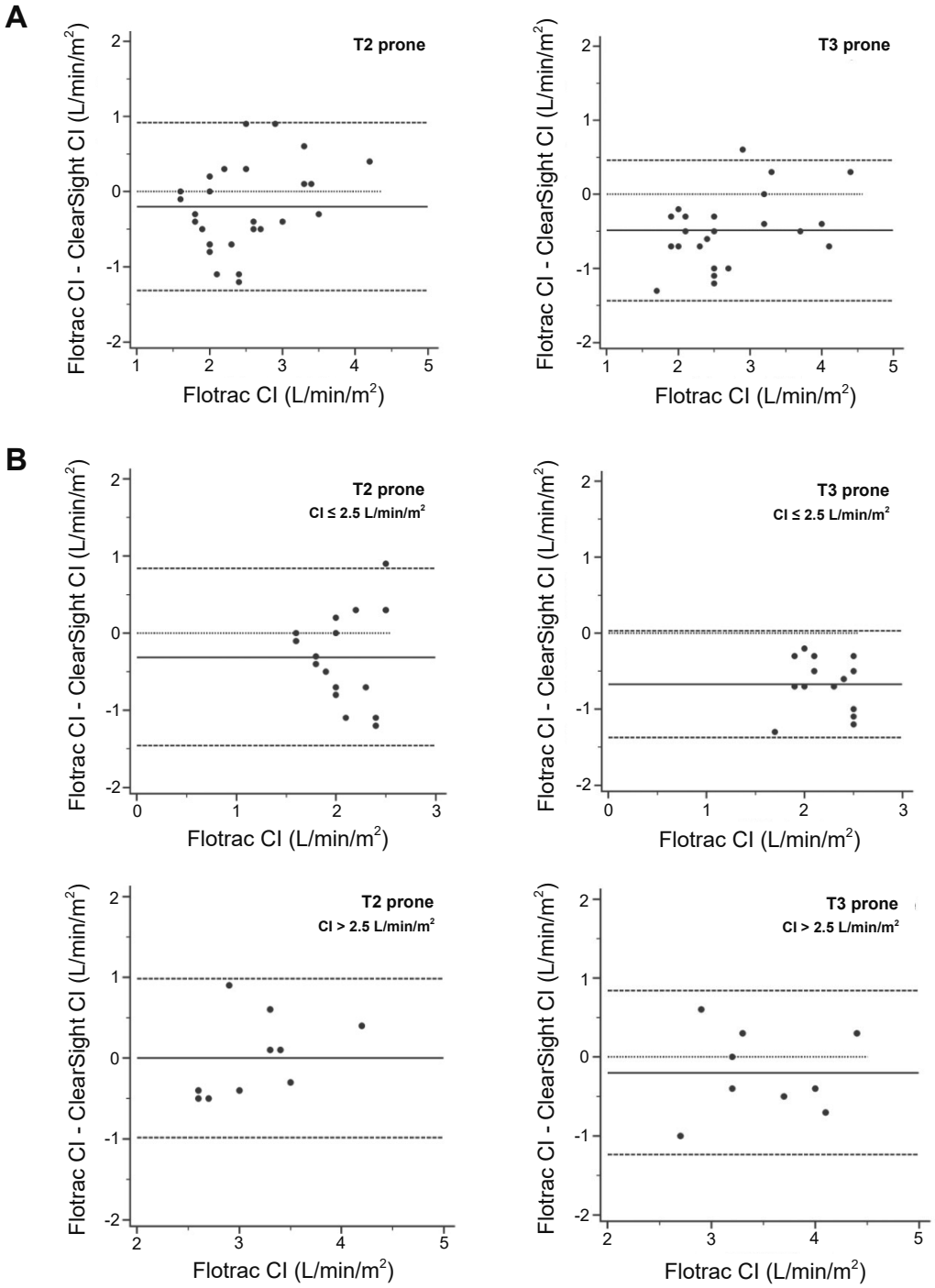

Fig. 3 Bland-Altman (BA) plotting for the corresponding cardiac index (CI) measured by the Flotrac and ClearSight methods at T2 and T3 prone positions. The x-axis of the BA plots represents the values measured by Flotrac, and the y-axis represents the difference between the Flotrac and ClearSight values. (A) BA plots of the overall CI's. (B) BA plots of low CI's (≤ 2.5 L/min/m^2) and normal-to-high CI's (> 2.5 L/min/m^2). The course dotted lines indicate the 95% limits of agreement, and the solid line in between the course dotted line indicates the mean of bias. The fine dotted line represents no differences in measuring the hemodynamic parameter using the two methods.

Table 3. Correlation and Bland-Altman analysis of low vs normal-to-high cardiac index (CI, L/min/m^2).

	Bland-Altman analysis				Lin's concordance correlation coefficient			
	n	Bias	LOA	PE (%)	CCC (ρc)	95% CI	ρ (precision)	Cb (accuracy)
T2 prone								
CI ≤ 2.5	18	-0.3	-1.5 to 0.8	50.9	0.24	-0.06 to 0.50	0.37	0.63
CI > 2.5	10	0.0	-1.0 to 1.0	33.3	0.52	-0.11 to 0.85	0.52	1.00
T3 prone								
CI ≤ 2.5	14	-0.7	-1.4 to 0.0	35.2	0.23	0.03 to 0.41	0.67	0.34
CI > 2.5	9	-0.2	-1.2 to 0.8	33.6	0.67	0.15 to 0.90	0.73	0.92

Bias: mean of difference; LOA: limits of agreement; PE: percentage error; CCC: concordance correlation coefficient; 95% CI: 95% confidence interval; ρ: Pearson ρ; Cb: bias correction factor Cb.

is known to affect the sympathetic tone and increase total peripheral vascular resistance.[15] In addition, inappropriate arm flexion or dependent site padding in a prone position may compromise the arterial blood pressure waveform signal quality, thereby making PWA unreliable. This is the first study to characterize the agreements between a non-invasive PWA system and a standard clinical minimally invasive PWA system in hemodynamic measurement when patients were switched from supine to prone positions during lumbar spine surgery. However, the rapid change from a supine to a prone position precluded adequate data collection when the patient was in a supine position.

Since the detection of arterial pulses was not affected by positional changes, heart rate measurement was considered the reference standard for the degree of agreement between the Flotrac and ClearSight systems in the T2 and T3 positions in this study. The high levels of CCC and narrow ranges of PE indicated that heart rate measurement could serve as an internal reference standard for precision and accuracy between the two measuring methods after changing from a supine to a prone position.

The ClearSight system continuously measures beat-to-beat arterial pressure through a single finger cuff using photoplethysmographic technology,[16] while Flotrac system directly measures systolic and diastolic pressures in the radial artery. Our results showed that systolic, diastolic and mean arterial pressures determined by the ClearSight system were associated with a low bias and a PE of < 30% in prone position, suggesting acceptable agreements between the ClearSight and Flotrac systems in measuring systemic blood pressure in the present clinical setting.[10] Besides, we found that the ClearSight system had a higher accuracy in the measurement of mean arterial pressures than the Flotrac system in prone position.

The ClearSight system utilizes high-frequency (approx. 1000 Hz) adjustments of the

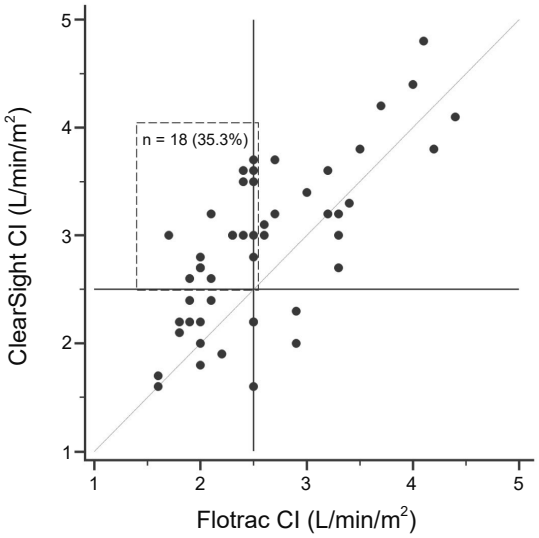

Fig. 4 Scatter plots of cardiac index (CI) measured simultaneously by Flotrac (x-axis) and ClearSight (y-axis) systems. Solid lines delineate levels of CI values of 2.5 L/min/m^2. 18 (35.3%) measurements of low CI (≤ 2.5 L/min/m^2) determined by the Flotrac system were shown as normal-to-high indices (> 2.5 L/min/m^2) in the ClearSight system (dashed box).

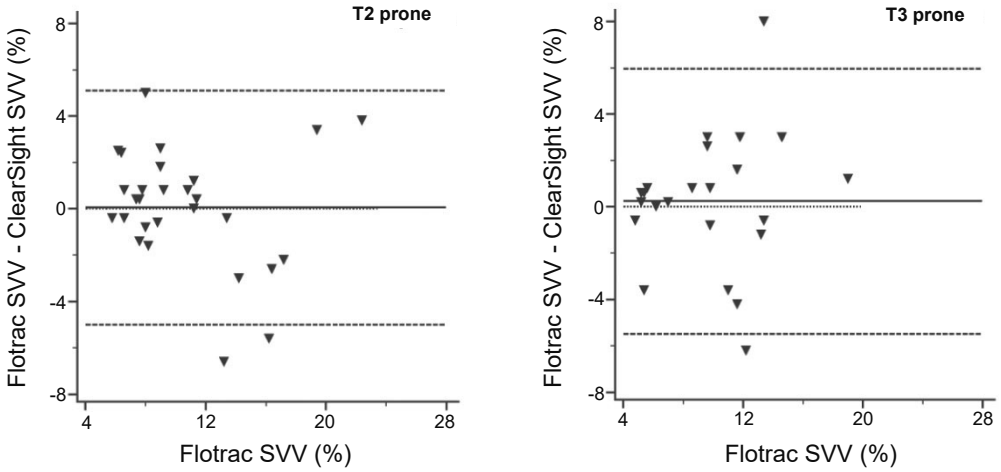

Fig. 5 Bland-Altman (BA) plotting for the corresponding stroke volume variation (SVV, %) measured by the Flotrac and ClearSight methods at T2 and T3 prone positions. The x-axis of the BA plots represents the values measured by Flotrac, and the y-axis represents the difference between the Flotrac and ClearSight values. The course dotted lines indicate the 95% limits of agreement, and the solid line in between the course dotted line indicates the mean of bias. The fine dotted line represents no differences in measuring the hemodynamic parameter using the two methods.

counter-pressure of the finger cuff to maintain a constant finger blood volume, which was measured with an infrared photodiode and light detector in the finger-cuff sensor.[14] The system then reconstructs the radial arterial pressure waveforms through analysis of finger cuff pressure changes and computes CO using the internally calibrated PWA method.[14] The results of our study showed that the bias of measuring CO using ClearSight system was low, but the PE was considerably high and CCC was low in the prone position. This suggests a relatively poor agreement of the ClearSight system in the measurement of CO when compared with the Flotrac system. Since previous studies showed a less accurate CO measurement with the ClearSight system in patients with a low CO compared with the invasive monitoring systems,[17] we reanalyzed the BA plots and correlation coefficient in patients with low (≤ 2.5 L/min/m^2) and normal-to-high (> 2.5 L/min/m^2) CIs. Table 3 and Figure 3B demonstrate an enhanced accuracy in the measurement of CO using the ClearSight system in patients with normal-to-high CIs, while the levels of precision and accuracy became worse in patients with a low CI. However, because of the potential CI overestimation using the ClearSight system compared with the Flotrac system with the patient in the prone position, the overall 95% LOA (i.e., CI assessed with the Flotrac system minus that acquired with the ClearSight system) tended to be negative. Therefore, the use of the ClearSight system for perioperative measurement of CO in patients undergoing surgery in the prone position should be interpreted with caution, as the values can actually be higher than those measured by the Flotrac system. The PWA systems estimated SV by calculating the proportional area under the systolic portion of the arterial waveform. SVV refers to the percentage of variation in SV during positive-pressure ventilation. The normal absolute value of SVV, which predicts fluid responsiveness or preload of the right ventricle, is less than 13%.[18] In the prone position, we found clinically sound concordance of these two systems in measuring SVV with high accuracy precision. Although we found that a small change in SVV (i.e., the denominator) could result in a wide variation in the PE ratio, this phenomenon had little effect on CCC due

to rarity of this situation.

Our results should be judiciously interpreted because of several limitations. First, because we focused on patients who received lumbar spine operations in prone and kneeling positions supported by an Andrews frame,[19] our results may not be extrapolated to other surgeries that utilize different techniques for sustaining a prone position. Second, our findings are more applicable to relatively healthy patients without severe major organ dysfunction (i.e., ASA PC ≤ III). Third, the results derived from the ClearSight system may not reflect those acquired with other similar non-invasive hemodynamic monitoring devices.

Conclusion

The non-invasive PWA ClearSight system provides clinically acceptable agreements for measuring systemic arterial pressure, particularly the mean arterial pressure, when compared with the minimally invasive PWA Flotrac system in non-critically ill patients who assumed a prone position for lumbar spine surgery. The ClearSight system provided reasonably consistent SVV values for guiding perioperative fluid administration to optimize intravascular volume for patients receiving surgery in a prone position. However, when the patient is in a prone position, data on CO acquired with the ClearSight system should be interpreted with caution because of potential overestimation compared with the Flotrac system.

Author Contributions

WC and CHC designed the study. WC and CHC contributed to data collection and data acquisition. WC, CHC and TSC contributed to the statistical analysis and interpretation of data. CHC contributed to drafting the manuscript. All authors read and approved the final version of manuscript.

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Institutional Review Board Statement

This study was conducted in accordance with the Declaration of Helsinki, and approved by the Institutional Review Board of E-Da Hospital located at Kaohsiung, Taiwan (protocol code EMRP52107N).

Informed Consent Statement

Informed consent was obtained from all subjects involved in the study.

Data Availability Statement

The data that support the findings of this study are available on reasonable request from the corresponding author.

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Conflicts of Interest

The authors declare no conflict of interest.

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