

ORIGINAL

Noninvasive continuous blood pressure monitoring by the ClearSight system during robot-assisted laparoscopic radical prostatectomy

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Abstract : Robot-assisted laparoscopic radical prostatectomy (RALRP) is commonly performed in the surgical treatment of prostate cancer. However, the steep Trendelenburg position (25°) and pneumoperitoneum required for this procedure can sometimes cause hemodynamic changes. Although blood pressure is traditionally monitored invasively during RALRP, the ClearSight system (BMEYE, Amsterdam, The Netherlands) enables a totally noninvasive and simple continuous blood pressure and cardiac output monitoring based on finger arterial pressure pulse contour analysis. We therefore investigated whether noninvasive continuous arterial blood pressure measurements using the ClearSight system were comparable to those obtained invasively in patients undergoing RALRP. Ten patients scheduled for RALRP with American Society of Anesthesiologists physical status I-II were included in this study. At each of the seven defined time points, noninvasive and invasive blood pressure measurements were documented and compared in each patient using Bland-Altman analysis. Although the blood pressure measured with the ClearSight system correlated with that measured invasively, a large difference between the values obtained by the two devices was noted. The ClearSight system was unable to detect blood pressure accurately during RALRP, suggesting that blood pressure monitoring using this device alone is not feasible in this small patient population. *J. Med. Invest.* 65 : 69-73, February, 2018

Keywords : blood pressure, noninvasive, robot-assisted laparoscopic radical prostatectomy

INTRODUCTION

Robot-assisted laparoscopic radical prostatectomy (RALRP) is commonly performed in the surgical treatment of prostate cancer. Its advantages over conventional surgery include nerve sparing, shorter hospitalization times, reduced blood loss, and reduced postoperative pain (1). However, to maximize the surgical visual field during this procedure, patients need to be placed in steep Trendelenburg position (25° or more), which can sometimes cause hemodynamic changes (2, 3). Indeed, a retrospective study revealed frequent use of vasoactive drugs to treat hypotension and hypertension during this procedure (4). Thus, an invasive radial arterial line is routinely inserted to monitor hemodynamic changes during RALRP.

It is possible, however, for blood pressure to be measured continuously and noninvasively with systems based on the volume clamp method. For example, the ClearSight system (previously known as Nexfin; BMEYE, Amsterdam, The Netherlands) enables a totally noninvasive continuous blood pressure and cardiac output monitoring based on finger arterial pressure pulse contour analysis. Specifically, the system reconstructs finger arterial pressure waveforms into brachial artery pressure waveforms using a generalized algorithm (5, 6). Its potential advantages include being noninvasive and easy to use, and multiple studies have already investigated its accuracy in comparison to invasive monitoring

methods, with varying results (5, 7-11).

Until recently, RALRP has been considered suitable for patients with American Society of Anesthesiologists (ASA) physical status I-II. However, this minimally invasive operation is performed in patients with ASA physical status III because of its fewer perioperative complications. Since steep Trendelenburg position and pneumoperitoneum can contribute to circulatory deterioration in patients who have cardiac or other diseases, we need more information from a continuous monitor during the operation. The purpose of this study was therefore to investigate whether noninvasive continuous arterial blood pressure measurements using the ClearSight system were comparable to those obtained invasively in patients undergoing RALRP.

PATIENTS AND METHODS

After receiving approval from the hospital ethics committee, 10 patients scheduled for RALRP with ASA physical status classifications of I-II were included in this study. All patients provided written informed consent.

Anesthetic procedure and intraoperative monitoring

No premedication was given. Anesthesia was induced with propofol (1.0-1.5 mg/kg intravenously [i.v.]) and remifentanyl (0.3-0.5 µg/kg/min i.v.). Tracheal intubation was facilitated by the administration of rocuronium (0.5 mg/kg i.v.). Anesthesia was maintained with desflurane (4.0%-5.0%) and remifentanyl (0.1-0.3 µg/kg/min i.v.). Rocuronium was repeated as needed for muscle relaxation.

After the induction of general anesthesia, a radial arterial cannula with a 22-gauge catheter was inserted into the left radial

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artery for blood sampling and pressure monitoring. A sensor/transducer system (FloTrac; Edwards Lifesciences Co., Irvine, CA, USA) was connected to the radial artery catheter to measure the arterial waveform. Intraoperative monitoring also included continuous electrocardiography as well as continuous heart rate, mean arterial pressure (MAP), peripheral capillary oxygen saturation, end-tidal carbon dioxide, and naso-nasal temperature measurements. For noninvasive blood pressure monitoring, the ClearSight device was placed on the middle finger of the right hand according to the manufacturer's recommendation, and its heart reference system (HRS) was zeroed at the level of the patient's midaxillary line. Pneumoperitoneum was then created by insufflation of carbon dioxide and five transabdominal ports were placed; after which, the patients were moved from the lithotomy to the Trendelenburg position with a 25° head-down tilt. Each time the patient's position was changed, the HRS and the arterial system were recalibrated.

At seven defined time points, systolic, diastolic, and mean arterial blood pressure were read out from both the FloTrac (invasive monitoring) and the ClearSight (noninvasive monitoring) devices. These time points were as follows: (1) 5 min after the start of the operation; (2) 5 min after the creation of pneumoperitoneum with carbon dioxide; (3) 15, (4) 30, and (5) 60 min after the patients were placed in the head-down position; (6) immediately after pneumoperitoneum was stopped and patients were returned to the horizontal lithotomy position; and (7) immediately after the operation. Invasive and noninvasive blood pressure measurement pairs at each of these seven time points were documented and compared in each patient.

Statistics

Agreement between invasive and noninvasive blood pressure measurements was assessed using the Bland-Altman method (12). Spearman correlation coefficients (ρ) were calculated after normality was checked and corrected for repeated measurements. Bland-Altman analysis was then carried out to reveal the bias (difference between invasive and noninvasive arterial pressure values), precision (standard deviation, or SD), and 95% limits of agreement (bias \pm 2SD) between the two measurement methods. Statistical analyses were carried out using the SPSS statistical software (IBM, New York, NY, USA).

RESULTS

Ten patients with ASA physical status I-II, from which a total of 210 blood pressure measurement pairs were collected, were included in this study. Patient characteristics are summarized in Table 1.

Bland-Altman analysis for FloTrac and ClearSight systolic arterial pressure (SAP) measurements revealed a mean bias and precision of -2.99 ± 15.8 mmHg and upper and lower LoAs of 28.06 and -34.04 mmHg, respectively. Additionally, the Spearman correlation coefficient was $\rho = 0.662$ ($P < 0.001$) (Figure 1).

Bland-Altman analysis for FloTrac and ClearSight diastolic arterial pressure (DAP) measurements revealed a mean bias and precision of -12.03 mmHg \pm 10.84 mmHg, and upper and lower LoAs of 9.21 mmHg and -33.27 mmHg, respectively. The Spearman correlation coefficient was $\rho = 0.521$ ($P < 0.001$) (Figure 2).

Finally, Bland-Altman analysis for FloTrac and ClearSight MAP measurements revealed a mean bias and precision of -9.26 mmHg \pm 11.61 mmHg and upper and lower LoAs of 13.50 and -32.02 mmHg, respectively. The Spearman correlation coefficient was $\rho = 0.625$ ($P < 0.001$) (Figure 3).

Table 1 : Patient characteristics.

	N = 10
Age (years), mean (SD), range	65 (6.3), 53-73
Height (cm), mean (SD), range	166.1 (8.0), 152-177
Weight (kg), mean (SD), range	65.5 (11.5), 46-84
BMI (kg/m ²), mean (SD)	23.4 (3.6)
ASA physical status I/II	4/6
Comorbidities	
Hypertension	5
Diabetes	3
CABG placement	1
Cerebral infarction	1

ASA, American Society of Anesthesiologists; BMI, body mass index; CABG, coronary artery bypass graft; SD, standard deviation.

DISCUSSION

The blood pressure obtained by the ClearSight system in this study does not meet the criteria applied to the currently used invasive monitoring system, but it correlated well with that measured invasively during RALRP. Specifically, all bias values for SAP, DAP, and MAP were negative (i.e., the device tended to overestimate blood pressure). Although the bias for SAP measurements was very low, the SD was still too high (i.e., the precision too low) to be clinically acceptable.

In the absence of validation criteria for continuous blood pressure monitoring systems, the Association for the Advancement of Medical Instrumentation criteria regarding intermittent noninvasive blood pressure monitoring devices is usually used (13). According to these criteria, two techniques can only be used interchangeably if the bias (in our case, the difference between ClearSight and FloTrac measurements) is less than 5 mmHg with an SD of less than 8 mmHg (14). A review by Ameloot et al. (6) on the accuracy of the finger cuff method in measuring blood pressure found that most authors reported a small bias (weighted average of 2 mmHg) with an almost acceptable SD (weighted average of 9 mmHg). Conflicting results within the literature were explained by differences in study populations and, in some cases, application of the method in patients with reduced perfusion of the hand due to severe hypotension, high peripheral resistance, administration of high-dose vasopressors, hypothermia, or peripheral edema (10). By contrast, Kim et al. (11) reviewed 28 studies comparing noninvasive arterial pressure monitoring with invasive arterial pressure, and they described that bias, as reported in method comparison studies using Bland-Altman analysis, would result in a greater mean error and SD than these standards recommend.

In this study, the differences between all bias values for SAP, DAP, and MAP were negative, that is, the device tended to overestimate blood pressure. It is widely known that systemic pressure increases as the measurement location is moved toward the periphery of the body and away from the heart, and with the ClearSight system predicting brachial artery pressure, the blood pressure should be lower than of the radial artery. These results were obtained despite the recalibration of the HRS and the radial artery pressure whenever the patient's position was changed. Therefore, we assume the possibility that the zero position might be displaced after placing the patient in steep Trendelenburg position.

Despite these conflicting results, such monitoring would be advantageous in RALRP. Although the procedure has postoperative benefits such as shorter hospitalization times, reduced blood loss, and reduced postoperative pain, intraoperative management is

Bland-Altman analysis (SAP)

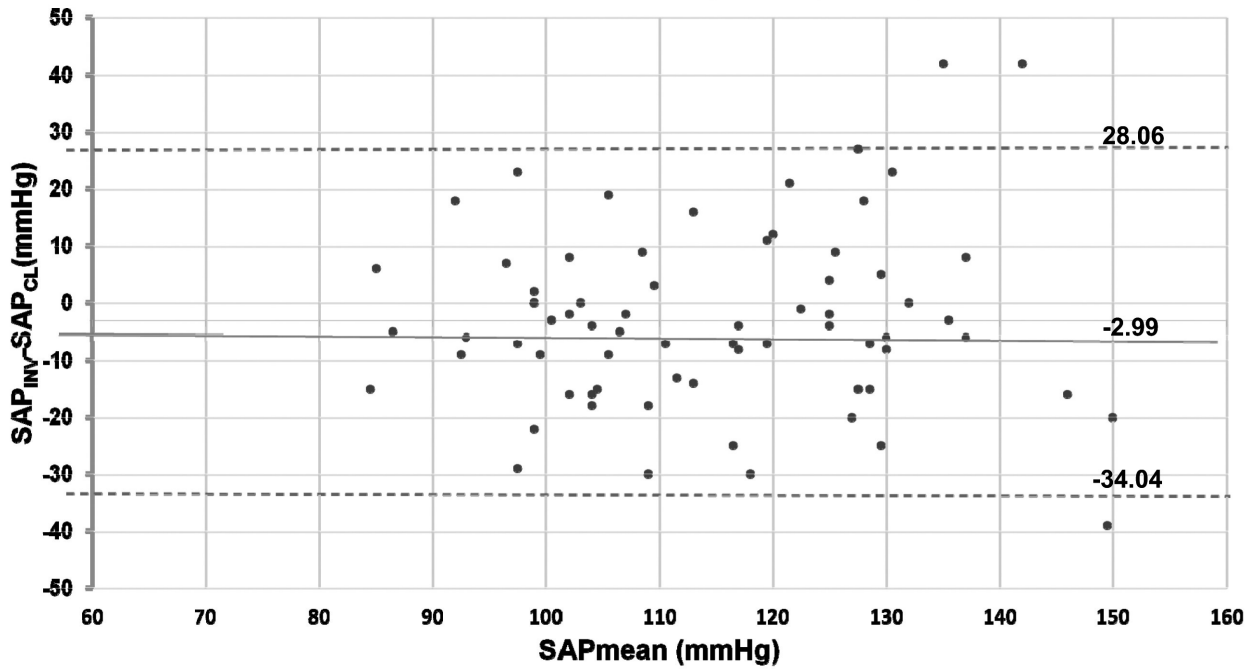


Figure 1. Bland-Altman plot for systolic blood pressure measurements. Dot, mean of the FloTrac (invasive) and ClearSight (noninvasive) blood pressure measurements at one time point in one patient ; continuous line, mean difference (bias) between the two measurement methods ; striped lines, 95% limits of agreement ($\text{bias} \pm 2 \times \text{standard deviation}$).

Bland-Altman analysis (DAP)

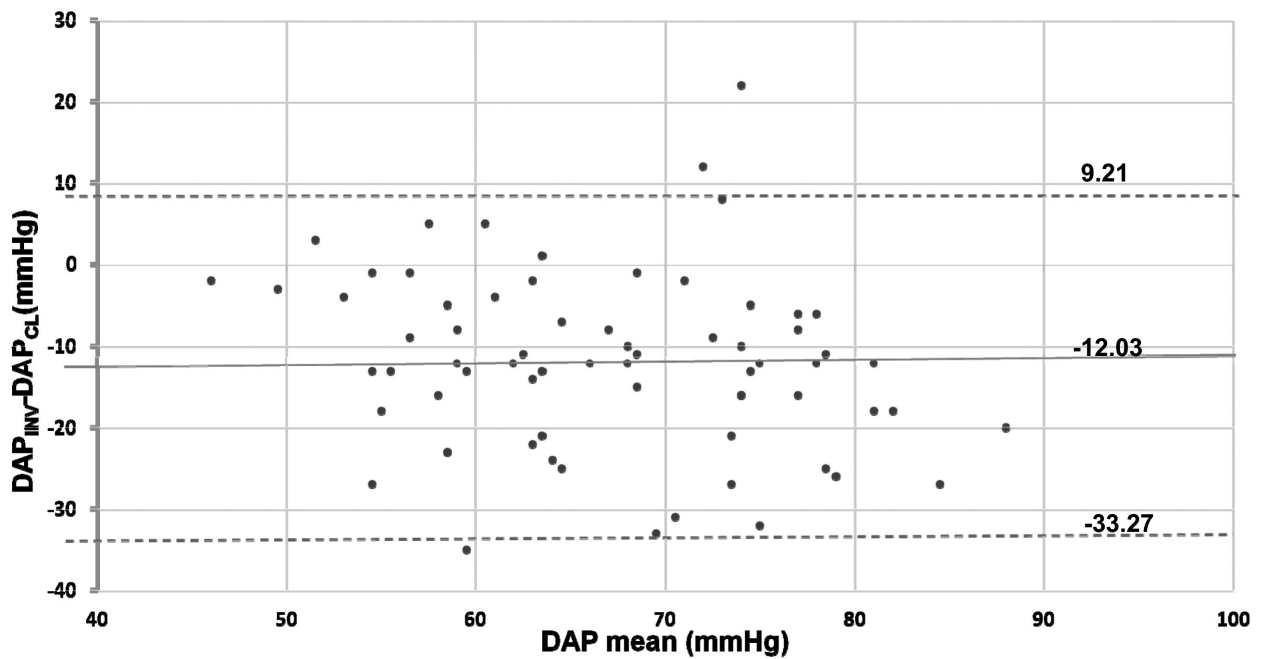


Figure 2. Bland-Altman plot for diastolic blood pressure measurements. Dot, mean of the FloTrac (invasive) and ClearSight (noninvasive) blood pressure measurements at one time point in one patient ; continuous line, mean difference (bias) between the two measurement methods ; striped lines, 95% limits of agreement ($\text{bias} \pm 2 \times \text{standard deviation}$).

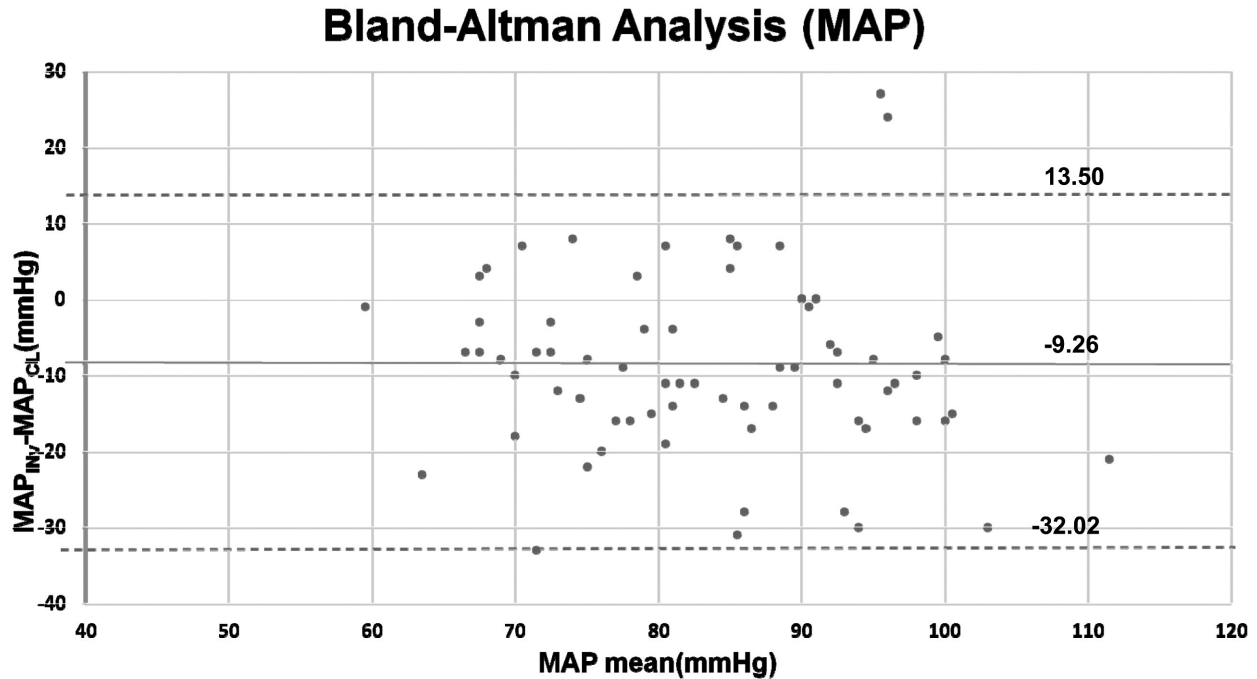


Figure 3. Bland-Altman plot for mean blood pressure measurements. Dot, mean of the FloTrac (invasive) and ClearSight (noninvasive) blood pressure measurements at one time point in one patient ; continuous line, mean difference (bias) between the two measurement methods ; striped lines, 95% limits of agreement (bias $\pm 2 \times$ standard deviation).

more complex. Namely, hemodynamic variables are affected by carbon dioxide pneumoperitoneum and the steep Trendelenburg position. This causes marked increases in MAP, central venous pressure, and pulmonary capillary wedge pressure as well as marked decreases in cardiac output and stroke volume (3, 14). Blood pressure monitoring with an intra-arterial catheter is therefore routinely used during RALRP because it provides continuous arterial pressure measurements and allows for blood sampling. However, continuous monitoring can cause cannulation-related side effects. Furthermore, intra-arterial pressure monitoring is not needed after RALRP because of its minimal invasiveness.

We therefore hypothesized that, in this context, the noninvasive ClearSight system could be used as an alternative to invasive arterial monitoring. However, based on our findings, noninvasive blood pressure measurements using the ClearSight system were not comparable to those obtained invasively. In this study, we only investigated blood pressure. The ClearSight system provides other hemodynamic parameters such as cardiac output, cardiac index, and stroke volume. We can control the depth of anesthesia, infusion rate, and use of vasoactive agents based on rapid changes of these parameters. Although the difference in the blood pressure values obtained was large, the ClearSight system seems to have the obvious advantage for monitoring.

Despite the insights provided by our study, it does have some limitations. First, the number of patients was too low to conclusively account for the low correlation between the two monitoring methods. Second, we chose only seven time points during the operation while taking into account different conditions, such as posture and pneumoperitoneum, that might have affected the accuracy of our measurements. More studies are required in other patient groups to determine the clinical usefulness of the ClearSight system.

In conclusion, although the ClearSight system is a safe and con-

venient tool, further studies on hemodynamic changes during RALRP are needed to clarify the benefit from this noninvasive technique.

DISCLOSURE STATEMENT

The authors declare no conflicts of interest associated with this manuscript.

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