



Original Research

Pleth Variability Index-Based Goal-Directed Fluid Management in Patients Undergoing Elective Gynecologic Surgery

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Abstract

Objectives: Data concerning the usefulness of pleth variability index (PVI)-based goal-directed fluid management (GDFM) in gynecologic surgery is limited.

This study purposed to compare the impact of PVI-based GDFM to conventional fluid management (CFM) on intraoperative hemodynamics and lactate levels in subjects undergoing gynecologic surgery.

Methods: This randomized and controlled trial was conducted on 70 patients undergoing elective gynecologic surgery. Subjects were randomly assigned to CFM or GDFM. Hemodynamic data and results of the arterial blood gas analysis, and total amount of the fluid infused were recorded throughout the surgery at 1-h intervals.

Results: The amount of the total fluids was significantly higher in the CFM group compared to that of the GDFM group ($p < 0.001$). Mean arterial pressure recorded at the 2nd h of the surgery was significantly lower in the CFM group compared to that of the GDFM group ($p = 0.047$). While there were no significant differences between the baseline and the 2nd h lactate levels in the GDFM group, the lactate level significantly increased from baseline to the 2nd h in the CFM group ($p = 0.010$).

Conclusion: Implementation of PVI-based GDFM provides better intraoperative hemodynamic stability and lower lactate levels compared to the CFM in subjects undergoing gynecologic surgery.

Keywords: Fluid responsiveness, Goal-directed fluid management, Gynecologic surgery, Pleth variability index

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Intraoperative fluid management is critical to maintain adequate organ perfusion. Intraoperative hypovolemia can lead to a number of complications, including renal hypoperfusion, arrhythmias, liver injury, cranial hypoperfusion, and poor wound healing, whereas excessive fluid administration may cause pulmonary and peripheral ede-

ma and tissue-healing complications.^[1] However, the optimum fluid management strategy is a matter of debate, and wide variability of practice exists among clinicians and institutes regarding the type and the volume of the fluid administered.^[2] Several fluid management protocols have been introduced in the last decade to seek the optimal

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fluid management strategy such as “liberal,” “restricted,” and “goal-directed” fluid management strategies. Although there are evidence-based fluid management strategies, the traditional “conventional fluid management” (CFM) strategy is still the most common protocol employed in intraoperative fluid administration.^[3]

Goal-directed fluid management (GDFM), which has been shown to improve perioperative outcomes, allows individualized fluid administration.^[4] GDFM utilizes monitoring techniques to help guide clinicians with administering fluids depending on individual intravascular volume. Fluid management with GDFM strategy is based on static parameters such as heart rate and central venous pressure, or dynamic indices including systolic pressure variation, pulse pressure variation (PPV), stroke volume variation (SVV), and plethysmographic waveform variation.^[5]

Pleth variability index (PVI), a simple and non-invasive dynamic indicator of fluid responsiveness, has been shown to predict fluid responsiveness as accurately as does SVV.^[6] The usefulness of PVI-based GDFM has been shown in patients undergoing various kinds of surgeries.^[7] However, data concerning the role of the PVI-based GDFM in subjects scheduled for gynecologic surgery is lacking.

The present study aimed to investigate the impact of PVI-based GDFM on intraoperative hemodynamics and lactate levels and to compare its efficiency with CFM in subjects undergoing gynecologic surgery.

Methods

Subjects

Following the approval of the research protocol by the Institutional Review Board, 70 consecutive patients undergoing an elective laparoscopic total hysterectomy between January 2020 and March 2020 were selected as the study group. Exclusion criteria were as follows: age <18 years or >70 years, American Society of Anesthesiologists Classification >III, coronary artery disease, heart failure with reduced or preserved ejection fraction, peripheral artery disease, liver or renal dysfunction, significant arrhythmia, and chronic obstructive pulmonary disease. Written informed consent was obtained from all subjects. The study was approved by the Local Ethics Committee and performed in accordance with the most recent version of the Helsinki Declaration (BSKKEAK-2019/538).

The power calculation was based on our pilot study with the first 20 patients. We used “*priori* t-tests; the difference between two independent means” for mean arterial pressure (MAP) recorded at the 2nd h in the two groups (PVI-based GDFM group: 86.2 ± 5.9 mmHg, CFM group:

80.3 ± 8.2 mmHg, alpha error: 0.05, power: 0.95, and effects size: 0.82). Results showed that at least 66 patients (33 patients for each group) were required for an adequate sample size.^[8]

Randomization

Random allocation software was used to randomly assign the subjects into one of two intervention groups: Experimental group included subjects who would receive GDFM according to the PVI monitoring and control group included subjects who would receive CFM. A card designating the study group of the index patients was placed into a sealed opaque envelope and was added to the patients’ chart. The sealed envelopes were opened by the anesthetist just before the induction of the anesthesia.

Interventions

All subjects were taken to the operation theatre following 8 h fasting without premedication. Venous and arterial blood samples were drawn from all subjects for complete blood count, arterial blood gas analysis and creatinine, and lactate measurements. On transfer to the operating room, non-invasive arterial blood pressure (BP), electrocardiogram, and pulse oximetry were monitored in all subjects (Dräger InfinityVista XL, Germany). The randomization envelope was then opened to identify the study group of the index patient. Subjects randomized to the GDFM group received additional PVI monitoring through the left index finger by Masimo Radical 7 (Masimo Corporation, Irvine, CA, USA). All laparoscopic total hysterectomies were carried out by the same surgical team under general anesthesia. All subjects received a standardized anesthesia protocol. 0.03 mg/kg of midazolam intravenously was administered for premedication. General anesthesia was induced with intravenous propofol 2 mg/kg, fentanyl 1 mg/kg, and 0.6 mg/kg rocuronium and was then maintained with sevoflurane 2–3 vol %. A volume-controlled mode at a tidal volume of 8–10 mL/kg was used for ventilation. Subjects randomized to CFM received 0.9% NaCl at a rate of 4–8 ml/kg/h, and a 250 ml bolus crystalloid/ colloid injection when the MAP decreased below 65 mmHg. Subjects randomized to GDFM received 0.9% NaCl at a rate of 2 ml/kg/h, and a 250 ml bolus crystalloid/colloid injection over a 5 min period when PVI was higher than 13%. In the case of a resistant hypotension (MAP <65 mmHg after fluid bolus infusion), 5 mg i.v. bolus ephedrine was administered in both groups. Operation time and anesthesia time were recorded for all subjects. Blood gas analysis was repeated at the 2nd h of the surgery, and complete blood count, creatinine, and lactate measurements were repeated following the completion of the surgery.

Primary Outcome

The differences in the fluid volume infused, MAP, and lactate levels between the GDM group and the CFM group throughout the surgery were the primary outcome measures of this study.

Statistical Analysis

All analyses were carried out using the SPSS v20 (SPSS) 22.0 (IBM Corp., Armonk, NY, USA). Shapiro–Wilk test was used for the normality check. Continuous variables are presented as mean±standard deviation. Categorical variables were compared with the Pearson Chi-square test. The student’s t-test was employed to compare the continuous variables of the GDFM and CFM groups. Paired samples t-test and repeated measures analysis of variance with Bonferroni correction were used to test the change in heart rate, MAP, blood gas parameters, lactate, creatinine, and hemoglobin. A two-sided p<0.05 was accepted as statistically significant.

Results

A total of 64 patients (mean age 52.2±7.5 years) were enrolled in the study (six patients were excluded for not meeting the inclusion criteria, (Fig. 1)). The baseline demographic and clinical characteristics of the subjects are given in Table 1. The GDFM and CFM groups were similar with respect to age, body mass index, ASA class, operation time and anesthesia time, and intraoperative bleeding. The amount of the total fluids administered throughout the surgery was significantly higher in the CFM group compared to that of the GDFM group (2657±470 ml vs. 1231±260 ml, p<0.001). Urine output during the surgery was also significantly

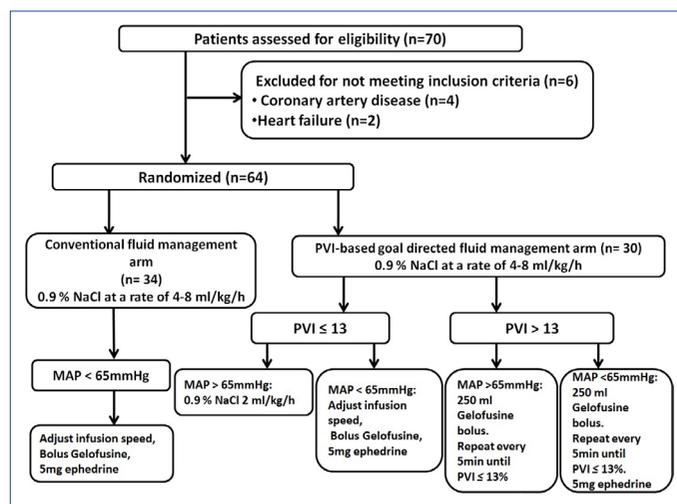


Figure 1. Flow-chart demonstrating patient enrollment.

higher in the DFM group than the GDFM group (719±258 ml vs. 336±81 ml, p<0.001).

Baseline heart rate, MAP, blood gas analysis results, lactate and creatinine levels, and hemoglobin were similar in the two groups. The changes in heart rate, MAP, blood gas analysis parameters, lactate and creatinine levels, and hemoglobin at different time points are given in Table 2. Heart rate and MAP decreased significantly at the 1st and 2nd h of the surgery in both groups. However, MAP recorded at the 2nd h of the surgery was significantly lower in the CFM group compared to that of the GDFM group (80±8 mmHg vs. 84±7 mmHg, p=0.047). pH value measured at the 2nd h of the surgery was also significantly lower in the CFM group compared to that of the GDFM group (7.36±0.04 vs.

Table 1. Demographic and clinical features of the study groups

	PVI-based GDFM n=30	CFM n=34	p
Age, years	53±6	51±8	0.176
BMI, kg/cm2	31.5±5.4	31.9±5.8	0.737
ASA			
I, n	3 (10.3%)	2 (5.9%)	
II, n	21 (72.4%)	29 (85.3%)	0.451
III, n	5 (17.2%)	3 (8.8%)	
Operation time, hours	2.5±0.6	2.5±0.4	0.895
Anesthesia time, hours	2.8±0.7	2.7±0.6	0.682
Intraoperative bleeding, ml	335±83	310±101	0.295
Intraoperative urine output, ml	336±81	719±258	<0.001
Crystalloids, ml	626±148	2589±552	<0.001
Colloids, ml	605±187	67±39	<0.001
Total fluid, ml	1231±260	2657±470	<0.001

Data are presented as mean±standard deviation for continuous variables and as frequency (percentage) for categorical variables, PVI-based GDFM: Pleth variability index-based goal-directed fluid management, CFM: Conventional fluid management.

Table 2. Intraoperative and post-operative changes in hemodynamic parameters, blood gas components and electrolytes and hemoglobin levels

	PVI-based GDFM n=30	CFM n=34	p
Baseline HR, beats/min	79±8	76±8	0.103
1 st h HR, beats/min	68±9	69±9	0.740
2 nd h HR, beats/min	65±7	65±9	0.797
P ^β value	<0.001	<0.001	
Baseline MAP, mmHg	105±14	104±20	0.832
1 st h MAP, mmHg	94±13	93±13	0.798
2 nd h MAP, mmHg	84±7	80±8	0.047
P ^β value	<0.001	<0.001	
Baseline pH	7.40±0.04	7.41±0.05	0.942
2 nd h pH	7.39±0.06	7.36±0.04	0.019
P ^γ value	0.520	<0.001	
Baseline PaO ₂ , mmHg	73.1±8.5	72.9±5.3	0.804
2 nd h PaO ₂ , mmHg	73.5±10.1	76.1±6.4	0.138
P ^γ value	0.898	0.201	
Baseline PaCO ₂ , mmHg	46.5±7.8	44.9±8.2	0.499
2 nd h PaCO ₂ , mmHg	43.3±7.2	42.3±7.5	0.131
P ^γ value	0.639	0.731	
Baseline HCO ₃ , mmol/l	24.7±1.9	25.3±2.6	0.417
2 nd h HCO ₃ , mmol/l	25.1±2.8	26.0±2.7	0.262
P ^γ value	0.464	0.213	
Baseline lactate, mmol/l	1.66±0.7	1.64±0.5	0.252
2 nd h lactate, mmol/l	1.65±0.6	2.1±0.6	0.011
P ^γ value	0.861	0.010	
Pre-operative Na, mEq/l	139.7±3.1	139.9±2.3	0.821
Post-operative Na, mEq/l	136.8±3.3	136.4±3.2	0.610
P ^γ value	<0.001	<0.001	
Pre-operative K, mEq/l	4.1±0.9	4.3±0.3	0.169
Post-operative K, mEq/l	3.7±0.5	3.8±0.4	0.239
P ^γ value	<0.001	<0.001	
Pre-operative Cr, mg/dl	0.74±0.14	0.75±0.09	0.162
Post-operative Cr, mg/dl	0.75±0.14	0.77±0.11	0.473
P ^γ value	0.292	0.415	
Pre-operative hemoglobin, g/dl	12.6±1.1	12.3±1.6	0.731
Post-operative hemoglobin, g/dl	11.6±0.9	10.9±0.9	0.004
P ^γ value	<0.001	<0.001	

Data are presented as mean±standard deviation, P_α: P-value derived from Student's t-test, P_β: P value derived from repeated measures analysis of variance test, P_γ: P-value derived from paired samples t-test, PVI-based GDFM: Pleth variability index- based goal-directed fluid management, CFM: Conventional fluid management.

7.39±0.06 ml, p=0.019). While there were no significant differences between the baseline and the 2nd h lactate levels in the GDFM group (1.66±0.7 vs. 1.65±0.6, p=0.861), the lactate level significantly increased from baseline to the 2nd h in the CFM group (1.64±0.5 vs. 2.1±0.6, p=0.010).

Compared to pre-operative levels both Na and K levels demonstrated significant declines postoperatively. Post-operative creatinine levels were similar in the two groups. However, post-operative hemoglobin level was significant-

ly lower in the CFM group than that of the GDFM group (10.9±0.9 g/dl vs. 11.6±0.9 g/dl, p=0.004).

Discussion

Results of the present study indicate that the need for intravenous volume administration to avoid intraoperative hypotension and resultant hypoperfusion is less in subjects receiving a PVI-based GDFM compared to those receiving CFM. Our findings also show that GDFM provides more

stable intraoperative MAP, pH, and lactate levels compared to CFM. Moreover, CFM is associated with lower post-operative hemoglobin levels compared to GDFM.

Perioperative fluid management basically targets a subtle balance between under-resuscitation and over-resuscitation since both conditions have deleterious effects on post-operative outcomes.^[9] While under-resuscitation brings with several complications associated with hypovolemia-induced hypotension and resultant impairment in tissue perfusion, over-resuscitation may lead to pulmonary and gastrointestinal edema and anastomotic compromise.^[10] Intraoperative fluid management, which aims to maintain the euvoletic state, has been shown to decrease post-operative complications up to 50%.^[11]

Conventional liberal fluid management and restrictive fluid management (RFM) strategies have been used for pre-operative fluid management for decades.^[12] While RFM was preferred in high-risk patients undergoing high- and moderate-risk surgeries CFM was employed in low-risk patients undergoing low- and medium-risk surgeries. The theoretical phenomenon of "third-spacing," which indicates an extracellular fluid shift toward a transcellular space during major surgery, has also become a foundation for the common use of CFM.^[13] However, despite being commonly practiced, the evidence underlying the CFM is quite weak.^[14] Moreover, the myth of a third space was further debunked by several tracer studies. Therefore, the current fluid management approaches primarily aim to treat extracellular fluid as either intravascular or interstitial. On the other hand, RFM is based on the replacement of intraoperative blood loss and insensible losses with the lowest possible amount of colloid and crystalloid. However, the determination of the insensible losses is error-prone in RFM protocol. Moreover, adjusting the amount of the fluid administered according to the hemodynamic instability in CFM and RFM cannot always be attributed to hypovolemia, because only 50% of intraoperative hemodynamically unstable patients are "fluid-challenge" responsive.^[15]

The need for patient-centric, evidence-based fluid management directing fluid responsiveness, led to the development of GDFM, which has been shown to reduce perioperative morbidity and shorten the length of the hospital stay.^[16,17] GDFM is based on the administration of the fluids to attain a specific target such as central venous pressure, arterial BP, heart rate, stroke volume, or cardiac index. However, the widespread use of heart rate and central venous pressure as specific targets is limited by the low sensitivity and specificity of these parameters.^[18,19] Implementation of the dynamic parameters including stroke volume, PPV, SVV, and plethysmographic waveform variation has been re-

ported to be superior to the static parameters in evaluating fluid responsiveness during GDFM.^[20] However, techniques using the dynamic parameters are either invasive with potential complications or are not constant.^[21]

Plethysmographic variability index measures the dynamic changes in the amplitude of the pulse oximeter plethysmographic waveform over respiratory cycles.^[22] Zimmermann et al. have shown that PVI displays accuracy similar to the arterial pressure-based SVV in the determination of the fluid responsiveness in patients undergoing major abdominal surgery.^[6] The usefulness of PVI in the evaluation of the fluid responsiveness has been demonstrated in subjects undergoing various types of surgery and in critically ill patients.^[23] PVI-based intraoperative fluid management has been shown to deliver less fluid intraoperatively in subjects undergoing major abdominal surgery compared to subjects receiving fluid to maintain arterial and central venous pressure. The preliminary studies seeking information regarding the role of PVI-based fluid management in subjects undergoing major abdominal surgery demonstrated that PVI-directed fluid management was not only associated with less intraoperative crystalloids and total volume, but also with lower lactate levels.^[24] Yu et al. investigated the efficacy of the PVI-based GDFM in patients undergoing major abdominal surgeries with combined general and epidural anesthesia.^[7] Findings of that study demonstrated that the total amount of intraoperative fluids, the amount of crystalloid fluid, and the 1st-h blood lactate levels were significantly lower in subjects receiving a PVI-based GDM compared to those receiving CFM. Recently, Bahlmann et al. compared PVI-based GDFM with esophageal Doppler-based stroke volume assessment in 146 subjects scheduled for open abdominal surgery.^[25] Their results showed that PVI was non-inferior to the esophageal Doppler in terms of the rate of the post-operative complications, and length of hospital stay when used to direct the GDFM. Similar results were derived from the study of Cesur et al., which compared CFM with PVI-based GDFM in subjects undergoing elective colorectal surgery.^[3]

The present study is the first to investigate the impact of PVI-based GDFM in subjects undergoing gynecologic surgery under general anesthesia. Our findings demonstrating less intravenous total volume administration with PVI-based GDFM compared to CFM are consistent with the results of the previous studies. Since GDFM involves the administration of

small-volume colloid boluses rather than maintenance crystalloid infusion, the amount of the colloids infused intraoperatively was significantly higher in the PVI-based GDM group compared to the CFM group. In addition, simi-

lar to the results indicated by Forget et al. and Yu et al., lactate levels measured at the 2nd h intraoperatively were significantly lower in the PVI-based GDFM group than that of the CFM group. The difference in the lactate levels between the two fluid management strategies might be a result of the lower MAP observed in the CFM group at the 2nd h intraoperatively. Our findings also showed that although the amount of intraoperative bleeding was similar in both groups, post-operative hemoglobin level was significantly lower in the CFM group compared to the hemoglobin level of the PVI-based GDFM group. This difference in the hemoglobin levels between the groups might have resulted from the higher amount of the crystalloids delivered to the patients in the CFM group, which may be responsible for dilutional anemia.

There are some limitations to be mentioned concerning this study. The PVI was measured with the Masimo Radical 7 device. Consequently, these results cannot be extrapolated to other devices that calculate the respiratory variation of the plethysmographic curve. In addition, we did not investigate the correlation of the PVI with other dynamic parameters of the fluid responsiveness, including stroke rate variability. SVV and PPV were not measured. Evaluation of the SVV and PPV along with the PVI would probably provide more information regarding the fluid responsiveness of the subjects. This is the major limitation of this study. Moreover, we did not demonstrate clinical outcomes such as time to mobilization, time to stool passage, or length of hospital stay. These results, therefore, need to be interpreted with caution.

Conclusion

The implementation of PVI-based GDFM provides better intraoperative hemodynamic stability and lower lactate levels compared to the CFM in subjects undergoing gynecologic surgery. Our findings confirm the results of the previous studies indicating that PVI is a simple, non-invasive, and effective tool to direct the GDFM. However, further studies are required to address the efficacy and safety of PVI-based GDFM in high-risk patients undergoing complex surgeries.

Disclosures

Ethics Committee Approval: The study was approved by the Local Ethics Committee and performed in accordance with the most recent version of the Helsinki Declaration (BSKKEAK-2019/538).

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Conflict of Interest: None declared.

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