

Intraoperative plethysmography variability index directed fluid management versus standard care during intraabdominal surgery in cancer patients



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ABSTRACT

Background: During the past 20 years, numerous publications have described the usefulness of systolic pressure variation, pulse pressure variation, stroke volume variation, etc., to guide intraoperative fluid administration. However, we still lack robust noninvasive physiological variables to successfully predict the response to fluid loading. **Aims and Objectives:** The present study was designed to evaluate the utility of plethysmography variability index (PVI) to optimize fluid management during intra-abdominal surgery in cancer patients. **Materials and Methods:** After the Institutional Ethics Committee approval and consent, 60 patients scheduled for elective lower abdominal cancer surgeries were randomized to receive fluid by either PVI-directed management (2 mL/kg/h) or using central venous pressure (8 mL/kg/h) after standardized technique of general and lumbar epidural anesthesia. The PVI was calculated by measuring changes in the PI during the respiratory cycle ($PVI = [(PI_{max} - PI_{min})/PI_{max}] \times 100$). Arterial blood samples were taken at the time of incision and after 6 h postoperatively. Instances of intraoperative hypotension and oliguria were recorded. **Results:** Among the 60 patients enrolled in the study, demographic data, ASA status, duration of surgery, and hemodynamics were found to be comparable. The amount of crystalloid given was significantly lesser in Group P (984.70 ± 51.16) as compared to Group C (2395.27 ± 209.68) ($P < 0.001$). Four patients in Group P and three patients in Group C required vasopressors. **Conclusion:** The use of PVI-guided fluid management was associated with lower lactate levels and crystalloid requirement. Reduced lactate levels in PVI-guided patients suggest that PVI-guided fluid management may be tailored to everyone's needs.

Key words: Plethysmography; Fluid therapy; Lactate; Central venous pressure

INTRODUCTION

Adequate fluid ensures optimum cardiac filling which is essential to maintain adequate cardiac output (CO) and organ perfusion. Excess fluid, on the other hand, can produce overload, pulmonary edema, and hemodilution. There is wide variability of practice, both among individuals and institutions in terms of the type of fluid used, the timing of administration, and the volume administered.¹ Static parameters such as central venous pressure (CVP)

and pulmonary artery occlusion pressure (PAOP) estimate preload because CO directly corresponds to end-diastolic volumes. In the past 20 years, numerous publications aimed at developing new methods for fluid responsiveness prediction.² To overcome their shortcomings, goal-directed fluid therapy was proposed and a dynamic approach to assess fluid responsiveness was offered by measuring the effect of the decrease in venous return on the CO during a mechanical positive pressure breath.³ Position on frank starling curve is assessed by these variables predicting their

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response to fluid. Fluid administration involves the benefit of improving perfusion and the risk of potential harm at the same time.⁴ Since most of the above indicators are of invasive nature, efforts are being made to find non-invasive parameters. Recently, respiratory variations in the pulse oximeter plethysmography waveform amplitude (Δ POP) have shown to be able to predict fluid responsiveness in the operating theatres and in the intensive care units.⁵ Several studies have established the fact that it corresponds well with the arterial pressure waveform. Similar to other dynamic variables, it is also affected by factors such as arrhythmias, right heart failure, low tidal volume, ratio of pulse rate (PR) to respiratory rate, and positive end expiratory pressure. In addition, its reliability is reduced in spontaneously breathing patients.⁶

Plethysmography variability index (PVI) is a novel algorithm allowing for automated and continuous calculation of the respiratory variations in the pulse oximeter waveform amplitude.⁷

Decreased oxygen delivery to splanchnic circulation causes gastrointestinal dysfunction which may lead to reduced motility or even ischemic injury. Whether it is the administration of large volume of fluid to compensate for third space loss or the zero-balance approach where no replacement to third space loss is given, the basic requirement is prevention of hypovolemia.⁸

More evidence is required to validate the application of this monitor. Thus, we conducted this study in patients undergoing lower intra-abdominal surgeries to determine whether PVI, in comparison to standard fluid regime, predict fluid responsiveness during dynamic intraoperative conditions.

Aims and objectives

The aim of the study was to evaluate the utility of PVI measurement to optimise intraoperative fluid therapy during intraabdominal cancer surgeries with the primary objective of measuring tissue perfusion. The secondary objectives were

1. Lactate level measurement.
2. Amount of fluids given.
3. Haemodynamic stability.

MATERIALS AND METHODS

After approval from the Ethics and Scientific Committee (IRB-BHR/16/2021 dated January 06, 2021), patients to be operated for elective major lower intra-abdominal surgeries over 1 year were included in the study with informed consent.

Inclusion criteria

The following criteria were included in the study:

1. ASA Grade I-III
2. Abdominal surgery time ≥ 4 h
3. 18–65 years.

Exclusion criteria

The following criteria were excluded from the study:

1. Patient of diabetes mellitus with neuropathy and nephropathy
2. Patient with low ejection fraction ($<40\%$) and arrhythmias
3. Patient with chronic respiratory failure/chronic lung disease
4. Drugs causing increase in lactate level
5. Patients with pre-operative dehydration, hypovolemia, and intraoperative massive blood loss.

The patients will be randomized into two groups

- a. Group P (Fluid given as directed by PVI)
- b. Group C (Fluid given as directed by conventional methods):

Sample size calculation

Our estimated sample size was based on post-operative lactate levels. We expected that mean post-operative lactate level would be 2.5 with a standard deviation of ± 0.65 , in the control group. With the reference of previous study, we found that results showed an improvement of 20% of the primary outcome (whole blood lactate levels) with the use of the PVI. Considering the same, using a two-tailed alpha value (0.05) and a beta value (0.2), 30 patients per group would be sufficient to detect a significant difference.

Equipment

Radical-7®; Masimo Corp., Irvine, CA, an instrument containing Masimo Rainbow SET technology use a multi-



Figure 1: Radical-7®; Masimo Corp

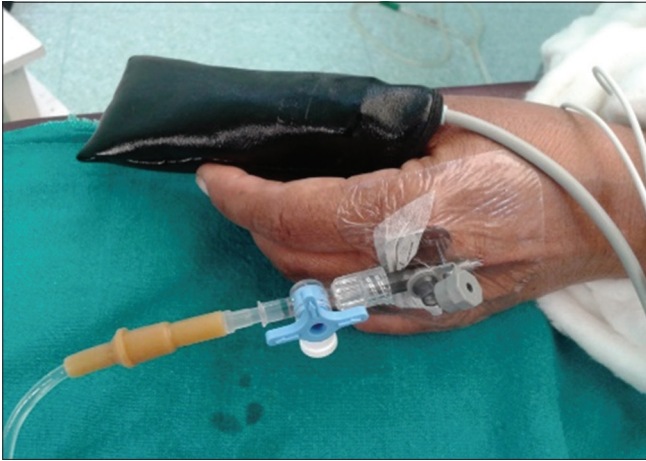


Figure 2: Radical-7®; Masimo Corp., reusable sensor

wavelength sensor to distinguish between oxygenated blood, deoxygenated blood, blood with carbon monoxide, blood with oxidized hemoglobin, and blood plasma was used in this study (Figures 1 and 2). Signal data are obtained by passing various visible and infrared lights (LED's, 620–1270 nm) through a capillary bed (for example, a fingertip, a hand, and a foot) and measuring changes in light absorption during the blood pulsatile cycle.⁹ It works on the principal of pulse oximetry which is a continuous and non-invasive method of measuring the level of arterial oxygen saturation in blood. The instrument displays the calculated data in two ways:

- As a percent value for arterial oxygen saturation (SpO₂)
- As a PR.

Perfusion index (PI) is an assessment of the pulsatile strength at a specific monitoring site (e.g. the hand, finger, or foot), and as such PI is an indirect and non-invasive measure of peripheral perfusion. It is calculated by means of pulse oximetry by expressing the pulsatile signal (during arterial inflow) as a percentage of the non-pulsatile signal, both of which are derived from the amount of infrared (940 nm) light absorbed.⁹ PI display ranges from 0.02% (very weak pulse strength) to 20% (very strong pulse strength). PVI is a measure of the dynamic changes in the PI that occurs during the respiratory cycle (Equation 1).

$$PVI = \frac{PI_{Max} - PI_{Min}}{PI_{Max}} \times 100 \quad (1)$$

The calculation is accomplished by measuring changes in PI over a time interval where one or more complete respiratory cycles have occurred. PVI, therefore, is displayed as a percentage. The lower the number, the less variability there is in the PI over a respiratory cycle.

PVI >14% before volume expansion is predictive that a patient will respond to fluid administration (81% sensitivity). PVI <14% before volume expansion is predictive that a patient will not respond to fluid administration (100% specificity).⁷

Anesthetic technique

Patients were premedicated with ranitidine 150 mg, granisetron 2 mg, and alprazolam 0.5 mg on the night before surgery. An epidural catheter was placed before the induction of the general anesthesia. The following monitors were applied before induction: Heart rate, non-invasive blood pressure, SpO₂, electrocardiogram, and temperature were measured continuously. A pulse oximeter (Masimo Co., Irvine, California) was used for measuring the SpO₂, PVI, and PI. All patients were preoxygenated with 100% oxygen (3 min). Anesthesia was induced with propofol 2 mg/kg, fentanyl 2 mcg/kg, and atracurium 0.6 mg/kg and IPPV was set to maintain normocapnia (EtCO₂ target = 40±3 mm Hg). The following intubation patients were maintained on oxygen and nitrous (40:60), along with inhalational agents. Catheters for invasive blood pressure and CVP were inserted after the induction phase.

In Group A (PVI group), 500 mL of crystalloid (Ringer lactate) was infused during induction, followed by a 2 mL/kg/h continuous infusion. If PVI is higher than 13% for >5 min, a 250-mL bolus of colloid (Tetraspan) was infused. The dose was repeated every 5 min if PVI is still higher than 13%. Nor epinephrine was given as required to maintain a mean arterial blood pressure (MAP) >65 mm Hg.

In Group B (control group), 500 mL of ringer lactate was infused during induction, followed by a continuous infusion of crystalloids (8 mL/kg/h) to cater the needs of third space loss in addition to maintenance fluid. A bolus of colloids was given if acute blood loss of >50 mL occurs, if the MAP decreased below 65 mm Hg, or if the CVP decreased below 6 mm Hg. A repeat bolus was given after waiting for 5 min if any one of the criteria was met. If the MAP decreased below 65 mm Hg and the patient remained unresponsive to fluids, then norepinephrine was given to maintain the MAP above 65 mm Hg.

Arterial blood gas (ABG) samples were taken at the time of incision as base line and then after 6 h postoperatively and analyzed for ABG levels, electrolytes, hematocrit, lactate, and blood sugar. Instances of intraoperative hypotension (systolic blood pressure 20% below the value measured during the preanesthetic evaluation the night before surgery) and oliguria (urine output <0.5 mL/kg for >2 h) was recorded. Post-operative complication in the next 48 h, if any, was recorded.

Statistical analysis

The descriptive statistics is presented using mean (with SD) and median (with range) for quantitative variables and categorical variables are presented in frequencies along with respective percentages. Pie charts, bar diagrams, and histogram

were made for graphical presentation of data. The statistical comparisons for quantitative variables were done using Student’s “t” test for parametric variables and Mann–Whitney “U”-test for non-parametric data. For categorical variables, Chi-square test or Fisher’s exact test was used according to the nature of data. Data were entered and coded in MS Excel (Version, 2007) and all statistical analyses were performed using SPSS software (Version 22, SPSS Inc, Chicago, IL, USA). P<0.05 was considered statistically significant.

RESULTS

Sixty-five patients with ASA grades I-III were enrolled in this prospective randomized controlled study. Five patients were excluded from the study as they had excessive intraoperative blood loss which required massive blood transfusion and high dose of vasopressor. Sixty patients were divided into two groups of 30 each group as Group P (PVI group) and Group C (CVP group).

Demographic data including age, sex, weight, height, and ASA status of all the patients in the two groups were comparable. All patients underwent surgery ≥4 h. The average duration of anesthesia was comparable in both the groups. The various types of surgeries conducted in both the groups are summarized in Table 1 below:

Table 1: Type of surgeries conducted in the study population

Type of surgery	Group P	Group C	Total patients
Bowel surgery	6	5	11
Radical hysterectomy	10	11	21
Ovarian laparotomy	10	10	20
Total abdominal hysterectomy + bilateral salpingo-oophorectomy	0	1	1
Cytoreductive surgery	3	3	6
Retroperitoneal lymph node dissection	1	0	1

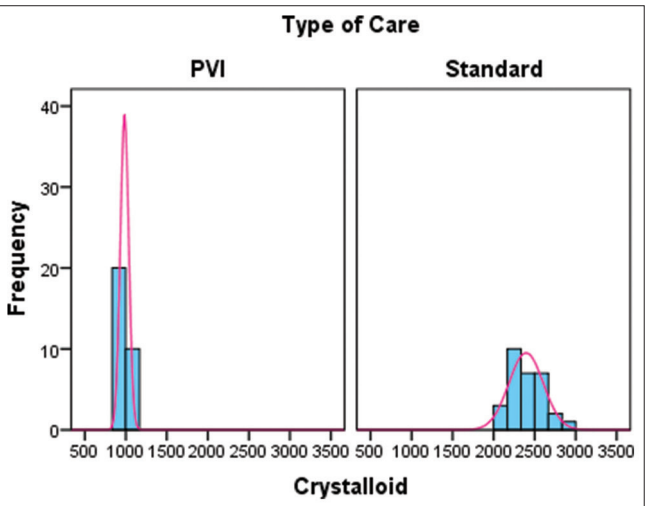
Hemodynamics in terms of PRs and MAP were found to be comparable in both the groups throughout the duration of anesthesia.

It was found that the requirement of crystalloid infusion in Group P was significantly lesser (984.70±51.16 mL) as compared to Group C (2395.27±209.68 mL), as shown in Table 1 and Graph 1. (P<0.001 calculated using Student’s t-test.)

Table 2: Amount of colloid given in the intraoperative period

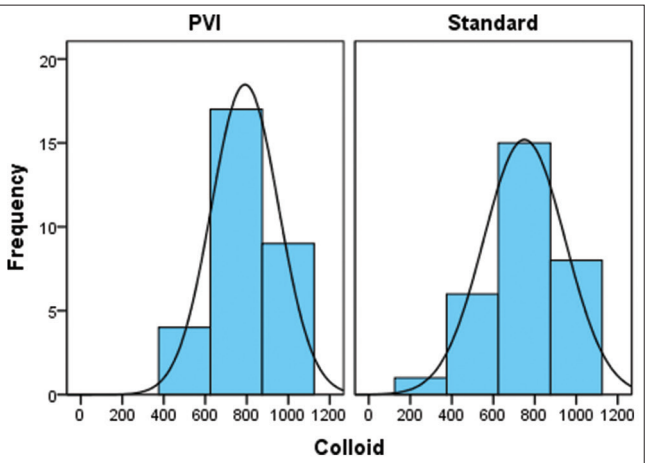
Parameter (mL)	Group P	Group C	P-value
	Mean±SD	Mean±SD	
Amount of colloid given	791.67±161.93	750.00±196.96	0.374

As evident from Table 2 to Graph 2, the amount of colloid given was insignificantly greater in Group P (791.67±161.93) as compared to Group C (750.00±196.96). P>0.05 calculated using Student’s t-test.



Graph 1: Amount of crystalloid given in the intraoperative period

The total amount of fluid given was significantly lesser in Group P (1776.37±189.11) as compared to Group C (3145.27±273.80), as shown in Graph 3 (P<0.001).



Graph 2: Amount of colloid given in the intraoperative period

The lactate levels at the time of incision and 6 h postoperatively were comparable in both the groups. The requirement for blood transfusion was also similar in the two groups. There was no statistical difference in the incidence of oliguria.

As depicted in Graph 4, patients in Group P and three patients in Group C had vasopressor requirement. P-value was statistically insignificant (P>0.05).

In the post-operative period, some other parameters such as kidney function test, return of bowel sounds, and time for return of flatus passage were compared in Group P and Group C. $P > 0.05$ for all these parameters found to be statistically insignificant, as shown in Table 3.

DISCUSSION

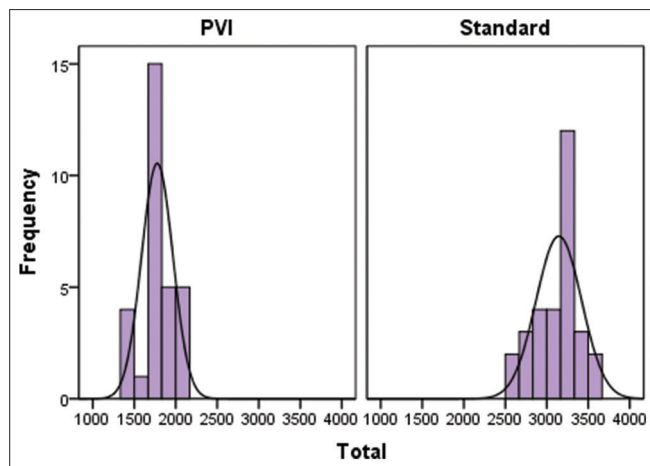
Among the various predictors to guide fluid therapy, CVP has always been considered as the most common indicator for assessing fluid status. It is a common notion that CVP gives appropriate information about the circulatory status,

but it was found to be untrue.¹⁰ Interpretation of CVP is not straight forward as pleural and abdominal pressures can also affect venous compliance, so a given value of CVP is not always a proper indicator of preload.¹¹ A systemic review done by Marik et al., showed that there is no correlation between CVP and circulating blood volume and it is important to mention that neither high, normal or low CVP nor the response to fluid loading should be used as a guide to fluid management.²⁰ This leads to evolution of minimally invasive and non-invasive dynamic indicators which rely on cardiopulmonary interactions in mechanically ventilated patients and are better predictors of fluid responsiveness than static indicators such as CVP and PAOP. The most recent modality which is gaining popularity due to its non-invasive nature and simplicity in interpretation is the use PVI to guide fluid therapy.

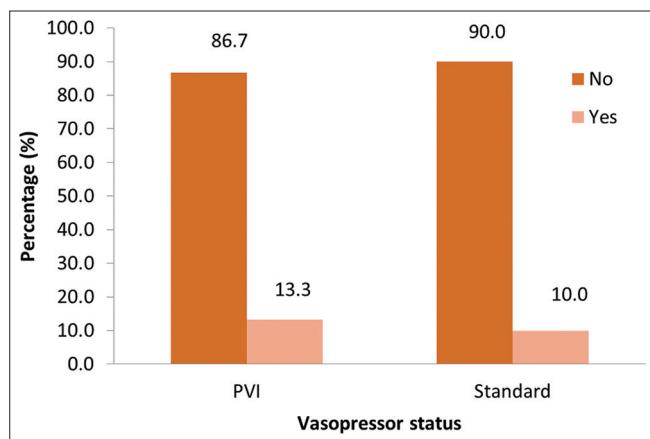
This was in concordance with the study done by Cannesson et al., who demonstrated that the PVI predicts fluid responsiveness in the operating room and they showed that if the cutoff value of PVI is taken as 14% then patients with higher values can be taken as responders and patients with lower values are most likely non-responders to intravascular volume expansion (in terms of an increase of cardiac index).⁶ It is superior to the findings of Keller et al., and Loupec et al., who used cutoff value as 19% and 17%, respectively.¹³

We found that fluid management according to PVI resulted in less crystalloid administration amounting to 984.70 ± 51.16 mL as compared to the patients who were managed using CVP as a guide to fluid therapy 2395.27 ± 209.68 mL ($P < 0.001$), and the total amount of fluid in the PVI group (1776.37 ± 189.11) mL was lower as compared to the CVP group where it was (3145.27 ± 273.80) mL ($P < 0.001$). Our results agree to the conclusion of Forget et al., who reported a significant decrease in crystalloid ($P = 0.004$) and total fluid ($P = 0.049$).¹⁴ Thus, the use of the non-invasive PVI appears to be better than the traditional hemodynamic parameters such as CVP in predicting fluid responsiveness. These data support previous work showing that plethysmography variability can predict fluid responsiveness in cardiac, general surgical, and intensive care patients. The amount of colloid given in the PVI group was higher (791.67 ± 161.93) mL than the CVP group (750.00 ± 196.96) mL, but it was not statistically significant. This could be due to relatively more blood loss in Group P.

If the mean arterial pressure goes below 65 mm Hg, we used noradrenaline infusion to maintain it and its requirement was comparable in both groups which are statistically insignificant ($P = 0.688$). The adequacy of renal perfusion was assessed by taking serum creatinine value



Graph 3: Total amount of fluid given in the intraoperative period



Graph 4: Requirement of vasopressors intraoperatively

Table 3: Comparison of other variables in the study groups					
Variables	Group				P-value
	P		C		
	Mean	SD	Mean	SD	
Blood urea	17.50	5.73	18.83	6.93	0.420
Serum creatinine	0.77	0.13	0.77	0.12	0.878
Bowel sounds (h)	59.30	11.68	58.80	11.86	0.870
Flatus passage (h)	61.30	11.68	60.80	11.86	0.860

postoperatively which was normal in both the groups and statistically insignificant ($P=0.766$).

When urine output <0.5 mL/kg for >2 consecutive h, it was considered as oliguria. The main culprit of this drop in GFR is hypotension, which may be secondary to hypovolemia, cardiogenic, or septic shock. Prolonged or severe hypotension can lead to intraoperative oliguria and if hypotension persists for prolonged period that it can result in postoperative acute tubular necrosis, a form of severe renal insult. Eight patients in the PVI group and 7 patients in the control group had an episode of oliguria ($P=0.417$) which is statistically insignificant. Fluid administration in response to intraoperative oliguria can lead to diuresis.^{15,21} Neither the oliguria nor the intraoperative diuresis seem to predict post-operative renal failure (defined as need of dialysis) in elective surgical patients. However, further studies are needed to confirm it.

Several variables can be used to measure tissue perfusion and oxygenation. Apart from the hemodynamic parameters, we chose lactate levels in this study. It is a surrogate marker of tissue hypoxia and hence intravascular volume status.^{16,20} Lactate production occurs as a compensatory response due to decreased oxygen delivery and resulting anaerobic metabolism. It is an indirect but sensitive marker of organ perfusion. It has been used in critically ill patients as a risk stratification index for poor outcome. Serial lactate measurements are considered more important as a prognostic indicator than a single value as it reflects the interaction between lactate production and elimination.¹⁷ In this study, lactate was measured at the time of incision and then 6 h after the completion of the surgery.

In the PVI group, the initial lactate value was 1.13 ± 0.25 meq/L, and in CVP group, it was 1.10 ± 0.22 meq/L ($P=0.670$). Post-operative value rose to 2.18 ± 0.53 meq/L in the PVI group and 2.33 ± 0.47 meq/L in the CVP group ($P=0.257$). Although the value is not statistically significant, the rise in lactate level was lower in the PVI group. This is not in accordance with the study of Forget et al., who showed clinically significant lower values of lactate in the intraoperative period ($P=0.04$), 24 h postoperatively ($P=0.02$), and 48 h postoperatively ($P=0.03$).¹⁴ We compared the lactate levels at 6 h after the surgery which is at a different timing than the previous study and could not find a significant difference. Increasing the number of ABG would add to the cost of the study.

Several other factors are also involved in the rise of lactate levels. A solution containing lactate or acetate, blood transfusion, and anesthetic agents used are some of the causes. We used ringer lactate as the crystalloid solution as it is observed that infusion containing ringer lactate

does not interfere with the lactate measurement.¹⁸ Blood transfused in both the groups was statistically insignificant with $P=0.417$.

However, as PVI is directly influenced by the magnitude of cyclic changes in pleural pressure induced by mechanical inspiration, it cannot be recommended as a guide to fluid administration in patients who are not mechanically ventilated with regular tidal volume (for example patients undergoing surgery under regional anesthesia) or when chest compliance is abnormally increased (for example during open chest surgery) or decreased (for example in morbidly obese patients).¹⁹ Michard F et al. suggested the use of PPV monitoring in mechanically ventilated patients for not only monitoring fluid therapy but also before applying recruitment manoeuvres and positive end-expiratory pressure.²²

To summarize, this study showed that fluid administration guided by PVI resulted in less amount of crystalloid infusion and it can act as a reliable indicator for fluid infusion and preload responsiveness in patients receiving mechanical ventilation during the perioperative period.

Limitations of the study

Our study is not without limitations. The variation in PVI with respiration, mechanical ventilation, arrhythmias, etc. have not been studied. The same can be done with a larger sample size.

CONCLUSION

The use of PVI-guided fluid management was associated with lower lactate levels during major abdominal surgery. Patients in the PVI-guided group were given less crystalloid. Reduced lactate levels in PVI-guided patients suggest that PVI-guided fluid management may lead to fluid administration that is tailored to each individual patient's needs.

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PK- Definition of intellectual content, review of literature, implementation of study protocol, data collection, manuscript preparation and submission of article; **UA-** Concept design, review of literature, protocol preparation, data analysis, manuscript preparation, editing, proof reading, formatting and revision; **SB-** Preparation of tables and figures, data analysis, review manuscript; **JPR-** Review of manuscript, manuscript revision.

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