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ORIGINAL RESEARCH PERIOPERATIVE MEDICINE

Effectiveness of goal-directed fluid therapy guided by estimated continuous cardiac output (esCCO) in major gastrointestinal surgeries: a randomized controlled trial

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ABSTRACT

Background & Objective: This study was conducted to compare the effectiveness between goal-directed fluid therapy guided by Estimated Continuous Cardiac Output (esCCO) monitoring and liberal infusion therapy on the early perioperative and postoperative complications, as well as long-term complications in major gastrointestinal surgeries.

Methodology: A randomized controlled trial was conducted at Hanoi Medical University Hospital, Hanoi, Vietnam from October 2020 to October 2021. There were 138 patients enrolled in the study and divided randomly into two groups: Group LIF (liberal infusion therapy) and Group GD (goal-directed fluid therapy using esCCO monitors). The logistic regression (univariate and multivariate) analysis models were performed to evaluate the relationship between the complication (yes or no) and potential predictors.

Results: Mortality and length of hospital stay in the esCCO group were not different from those in the liberal infusion therapy group ($P > 0.05$). Postoperative respiratory complications such as pneumonia and pulmonary edema were lower in the Group GD but not statistically significant compared with the Group LIF (5.7% vs 7.4% with $P > 0.05$). There was a higher rate of acute kidney injury in the Group GD than in the Group LIF, but the difference was not statistically significant (5.7% vs 1.5% with $P > 0.05$). Other complications such as bleeding, wound infection, and tissue edema in the Group GD was almost equivalent to those in the Group LIF and the difference was not statistically significant.

Conclusion: Goal-directed fluid therapy according to esCCO guidelines reduced the amount of intraoperative fluids while maintaining hemodynamic stability during surgery, but has not shown a real effect in reducing postoperative complications. Further studies with a larger number of patients are needed, in high-risk groups of patients requiring intravenous fluids according to esCCO guidelines to better evaluate the effectiveness of reducing postoperative complications.

Abbreviations: esCCO - Estimated Continuous Cardiac Output; esSVI - Estimated Stroke Volume Index; PEEP - Positive End-Expiratory Pressure; MAC - Minimum Alveolar Concentration

Key words: esCCO; Gastrointestinal Surgeries; Goal-directed Fluid Therapy; Infusion Therapy; Randomized Controlled Trial

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1. INTRODUCTION

The process of intraoperative fluid infusion is to help the patient's body have enough effective circulating volume to compensate for the preoperative volume deficit due to fasting and the loss during surgery, to support perfusion and oxygenation of tissues, and maintain homeostasis and electrolyte balance.[1,2] In major gastrointestinal surgery, dehydration and electrolyte loss follow different mechanisms and degrees. Severe dehydration causes hypovolemia, which can lead to hypoperfusion and impaired organ function. Therefore, after gastrointestinal surgery, ensuring visceral perfusion also helps restore the anastomosis after surgery.[2–4] However, fluid overload (hypervolemia) can lead to interstitial edema, increased risk of volume overload, lung complications, acute kidney damage, and anastomotic dehiscence.[3,5] Inappropriate infusion during surgery can cause many serious complications for patients during and after surgery.[3,5]

There are many perspectives on fluid management in major gastrointestinal surgery. 'Liberal infusion therapy' (LIF) is one of the traditional infusion strategies, mainly based on patient weight, using a sizable volume of fluid up to 6−8 L on the first day of surgery.[5–7] However, the infusion of a large volume of fluid can lead to fluid overload, causing the risk of postoperative complications such as edema, weight gain, pulmonary complications, infections, and poor wound healing.[7,8] Fluid restriction on the other hand, may result in hypovolemia, failure to ensure stable hemodynamics and organ perfusion. Recently, 'Goal-directed fluid therapy' has been proposed to solve this problem. It is a targeted infusion therapy that optimizes fluids, responds to individual needs, maintains effective hemodynamics, reduces the rate of postoperative complications, and improves patient outcomes.[9] However, the benefit of this therapy is still controversial.[10,11] In addition, the most widely used hemodynamic monitoring devices require complicated processes and gadgets; and are invasive so can cause patient complications such as bleeding, infection, or thrombosis.[12]

Estimated Continuous Cardiac Output (esCCO) monitoring is a non-invasive and continuous method of cardiac output assessment. Previous evidence demonstrated that esCCO was sufficiently accurate for clinical use,[13–15] and provids several hemodynamic parameters and trends in cardiac output during monitoring and treatment of patients.[14,15] Compared to invasive or minimally invasive techniques, esCCO is safe for the patient and easy to operate for the anesthesiologist. This study was conducted to compare the effectiveness of goal-directed fluid therapy guided by esCCO monitoring and LIF on the early perioperative and postoperative complications, as well as long-term complications in major gastrointestinal surgeries.

2. METHODOLOGY

2.1. Design of the study

A randomized controlled trial was conducted at Hanoi Medical University Hospital, Hanoi, (Vietnam) from October 2020 to October 2021. Ethical approval for this study was obtained from Hanoi Medical University Institutional Ethical Review Board (HMU IRB) with approval number IRB-VN01.001/IRB00003121/FWA00004148. The inclusion criteria were; patients aged 18−70 y, scheduled for major abdominal surgery. The exclusion criteria included, urgent or minor surgeries; chronic renal/cardiac failure; cardiac arrhythmias; patients had a temporary/permanent pacemaker; patients with body mass index (BMI) over 30 kg/m^2. We enrolled 138 patients in the study and divided randomly into two groups by computer software: Group LIF (LIF) and Group GD (goal-directed fluid transfusion using esCCO monitors, Nihon Kohden, the Life Scope PMV-4763 ver.01-10, 2020). The sample size was computed by using a reference from Kaiyu Yin et al. in elderly adults,[16] with type I error of 0.05 and type II error of 0.2, 15% of difference between two groups. The required sample size for each group was 66 patients. We added 5% to compensate withdrawals or did not complete the study, so the final sample size for each group was 70 patients.

2.2. Management of anesthesia

Before induction of anesthesia, esCCO monitors were applied to patients of Group GD: 3-electrodes ECG, pulse oximetry, non-invasive blood pressure, and demographic information of the patient (e.g., gender, age, weight, height) were entered into the esCCO monitor. After that, esCCO, estimated continuous cardiac index (esCCI), estimated stroke volume index (esSVI) were calculated. Regular monitoring, e.g., ECG, pulse oximetry, and non-invasive blood pressure was done.

Anesthesia was induced with fentanyl 2 µg/kg, propofol 2 mg/kg, and rocuronium 0.6 mg/kg for intubation. Mechanical ventilation was set with following settings: tidal volume (VT) 6−8 ml/kg, the fraction of inspired oxygen (FiO_2) 50%, positive end-expiratory pressure (PEEP) 5 cmH_2O, inspiration to expiration ratio (I:E) and respiratory rate were adjusted to maintain $EtCO_2$ 30−35 mmHg. Anesthesia was maintained by sevoflurane 1.5−2% to guarantee minimum alveolar concentration (MAC) 1−1.2.

Patients in Group LIF were treated with LIF: a bolus of 10 ml/kg of Ringerfundin® (B Braun) (ringer acetate malate) was infused 30 min before induction of anesthesia, then 8 ml/kg/h during surgery. If the patient had hypotension, systolic blood pressure (SBP) > 90 mmHg or a decrease in SBP of > 20% of baseline), managed following CVP: if CVP was < 5 cmH_2O, 3 ml/kg Gelofusine® was infused for 15 min. If CVP was ≥ 5 cmH_2O, 6 mg ephedrine or 100 µg phenylephrine was injected. The process was repeated until the SBP was normal. The postoperative infusion was continued at a dose of 1.5 ml/kg/h for 24 h.

Patients in Group GD were treated with goal-directed fluid therapy. Before induction, a bolus of 250 ml Ringerfundin infusion was infused if esSVI < 40 ml/beat/m^2. The infusion was continued @ 3 ml/kg during operation with the goal of keeping esSVI from 40−60 ml/beat/m^2. If the patient developed hypotension, a fluid challenge was offered in the form of a bolus of 250 ml Ringerfundin over 15 min. The fluid challenge was repeated if the increase in esSVI was ≥10% (fluid challenge positive). If the esSVI increased < 10% (fluid challenge negative) and the esCCI < 2.5 L/min/m^2, then we started dobutamine 3 µg/kg/min; if esCCI was ≥ 2.5 L/min/m^2, we used 6 mg ephedrine or phenylephrine until the patient's SBP was normal. The infusion of Ringerfundin was maintained postoperatively with the target esSVI to be 40−60 ml/beat/m^2.

2.3. Research outcome

The primary outcomes were; the perioperative hemodynamic changes, the amount of fluid infused, the response to the fluid challenge, and the vasopressor used. Secondary outcomes were surgical complications, e.g., bleeding, surgical-site infection, anastomotic failure, pneumonia, pulmonary edema, tissue edema, acute kidney injury, unplanned ICU admission and death in the first 28-day postoperative period.

Covariates included age, gender, weight, height, BMI, Charlson comorbidity score, endoscopic surgery, morbidity (e.g. chronic obstructive pulmonary disease, coronary disease, diabetes, hypertension), history of abdominal surgery, and history of abdominal radiotherapy.

2.4. Statistical analysis

Statistical analysis was performed using SPSS 20.0. Continuous variables are presented as mean ± standard deviation (SD) or median (lower quartile−upper quartile), while categorical variables are presented as percentages. The t-test student or the Mann-Whitney U-test was used for the comparison between continuous variables. The chi-square test was used for the categorical variables. The logistic regression (univariate and multivariate) analysis models were performed to evaluate the relationship between the complication (yes or no) and predictor variables. The odds ratio and 95% confidence intervals were calculated with the two-sided P value less than 0.05 indicating statistical significance.

3. RESULTS

3.1. Patient enrollment and follow up

From October 2020 to October 2021, a total of 152 patients were assessed for eligibility. There were 5 patients who refused to give consent, 5 patients refused to undergo surgery, 2 patients did not meet inclusion criteria, 2 patients failed to complete the study. Therefore, a total of 138 patients were enrolled in the study. 68 patients were divided into Group LIF and the rest were divided into Group GD (Figure 1).

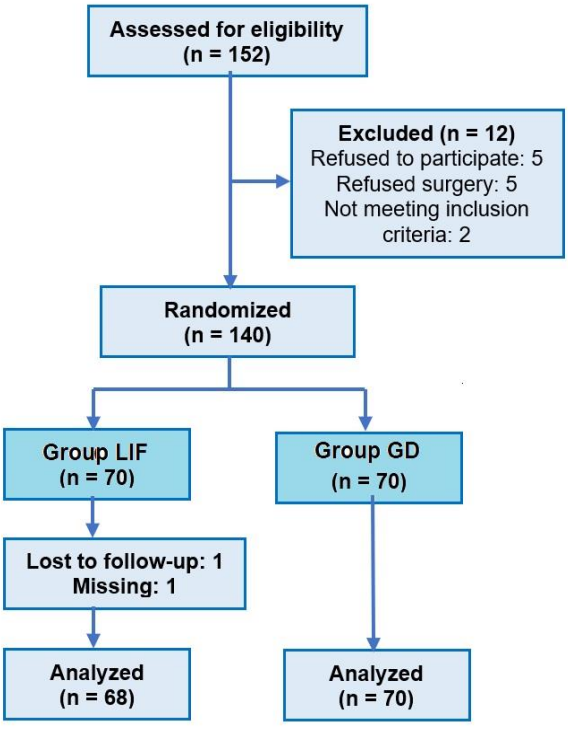

Figure 1: Flow diagram of the study participants

Table 1: Demographic characteristics

Demographic data	Group LIF (n = 68)	Group GD (n = 70)	P
Age (min−max) median (LQ−UQ)	57.9 ± 11.5 32−80 59.5 (51.5−65.8)	60.5 ± 12.3 25−84 61 (55.8−69.3)	0.20
Male (%)	57.4%	50%	0.39
Weight (kg) (min−max) median (LQ−UQ)	52.7 ± 7.7 30−74 52 (48−56)	52.7 ± 8.2 35−70 50 (46−58.3)	1.00
Height (cm) (min−max) median (LQ−UQ)	159.7 ± 7.1 145−176 160 (155−165)	157.0 ± 8.4 140−175 156 (150−165)	0.05
BMI (kg/m^2) (min−max) median (LQ−UQ)	20.6 ± 2.5 12.5−25.4 20.9 (19.0−22.5)	21.4 ± 2.8 15−30 21.3 (19.1−23.2)	0.12
Charlson score (points) (min−max) median (LQ−UQ)	3.4 ± 1.6 0−9 3 (2−4)	3.8 ± 1.8 0−10 4 (3−4)	0.14
Endoscopic surgery (%)	44.1%	55.7%	0.23
Chronic Obstructive Pulmonary Disease	5 (7.4)	4 (5.7)	0.74
Coronary disease	1 (1.5)	1 (1.4)	0.99
Diabetes mellitus	5 (7.4)	8 (11.4)	0.56
Hypertension	12 (17.6)	17 (24.3)	0.41
History of abdominal surgery	13 (19.1)	9 (12.9)	0.36
History of abdominal radiotherapy	6 (8.8)	5 (7.1)	0.76

LQ−UQ: Lower Quartile−Upper Quartile; Data presented as mean ± SD, Range (min−max) or percent or n (%)

The demographic data are shown in Table 1. There were no significant differences between the two groups with age, gender ratio, weight, height, body mass index, Charlson score, preoperative history, operative/anesthesia duration (P > 0.05).

3.2. Comparative fluid infusion

Compared with Group LIF, the amount of preoperative/intraoperative crystalloid infusion in Group GD was remarkably less. There was no significant difference in the duration of operation, fasting time, the amount of intraoperative colloids, urine volume, blood loss, net fluid balance and the rates of using vasopressor intraoperative in both groups (P > 0.05) (Table 2).

3.3. Comparative perioperative hemodynamic changes

There was statistically no significant difference in the mean heart rate, mean systolic blood pressure (SBP) and mean diastolic blood pressure (DBP) of the two groups (P > 0.05). There was statistically no significant difference in the percent of post-induction hypotension and the number of intraoperative hypotension events between the two groups. The intraoperative hypotension rate and the rate of positive fluid challenge in Group LIF were significantly lower than Group GD (Table 3).

3.4. Comparative postoperative complications

Both groups had no significant difference in the length of hospital stay, the postoperative recovery time, and postoperative complications (Table 4).

Univariate logistic regression analyses of the variables associated with postoperative complications

Postoperative complications were observed in 28 patients of both groups (13 patients in Group LIF and 15 patients in Group GD). Results of multivariate analysis show that there were some significant predictors for the postoperative complications: operative duration ≥ 4 h, intraoperative crystalloid infusion ≥ 2 L, number of intraoperative hypotension events ≥ 5, net balance fluid ≥ 2 L and history of abdominal radiation/surgery (P < 0.05) (Table 5).

4. DISCUSSION

This study provided evidence regarding the use of esCCO guidance for goal-directed fluid therapy and 'Liberal infusion therapy' (LIF) on the early perioperative and postoperative complications, as well as

Table 2: Fluid infusion characteristics

Parameters		Group LIF (n = 68)	Group GD (n= 70)	P-value
Fasting time (h)	Mean ± SD (min−max) median (LQ−UQ)	14.6 ± 7.8 (8−72) 12 (12−16)	13.8 ± 3.9 (8−26) 12 (11−16)	0.43
Time of surgery (min)	Mean ± SD (min−max) median (LQ−UQ)	201.3 ± 80.4 (120−430) 180 (132.5−240)	179.0 ± 64.7 (120−330) 160 (120−216.25)	0.07
Blood loss (ml)	Mean ± SD (min−max) median (LQ−UQ)	130.9 ± 99.1 (50−400) 100 (50−200)	114.3 ± 83.9 (50−400) 100 (50−100)	0.29
Intraoperative crystal infusion (ml)	Mean ± SD (min−max) median (LQ−UQ)	1757.8 ± 565.9 (900−3900) 1560 (1425−2000)	1195.0 ± 553.5 (500−3500) 1000 (800−1500)	**0.0001***
Intraoperative colloid infusion (ml)	Mean ± SD (min−max) median (LQ−UQ)	233.8 ± 314.6 (0−1000) 0 (0 −500)	137.9 ± 211.7 (0−500) 0 (0−400)	**0.04***
Preoperative crystal infusion (ml)	Mean ± SD (min−max) median (LQ−UQ)	511.9 ± 81.2 (300−740) 500 (472.5 −550)	40.7 ± 115.2 (0−600) 0 (0−0)	**0.0001***
Urine volume (ml/kg/h)	Mean ± SD (min−max) median (LQ−UQ)	1.59 ± 1.07 (0.50−6.81) 1.59 (1.11−2.12)	1.42 ± 0.83 (0.2−5) 1.29 (0.82 −1.90)	**0.03***
Net fluid balance (ml)	Mean ± SD (min−max) median (LQ−UQ)	2083.0 ± 703.0 (870−4640) 1900 (1692.5−2392.5)	1050.0 ± 597.0 (400−3600) 875 (700−1262.5]	**0.0001***

Table 3: Comparative hemodynamic changes during surgeries

Parameters		Group LIF (n = 68)	Group GD (n= 70)	P-value
Intraoperative hypotension	n (%)	43 (63.2%)	55 (78.6%)	**0.04***
Post-induction hypotension	n (%)	29 (42.6%)	33 (47.1%)	0.40
Number of intraoperative hypotension event	Mean ± SD	2.1 ± 2.7	2.1 ± 2.1	0.17
Positive fluid challenges	n (%)	11 (16.2%)	43 (61.4%)	**0.0001***

long-term complications in major gastrointestinal surgeries. We investigated the complications related to infusion by the above two methods, including postoperative bleeding, surgical site infection, pulmonary infection, acute kidney injury, pulmonary edema, tissue edema and anastomotic failure. The occurrence of complications 28 days after surgery is more important than preoperative risk and intraoperative factors in determining postoperative survival.[17]

The study results showed that the differences in the above-mentioned postoperative complications between the two groups were equivalent; 21.4% and 19.1% in the Group GD and Group LIF respectively. This result is similar to a previous study in terms of complication rates as well as the relationship of complication rates between the two groups, because of similar study populations.[18] Another study performed by David Pestana et al. on the effectiveness of goal-directed fluid therapy by noninvasive cardiac output monitor (NICOM) in patients

Table 4: Postoperative complications

Parameters	Group LIF (n = 68)	Group GD (n = 70)	P-value
Postoperative bleeding	2 (2.9)	1 (1,4)	0.62
Surgical site infection	1 (1.5)	2 (2.9)	1.00
Pulmonary infection	5 (7.4)	4 (5.7)	0.74
Acute kidney injury	1 (1.5)	4 (5.7)	0.37
Pulmonary edema	0 (0)	0 (0)	1.00
Tissue edema	3 (4.4)	2 (2.9)	0.68
Anastomotic failure	1 (1.5)	2 (2.9)	1.00
Complications	13 (19.1)	15 (21.4)	0.83
Death within postop 28 days	0 (0)	0 (0)	1.00
Unplanned postop ICU admission	4 (5.9)	9 (12.9)	0.24
Postop recovery time (day)	0.34 ± 0.75	0.54 ± 1.11	0.16
Length of hospital stay (day)	10.5 ± 3.9	9.6 ± 3.6	0.17

Data presented as n (%) or Mean ± SD

undergoing major abdominal surgery in 2014 also concluded that there was no statistically significant difference in morbidity and mortality between the infusion group according to the target and the control group (P > 0.05), which was similar to our study.[19] However, the rate of complications was significantly higher than in our study, especially in the group of complications related to surgery such as postoperative bleeding, wound infection, open anastomosis, and more patients died than our study.[19] A previous systemic Review analyzing 23 randomized controlled trials concluded that the benefit of goal-directed fluid therapy might not be as clear as previously suggested, where the reduction in the rate of complications after surgery was not confirmed.[20] However, the author recommended the practice of goal-directed fluid therapy in the group of high-risk patients after surgery because of the improvement in complications in some studies in this patient population. We recognized the need for more studies of Goal-directed fluid therapy under esCCO guidelines in high-risk patient populations with larger sample sizes to better assess the effect on postoperative complications.

No patient in our study died after 28 days of study. This result was lower than the studies of David Pestana,[19] in which 4.2% died in the Group GD and 5.7% in Group LIF. The study of Rubert Pearse[21] had a result of 9.7% and 11.7%, respectively, due to the reasons of the study population being on high-risk subjects mentioned above. However, these authors all concluded similarly to us that there was no difference in mortality between the two infusion groups (P > 0.05). Several larger studies examining mortality at 28 days, 90 days, and 1 year also showed similar results.[21] A previous review also showed similar results on the risk of death in the infusion-targeted and control groups.[20] Postoperative hospital stay in our study was not a normally distributed variable. This is because the study subjects belonged to many different types of surgery and the distribution of surgical types varied greatly in number. Furthermore, the study sample was not large enough. The length of hospital stay in the targeted infusion group was 8.59 ± 3.6 days and the liberal therapy group was 9.38 ± 4.11 days, the median homology was 8 days. The length of hospital stay after surgery is a complex

Table 5. Multivariate regression analyses of postoperative complications

Parameters	Multivariate analysis	
	OR (95% CI)	P value
Age (≥ 65)	1.79 (0.62–5.12)	0.278
BMI (< 18.5)	3.28 (1.00−10.69)	**0.049***
Duration of operation (≥ 240 min)	4.86 (1.34−17.61)	**0.016***
Intraoperative crystal infusion (≥ 2.0L)	1.008 (0.14−6.82)	0.994
Blood loss (> 300 ml)	1.32 (0.20−8.75)	0.769
Intraoperative using vasopressor	1.19 (0.39−3.66)	0.750
Number of intraoperative hypotension event (≥ 5)	5.59 (1.15–27.11)	**0.032***
Net balance fluid (≥ 2L)	1.33 (0.21−8.21)	0.757
History of abdominal surgery/radiation	2.80 (1.02−7.72)	**0.047***
Intraoperative fluid therapy guided by esCCO	2.32 (0.71−7.58)	0.164
Postop recovery time (day)	1.79 (0.62–5.12)	0.278
Length of hospital stay (day)	3.28 (1.00−10.69)	**0.049***

*Data presented as n (%) or Mean ± SD; * P is sigmificant*

variable influenced by many factors, before, during, and after surgery, namely the patient's physical condition and health status, the patient's pre-operative pathology, compliacted and prolonged surgery, the rate of complications after surgery all lead to a longer hospital stay. The length of hospital stay also depends on social aspects such as the postoperative care system and the discharge protocol of each medical center. The hospital stay of the infusion group according to our study was 8.59 ± 3.6 days, shorter than the studies of David Pestana, which showed that the hospital stays of 11.5 (8−15) days.[19] Other authors showed 12, 6 ± 2.4 days and 17.5 days.[21,23] This issue can be explained by the patient characteristics in the above-mentioned studies with the elderly or high-risk group.

5. CONCLUSIONS

Goal-directed fluid therapy according to Estimated Continuous Cardiac Output (esCCO) monitoring guidelines reduced the amount of intraoperative fluids while maintaining hemodynamic stability during surgery, but has not shown a significant effect in reducing postoperative complications. Further studies with a larger number of patients are needed, in high-risk groups of patients requiring intravenous fluids according to esCCO guidelines to better evaluate the effectiveness of reducing postoperative complications.

6. Data availability

Numerical data of this study are available upon request. Please contact corresponding author (Vu Hoang Phuong, vuhoangphuong@hmu.edu.vn) for further information.

7. Conflicts of Interest

The authors declare that there is no conflict of interest regarding the publication of this paper.

8. Funding Statement

This study was funded by Hanoi Medical University.

9. Authors' contribution

HPV: conduct study, literature search, statistical analysis and manuscript write

NDAD: literature search, statistical analysis and manuscript write

VDT: conduct study, statistical analysis and manuscript write

XVL, QTT, THT, HTN: statistical analysis and manuscript write

RO: conduct study, manuscript write

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