Randomised Controlled Trial

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# Impact of transesophageal echocardiography dynamic monitoring of left ventricular preload on postoperative gastrointestinal function in colorectal cancer patients undergoing radical surgery

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**Background:** Patients undergoing intestinal tumour surgery are fasted preoperatively for a series of bowel preparations, which makes it difficult to assess the patients' volume, posing a challenge to intraoperative fluid replacement. Besides, inappropriate fluid therapy can cause organ damage and affect the prognosis of patients ,and it increases the burden of patients and has a certain impact on patients and families.

**Material and methods:** The authors designed a single-centre, prospective, single-blinded, randomized, parallel-controlled trial. Fifty-four patients undergoing elective radical resection of colorectal cancer were selected and divided into two groups according to whether transesophageal echocardiography (TEE) was used or not during the operation, that is the goal-directed fluid therapy (GDFT) group (group T) guided by TEE and the restrictive fluid therapy group (group C). Fluid replacement was guided according to left ventricular end-diastolic volume index (LVEDVI) in group T and according to restrictive fluid replacement regimen in group C.

**Results:** The first postoperative exhaust time and defecation time in group T [(45 ± 21), (53 ± 24) h] were significantly shorter ($P < 0.05$) than those in group C [(63 ± 26), (77 ± 30) h]. There were no significant differences ($P > 0.05$) in liquid intake time and postoperative nausea and vomiting incidences between the two groups. The total intraoperative fluid volume in group T was significantly higher ($P < 0.05$) than that in group C. There was no significant difference ($P > 0.05$) in urine volume between the two groups. There were no significant differences ($P > 0.05$) in lactate content, mean arterial pressure, and heart rate at various time points between the two groups. The length of hospital stay in group C [(18 ± 4) days] was significantly longer ($P < 0.05$) than that in group T [(15 ± 4) days].

**Conclusions:** For patients undergoing colorectal cancer surgery, fluid therapy by monitoring LVEDVI resulted in faster recovery of gastrointestinal function and shorter hospital stay.

**Key words:** Colorectal cancer, gastrointestinal function, left ventricular end-diastolic volume, transesophageal echocardiography

## Introduction

Fluid therapy is an important part of perioperative management, and inappropriate fluid therapy can cause organ damage and affect the prognosis of patients. It is well-known that the fluid replacement is conducted based on the patient's weight and fasting time in the conventional fluid therapy, regardless of the patient's individual differences, cardiopulmonary function, and other conditions[1]. Therefore, the conventional fluid replacement can cause tissue and organ oedema, delayed recovery of gastrointestinal function, and anastomotic leakage, thus affecting the prognosis of patients[2]. Besides, patients undergoing intestinal tumour surgery are fasted preoperatively for a series of bowel preparations, which makes it difficult to assess the patients' volume, posing a challenge to intraoperative fluid replacement. Restrictive fluid replacement in major abdominal surgery was previously considered to facilitate reducing the incidence of wound infection[3], shortening the length of hospital stay, and decreasing mortality. However, it has also been proposed that

### HIGHLIGHTS

- The goal-directed fluid therapy group with transesophageal echocardiography dynamic monitoring had faster recovery of gastrointestinal function and relatively shorter length of hospital stay after surgery.
- Transesophageal echocardiography-guided goal-directed fluid therapy can be used as a method to clinically guide fluid replacement.

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restrictive fluid therapy causes hypotension in patients during surgery and increases the probability of the use of vasoactive drugs[4], which may impair organ perfusion and cause myocardial damage[5]. The vasoactive-inotropic score ( VIS) proposed by Gaies *et al.*[6] It is a valid index for evaluating the supportive effects of vasoactive drugs on the cardiovascular system. Therefore, the VIS was used to count the intraoperative use of vasoactive drugs in this study; meanwhile, the changes of troponin values between the two groups before and after surgery was compared. By analyzing the changes of troponin in the two groups after surgery, whether vasoactive drugs cause myocardial damage was assessed. Goal-directed fluid therapy (GDFT) is a new concept of perioperative fluid therapy, which aims to achieve good therapeutic outcomes by developing individualized volume therapy regimen for patients[7]. Parameters for GDFT monitoring are pulse pressure variation (PPV), inferior vena cava, etc[8,9]. The aim of this study is to evaluate whether goal-directed fluid therapy guided by left ventricular end-diastolic volume index (LVEDVI) measured by transesophageal echocardiography (TEE) can promote the recovery of gastrointestinal function in patients undergoing intestinal tumour surgery.

## Materials and methods

### *Patients*

In this single-centre, prospective, single-blinded, randomized, parallel-controlled trial, patients undergoing elective radical resection of colorectal cancer in the Department of Gastrointestinal Surgery from April 2023 to September 2023 were selected. The research project was ethically approved by the Research Ethics Committee of the First people's hospital of Lianyungang and principles of Helsinki Declaration were duly followed. Furthermore, the trial was registered by the Chinese Clinical Trial Registry and carried out according to the reporting guidelines of CONSORT criteria. Patients with American Society of Anesthesiologists (ASA) Class I-III, aged 18–75 years, male or female. Exclusion criteria were significant heart, liver or kidney disease, history of oesophageal disease or oesophageal surgery, oropharyngeal tumour, malformation, and maxillofacial injury, proximal aortic stenosis, recurrent Colon Cancer aortic aneurysms, and severe coagulation disorders.

### *Randomization and blinding*

Patients were randomized to either GDFT group (group T) or the restrictive fluid therapy group (group C) in a 1:1 ratio according to a computer-generated randomization sequence. The random sequence was generated with sequentially numbered, opaque, and sealed envelopes by an anesthesiologist. Considering that there are great differences in the experimental process between a group using TEE and a group not using TEE, the anesthesiologists were aware of the group assignments and performed the experimental procedures. However, all patients, the surgeons, and the postoperative outcome assessor were blinded to the group allocation.

### *Standard procedure of anaesthesia*

All the patients were divided into two groups according to the random number table that is the GDT group (group T, 27 cases) guided by transesophageal echocardiography (TEE) and the restrictive fluid therapy group (group C, 27 cases). Electrocardiogram, pulse oximetry ($SpO_2$), noninvasive blood pressure (NIBP), invasive arterial blood pressure (IBP), and bispectral index (BIS) were monitored after patient admission. All monitoring sensors were localized and zeroed at the place staying horizontally to the fourth intercostal space—mid axillary line, that is the heart's place. The data would be rejected when the fast-flush test indicated unacceptable pressure records.

Induction of anaesthesia: 0.2 mg/kg remazolam, 0.2 mg/kg cisatracurium, 0.5 ug/kg sufentanil, and 2 mg/kg propofol were intravenously injected, and tracheal intubation was assisted by video laryngoscope. All patients inhaled 60% air-oxygen mixture during surgery and were ventilated in pressure-controlled ventilation-volume guaranteed (PCV-VG) mode with the tidal volume set at 6–8 ml/kg to regulate respiratory rate and maintain partial pressure of end-tidal carbon dioxide between 35 and 45 mmHg. After induction of anaesthesia, the right internal jugular vein was selected for deep vein puncture and catheterization on the patient. During the operation, propofol and remifentanil were used to maintain anaesthesia, the BIS index was maintained at 40–60, nasopharyngeal temperature was monitored during the operation, room temperature was controlled at 22–24°C, and central body temperature greater than 36°C was maintained by liquid warming device, peritoneal washings warming, warming blanket, and other measures.

### *Intraoperative fluid infusion protocol*

In both groups, infusion was performed according to different fluid replacement regimens immediately after intubation and induction. In group T, fluid infusion was guided by LVEDVI measured by TEE: when LVEDVI was less than 37 ml/$m^2$ in male or 29 ml/$m^2$ in female, fluid replacement therapy was performed to maintain LVEDVI at 37–74 ml/$m^2$ (male) or 29–61 ml/$m^2$ (female)[10]. When blood pressure is reduced by more than 20% of preoperative basal blood pressure, we would measure LVEDVI again. In group C, balanced salt solution was administered at no more than 5 ml/kg during induction of anaesthesia and maintained at 5 mL/(kg*h) during surgery until the end of surgery. In the case of body weight greater than or equal to 100 kg, fluid replacement was calculated with 100 kg as the maximum body weight; intraoperative blood loss could be replaced with colloids or red blood cells (replace whatever fluid is being lost), and intravenous fluid replacement was continued postoperatively at 0.8 ml/(kg*h). If the fluid replacement amount exceeded the upper limit of the above values but the patient's blood pressure was less than 20% of the basal blood pressure, norepinephrine 0.1–0.3 μg/(kg*min) was infused by an intravenous pump; urapidil of 0.2–0.5 mg/kg was injected by intravenous bolus in case of high blood pressure; blood pressure was maintained at ± 20% of the basal value. Blood pressure was also controlled according to this regimen in group C.

### *Outcome measures*

The following parameters were recorded: the first postoperative exhaust time and defecation time, I-FEED score, maximum and mean intraoperative use of VIS, total intraoperative fluid volume, urine volume after the surgery, respective blood lactate content (LAC), mean arterial pressure (MAP), and heart rate (HR) before the start of surgery, after tumour resection, and after the surgery, postoperative liquid intake time, postoperative nausea

and vomiting incidences were recorded for the first 24 h postoperatively; anastomotic leakage and surgical site infection rate were recorded for the first postoperative day to the time of discharge, length of hospital stay, and other complications.

The primary outcome of the study were the first postoperative exhaust time and defecation time. The secondary outcomes were I-FEED score, maximum and mean of VIS; troponin values before and after surgery and length of hospital stay. Additionally, total intraoperative fluid volume, urine volume, three time points of LAC, MAP ,HR, postoperative liquid intake time, postoperative nausea and vomiting incidences, anastomotic leakage, surgical site infection rate were recorded.

### *Sample size*

Before beginning this study, we had performed a pilot study to identify the sample size. According to the results of the pre experiment, the mean value of the exhaust time in the T group was 36 h after surgery, and the standard deviation was 20. The mean value of the exhaust time in the group C was 55 h after surgery, and the standard deviation was 23. A total of 46 patients were required for a two-sided alpha of 5% and 90% power (*t*-test). We anticipated 20% dropout, and considering the 1:1 ratio, 56 patients were eventually recruited in the study.

Data were processed by SPSS 25.0 statistical software (IBM). Continuous variables were expressed as the mean ± SD or median (first quartile [Q1]-third quartile [Q3]), and the comparison between groups was performed by two independent sample *t*-test or the Mann–Whitney U test. Categorical variables were reported as numbers and percentages, and the comparison was analyzed with the $\chi^2$ test or Fisher exact test. Generalized estimating equations (GEE) were used to analyze I-FEED scores. The I-FEED scores of the two groups were calculated using GEE with time, group, and group-by-time interaction as the covariates.

## Results

From April 2023 to September 2023, 56 patients had been assessed, and 2 patients had been excluded due to not meeting inclusion criteria or surgery being cancelled. A total of 54 patients entering the study were randomly allocated to two groups. 1 patient in the GDFT group and 2 patients in the restrictive fluid therapy group failed to complete the study. Finally, 26 patients in the GDFT group and 25 patients in the restrictive fluid therapy group were included in the analysis (Fig. 1).

### *Baseline clinical characteristics*

There was no significant difference in age, gender, body weight, BMI, ASA class, health status, and gastrointestinal disorder symptoms between the two groups ($P > 0.05$), as shown in Table 1.

### *Comparison of intraoperative conditions and fluid replacement*

There was no difference in operation type, tumour site, urine volume, and blood loss volume between the two groups. The infusion volume in group T was significantly higher than that in group C, and the maximum and mean VIS in group C were significantly higher than those in group T ($P < 0.05$), as shown in Table 2.

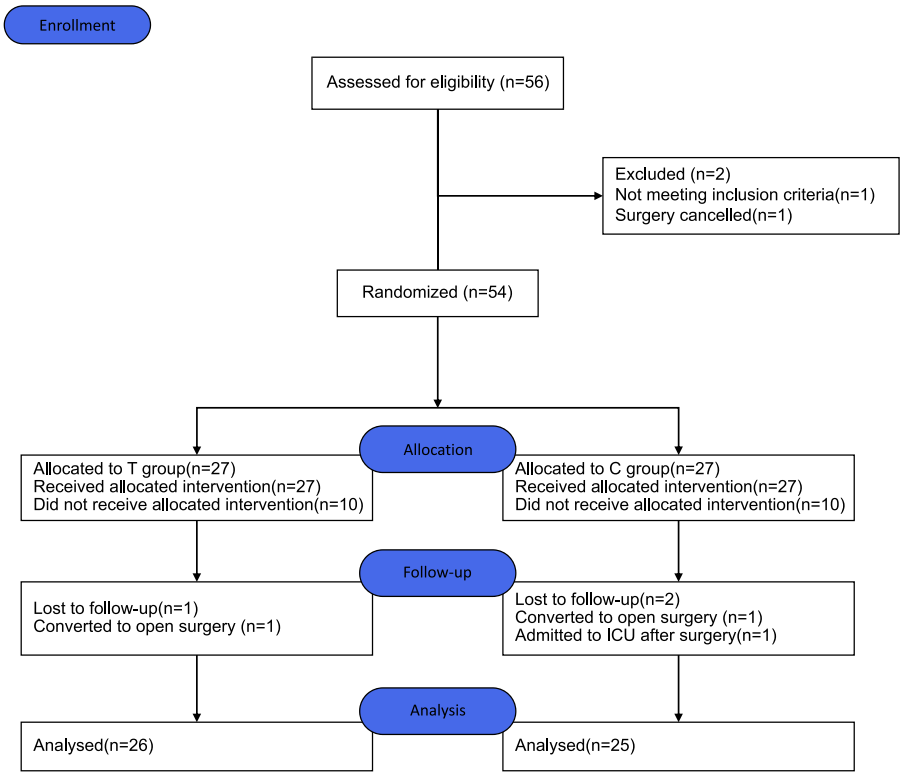


**Figure 1.** CONSORT flow diagram for the study.

### *Comparisons of LAC, MAP, HR, and postoperative gastrointestinal function and complications*

There were no significant differences ($P > 0.05$) in LAC, MAP, and HR at various time points between the two groups. The first postoperative exhaust time and defecation time in group T [(45 ± 21), (53 ± 24) h] were significantly shorter ($P < 0.05$) than those in group C [(63 ± 26), (77 ± 30) h]. The length of hospital stay in group C [(18 ± 4) days] was significantly longer ($P < 0.05$) than that in group T [(15 ± 4) days]. There were no significant differences ($P > 0.05$) in liquid intake time and postoperative nausea and vomiting incidences between the two groups, as shown in Table 3. One patient in the control group developed anastomotic leakage as of discharge.

The daily I-FEED scores are shown in Table 4. The main effect of the I-FEED score did not differ between the two groups ($P = 0.318$). Within 7 days after surgery, the time effect of the I-FEED score differed in both groups.

The effects of the group-by-time interaction did not differ significantly ($P = 0.292$).

The comparison of preoperative and postoperative troponin are shown Table 5. Group T and Group C preoperative and postoperative troponin were statistical differences ($P < 0.05$), Preoperative T and C groups troponin were not statistically significant ($P > 0.05$), Postoperative T and C groups troponin were not statistically significant ($P > 0.05$).

## Discussion

Effective perioperative fluid management is crucial for anaesthesia and postoperative recovery. GDFT offers new methods for fluid management during surgery. I In this study, the impacts of intraoperative fluid therapy by a restrictive regimen and LVEDVI on outcomes in patients undergoing gastrointestinal surgery were compared. The results of this study showed that, compared to restrictive infusion, LVEDVI-guided fluid therapy increased gastrointestinal function recovery and decreased postoperative hospital stay. However, the incidences of postoperative complications were similar in patients treated with both strategies.

Studies have shown that GDFT benefits the recovery of postoperative gastrointestinal function in patients undergoing gastrointestinal surgery. Lahner *et al.*[11] showed that intraoperative monitoring of PPV could be used to guide fluid replacement therapy based on changes in blood volume. However, the monitoring of PPV has some limitations. For example, for patients with atrial fibrillation, PPV monitoring can be biased. In addition, a decrease in PPV caused by vasodilatation after anaesthesia or inflammation does not represent hypovolemia. Therefore, in this study, TEE was used to monitor LVEDVI for volume assessment, which avoids inaccurate PPV monitoring and facilitates more intuitive patient volume monitoring and real-time assessment of patient blood volume, providing certain benefits to clinical fluid replacement.

Identifying intravascular volume status accurately and early via intraoperative fluid monitoring is essential to prevent hypoperfusion and volume overload for perioperative management. TEE monitoring directly observes the structure and function of the heart and accurately determine the preload status of patients for improveing the accuracy and effectiveness of circulatory processing measures. Additionally, TEE probe frequency is higher than TTE probe, and the images are clearer

**Table 1**

**General conditions of patients**

| | Group T | Group C | *P* |
|---|---|---|---|
| Age (year) | 62.1 ± 2.2 | 62.8 ± 2.6 | 0.829 |
| Body weight (kg) | 62.8 ± 2.2 | 62.4 ± 2.1 | 0.887 |
| Height (cm) | 165.7 ± 1.7 | 161.6 ± 1.7 | 0.149 |
| BMI (kg/m$^2$) | 22.8 ± 0.7 | 23.5 ± 0.77 | 0.566 |
| Body surface area (m$^2$) | 1.8 ± 0.2 | 1.7 ± 0.1 | 0.511 |
| Gender, male, *n* (%) | 13 (50) | 8 (32% | 0.079 |
| ASA class, *n* (%) | | | 0.068 |
| I | 0 | 0 | |
| II | 20 (76.9) | 20 (80) | |
| III | 6 (23.1) | 5 (20) | |
| Health status, *n* (%) | | | |
| Hypertension | 3 (11.5) | 5 (20) | 0.49 |
| Diabetes mellitus | 0 | 1 (4) | 0.336 |
| Heart disorder | 1 (3.8) | 0 | 0.311 |
| Cerebral infarction | 1 (3.8) | 0 | 0.336 |
| Gastrointestinal disorders | 3 (11.5) | 2 (10) | 0.600 |
| Symptom, *n* (%) | | | |
| Abdominal pain | 9 (34.6) | 11 (44) | 0.644 |
| Hematochezia | 10 (38.5) | 14 (56) | 0.277 |
| Abdominal mass | 1 (3.8) | 0 | 0.311 |
| Diarrhoea | 9 (34.6) | 10 (40) | 0.886 |
| Bowel obstruction | 1 (3.8) | 1 (4) | 0.971 |
| Increased stool frequency | 8 (30.8) | 7 (28) | 0.860 |
| Stool appearance change | 5 (19.2) | 5 (20) | 0.421 |

Data are expressed as mean ± SD or number (percentage).
ASA, American Society of Anesthesiologists; C, restrictive fluid therapy; T, GDFT.

**Table 2**

**Intraoperative conditions**

| | Group T | Group C | *P* |
|---|---|---|---|
| Tumour site, *n* (%) | | | 0.200 |
| Ascending colon | 6 (23.1) | 5 (20) | |
| Transverse colon | 1 (3.8) | 1 (4) | |
| Descending colon | 10 (38.5) | 4 (16) | |
| Sigmoid colon | 9 (34.6) | 3 (12) | |
| Rectum | 7 (26.9) | 7 (28) | |
| Surgery type, *n* (%) | | | 0.522 |
| Laparoscopic left hemicolectomy | 1 (3.8) | 1 (4) | |
| Laparoscopic right hemicolectomy | 5 (19.2) | 4 (16) | |
| Laparoscopic sigmoidectomy | 7 (26.9) | 2 (8) | |
| Laparoscopic recto-sigmoidectomy | 2 (7.7) | 1 (4) | |
| Laparoscopic anterior resection | 2 (7.7) | 5 (20) | |
| Laparoscopic total mesorectal excision | 3 (11.5) | 1 (4) | |
| Laparoscopic partial transverse colectomy | 1 (3.8) | 1 (4%) | |
| With or without stoma (Y), *n* (%) | 6 (23.1) | 6 (24) | 0.918 |
| Intraoperative infusion volume (ml) | 1910.5 ± 640.1 | 1036.2 ± 326.4 | < 0.01 |
| Intraoperative urine volume (ml) | 194.7 ± 103.9 | 240.0 ± 165.1 | 0.315 |
| Intraoperative blood loss volume (ml) | 92.1 ± 23.3 | 97.5 ± 16.0 | 0.849 |
| Intraoperative maximum VIS | 3.7 ± 0.8 | 6.2 ± 1.8 | < 0.01 |
| Intraoperative mean VIS | 3.2 ± 0.8 | 5.0 ± 0.8 | < 0.01 |
| With or without blood transfusion (Y), *n* (%) | 1 (3.8) | 3 (12) | 0.329 |
| Surgery duration (min) | 184.3 ± 60.9 | 210.2 ± 62.4 | 0.198 |
| Anesthetization duration (min) | 136.1 ± 51.5 | 159.4 ± 47.6 | 0.151 |

Data are expressed as mean ± SD or number (percentage)
C, restrictive fluid therapy; T, GDFT; VIS, vasoactive-inotropic score.

**Table 3**

**Postoperative conditions of patients**

| | Group T | Group C | *P* |
|---|---|---|---|
| First postoperative exhaust First postoperative exhaust time (h) | 45 ± 21 | 63 ± 26 | 0.026 |
| First postoperative defecation time (h) | 53 ± 24 | 77 ± 30 | 0.011 |
| First postoperative liquid | 104 ± 38 | 126 ± 34 | 0.071 |
| Intake time (h) | 15 ± 3 | 18 ± 4 | 0.021 |
| Hospital stay (days) | 2 (7.7) | 7 (28) | 0.179 |
| Nausea (Y), *n* (%) | 2 (7.7) | 7 (28) | 0.179 |
| Vomiting (Y), *n* (%) | 1 (3.8) | 4 (16) | 0.686 |
| Anastomotic leakage (Y), *n* (%) | 0 | 1 (4) | 0.336 |
| Wound infection (Y), *n* (%) | 1 (3.8) | 2 (8) | 0.591 |

Data are expressed as mean ± SD or number (percentage).
C, restrictive fluid therapy; T, GDFT.

when measured[12,13]. The dynamic size change of left ventricular chamber monitored by TEE can be used as a reference to assess volume change and provide a basis for fluid therapy. The LVEDV is the "gold standard" for monitoring cardiac preload[14]. Therefore, in this study, we used TEE to monitor left ventricular end-diastolic volume for determining a patient's intraoperative volume status, facilitating more accurate fluid replacement.

Many research studies have compared liberal fluid replacement with restrictive fluid replacement, and early clinical trials have shown that the latter is beneficial for major abdominal surgery by accelerating the recovery of gastrointestinal function and reducing complications and length of hospital stay[3,15]. However, restrictive fluid therapy may cause hypotension and increase vasoactive drug use, leading to organ damage and myocardial injury, potentially causing arrhythmias[16]. In addition, increased catecholamines can cause sustained activation of β-adrenoceptors, resulting in heart visceral remodelling and cardiomyocyte apoptosis, which are key drivers of cardiac failure, a phenomenon known as catecholamine cardiotoxicity[17]. Therefore, the VIS was introduced to count the dosage of vasoactive drugs, and analyze the myocardial injury. Troponin was also monitored to determine the severity of myocardial injury. According to relevant literature[18], troponin is found to be somewhat elevated at 24 h after surgery, therefore, in this study, we compared troponin before and 24 h after surgery; we also analyzed the changes in troponin in both groups post-surgery. The study results showed a statistical difference in the troponin levels before and after surgery. However, there was no significant difference in the postoperative troponin levels between the two groups, which was unexpected. The possible reason for this could be the stress induced by surgery, which may have caused some changes in the preoperative and postoperative troponin levels. Although the control group had a higher VIS than the study group, the postoperative troponin change was not significantly different between the two groups. This may be because the intraoperative dosage of vasoactive drugs was considered in this study and the operation time was limited, resulting in shorter duration of vasoactive drug use than in the ICU. Therefore, the short-term effect of vasoactive drugs on the myocardium could not be reflected.

**Table 5**

**Comparison of preoperative and postoperative troponin.**

| | Group T | Group C | *P* |
|---|---|---|---|
| Preoperative troponin (ug/l) | 2.8 ± 0.99 | 3.43 ± 2.19 | 0.456 |
| Postoperative troponin (ug/l) | 5.51 ± 3.06 | 4.42 ± 2.23 | 0.357 |
| *P* value | 0.011 | 0.026 | |

Data are expressed as mean ± SD or number (percentage).
C, restrictive fluid therapy; T, GDFT.

In the GDFT group, TEE was used to dynamically monitor the dynamic changes of left ventricular end-diastolic volume with a goal to ensure the volume was sufficient during the procedure. The results indicated that the GDFT group had earlier postoperative exhaust time and defecation time ($P < 0.05$), postoperative I-FEED score was not significantly different between the two groups, incidences of postoperative nausea and vomiting were not significantly different from the control group, incidences of postoperative wound infection and other complications were not significantly different, and length of hospital stay was shorter than that in the control group ($P < 0.05$). The study's results indicate that GDFT has a positively impacts the recovery of gastrointestinal function. This is because TEE guidance helps to rectify the decreased intraoperative circulating volume based on real-time monitoring results, which helps maintain tissue perfusion, reduces adverse reactions likes intestinal oedema, postoperative ileus and gastrointestinal barrier dysfunction, and ultimately aids in the recovery of gastrointestinal function.

This study has several limitations. Firstly, the sample size was too small and should be increased for further analysis. Secondly, the effect of colloid on gastrointestinal function during volume replacement was not further analyzed, while treatment was performed only according to balanced salt solution replacement. However, different fluid types may have varying effects on the recovery of gastrointestinal function in patients after surgery. Thirdly, the VIS was used to assess the dosage of vasoactive drugs during surgery; however, the length of surgery was too short to reflect the damage of vasoactive drugs to the myocardium.

**Table 4**

**Postoperative I-FEED score**

| | POD1 | POD2 | POD3 | POD4 | POD5 | POD6 | POD7 | Statistics | *P* |
|---|---|---|---|---|---|---|---|---|---|
| T group | 3 (3, 4.75) | 3 (3, 4) | 3 (2.25, 3) | 3 (2, 3) | 2 (1.25, 2.75) | 1.5 (1, 2) | 1 (0, 1) | 184 | < 0.001 |
| C group | 5 (3, 4) | 3.5 (3, 4) | 3 (3, 3) | 3 (3, 3) | 2 (2, 3) | 2 (1, 2) | 1 (1, 2) | 269 | < 0.001 |
| Statistics | − 0.14 | − 0.49 | − 0.31 | − 1.40 | − 1.082 | − 1.602 | − 2.107 | | |
| *P* value | 0.889 | 0.625 | 0.758 | 0.168 | 0.286 | 0.117 | 0.042 | | |

C, restrictive fluid therapy; POD, postoperative day; T, GDFT.

## Conclusion

In summary, the GDFT group with TEE dynamic monitoring had faster recovery of gastrointestinal function and relatively shorter length of hospital stay after surgery, therefore, the TEE-guided GDFT can be used as a method to clinically guide fluid replacement.

## Ethical approval

The trial was reviewed, approved, and monitored by the Medical Ethics Committee of the First People's Hospital of Lianyungang with the following ethical code: KY -20230127001. Furthermore, the trial was registered by the Chinese Clinical Trial Registry with the following code: ChiCTR2300070421.

## Consent

Written informed consent was obtained from all patients prior to the interviews and copy of the written consent is available for review by the Editor -in-Chief of this journal on request.

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No funding was received to perform this study.

## Author contribution

J.D.: study concept or design, data collection, data analysis or interpretation, writing the paper. T.Z., H.X., Z.C.: investigation software. C.H.: investigation resources. M.D.:study concept or design data curation methodology.

## Conlicts of interest disclosure

The authors have no conflicts of interest to declare.

## Research registration unique identifying number (UIN)

the trial was registered by the Chinese Clinical Trial Registry with the following code: ChiCTR2300070421.

## Guarantor

Mengyao Ding.

## Data statement

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

## Provenance and peer review

Not applicable.

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