ORIGINAL ARTICLE

Early Goal-Directed Therapy Using FloTrac/EV1000 Platform for Hemodynamic Optimization to Improve Perioperative Outcomes in Patients Undergoing Major Abdominal Surgery: A Randomized Controlled Trial

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Objective: To compare the efficacy of early goal-directed therapy (EGDT) based on the FloTrac/EV1000 platform versus standard care to improve perioperative outcomes in patients undergoing major abdominal surgery.

Materials and Methods: Forty patients undergoing major abdominal surgery were randomized to the Control or EGDT group. The Control group was managed to achieve a mean arterial pressure (MAP) of 65 to 90 mmHg, a central venous pressure of 8 to 12 mmHg, a urine output of 0.5 mL/kg/h or more, and an SpO_2 of more than 95%. The EGDT group was managed to achieve similar goals using information from the FloTrac/EV1000 platform by receiving fluid to maintain stroke volume variation (SVV) of less than 13%, inotropic drugs to achieve a cardiac index (CI) of 2.2 to 4.0 L/min/m^{-2}, and/or vasoactive drugs to achieve a systemic vascular resistance index (SVRI) of 1,600 to 2,500 dynes·s/cm^{-5}/m^2.

Results: There were 20 patients in each group. The EGDT group received more colloid (p=0.035). The MAP and SVRI of both groups were comparable. The SVV of the Control group was higher (p=0.002), while the CI of the EGDT group was higher (p<0.001). The EGDT group had a shorter intubated time and a shorter stay in the ICU, with a mean difference of –3.95 h (95% CI –7.85 to –0.05, p=0.047) and –14.75 h (95% CI –25.38 to –4.12, p=0.008), respectively. The EGDT group had shorter hospital stays, albeit without significance (p=0.273). No postoperative complication was detected.

Conclusion: Implementation of EGDT using FloTrac/EV1000, compared to conventional care, in patients undergoing major abdominal surgery results in shorter intubated time and shorter stay in the ICU. The shorter hospital stay did not achieve statistical significance.

Keywords: Early goal-directed therapy; Major abdominal surgery; Perioperative outcome; Intubation time; ICU stay; Hospital stay

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Patients undergoing major abdominal surgery develop postoperative complications up to 33.5%, leading to a prolonged intensive care unit (ICU) and hospital stay[1]. These adverse outcomes are associated with intraoperative hypotension (IOH), which compromises the perfusion of vital organs. To minimize the complication, the mean arterial pressure (MAP) of the patient should be maintained at not less than 65 mmHg[2]. The conventional protocol for hemodynamic optimization is based on static clinical parameters such as blood pressure, heart rate, urine output, and central venous pressure. Early goal-directed therapy (EGDT) involves early, within three hours, detecting alterations in dynamic hemodynamic parameters such as cardiac index (CI), stroke volume (SVV) or pulse pressure variation (PPV), and systemic vascular resistance index (SVRI), to guide intravenous fluid and inotropic or vasoactive therapy. These interventions enable early manipulation of cardiac preload, contractility, and afterload to achieve predefined goals to balance tissue oxygen supply with demand[3,4]. Many systematic reviews conclude that EGDT reduces morbidity and mortality in patients undergoing major abdominal surgery, but there was high heterogeneity among the EGDT devices and protocols[5,6].

Many platforms are used to determine the goals of EGDT such as viz, PICCO Plus, FloTrac,

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esophageal Doppler, and thermodilution pulmonary artery catheter[7]. FloTrac can be setup easily by connecting the sensor to a radial artery catheter used for invasive blood pressure (IBP) monitoring and a central venous cannula used to monitor central venous pressure (CVP). FloTrac then displays real-time values, updated every 20 s, of the SVV, CI, and SVRI. The earlier version of FloTrac was operated with the Vigileo monitor, which does not provide real-time SVRI. The new version operates on the EV1000 monitor and can display real-time SVRI.

Most studies used the FloTrac/Vigileo platform for EGDT[8]. The objective of the present study was to assess the efficacy of the FloTrac/EV1000 platform, compared to standard care, to improve perioperative outcomes in patients undergoing major abdominal surgery. The primary outcome was the ICU stay while the secondary outcomes were intubated time in the ICU and hospital stay.

Materials and Methods

The present study was approved by the Institutional Review Board (HE611321). The study was conducted as per the Declaration of Helsinki and the International Conference on Harmonization (ICH) Good Clinical Practice (GCP). All patients gave written informed consent before being recruited. The present study was reported according to the Consolidated Standards of Reporting Trials (CONSORT) guidelines.

The present study was a prospective, randomized, controlled trial. Randomization with allocation ratio of 1:1 was performed using a computer-generated list kept in sealed opaque envelopes. Inclusion criteria were patients 1) age 18 y or older, 2) diagnosis of carcinoma of abdominal organs undergoing elective laparotomy at Srinagarind Hospital, Khon Kaen University, Khon Kaen, Thailand, and 3) American Society of Anesthesiologists (ASA) classification I-III. Exclusion criteria were patients with 1) cardiac arrhythmia, 2) heart failure, and 3) renal or hepatic insufficiency.

The patients were randomized to the EGDT or Control group. The patients and outcome assessors were unaware of the implemented protocol. All patients received standard anesthesia care according to the present study institution protocol. The monitoring in the operating room consisted of electrocardiogram, pulse oximetry, non-invasive blood pressure, body temperature, capnography, anesthetic gas monitor, and urine output. All patients received continuous thoracic epidural block to achieve T4-T12 segmental block for intraoperative and postoperative pain management. Radial artery was cannulated with a 20G catheter and connected to a FloTrac transducer (Edwards Life Sciences, Irvine, CA, USA), which linked with an EV1000 monitor (Edwards Life Sciences, Irvine, CA, USA) to measure IBP, SVV, and CI. The internal jugular vein was cannulated and connected to a pressure transducer connected to the EV1000 monitor to measure CVP and SVRI. The IBP and CVP signals were connected and displayed on the standard monitor. In the Control group, the EV1000 monitor was covered with an opaque cloth so that the attending anesthesiologist did not see the information on the screen. All patients received fentanyl 1 to 2 µg/kg as premedication and propofol 2 mg/kg as an induction agent. Endotracheal intubation was facilitated with cisatracurium 0.15 to 0.2 mg/kg. The ventilation was controlled using a tidal volume of 6 to 8 mL/kg and a rate of 12 to 14 breath/min, adjusted to achieve end-tidal CO_2 of 35 to 40 mmHg. Anesthesia was maintained with 50% oxygen in nitrous oxide and 1% to 2% sevoflurane or 3% to 4% desflurane adjusted to achieve a minimum alveolar concentration (MAC) of 0.8 to 1 on the anesthetic gas monitor, 1.5% to 2% lidocaine with adrenaline 1:200,000 of 3 to 5 mL/h was continuously infused through the epidural catheter. Fentanyl 25 µg was given every 30 min to maintain analgesia. Cisatracurium 3 to 4 mg/h was continuously infused to maintain muscle relaxation. At the end of the surgery, atropine 0.02 mg/kg with neostigmine 0.05 mg/kg was administered for muscle relaxant reversal. The patient was then transferred to the ICU to receive mechanical ventilation and standard intensive care. The data from the EV1000 monitor including SVV, CI, and SVRI of all patients were recorded every five minutes and downloaded for analysis.

In the ICU, the patient received 0.08% bupivacaine with morphine 0.05 mg/mL infusion rate 4 to 6 mL/h through the epidural catheter for postoperative pain management. The patient was weaned from the ventilator and extubated after the extubation criteria were fulfilled. The extubation criteria were full consciousness and good motor power, stable cardiovascular condition, a PaO_2/FiO_2 ratio of 250 mmHg or greater, and a respiratory rate of 12 to 20 breath/min. The patients were discharged from the ICU if they had full consciousness and normal neurological signs, stable cardiovascular condition that did not need inotropic or vasopressor drug support, and ICU monitoring, and stable

respiratory condition with oxygen requirement less than 50% by face mask. The patients were discharged from the hospital if they had stable cardiovascular and respiratory conditions, no drain or catheter detained, normal ambulation, no infection or serious complications, wound stitch removed, and normal diet.

During the intraoperative period, the Control group received intravenous fluid, vasoactive, or inotropic at the discretion of the attending anesthesiologist to achieve the following goals, MAP 65 to 90 mmHg, CVP 8 to 12 mmHg, urine output of 0.5 mL/kg/h or greater, SpO_2 of more than 95%, and hematocrit at 26% to 30%. Arterial blood gas (ABG) and electrolytes were checked and corrected hourly. In the EGDT group, the patients were managed to achieve similar goals as MAP 65 to 90 mmHg, urine output of 0.5 mL/kg/h or more, SpO_2 of more than 95%, and hematocrit at 26% to 30%, using information from the FloTrac/EV1000 platform. The EGDT group received fluid to maintain a SVV of less than 13%, inotropic drugs to achieve a CI of 2.2 to 4.0 L/min/m^{-2}, and/or vasoactive drugs to achieve an SVRI of 1,600 to 2,500 dynes·s/cm^{-5}/m^2. The ABG and electrolytes were checked and corrected in the same way. All patients received crystalloid and colloid at the discretion of the attending anesthesiologists.

Parameters recorded included IBP, SVV, CI, SVRI, fluid and blood components intake, urine output, intubation time, ICU stay, hospital stay, and postoperative complications related to fluid administration such as pulmonary edema, increased creatinine or acute kidney injury (AKI), cardiac arrhythmia, congestive heart failure (CHF), and pneumonia.

Statistical analysis

The sample size was calculated based on the results of a previous study which showed that the ICU stay of the control group was 5.4±2.7 d[9]. With an α-value of 0.05, a power of 0.80, an expected difference in length to stay (LOS) in the ICU of 2.5 d, and a possible dropout of 15%, a sample of 20 patients per group was required. Continuous data were tested for normal distribution using the Shapiro-Wilk test. Continuous data were presented as mean ± standard deviation (SD) or median (interquartile range) and compared using the unpaired Student's *t*-test, the Mann-Whitney *U* test, or repeated measures ANOVA, as appropriate. Categorical data were presented as numbers (%) and compared using a chi-square test or Fisher's exact test. The primary outcome was presented as a mean difference with a 95% confidence interval (95% CI). The p-value less than 0.05 was considered statistically significant. All data were analyzed using SPSS Statistics, version 16.0 (SPSS Inc., Chicago, IL, USA).

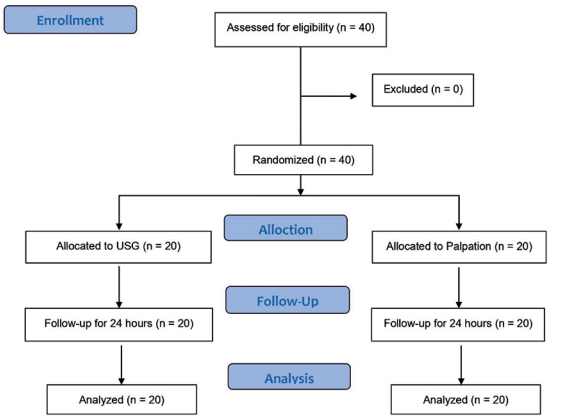

Figure 1. CONSORT diagram.

Results

Forty patients were recruited between October 2017 and September 2018, with 20 in each group (Figure 1). The gender, age, weight, height, functional class, ASA status, diagnosis, operation, and preoperative laboratory tests were similar between both groups (Table 1). The intraoperative data, as the anesthetic time, operative time, blood loss, and amount of crystalloid, packed red cell, and fresh frozen plasma, were similar between the groups. The EGDT group received more colloid (p=0.035) and had more urine output (p<0.001) (Table 2). The MAPs of both groups were similar (Figure 2). The SVV of the Control group was higher than that of the EGDT group (p=0.002) (Figure 3). The CI of the EGDT group was higher than the Control group (p<0.001) (Figure 4). The SVRI of both groups was comparable (p=0.771) (Figure 5). The intubated time and ICU stay of the EGDT group was shorter than the Control group, with a mean difference of –3.95 h (95% CI –7.85 to –0.05, p=0.047), and –14.75 h (95% CI –25.38 to –4.12, p=0.008), respectively. The hospital stay of the EGDT group was shorter, albeit without statistical significance (p=0.273) (Table 3). There was no postoperative complication, including pulmonary edema, AKI, cardiac arrhythmia, CHF, or pneumonia.

Discussion

The results of the present study revealed that

Table 1. Patient demographic and clinical data

Variables	EGDT (n=20)	Control (n=20)	p-value
Sex			0.749
Male	11 (55)	12 (60)	
Female	9 (45)	8 (40)	
Age (y)	59.75±13.70	59.15±8.57	0.869
Weight (kg)	56.11±8.62	58.02±11.08	0.547
Height (cm)	161.35±6.63	161.40±5.64	0.980
BMI (kg/m^2)	21.63±3.62	22.24±3.94	0.613
Functional class: I/II/III	11/8/1	10/10/0	0.751
ASA status: I/II/III	2/14/4	2/16/2	0.770
Diagnosis			
Hepatocellular carcinoma	3 (15)	3 (15)	1.000
Cholangiocarcinoma	8 (40)	8 (40)	1.000
Carcinoma of pancreas	2 (10)	5 (25)	0.249
Carcinoma of stomach	2 (10)	1 (5)	0.615
Carcinoma of intestines	2 (10)	2 (10)	1.000
Carcinoma of adrenal gland	1 (5)	0 (0)	0.500
Others	2 (10)	1 (5)	0.615
Operation			
Explore laparotomy with tumor removal	9 (45)	9 (45)	1.000
Explore laparotomy with bypass/biopsy	7 (35)	6 (30)	0.736
Whipple	3 (15)	4 (20)	0.703
Lower anterior resection	1 (5)	1 (5)	1.000
Preoperative laboratory test			
Creatinine (mg/dL)	0.80±0.16	0.78±0.23	0.751
Hemoglobin (g%)	12.24±1.44	11.77±1.93	0.388
Platelet counts (×10^9/L)	267.90±106.30	300.80±109.50	0.341
INR	1.07±0.12	1.09±0.14	0.630
Albumin (mg/dL)	3.90±0.55	3.78±0.64	0.529

Continuous data are presented as mean ± standard deviation and compared using the unpaired Student's *t*-test. Categorical data are presented as numbers (%) and compared using a chi-square test or Fisher's exact test.

EGDT=early goal-directed therapy; BMI=body mass index; ASA=American Society of Anesthesiologists; INR=international normalized ratio

Table 2. Intraoperative data

Variables	EGDT (n=20)	Control (n=20)	p-value
Anesthetic time (min)	298.9±141.0	347.2±112.6	0.259
Operative time (min)	243.9±139.4	294.7±108.6	0.226
Blood loss (mL)	800 (600 to 1,000)	775 (525 to 1,150)	0.298
Crystalloid (mL)	1,985.3±1,012.0	2,585±1,324.8	0.436
Colloid (mL)	500 (0 to 1,000)	0 (0 to 475)	0.035
PRC (mL)	677.5±463.3	368.3±176.9	0.168
FFP (mL)	442.0±254.6	671.6±296.2	0.225
Urine output (mL/kg/h)	1.6±0.6	0.9±0.3	<0.001

Continuous data are presented as mean ± standard deviation or median (interquartile range) and compared using the unpaired Student's *t*-test or Mann-Whitney *U* test.

EGDT=early goal-directed therapy; PRC=packed red cell; FFP=fresh frozen plasma

EGDT using data from the FloTrac/EV1000 platform for hemodynamic optimization in adult patients undergoing major abdominal surgery results in a shorter intubated time and ICU stay. The present study

Table 3. Outcomes of the study

Variables	EGDT (n=20)	Control (n=20)	Mean difference	95% CI	p-value
Intubated time in ICU (h)	1.25±5.59	5.20±6.56	−3.95	−7.85 to −0.05	0.047
ICU stay (h)	8.10±14.57	22.85±18.40	−14.75	−25.38 to −4.12	0.008
Hospital stay (d)	10.45±3.56	12.3±6.50	−1.85	−5.24 to 1.54	0.273

Continuous data are presented as mean ± standard deviation and compared using the unpaired Student's *t*-test.

EGDT=early goal-directed therapy; CI=confidence interval; ICU=intensive care unit

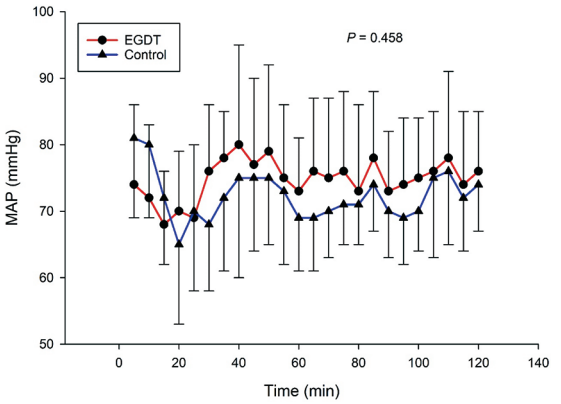

Figure 2. Mean arterial pressure of both groups.

Data are presented as mean±SD and analyzed using repeated measures ANOVA.

EGDT=early goal-directed therapy; MAP=mean arterial pressure

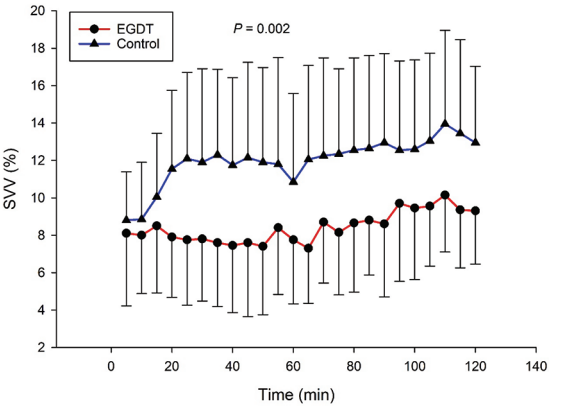

Figure 3. Stroke volume variation of both groups.

Data are presented as mean±SD and analyzed using repeated measures ANOVA.

EGDT=early goal-directed therapy; SVV=stroke volume variation.

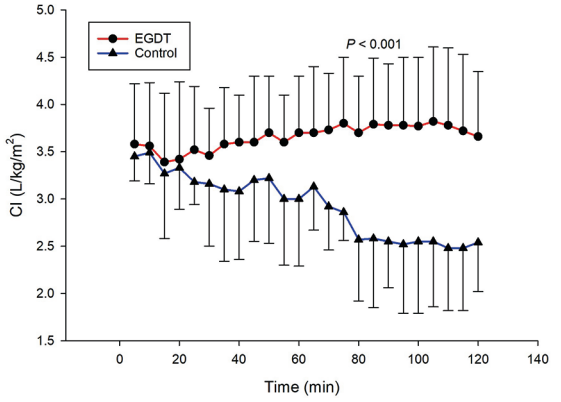

Figure 4. Cardiac index of both groups.

Data are presented as mean±SD and analyzed using repeated measures ANOVA.

EGDT=early goal-directed therapy; CI=cardiac index

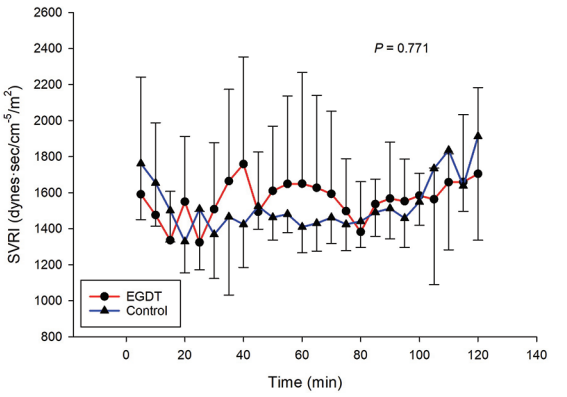

Figure 5. Systemic vascular resistance index of both groups.

Data are presented as mean±SD and analyzed using repeated measures ANOVA.

EGDT=early goal-directed therapy; SVRI=systemic vascular resistance index

results are similar to other studies using the FloTrac/Vigileo platform for intraoperative fluid optimization in patients undergoing major abdominal surgery resulting in improved postoperative outcomes. Benes et al. revealed that the patients in the EGDT group received more colloid, had a lower number of hypotensive events and complications, and a shorter hospital stay[10]. Ramsingh et al. showed that EGDT guided fluid hemodynamic management hastened gastrointestinal recovery and improved quality of recovery score compared to standard management practices[11]. Scheeren et al. reported a multicenter study showing that the EGDT optimization protocol

decreased postoperative wound infection[12]. Kumar et al. found that patients in the EGDT group, compared to the control group, had a shorter postoperative ICU stay[9]. A systematic review including 23 studies with 2,099 patients, evaluating the effect of EGDT versus standard fluid therapy, concluded that EGDT reduced ICU stay, with a mean difference of –0.63 d (95% CI –1.18 to 0.09, p=0.02)[13].

Postoperative morbidity arises from one or more organ dysfunction, which is caused by inadequate perfusion during the intraoperative period. Idiopathic orthostatic hypotension (IOH) is the main cause of decreased tissue perfusion leading to postoperative complications[2]. To minimize postoperative morbidity, the anesthesiologists use MAP as the goal to manage the patients, however, normal MAP does not guarantee adequate tissue perfusion. Blood pressure depends on two factors, cardiac output and afterload, while cardiac output is the effect of preload, contractility, and heart rate. Normal blood pressure can be found in a situation of low cardiac output with compensated high afterload, which results in poor perfusion. To effectively optimize hemodynamics, a thorough understanding of the four primary factors, preload, contractility, afterload, and heart rate, is necessary. This knowledge empowers physicians to accurately address the root cause using targeted interventions, thereby ensuring sufficient perfusion. The FloTrac/EV1000 platform provides real-time information on these factors so that physicians can give early treatment to prevent IOH with adequate perfusion. Even though the MAP of both EGDT and Control group were comparable as shown in Figure 2, the SVV of the Control group was higher while the CI was lower than the EGDT group (Figure 3, 4). This indicates that the Control group had lower preload and CI leading to poorer tissue perfusion, resulting in lower urine output, longer intubation time, and ICU stay.

The EGDT group was administered a higher volume of colloid, which is inconsistent with the previous studies[8,12]. Nevertheless, the present study lacked a stringent protocol for determining when colloid should be administered. As a result, the decision to administer colloid was left to the discretion of the attending anesthesiologists. EGDT using colloid was reported to increase intestinal microcirculatory blood flow and tissue oxygen tension[14]. Michard et al. conducted a systematic review with meta-analysis that included 19 studies, with 2,159 patients, which used the FloTrac/Vigileo platform as the tool for EGDT, and found that the EGDT group received a higher volume of colloid, lower volume of crystalloid, although a comparable total volume of fluid. They concluded that the EGDT group had lower postoperative morbidity[8].

In the present study, patients were administered thoracic epidural blocks for postoperative pain management. This intervention has the potential to decrease SVRI and could lead to an increased need for fluid and vasopressor to optimize hemodynamics. Notably, both the Control and EGDT groups underwent the same intervention, with the intention of minimizing its impact on the study outcomes.

The present study EGDT protocol included not only fluid therapy to optimize preload, but also the use of inotropic and vasoactive drugs to optimize cardiac contractility, afterload, and heart rate. Once the hemodynamic is optimized, the perfusion to vital organs is guaranteed and results in better outcome reflected by shorter intubation time and ICU stay. Although the hospital stay of the EGDT group was shorter than that of the Control group with clinical significance and a mean difference of –1.85 d, it did not reach statistical significance (95% CI –1.50 to 5.20, p=0.273), due to the limited sample size.

Limitation

The present study had limitations. The included subjects were patients with carcinoma of the abdominal organs undergoing elective laparotomy. Therefore, the results may not be generalized to other groups with different operations. The present study lacked the strict protocol for colloid administration. Although the attending anesthesiologists could not be blinded, the outcome assessors were unaware of the group assignment. It was carried out in a single center with limited samples. Therefore, further studies in multicenter with larger samples are warranted. The use of the FloTrac/EV1000 platform has extra cost, a cost-effectiveness analysis is recommended.

Conclusion

Hemodynamic optimization using the FloTrac/EV1000, compared to conventional care, in patients undergoing major abdominal surgery results in shorter ICU stay as well as intubated time in the ICU. The shorter hospital stay did not achieve statistical significance.

What is already known on this topic?

Patients undergoing major abdominal surgery may develop intraoperative hypotension leading to high morbidity and a prolonged stay in the ICU

and hospital. EGDT using FloTrac/Vigileo platform reduces morbidity and mortality in this group of patients. The Vigileo monitor does not provide real-time SVRI while the EV1000 monitor does. There are only a few studies using the FloTrac/EV1000 platform for EGDT in major abdominal surgery study.

What does this study add?

EGDT using the FloTrac/EV1000 platform improves perioperative outcomes, resulting in a shorter intubation time and ICU stay in major abdominal surgery.

Availability of data

The data used to support the findings of the present study are available upon request from the corresponding author.

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Conflicts of interest

The authors declare no conflicts of interest.

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