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Original Article

Randomized controlled trial of regional tissue oxygenation following goal-directed fluid therapy during laparoscopic colorectal surgery

Fengzhi Liu[1,2], Jing Lv[3], Weixia Zhang[4], Zhongkai Liu[2], Ling Dong[1], Yuelan Wang[1]

[1]Department of Anesthesiology and Perioperative Medicine, Qianfoshan Hospital Affiliated to Shandong University, Jinan 250014, Shandong, China; [2]Department of Anesthesiology, Linyi People's Hospital, Linyi 276003, Shandong, China; [3]Department of Anesthesiology, Zibo Central Hospital, Zibo 255000, Shandong, China; [4]Department of Critical Care, Linyi People's Hospital, Linyi 276003, Shandong, China

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Abstract: Background: A randomized, double-blinded controlled trial was performed to evaluate how perioperative goal-directed fluid therapy (GDFT) influences tissue oxygenation in laparoscopic colorectal surgery. Methods: A total of 74 patients undergoing elective laparoscopic colorectal surgery were treated with GDFT (G group) guided by stroke volume variation or conventional fluid therapy (C group). Forearm, crural, and cerebral tissue oxygen saturation (rSO_2) were simultaneously measured by near-infrared spectroscopy. Parameters of hemodynamics and rSO_2 were obtained at seven time points including before induction of anesthesia (T1), 5 min after trachea cannula (T2), 5, 60, and 120 min after pneumoperitoneum in the Trendeleburg position (T3, T4 and T5, respectively), after desufflation in the Trendeleburg position (T6), and at the end of the operation in a supine position (T7). The postoperative outcomes were recorded. Results: Compared to C group, intraoperatively, patients in the G group received more colloid ($P<0.05$). The stroke volume variation in G group at T5, T6 and T7 was significantly lower than that in C group ($P<0.05$). The cardiac index, forearm and crural rSO_2 in G group at T4, T5, T6 and T7 were significantly higher than those in C group ($P<0.05$). No significant differences were observed for the cerebral rSO_2 between the two groups ($P > 0.05$). The postoperative hospital stay and complications also showed no differences between these two groups. Conclusions: Although the implementation of GDFT cannot increase cerebral rSO_2, the forearm and crural rSO_2 are improved during the laparoscopic colorectal surgery, which is helpful to reduce the risk of regional tissue hypoxia.

Keywords: Goal-directed fluid therapy, tissue oxygen saturation, cardiac index, colorectal surgery

Introduction

Laparoscopic surgery is widely used for colorectal cancer, which can decrease pain, reduce postoperative infection and shorten duration of hospitalization [1]. A steep Trendelenburg position is often required during laparoscopic colorectal surgery, which alters fluid balance and increases oxygen consumption [2]. Meanwhile, it increases intraabdominal pressure, but reduces microcirculatory flow and tissue oxygenation tension [3, 4]. The blood may reallocate to the "more vital" organs (such as brain and heart), thus reducing the peripheral tissue perfusion and oxygen delivery [5]. The changes will have significant effects on the body recovery and may result in the development of the dysfunctions [6-8]. Therefore, it is important to keep appropriate capacity and oxygenation in patients, especially in older people [9].

Goal-directed fluid therapy (GDFT) is a method based on standardized fluid-related hemodynamic variables to achieve an optimized stroke volume (SV), cardiac index (CI) and oxygen delivery [10]. Although GDFT is reported to be associated with improved clinical outcomes based on clinical investigations, the utility and advantage of GDFT in clinical practice remain controversial [10-12]. Some researchers suggested that GDFT has few or no benefit to the patients undergoing major abdominal surgery, and pointed out that only the patients with decreased aerobic fitness may benefit from GDFT [2, 13].

However, they did not directly test whether GDFT could improve the tissue perfusion and oxygenation in patients who received laparoscopic colorectal surgery.

Various measures such as CI, SV, systemic vascular resistance (SVR), stroke volume variation (SVV), mixed venous oxygen saturation (SvO_2) and plethysmography variability index (PVI) have been investigated in GDFT [14-20]. From the viewpoint of physiology, it is speculated that the flow-derived dynamic variable (i.e. SVV) is very meaningful in predicting fluid responsiveness, since blood flow is the primary determinant of oxygen delivery [14]. Moreover, the method to monitor SVV using the FloTrac system is less invasive, because the complications of peripheral arterial catheter placement are less than 1% [15]. SVV is currently considered to be a simple and sensitive predictor of fluid responsiveness and preload status [16, 17]. The changes of regional tissue oxygenation (rSO_2) reflecting early organ ischemia and/or local metabolic disturbance, have been reported to precede the lactate levels, hemodynamics, and pulse oximetry (SpO_2) [18, 19]. The cerebral rSO_2 is even regarded as a surrogate for central venous oxygen saturation ($ScvO_2$) and SvO_2 [20].

In the present study, in order to explore whether GDFT can increase tissue oxygenation and thereby improve clinical outcomes of patients, we monitored the changes of brain oxygenation and peripheral muscular tissue oxygenation following GDFT in laparoscopic colorectal surgery. The results may provide guidance to the clinical application of GDFT in colorectal therapy.

Materials and methods

Patients

The prospective double-blind randomized controlled study was undertaken at the Qianfoshan Hospital, Shandong University, Jinan, China. A total of 74 patients undergoing elective laparoscopic colorectal surgery between September 2017 and December 2018 were enrolled in this study. Inclusion criteria: patients aged between 65 and 80 years old, undergoing general anesthesia during laparoscopic resection for colorectal cancer, and classified as American Society of Anesthesiologists (ASA) physical status I-II. Exclusion criteria: patients with uncompensated cardiac (including arrhythmias) and/or respiratory disease, neurological diseases, peripheral vascular disease, coagulopathy, anemia (Hb<90 g/L), renal impairment (creatinine > upper limit of normal values), and major operation history. Prior written and informed consent was obtained from every patient, and the clinical trial was approved by the Institutional Review Board (Approval No: S056), and registered at http://www.chictr.org.cn (Registration number: ChiCTR-IIR-17012414).

Perioperative care

On the morning of the surgery, the participants were allocated by a random number table generator to either the GDFT group (G group) or the traditional fluid therapy group (C group). The surgeons, patients and investigators were kept blinded. Prophylactic antibiotics were given to all patients in the operating room. Both groups had the arteria radialis puncture and catheterization, and arterial cannula was connected to a FloTrac/Vigileo monitoring system (Edwards Lifesciences, Irvine, CA, USA). All patients were monitored for hemodynamics, SpO_2, bispectral index (BIS), temperature, rSO_2. Anesthesia was induced with midazolam (0.05 mg/kg), sufentanil (0.5 μg/kg), atracurium (0.8 mg/kg) and etomidate (0.3 mg/kg). After intubation, volume control mechanical ventilation was carried out in a mixture of 50% oxygen and 50% air. End-tidal carbon dioxide ($ETCO_2$) was maintained between 35 and 45 mmHg. Anesthesia was maintained with propofol and remifentanil to keep BIS between 40 and 60. After the surgery, transversus abdominis plane (TAP) block was performed with a portable ultrasound device (Sonosite Inc., Bothell, WA, USA). All patients received 15 mL of 0.375% (w/v) ropivacaine to each side for bilateral block [21, 22]. Then patients controlled intravenous analgesia (PCIA) were administered with the mixture of 1 μg/mL sufentanil, 1 mg/mL flurbiprofen axetil and 2.5 μg/mL palonosetron.

Fluid management

All patients took polyethylene glycol electrolyte powder and/or received mechanical bowel preparation on the day before the surgery. A forearm vein was used for the administration of study fluid. Before the induction of anesthesia, 5 mL/kg lactated Ringer's was infused for the patients. All fluid was pre-warmed before use.

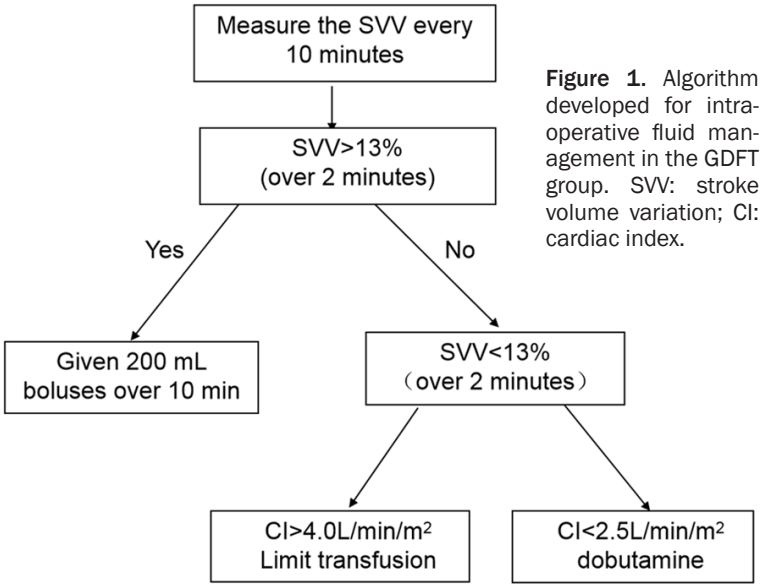

Figure 1. Algorithm developed for intraoperative fluid management in the GDFT group. SVV: stroke volume variation; CI: cardiac index.

In the GDFT group, SVV was used as a predictor of fluid responsiveness. When the SVV was below 13%, additional boluses of 200 mL colloidal solution were administered in 10 min. Otherwise, the CI was further assessed based on the algorithm given in **Figure 1**. Lactated Ringer's solution (2 mL/kg/h) was administered as a background maintenance infusion until the end of the surgery.

In the control group, lactated Ringer's solution (5-10 mL/kg/h) was administered to avoid the urinary rate less than 0.5 mL/kg/h. In the case of systolic pressure and heart rate variation more than 20%, dobutamine, norepinephrine or nitroglycerin was administered. The starting rates of the three drugs were 2.5 μg/kg.min, 0.03 μg/kg.min and 25 μn/min, respectively. In addition to vasoactive agent, colloid was administered according to clinical requirement. To avoid the bias, the FloTrac/Vigileo monitor screen was concealed from the anesthetist and surgeons.

Measurement of tissue oxygenation

For cerebral rSO_2 measurement, Near Infrared Spectroscopy (NIRS) tissue oximeter (FORE-SIGHT™, CASMED, Branford, CT, USA) was used. Cerebral oximeter probes were placed at least 2 cm above the eyebrow on the left forehead, while BIS motor was placed on the right forehead. For the brachioradialis muscle rSO_2 measurement, NIRS tissue oximeter (INVOS® 5100C, Mansfield, MA, USA) was placed on the lateral side of the anterior surface of the left forearm contralateral to the vein and radial artery cannulation site. For the gastrocnemius muscle rSO_2 measurement, the NIRS probe was placed on the lateral side of the left calf, proximally 15 cm from the ankle joint. For the three sites, single-depth 25 mm probes were attached to the measurement spots with opaque elastic bandages enfolded. All measurements were performed at the same room temperature of 20°C.

Data collection

Heart rate (HR), mean arterial pressure (MAP), SVV, CI and rSO_2 were all measured before induction of anesthesia (T1), 5 min after trachea cannula (T2), 5, 60 and 120 min after pneumoperitoneum in a 20 Trendeleburg position (T3, T4 and T5, respectively), after desufflation in a Trendeleburg position (T6), and at the end of operation in a supine position (T7). Arterial blood samples were collected at T1, T4 and T7, and oxygen delivery index (DOI) was calculated.

Clinical outcomes were collected by a different investigator, blinded to group allocation. The exhaust time, fasting time and postoperative hospital stay were recorded. The presence of postoperative complications, including vomiting, bleeding, infection, acute kidney injury, anastamotic leak and so on were chosen and graded according to predefined criteria [23, 24].

Statistical analysis

Shapiro-Wilk analysis was performed to assess the normal distribution of the data. Continuous variables were summarized as the mean ± standard deviation (SD) or median with interquartile range if appropriate. Categorical variables were analyzed using χ^2 or Fisher's exact test as appropriate. Time-dependent data were compared using repeated measures analysis of

Table 1. Patient characteristics

Items	G group	C group	*P* value
Age (yr)	69.2±4.7	70.3±4.8	0.320
Sex (M/F)	23/14	23/14	1.000
Body mass index (kg/m^2)	22.0±2.3	22.6±2.8	0.381
Hypertension	13	15	0.632
Diabetes	7	6	0.760
ASA			0.744
I	6	5	
II	31	32	
Type of surgery			0.619
Abdomino-perineal resection (Miles)	16	12	
Rectal low anterior resection (Dixon)	12	17	
Hartmann's procedure	2	1	
Colectomy	7	7	
Duration of surgery (min)	185.1±22.4	177.6±22.9	0.159
Duration of anaesthesia (min)	223.2±25.0	216.1±27.4	0.247
Intraoperative fluids (mL)	1979.7±170.6	2001.4±228.7	0.646
Crystalloid (mL)	904.1±97.5*	1340.5±265.3	0.000
Colloid (mL)	1075.7±201.9*	660.8±199.4	0.000
Blood loss (mL)	65.7±17.1	62.4±15.9	0.401
Urine output (mL)	547.6±155.3	515.4±135.2	0.345
Proportion of vasoactive drugs (%)			
Dobutamine	73.0*	21.6	0.000
Norepinephrine	16.2*	67.6	0.000
Nitroglycerin	13.5	18.9	0.528
Total dose of vasoactive drugs			
Dobutamine (mg)	14.2*	2.5	0.000
Norepinephrine (μg)	3.0*	74.2	0.000
Nitroglycerin (μg)	10.8	13.5	0.705

Note: Values are expressed as mean ± SD or absolute number. *P<0.05 *vs*. Group C. ASA, American Society of Anesthesiologists.

variance (between periods in each group and between groups). A preplanned subgroup analysis was conducted using unpaired *t*-test if the data were normally distributed, while the Mann-Whiteney U-test was conducted if they were not normally distributed. All statistical tests were two-sided and a *P* value <0.05 was considered significant. Data analysis was performed using Statistical Product and Service Solutions (SPSS) version 21.0 (IBM Corp., USA) and Microsoft Excel 2007 (Microsoft Co., USA).

Results

General information

Overall, general information including the demographic (age, sex, body mass index), risk indices (hypertension, diabetes, ASA), operative data (type of surgery, duration of surgery, intraoperative fluids, Hartmann's procedure, colectomy) and anesthetic characteristics (duration of anaesthesia, proportion and total dose of vasoactive drugs) was compared between the two groups (**Table 1**). It was found that there were no differences in age, sex, body mass index, hypertension, diabetes, ASA, type of surgery, duration of surgery, duration of anaesthesia, and intraoperative fluids between G group and C group. Furthermore, compared with C group, less crystalloid and more colloids were needed in the G group. There were imbalances in the vasopressors: more dobutamine was needed in the G group, while more norepinephrine was needed in the C group.

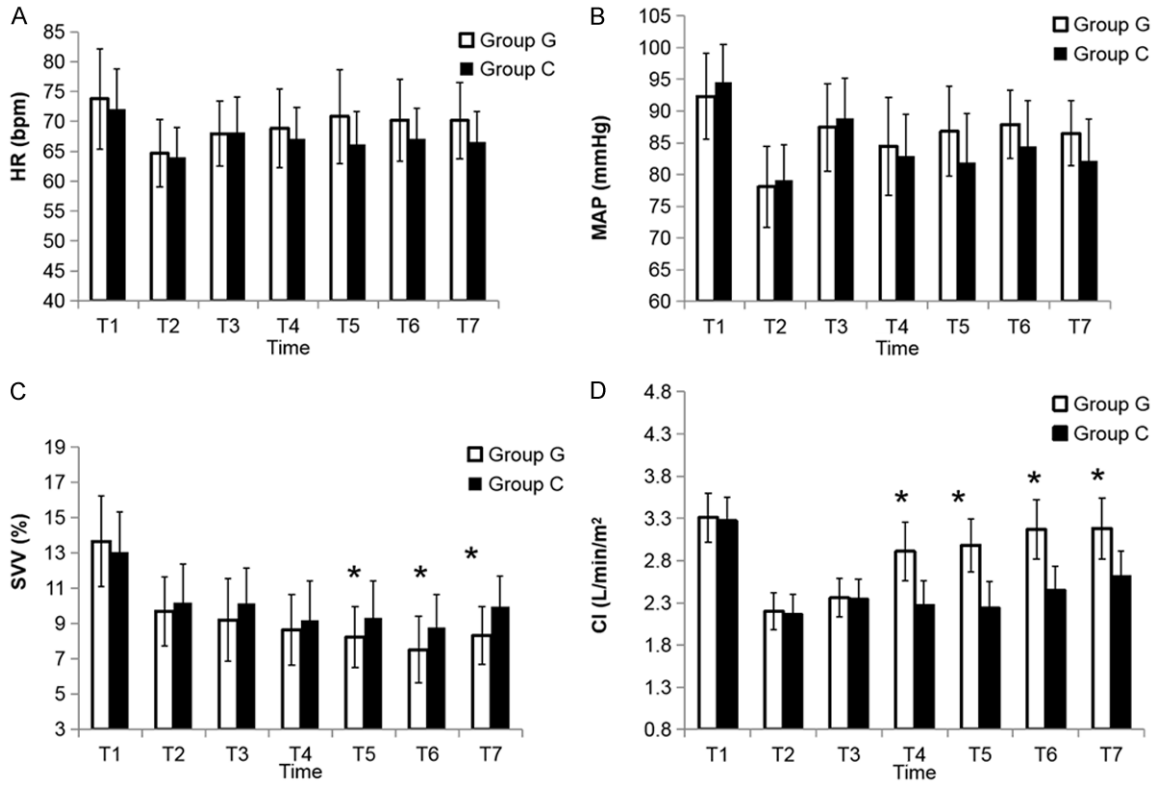

Figure 2. Cardiovascular variables during the study periods. Data are presented as mean ± SD; *P<0.05, vs. C group. A. HR: heart rate; B. MAP: mean arterial pressure; C. SVV: stroke volume variation; D. CI: cardiac index. Measurements were performed at 5 min before induction of anesthesia (T1), 5 min after intubation (T2), 5, 60 and 120 min after pneumoperitoneum in a Trendelenburg and lithotomy position (T3, T4 and T5, respectively), 5 min after desufflation in a Trendelenburg position (T6), and 5 min after operation in a supine position (T7).

Intraoperative haemodynamics and oxygenation

Hemodynamic monitoring was performed to evaluate the changes of the circulation using different fluid therapies. HR (**Figure 2A**) and MAP (**Figure 2B**) were significantly lowered compared with the basic value at T1 (P<0.05). However, there were no statistical significances in HR (**Figure 2A**) and MAP (**Figure 2B**) between the G group and the C group at any time points (P > 0.05). Compared to T1, the SVV (**Figure 2C**) and CI (**Figure 2D**) were significantly reduced at the other time points in both groups (P<0.05). At T5, T6 and T7, the SVV of the G group was significantly lower than that in the C group (P<0.05) (**Figure 2C**). Patients in the G group had significantly greater CI than the C group at T4, T5, T6 and T7 (**Figure 2D**).

To compare the effects of different fluid therapies on regional tissue oxygenation, forearm, crural, and cerebral rSO_2 monitoring was simultaneously performed. Compared with the baseline, the cerebral rSO_2 at T3 was significantly upregulated (P<0.05), but it was decreased at T5, T6 and T7 (P<0.05) (**Figure 3A**). The changes over time were similar between the two groups. Forearm rSO_2 in both groups was increased throughout the operation, but it was significantly higher in the G group than that in the C group at T4-T7 (P<0.05) (**Figure 3B**). Compared to the G group, the crural rSO_2 was increased in the C group at T4-T7 (P<0.05). The crural rSO_2 at T3 was the lowest within both groups (**Figure 3C**).

In addition, the DOI showed no difference between the G group and the C group at T1 (P > 0.05, **Table 2**). Moreover, the DOI was downregulated in the G group in comparison with the control at T4 and T7 (P<0.05). For Lac and Hb, the differences between the two groups did not show statistical significance (P > 0.05, **Table 2**). These results indicate that the changes in rSO_2 between the two groups are not caused by changes in Hb during surgery.

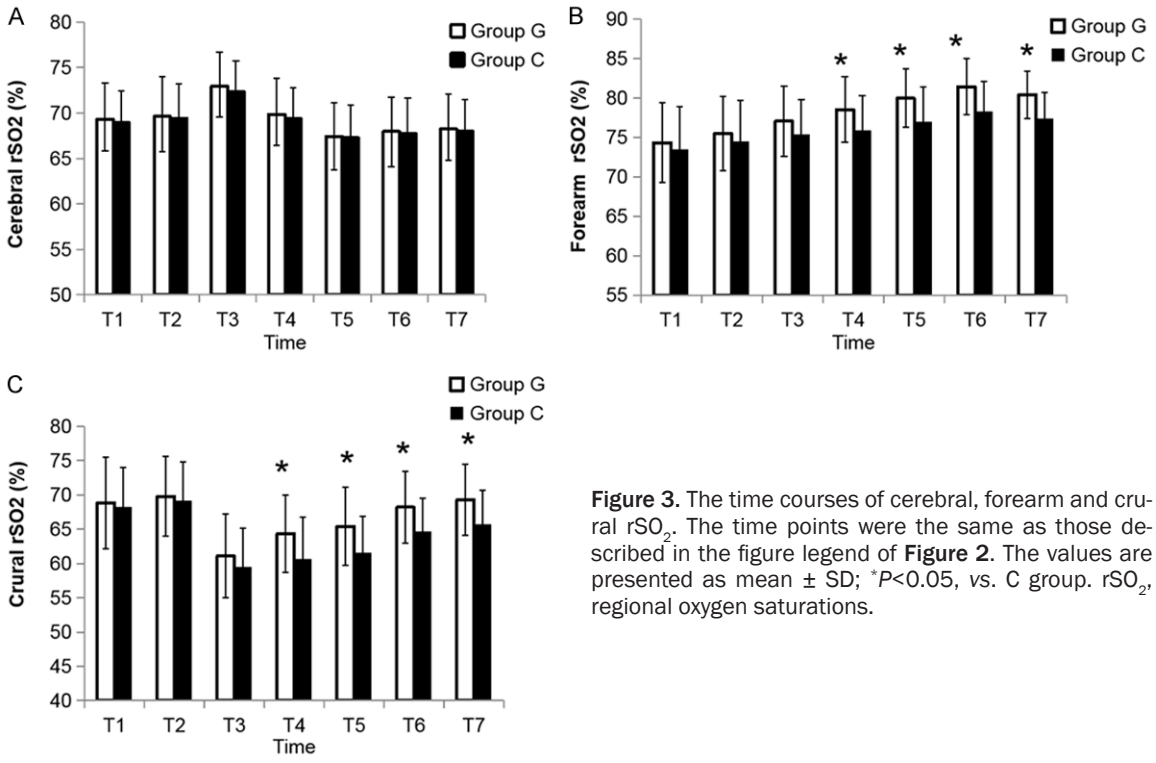

Figure 3. The time courses of cerebral, forearm and crural rSO_2. The time points were the same as those described in the figure legend of **Figure 2**. The values are presented as mean ± SD; $^*P<0.05$, *vs*. C group. rSO_2, regional oxygen saturations.

Table 2. Data of oxygen delivery index and blood gas

Items	G group	C group	*P* value
DOI (mL/min/m^2)			
T1	523.4±41.5	515.8±90.6	0.644
T4	473.9±40.7*	402.4±31.4	0.000
T7	493.1±38.1*	440.4±40.6	0.000
Hb (g/L)			0.217
T1	121.9±13.5	124.8±13.9	
T4	113.2±11.7	116.9±12.0	
T7	108.1±10.7	111.7±12.0	
Lac (mmol/L)			0.102
T1	0.85±0.23	0.87±0.19	
T4	0.92±0.23	1.0±0.23	
T7	0.96±0.28	1.1±0.35	

Note: Data are presented as mean ± SD. $^*P<0.05$ *vs*. Group C. T1, 5 min before induction of anesthesia; T4, 60 min after pneumoperitoneum in a Trendelenburg and lithotomy position; T7, 5 min after operation in a supine position. DOI, oxygen delivery index; Hb, haemoglobin; Lac, lactate.

Postoperative outcomes

To find whether GDFT leads to improved surgical outcomes, postoperative clinical data including exhaust time, fasting time, postoperative hospital stay, nausea and vomiting, abdominal distension, infection, anastomotic leak, bleeding, lower limb venous thrombosis, hypotension, ventricular arrhythmias, acute kidney injury, and wound dehiscence were analyzed. It was found that there were no differences in all measured postoperative clinical data ($P > 0.05$). Each group had two patients who developed an anastomotic leak and the one in the C group required reoperation. Major and minor complications were not significantly different (**Table 3**).

Discussion

Laparoscopic colorectal surgery has been widely adopted for the treatment of colorectal neoplasia, with steady increases in use over the past 15 years, and this technique includes multiport laparoscopy, single-incision laparoscopy, and hand-assisted laparoscopy [25, 26]. Previous studies have suggested a positive effect of GDFT on clinical outcome, which has long been assumed to be related to the improved tissue perfusion and oxygenation [27, 28]. In this study, a randomized, double-blinded controlled trial was designed to evaluate the influences of perioperative GDFT on tissue oxygenation in laparoscopic colorectal surgery.

Table 3. Postoperative outcome following different therapies

Items	G group	C group	*P* value
Exhaust time (days)	2.2±0.9	2.5±0.9	0.123
Fasting time (days)	3.1±1.1	3.5±1.1	0.141
Postoperative hospital stay (days)	10.6±2.3	11.4±2.6	0.185
Nausea and vomiting	8	11	0.425
Abdominal distension	10	13	0.451
Infection	4	7	0.327
Anastomotic leak	2	2	1.000
Bleeding	4	2	0.670
Lower limb venous thrombosis	0	1	1.000
Hypotension	1	5	0.201
Ventricular arrhythmias	1	0	1.000
Acute kidney injury	2	0	0.2473
Wound dehiscence	2	2	1.000

Measures, such as arterial pressure and oxygen content, cannot reflect tissue-level perfusion or oxygenation, and other indices including central venous oxygen saturation and Lac are relatively nonspecific [18, 29]. This study is distinguished from previous works because the change of tissue oxygenation was directly measured in a noninvasive way during the laparoscopic surgery. Cerebral rSO_2 and forearm rSO_2 were chosen as the parameters representing the upper-body oxygenation, and crural rSO_2 was used to represent the lower-body oxygenation status. In the trial, NIRS probe was put on the lateral side of the anterior surface of the forearm brachioradialis muscle rather than the thenar eminence, the most widely used site of measurement. This is because several researchers have suggested that, compared with thenar rSO_2, the forearm rSO_2 is more appropriate to monitor the change of peripheral microcirculation [30, 31]. The gastrocnemius lateralis is the common measurement spot for crural rSO_2 [32]. The result of this study showed that the forearm rSO_2 is continuously increased during the surgery, suggesting the preoperative peripheral tissue has inadequate perfusion and oxygenation due to the fasting and bowel preparation. The high SVV level also confirms the condition. The DOI is reduced in both groups because of the pneumoperitoneum and anesthetic, while the forearm rSO_2 is increased during the operation. One explanation for this phenomenon can be an increase of oxygen extraction. In the present study, forearm rSO_2 is maintained higher by GDFT than by the conventional method. The changing trend is in accordance with CI, suggesting that the increase in cardiac output benefits the oxygenation. The reason for a significant difference between the two groups is related to dobutamine administration. A β1-agonist-mediated increase in myocardiac contractility and β2-agonist-mediated increase in peripheral vasodilation may generate an increased rSO_2 and CI [33]. This study showed that the dosage and frequency used in the G group are significantly higher than those in the C group. Therefore, the use of GDFT to achieve a higher CI is responsible for the higher rSO_2. The elevated values of crural rSO_2 in the G group have also been observed. At 5 min after the Trendelenburg and lithotomy positioning, there is an obvious decline of crural rSO_2 in both groups, contributing to the great changes of blood redistribution.

In the present study, cerebral rSO_2 reaches the highest in this period and followed by a falling at 120 min after pneumoperitoneum in a Trendelenburg position. These results are in agreement with Kumagai's research [34]. The trend of cerebral rSO_2 between the two groups is similar, suggesting that the cerebral blood flow has a relatively strong autoregulation [35]. Likewise, the cerebral rSO_2 varies to a lower degree in comparison with the peripheral muscle tissue. Furthermore, although forearm and crural rSO_2 are higher in the G group than that in the C group, the clinical outcomes showed no significant differences between two groups. These results indicate that peripheral rSO_2 may not be used for predicting the risk of complications. Nevertheless, the forearm and crural rSO_2 are more sensitive to hemodynamic changes than the Lac, which suggests that peripheral rSO_2 can reflect the early inadequate tissue perfusion, and can be beneficial to the patients with peripheral vascular disease or shock.

The current study showed no obvious clinical benefit in outcome when comparing GDFT with the routine method, which was different from some previous studies [36]. One factor accounting for the finding is that neither the GDFT nor the routine infusion gives rise to fluid overload or hypoxia. At the end of operation, the value of the oxygen delivery index is favorable

evidence. Another factor is that good-quality perioperative care, included proper temperature, antibiotics, and adequate postoperative analgesia have offset the advantage of the GDFT [7].

There are some weaknesses in this study. First, cerebral rSO_2 and peripheral rSO_2 were measured by different machines produced by different manufacturers, using distinct algorithms. However, the applied methodology is not rare. Recently, multisite monitoring of rSO_2 using NIRS is increasing [37, 38]. In this study, they were performed simultaneously using the same 25 mm probes. Therefore, it is more valuable to follow the trend but not the absolute values in this practice. Second, the observation of the post-operative outcomes is limited to the hospitalization period only. Although the results tend to demonstrate better outcomes in the G group, no significant benefit are found in the pilot study. A further research with larger sample size and longer period is needed. Third, central venous oxygen saturation ($ScvO_2$) was not collected to obtain the oxygen consumption index, because our institutional protocol was not to implement central vein catheterization during the surgery. Finally, during the period from general anaesthetic to the end of surgery, the average CI of the control group is less than 2.5 L/min/m^2, but do not cause tissue acidosis and affect postoperative reassignment. Therefore, it is more appropriate to maintain the value of CI after anesthesia, which needs a further investigation.

Conclusion

In summary, a higher level of forearm and crural rSO_2, but no statistically significant changes in cerebral rSO_2, were observed in GDFT compared to the conventional fluid therapy during laparoscopic colorectal surgery. This indicates that GDFT could dramatically reduce the risk of regional tissue hypoxia and has an important significance in laparoscopic colorectal surgery.

Disclosure of conflict of interest

None.

Address correspondence to: Yuelan Wang, Department of Anesthesiology and Perioperative Medicine, Qianfoshan Hospital Affiliated to Shandong University, No. 16766, Jingshi Road, Jinan 250014, Shandong, China. Tel: +86-0531-89268538; E-mail: yuelanwang2018@aliyun.com

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