A Prospective Comparison of TL-400 and NICOM for Goal-Directed Fluid Therapy in Gastrointestinal Tumors Surgery

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Research Article

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Abstract

Objective: Goal-directed fluid therapy (GDFT) based on NICOM(CheetahMedical, Vancouver, Washington) was highly associated with improved postoperative prognosis, but has several limitations. T-Line-400(TL-400, TensysMedical, San Diego, California) which is an emerging non-invasive hemodynamic monitor may be applicable for GDFT. Thus, the trial was to determine whether GDFT based on TL-400, when compared to GDFT based on NICOM, would lead to similar outcomes on patients undergoing gastrointestinal tumor resection.

Methods: 100 patients who underwent laparoscopic resection of gastrointestinal tumors in Yongchuan Hospital of Chongqing Medical University from October 2020 to May 2021 were randomized into either TL-400 GDFT group (group T) or NICOM GDFT group (group N). The intraoperative fluid volume and the postoperative complications within 30 days were recorded.

Results: There were no significantly statistical differences between groups with respect to the total fluid volume ($2360 \pm 282\text{ml}$ vs $2295 \pm 223\text{ml}$), the colloid volume ($1167 \pm 153\text{ml}$ vs $1126 \pm 109\text{ml}$), the crystalloid volume($1193 \pm 156\text{ml}$ vs $1173 \pm 157\text{ml}$). Both GDFT based on TL-400 and NICOM strategies were equivalent for the first flatus(57.3 ± 7.9 vs $58.5 \pm 8.5\text{hours}$), wound healing time($11.2 \pm 1.2\text{days}$ vs $10.9 \pm 1.1\text{days}$) and LOS(hospital length of stay) ($13.3 \pm 1.4\text{days}$ vs $13.1 \pm 1.2\text{days}$). In addition, the TL-400 had less data missing than the NICOM.

Conclusion: TL-400 performs similarly to NICOM in guiding GDFT, with no significant differences in perioperative fluid infusion and postoperative prognosis in patients undergoing gastrointestinal tumor resection. Compared with NICOM, TL-400 can avoid the interference of electrocoagulation and can capture more data.

Trial registration: This study has been registered on the Chinese Clinical Trial Registry (ChiCTR2100046350) (<http://www.chictr.org.cn/index.aspx>).

Background

Liberal infusion often induces hypervolemia, resulting in intestinal edema, pulmonary edema, acute renal injury, even respiratory and heart failure^[1–5]. Restricted infusion may lead to hypovolemia, poor tissue perfusion and so on^[6–8]. Both excess and insufficient fluid infusion may increase LOS and mortality^[9]. GDFT regulates fluid infusion to an amount required which is based on fluid responsiveness. It can optimize hemodynamics and provide better tissue perfusion in perioperative period.

Over the years, PAC (pulmonary artery catheter) and PiCCO (pulse index continuous cardiac output) were widely used to evaluate hemodynamics. Nevertheless, their application in surgery is limited due to the fact that they may cause serious complications^[10–12]. Non-invasive hemodynamic monitors, such as TL-400 and NICOM which has been shown to be in good agreement with PAC and PiCCO in terms of accuracy^[13–16], may be a valuable alternative.

NICOM, a bioactance-based monitor, uses four electrodes placed on the chest to measure changes in the frequency of the electrical currents from which hemodynamic variables, including CI (cardiac index), SV (stroke volume), SVV (stroke volume variation), can be calculated^[15–16]. And SVV and CI are sensitive to assess fluid responsiveness and cardiac function^[17–19]. GDFT based on NICOM has been shown to improve prognosis, reduce postoperative complications, and facilitate gastrointestinal function recovery^[20].

TL-400 is based on applanation tonometry, the arterial pulse wave is obtained by flattening the artery to make the transmural pressure zero, then uses a transducer which is strapped to the artery to measure CI and SVV continuously^[21–22]. However, no prospective studies have compared TL-400 and NICOM in guiding GDFT. So this prospective trial will compare GDFT guided by TL-400 and NICOM to determine whether they could lead to similar outcomes on patients undergoing gastrointestinal tumor resection.

Methods

Participants

This trial has been approved by the Medical Ethics Committee of Yongchuan Hospital of Chongqing Medical University (2020 Collen trial 92) and was registered on Chinese Clinical Trial Registry (ChiCTR2100046350).

Only after informed consent was signed by patients and their families, it can be performed. Patients who were scheduled for laparoscopic resection of gastrointestinal tumors in our hospital were enrolled to this trial from October 2020 to May 2021. They were allocated with a rate of 1:1 to one of the two groups by random number table method: TL-400 GDFT group (group T) or NICOM GDFT group (group N). Numbers were concealed in sealed envelopes and it would not be opened before anesthesia induction. Exclusion criteria were contraindications to ASA (American Society of Anesthesiologists) classification greater than III, BMI (body mass index) >35kg/m², [serious](#) heart, liver, brain, lung, kidney, metabolic and central nervous system diseases, whose radial artery pulsation was not obvious and unable to be measured by TL-400, also those who had a skin defect and can not use NICOM.

Study protocol

All patients fasted 8 h for solids and 2 h for clear liquids before operation, and were monitored non-invasive blood pressure (BP), peripheral pulse oximetry and electrocardiogram. Group T and group N were connected to TL-400 and NICOM [respectively](#) and monitored SVV, CI. Then finished catheterization of radial artery and internal jugular vein after local anesthesia and monitored MAP, CVP. All patients were treated with the same anesthetic scheme by the same anesthesiologist. Anesthesia induction: midazolam 0.05mg/kg, sufentanil 0.4ug/kg, etomidate 0.3 mg/kg, rocuronium 0.6mg/kg, penicillidine 0.5mg and dexamethasone 10mg. Anesthesia maintenance: remifentanyl 0.2–0.4ug.kg⁻¹min⁻¹, propofol 2–4 mg.kg⁻¹h⁻¹, and sevoflurane 0.8–1.3MAC, rocuronium 1/3–1/5 induced dose intermittently, to maintain the BIS (bispectral index) 40–60. Tidal volume was 8 mL/kg and the respiratory frequency was set to maintain PetCO₂ (end-tidal carbon dioxide concentration) 35–45 mmHg. Infusion heater and heating blanket were used to maintain the patient's body temperature was not lower than 36°C.

The baseline infusion was 6 ml/kg.h compound sodium chloride, and red blood cell suspension would be given when hemoglobin <70g/L. When SVV was > 13% for at least two minutes, additional 250 ml colloid would be infused within 5 min. Fluid challenge would be repeated until SVV falls below 13%. Dopamine would be administered if CI remained below 2.5 L/min·m² despite preload optimization. MAP, CVP, CI, SVV were recorded continuously every 10 minutes. All the patients were treated by the same surgeon group. Observation indicators were as follows: perioperative fluid volume (total fluid volume, colloid volume and crystalloid volume), estimated blood loss volume, blood transfusion volume, use of vasoactive agents and urine output. postoperative prognosis: first flatus, wound healing time and LOS. incidence of surgical related complications (incision infection, anastomotic leakage, intestinal edema, intestinal obstruction, ascites), respiratory system related complications (lung infection, pulmonary edema, respiratory failure), circulatory system related complications (arrhythmia, heart failure, myocardial infarction) and urinary system related complications (oliguria, anuria, acute renal failure).

Statistical analysis:

According to previous and relevant statistical data^[20 26], the sample size of this study was calculated by PASS15.0 software to achieve a power of 0.8 and an alpha of 0.05 using a two-sided test. Considering a drop-out rate of 20%, 50 patients were recruited per group. The data were analyzed by SPSS 26.0 statistical software and the measurement data were expressed by mean ± standard deviation and were compared by independent samples T tests. Counting data is expressed by rate (%), and χ^2 test is adopted, fisher's exact test will be used when the incidence rate is very low. The difference was considered to be statistically significant when P<0.05.

Results

A total of 100 patients undergoing gastrointestinal tumor resection were randomized into two groups(50 per group). Baseline characteristics were equivalent. There were no significantly statistical differences in anesthesia duration, operative duration and pneumoperitoneum duration between groups (P > 0.05) (Table-1).

Table-1. Patients baseline characteristics ($\bar{x} \pm S$).

	Group T	Group N	P-value
Gender(male / female)	29/21	31/19	0.683
Age	64.6 ± 12.1	62.5 ± 11.8	0.373
BMI(Kg/m ²)	23.7 ± 2.0	24.1 ± 2.1	0.312
ASA(Ⅰ/Ⅱ)	33/17	38/12	0.271
Cardiac disease	2	4	0.678
Hypertension	6	7	0.766
Diabetes mellitus	6	5	0.749
Respiratory disease	7	6	0.766
Renal disease	1	2	0.617
Liver disease	3	5	0.715
Baseline MAP(mm Hg)	71.5 ± 6.4	73.0 ± 6.4	0.219
Baseline CI (L/min/m ²)	3.4 ± 0.4	3.4 ± 0.5	0.687
Preoperative Hb(g/L)	116.2 ± 12.0	111.8 ± 13.3	0.082
Anesthesia duration (min)	324.0 ± 50.0	315.0 ± 39.8	0.299
Operation duration(min)	265.7 ± 49.2	251.7 ± 41.8	0.128
Pneumoperitoneum duration(min)	166.3 ± 40.7	153.7 ± 36.3	0.107

Comparison of intraoperative fluid inflow and outflow and vasoactive drugs between groups

No significant differences were found between groups with respect to the total fluid volume, the crystalloid volume, the colloid volume, estimated blood loss, blood transfusion, urine output. The use of dopamine to correct hypotension was not different between groups. ($P > 0.05$)(Table-2).

Table-2. Comparison of intraoperative fluid inflow and outflow

	Total infusion (ml)	Colloid volume(ml)	Crystalloid volume(ml)	blood loss (ml)	blood transfusion(ml)	urine output(ml)	Use of dopamine agents (case)
Group T	2360 ± 282	1167 ± 153	1193 ± 156	166 ± 92	36 ± 112	670 ± 120	7
Group N	2295 ± 223	1126 ± 109	1173 ± 157	135 ± 74	32 ± 102	625 ± 118	5
P-value	0.202	0.119	0.525	0.070	0.852	0.059	0.538

Comparison of postoperative prognosis between groups

The first flatus, wound healing and LOS were not different between groups($P > 0.05$). There were no significantly statistical differences in respiratory, cardiovascular,urinary system, and surgical related complications($P > 0.05$). (Table-3). The intervention caused no harm and no patients died during the trial period. No correction was made for missing data.

Table-3. Comparison of postoperative prognosis

	First flatus (h)	Wound healing time (d)	LOS (d)	Cardiovascular (case)	Respiratory (case)	Urinary (case)	Surgical related complications (case)
Group T	57.3 ± 7.9	11.2 ± 1.2	13.3 ± 1.4	5(10%)	7(14%)	6(12%)	6(12%)
Group N	58.5 ± 8.5	10.9 ± 1.1	13.1 ± 1.2	6(12%)	5(10%)	6(12%)	5(10%)
P-Value	0.472	0.268	0.588	0.749	0.538	1.000	0.749

Discussion

The main finding of the study was that GDFT based on TL-400, when compared to GDFT based on NICOM, could lead to similar perioperative fluid infusion and postoperative prognosis in patients undergoing gastrointestinal tumor resection. Furthermore, TL-400 can avoid the interference of electrocoagulation and capture more data.

Fluid administration is an important part of clinical anesthesia in the perioperative period. Inappropriate fluid infusion will not be conducive to the patient's recovery. The volume status cannot be accurately reflected by static indicators used to guide fluid management, such as HR, BP, CVP and urine output^[23-24]. GDFT remains the preferred method for perioperative fluid infusion and hemodynamic optimization for most patients undergoing major surgery^[25].

Bioreactance-based NICOM is developed out of bioimpedance, with the fact that the electrical currents of a low-amplitude, high-frequency alternating current passed through the thorax changes varies with blood flow each cardiac cycle. NICOM has been validated for acceptable clinically precision and accuracy when compared with PAC and PiCCO^[15–16]. And there was no significant difference between NICOM and esophageal Doppler in ability to evaluate fluid responsiveness for GDFT^[26]. As a non-invasive hemodynamic monitor, NICOM was regarded as a valuable alternative for invasive hemodynamic monitor. We therefore compared the relationship between TL-400 and NICOM.

TL-400, a totally non-invasive hemodynamic monitor, obtain the real-time arterial waveform using pulse contour analysis of the radial artery applanation tonometry. Taken data points such as gender, age, height, body weight and blood pressure variables into account, it allows for measurement of CI and SVV. Several studies have shown that using noninvasive applanation tonometry is basically feasible in ICU patients, it has an clinically acceptable agreement with PAC and PiCCO^[13–14]. Trials comparing different patient populations, such as ICU patients after liver transplantation, have however resulted in conflicting results^[27]. And also in patients with poor arterial pulse pressures, the precision and accuracy of the applanation tonometry is not always guaranteed^[28]. These differences might be partly explainable by the patient selection and surgical operation types. A substantial proportion of patients in these trials showed significant cardiovascular fluctuations frequently. This underlines that identifying appropriate patient populations and clinical surgeries for the sensible use of applanation tonometry is pivotal. Compared with these previous trials, in the present study, we observed a similar fluid infusion and postoperative prognosis between TL-400 and NICOM. It is important to consider that the target patient population and laparoscopic of gastrointestinal tumors resection may itself explain the lack of difference between groups. Patients enrolled was in good physical condition and minimally invasive surgery has little effect on circulation.

There was no significant difference in baseline characteristics between groups, it indicated that the preoperative conditions were well balanced. No significant difference was found in anesthesia method, anesthesia duration, operation duration, carbon dioxide pneumoperitoneum duration and blood loss. it can be considered that the effects of anesthesia and operation on the physiology of patients were similar. We believe that overall the groups were comparable. NO clinically significant differences were observed in fluid infusion and postoperative prognosis, we could speculate that both strategies seem to optimize fluid administration equally and lead to similar outcome. So TL-400 may be an suitable alternative for GDFT. Furthermore, compared with NICOM, TL-400 can avoid the interference of electrocoagulation and capture more data points.

Some limitations of this study should be taken into account. We did not regulate postoperative fluid treatment, which may affect the effect of intraoperative therapy. Although we made attempt to exclude the potential contributing factors, some other factors such as social and genetics may continue to interfere the accuracy of the results. In addition, the relatively small sample size limits the generalisability of our findings. So a definitive, large effective trail is needed to confirm the relationship of TL-400 and NICOM in guiding GDFT.

Conclusions

In conclusion, TL-400 performs similarly to NICOM in guiding GDFT, with no significant differences in perioperative fluid infusion and postoperative prognosis in patients undergoing gastrointestinal tumor resection. Compared with NICOM, TL-400 can avoid the interference of electrocoagulation and capture more data.

Abbreviations

ASA

American Society of Anesthesiology; BIS:bispectral index; BP:blood pressure; CI:cardiac index; CVP:central venous pressure; GDFT:Goal-directed fluid therapy; HR:heart rate; LOS:hospital length of stay; MAP:mean arterial pressure; PAC:Pulmonary Artery Catheter; PiCCO:Pulse index continuous cardiac output; PPV:pulse pressure variation; SV:stroke volume; SVV:stroke volume variation;

Declarations

Ethics approval and consent to participate

This study has been approved by the Medical Ethics Committee of Yongchuan Hospital of Chongqing Medical University (2020 Collen trial 92), and was performed only after informed consent was signed by participants.

Consent for publication

Not applicable.

Availability of data and materials

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

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

ML:conceived and designed the study, wrote manuscript. MP and JD: designed the study, analysed sample size and data. All authors have read and approved the final manuscript.

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References

1. Seeley E, Batirel, Da niel L. Miller. **Effect of the amount of intraoperative fluid administration on postoperative pulmonary complications following anatomic lung resections[J]**. Journal of Thoracic & Cardiovascular Surgery, 2015, **149**(1):314–321.e1.
2. Marjanovic G, Villain C, Juettner E, et al. **Impact of different crystalloid volume regimes on intestinal anastomotic stability**. Ann Surg. 2009;**249**:181--5.
3. Uray K S, Wright Z, Kislitsyna K, et al. **Nuclear factor-kappaB activation by edema inhibits intestinal contractile activity.[J]**. Critical Care Medicine, 2010, **38**(3):861 – 70.
4. Myles PS, Andrews S, Nicholson J, et al. **Contemporary Approaches to Perioperative IV Fluid Therapy[J]**. World Journal of Surgery, 2017, **41**(10):2457–2463.
5. Miller TE, Roche AM, Mythen M. **Fluid management and goal-directed therapy as an adjunct to Enhanced Recovery After Surgery (ERAS)[J]**. Canadian Journal of Anesthesia/Journal canadien d'anesthésie, 2015, **62**(2):158 – 68.
6. Myles P S, Bellomo R, Corcoran T, et al. **Restrictive versus Liberal Fluid Therapy for Major Abdominal Surgery.[J]**. New England Journal of Medicine, 2018, **378**(24):2263.
7. Nelson J A, Fischer J P, Grover R, et al. **Intraoperative perfusion management impacts postoperative outcomes: An analysis of 682 autologous breast reconstruction patients[J]**. J Plast Reconstr Aesthet Surg, 2015, **68**(2):175–183.
8. Shin C H, Long D R, D Mclean, et al. **Effects of Intraoperative Fluid Management on Postoperative Outcomes: A Hospital Registry Study[J]**. Annals of Surgery, 2017, **267**(6):1.
9. Miller T E, Roche A M, Mythen M. **Fluid management and goal-directed therapy as an adjunct to Enhanced Recovery After Surgery (ERAS)[J]**. Canadian Journal of Anesthesia/Journal canadien d'anesthésie, 2015, **62**(2):158–168.
10. Chen Y, Shlofmitz E, Khalid N, et al. **Right Heart Catheterization-Related Complications: A Review of the Literature and Best Practices[J]**. Cardiol Rev, 2020, **28**(1):36–41.
11. Gennari M, Bartorelli A L, Polvani G, et al. **Severe Tricuspid Regurgitation After Percutaneous Removal of a Swan-Ganz Catheter Caught by Suture[J]**. The Annals of Thoracic Surgery, 2017, **104**(3):e225–e226.
12. Wang Dong, Jiang Jiali. **Analysis of influencing factors of PICCO monitor [J]**. Journal of Nantong University (Medical Edition), 2013,**33** (5): 399–401.
13. Wagner JY, Sarwari H, Schön G, et al. **Radial Artery Applanation Tonometry for Continuous Noninvasive Cardiac Output Measurement: A Comparison With Intermittent Pulmonary Artery Thermodilution in Patients After Cardiothoracic Surgery[J]**. Critical care medicine,2015,**43**(7):1423–1428.
14. Saugel B, Meidert AS, Langwieser N, et al. **An autocalibrating algorithm for non-invasive cardiac output determination based on the analysis of an arterial pressure waveform recorded with radial artery**

- applanation tonometry: a proof of concept pilot analysis[J].** Journal of Clinical Monitoring and Computing, 2014, **28(4):357–362.**
15. Cheung H, Dong Q, Dong R, et al. **Correlation of cardiac output measured by non-invasive continuous cardiac output monitoring (NICOM) and thermodilution in patients undergoing off-pump coronary artery bypass surgery[J].** Journal of Anesthesia, 2015, **29(3):416–420.**
 16. Squara P, Rotcajg D, Denjean D, et al. **Comparison of monitoring performance of bioreactance vs. pulse contour during lung recruitment maneuvers.** Crit Care. 2009;**13**:R125.
 17. Yong-Hun, Lee, Hye-Won, et al. **Changes in plasma volume before and after major abdominal surgery following stroke volume variation-guided fluid therapy: a randomized controlled trial.[J].** Minerva anesthesiologica, 2019.
 18. Maxime, Cannesson, Henri, et al. **The ability of stroke volume variations obtained with Vigileo/FloTrac system to monitor fluid responsiveness in mechanically ventilated patients.[J].** Anesthesia and analgesia, 2009, **108(2):513-7.**
 19. Mayer J1, Boldt J, Mengistu AM, et al. **Goal-directed intraoperative therapy based on autocalibrated arterial pressure waveform analysis reduces hospital stay in high-risk surgical patients: a randomized controlled trial.** J Crit Care. 2010;**14(1):R18.** doi: 10.1186/cc8875
 20. Yin K, Ding J, Wu Y, et al. **Goal-directed fluid therapy based on noninvasive cardiac output monitor reduces postoperative complications in elderly patients after gastrointestinal surgery: A randomized controlled trial[J].** Pak J Med Sci,2018,**34(6):1320–1325.**
 21. Saugel B, Cecconi M, Hajjar LA. **Noninvasive cardiac output monitoring in cardiothoracic surgery patients: Available methods and future directions.** Journal of Cardiothoracic and Vascular Anesthesia 2019;**33:1742-52.**
 22. Dueck R, Goedje O, Clopton P. **Noninvasive continuous beat-to-beat radial artery pressure via TL-200 applanation tonometry.** J Clin Monit Comput 2012;**26:75–83.**
 23. Eskesen T G, Wetterslev M, Perner A. **Systematic review including re-analyses of 1148 individual data sets of central venous pressure as a predictor of fluid responsiveness[J].** Intensive Care Med, 2016, **42(3):324–332.**
 24. Öveges Nándor, László Ildikó, Tánczos Krisztián, et al. **Mean arterial pressure targeted fluid resuscitation may lead to fluid overload: A bleeding-resuscitation animal experiment[J].** PLoS ONE, 2018, **13(6):e0196188.**
 25. Grocott M, Dushianthan A, Hamilton M A, et al. **Perioperative increase in global blood flow to explicit defined goals and outcomes after surgery: a Cochrane Systematic Review[J].** BJA British Journal of Anaesthesia, 2013, **111(4):535–548.**
 26. Waldron N H, Miller T E, Thacker J K, et al. **A Prospective Comparison of a Noninvasive Cardiac Output Monitor Versus Esophageal Doppler Monitor for Goal-Directed Fluid Therapy in Colorectal Surgery Patients[J].** Anesthesia & Analgesia, 2014, **118(5):966.**
 27. Langemann, Schoen, Reuter, et al. **Autocalibrating pulse contour analysis based on radial artery applanation tonometry for continuous non-invasive cardiac output monitoring in intensive care unit**

patients after major gastrointestinal surgery-a prospective method comparison study. Anaesth Intensive Care, 2016, **44(3):340–345.**

28. Saugel B, Fassio F, Hapfelmeier A, et al. **The T-Line TL-200 system for continuous non-invasive blood pressure measurement in medical intensive care unit patients.** Intensive Care Med 2012;**38:1471-7.**