Original Article

Retrospective Analysis of Outcomes of a Modified Enhanced Recovery after Surgery Protocol for Patients with cT4 Colon Cancer

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Background. Use of the enhanced recovery after surgery (ERAS) protocol reduces morbidity and enhances recovery in patients undergoing colorectal surgery. Patients presenting with T4 cancers are frequently excluded from the ERAS protocol because they typically exhibit a higher rate of perioperative complications. In this study, we examined the feasibility of applying a modified ERAS protocol to patients undergoing colon resection for clinical stage cT4 colon cancer and evaluated the short-term outcomes.

Methods. In this retrospective study, all patients with a clinical diagnosis of cT1 to cT4 colon cancer undergoing surgery between January 2019 and November 2020 at Taipei Medical University Hospital (TMUH) were treated in accordance with the modified ERAS protocol. Short-term postoperative outcomes were compared between the control (< cT4) and experimental group (cT4). Data were collected retrospectively from the TMUH database.

Results. Fifty patients with the diagnosis of colon cancer, 32 with clinical cT4 cancer, and 18 with cancer at a stage lower than T4 (cT < 4) were enrolled. Neither the mean time of tolerance to solid food nor postoperative length of stay differed significantly between the two groups ($p = 0.55$ and $p = 0.47$, respectively). No differences in short-term complications were observed.

Conclusions. Use of the modified ERAS protocol for patients with clinical stage cT4 cancer is feasible and associated with a faster recovery and shorter length of hospital stay. No increase in complication rates was detected in these patients compared with those at a clinical stage lower than cT4. A larger study with a larger sample is required to validate these results.

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Globally, colorectal cancer (CRC) constitutes a major public health burden, and it is increasingly affecting populations in Asian countries.[1] In Taiwan, colon cancer is the most common cancer and the third leading cause of cancer-related death. Surgery remains the main treatment modality.[2]

For colorectal surgery, the enhanced recovery after surgery (ERAS) protocol is the standard of care. ERAS is an evidence-based multimodal perioperative protocol focusing on early recovery and reducing post-

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operative complications.[3,4] It was first introduced by Kehlet et al. in 1995 for patients undergoing CRC surgery.[5] Because this protocol produced favorable outcomes in terms of safety and early recovery, it has gradually been implemented in other fields of surgery.[6,7] An European group has also reported the benefit of ERAS compared to conventional care in reducing the length of stay, surgical morbidity and readmission rate for patients undergoing colorectal surgery[8].

ERAS fundamentally shifts traditional patient care in surgical wards to standardized evidence-based care.[9] Approximately 10%-15% of patients with colon cancer present with locally advanced (T4) disease.[10-12] Pathological stage pT4 colon cancer is a major indicator of poor prognosis in patients with stage II and III colon carcinoma,[13] and it has been reported that patients with pT4a colon cancer are at higher risk of metachronous peritoneal metastasis.[14] Therefore, most studies on the topic have excluded patients with T4 colon cancer because of the relatively high rate of complications in such patients.[15,16] To maximize the utility of the ERAS protocol, we analyzed whether patients with cT4 colon cancer were eligible for this protocol.

Materials and Methods

Study design and population

Two groups of patients undergoing laparoscopic colon surgery were included and analyzed. All patients aged > 18 years with a final diagnosis of adenocarcinoma of the colon were included.

It was designed to be divided into two groups based on the clinical T staging of CT scans during the retrospective period: cT4 (group A) versus < cT4 (group B).

- *Group A.* This group comprised patients undergoing surgical resection with a clinical diagnosis of stage cT4 CRC (defined according to the Union of International Cancer Control tumor-node-metastasis malignant tumor classification — 8th edition) between January 2019 and November 2020 at the colorectal surgery unit of Taipei Medical University Hospital (TMUH); they were treated under our newly established modified ERAS protocol (mERAS).
- *Group B.* This group comprised patients that had colorectal resections for cancers at a stage lower than cT4 who had also been treated under mERAS in the same institution between January 2019 and November 2020.

The exclusion criteria were the presence of rectal lesions undergoing TAMIS, patients undergoing robot-assisted surgery, synchronous cancers, lack of colonic resection, resection during a Covid-19 level 3 pandemic alert with inablility of surgical patients to apply ERAS, surgery done by non-colorectal surgeons and surgery done in an emergency setting. The decision to exclude patients who underwent resection in an emergency setting was made because of the inapplicability of mERAS items and lack of patient counseling.

Data for both cohorts were collected retrospectively from a prospectively maintained database. A comparison between the conventional ERAS protocol of the ERAS Society colorectal guidelines and the mERAS protocol in our hospital is provided in Table 1.

Endpoints

The primary endpoint was postoperative length of stay (LOS), defined as the number of postoperative days of in-hospital recovery. Secondary endpoints were time to postoperative oral intake, defined as tolerance of food, and the time of first bowel movement and first flatus. Other endpoints were overall morbidity (according to the Clavien-Dindo classification), an emergency department (ED) visit within 3 days of discharge, and 14-day readmission.

Statistical analysis

Descriptive statistics were used to characterize the sample.

Data are presented as mean and standard deviation (SD) for continuous variables except for carcinoembryonic antigen (CEA) levels. Because the distribution of CEA was not symmetric, we present CEA le-

Table 1. Comparison of conventional ERAS and modified ERAS protocols

Conventional ERAS protocol	Modified ERAS protocol
Preoperative	
Preadmission patient education and counseling	Preadmission education and preanesthesia consultation
Pre-operative nutrition evaluation	Pre-operative Nutrition evaluation
Management of anaemia	Same as conventional ERAS
No bowel preparation	Oral bowel preparation 2 days before surgery
Preoperative oral carbohydrate/no fasting	No solid food after midnight on the day of surgery; only clear liquids up to 2 h before surgery
Preoperative long-acting sedative medication	None
Thrombosis prophylaxis	All patients use well-fitting compression stockings and intermittent pneumatic compression from the time of surgery until getting out of bed after surgery
Antibiotic prophylaxis before incision	Single-dose cephalosporin (1,000 mg) 15-30 min before the incision; additional dose if surgery lasts longer than 4 h
Postoperative nausea and vomiting prophylaxis administered	Same as conventional ERAS
Intraoperative	
Epidural or spinal anesthesia	None
Upper-body forced-air heating cover used	Same as conventional ERAS
Nasogastric tube used intra-operatively	None
Resection-site drainage	Same as conventional ERAS
Intraoperative fluid and electrolyte therapy	Same as conventional ERAS
Postoperative	
Termination of urinary drainage within 24 h of surgery	Same as conventional ERAS
Stimulation of gut motility	Attempt oral water intake 2 h after surgery
Postoperative epidural analgesia	None
Patient weight on postoperative day 1	None
Nonopiate oral analgesics/NSAIDs	Same as conventional ERAS
Termination of intravenous fluid infusion	Termination of intravenous fluid infusion on postoperative day 1
Perioperative oral nutrition	Clear liquid diet for 1-2 days and then low residual soft food intake
Audit of compliance/outcomes	Same as conventional ERAS
Early mobilization	Same as conventional ERAS

NSAIDs, nonsteroid anti-inflammatory drugs.

vels as median, first quartile (Q1), and third quartile (Q3) values. Independent-sample t tests were used to analyze continuous variables, presented as means, and the Wilcoxon rank sum test was used assess CEA, presented as median values. Discrete data were evaluated using chi-square tests, and the variables are expressed as frequencies and percentages. When > 20% of cells with expected frequencies of < 5 or ≥ 1% of cells with expected frequencies of < 1 were identified, the chi-square test was not considered appropriate and Fisher's exact test was used instead. A two-sided *p* value of < .05 was considered statistically significant. Statistical analyses were performed using SAS 9.4.

Compliance with ethical standards

This study was approved by the Ethical Committee of TMUH (IRB No. N202203005).

Results

Study population

Of the patients diagnosed with colon cancer and who underwent surgical resection at the colorectal surgery unit of TMUH between January 2019 and November 2020, 50 had received a diagnosis of colon cancer and were included in the study analysis. Of these patients, 32 (Group A) had clinical cT4 cancer (cT = 4) and 18 (Group B) had cancer at a lower cT stage (cT < 4) treated electively. Of these patients, Group A had 32 patients with a final pathological staging of T4. Group B had 13 and 5 patients with a fi-

nal pathological staging of T3 and T4, respectively. All 50 patients underwent surgery in accordance with the mERAS protocol.

Patient demographics

The patient demographics are summarized in Table 2. The two groups were comparable with respect to age, sex, body mass index, CEA, American Society of Anesthesiology score, preoperative albumin, comorbidities (diabetes, hypertension, and heart, respiratory, and renal diseases), surgical approach, surgical procedures, operation times, and need for multi-visceral resection.

In our study, no difference was observed between Group A (cT = 4) and Group B (cT < 4) with regard to age or sex (p = 0.71 and 0.45, respectively) nor in CEA (p = 0.33). In terms of comorbidities, no difference between the two groups was detected regarding diabetes, hypertension, or heart, respiratory, and renal diseases (p = 0.13, 0.92, 0.69, 2, and 0.53, respectively). The two groups also did not differ with regard to multivisceral resection (p = 0.28).

Postoperative outcomes

The postoperative outcomes of the two groups are displayed in Table 3. Regarding the primary outcome,

Table 2. Patient demographics

Parameters	Group A (cT = 4) (n = 32)	Group B (cT < 4) (n = 18)	p value
Age, mean ± SD	62.19 ± 11.63	63.50 ± 12.92	0.71[a]
Sex, n (%)			0.45[b]
Female	16 (50.00%)	7 (38.89%)	
Male	16 (50.00%)	11 (61.11%)	
Preoperative BMI, mean ± SD	22.95 ± 3.39	22.91 ± 3.16	0.96[a]
CEA, median (Q1, Q3)	7.1 (2.7, 13.5)	9.2 (3.4, 45.4)	0.33[a]
ASA score, n (%)			0.85[d]
1	1 (3.13%)	1 (5.56%)	
2	27 (84.38%)	14 (77.78%)	
3	4 (12.50%)	3 (16.67%)	
Comorbidity			
Diabetes, n (%)	8 (25.00%)	1 (5.56%)	0.13[d]
Hypertension, n (%)	12 (37.50%)	7 (38.89%)	0.92[b]
Heart disease, n (%)	4 (12.50%)	3 (16.67%)	0.69[d]
Respiratory disease, n (%)	2 (6.25%)	1 (5.56%)	1.00[d]
Renal disease, n (%)	2 (6.25%)	0 (0.00%)	0.53[d]
Preoperative albumin (gr/dL), mean ± SD	3.81 ± 0.53	3.93 ± 0.47	0.44[a]
pT4, n (%)			0.07[d]
a	23 (71.88%)	17 (94.44%)	
b	9 (28.13%)	1 (5.56%)	
Surgical approach, n (%)			0.38[d]
Open	5 (15.63%)	0 (0.00%)	
Laparoscopic	18 (56.25%)	11 (61.11%)	
Robotic	7 (21.88%)	5 (27.78%)	
Converted	2 (6.25%)	2 (11.11%)	
Surgical procedure, n (%)			0.27[d]
Right hemicolectomy	15 (46.88%)	13 (72.22%)	
Left hemicolectomy	6 (18.75%)	1 (5.56%)	
Anterior resection	5 (15.63%)	3 (16.67%)	
Low anterior resection	6 (18.75%)	1 (5.56%)	
Multivisceral resection, n (%)			0.28[d]
Yes	4 (12.5%)	0 (0.00%)	
No	28 (87.5%)	18 (100.00%)	
OP times, mean ±SD	243.94 ± 105.35	236.67 ± 85.13	0.80[a]

[a] t test; [b] chi-square test; [c] Wilcoxon rank sum test; [d] Fisher's exact test. n, number.

LOS did not differ significantly between Group A (cT = 4) and Group B (cT < 4), with a mean of 8.94 ± 5.92 in the cT = 4 group compared with 8.06 ± 2.65 in the cT < 4 group (p = 0.47). For the secondary outcomes, no difference in terms of mean time to postoperative oral intake tolerance was observed between Group A (cT = 4) and Group B (cT < 4; 2.84 ± 2.05 vs. 2.67 ± 1.78; p = 0.55). ED within 3 days of discharge and 14-day readmission also did not differ between the two groups (p = 1.0, NA, respectively). The remaining recorded postoperative outcomes did not differ significantly between the two cohorts.

Discussion

ERAS is an evidence-based clinical practice known to enhance postoperative recovery and reduce postoperative complication rates. The impact of ERAS on postoperative outcomes in patients with T4 cancer has not been thoroughly addressed in the literature. Our results support the hypothesis that the adoption of the ERAS protocol would be applicable to patients with colon cancer at clinical stage T4.

Since the adoption of ERAS in 1997 for patients undergoing elective colon surgery,[6] its implementation has been demonstrated to reduce postoperative LOS and enhance recovery when compared with traditional care.[17-19] T4 colon cancer has been an issue of concern for patients receiving laparoscopic treatment due to relatively high rates of complications but the results coming from a systemic review has shown its safety and feasibility in T4a colon cancer patients undergoing laparoscopic colectomy.[20] Studies comparing ERAS to the standard care usually analyze all stages of CRC as a single group without making com-

Table 3. Postoperative outcomes

Parameters	Group A (cT = 4) (n = 32)	Group B (cT < 4) (n = 18)	p value
Time to first flatus (days), mean ± SD	2.63 ± 1.29	2.61 ± 1.14	0.97[a]
Time to food intake (days), mean ± SD	2.84 ± 2.05	2.67 ± 1.78	0.55[a]
Length of hospital stay (days), mean ± SD	8.94 ± 5.92	8.06 ± 2.65	0.47[a]
Complications, n (%)			
Pneumonia	4 (12.50%)	0 (0.00%)	0.28[b]
Surgical site infection	3 (9.38%)	0 (0.00%)	0.54[b]
Anastomotic leakage	0 (0.00%)	0 (0.00%)	NA
Ileus	2 (6.25%)	1 (5.56%)	1.00[b]
Intra-abdominal abscess	1 (3.13%)	1 (5.56%)	1.00[b]
Clavien-Dindo, n (%)			0.71[b]
0	25 (78.13%)	16 (88.89%)	
1			
2	3 (9.38%)	2 (11.11%)	
3	2 (6.25%)	0 (0.00%)	
4	2 (6.25%)	0 (0.00%)	
5			
ED visit within 3 days of discharge, n (%)			
Wound infection/discharge	1 (3.13%)	0 (0.00%)	1.00
Adhesion ileus	0 (0.00%)	0 (0.00%)	NA
Wound pain	0 (0.00%)	0 (0.00%)	NA
Readmission within 14 days of discharge, n (%)			
Wound infection/discharge	0 (0.00%)	0 (0.00%)	NA
Poor appetite and weakness	0 (0.00%)	0 (0.00%)	NA
Neorectal abscess	0 (0.00%)	0 (0.00%)	NA
Adhesion ileus	0 (0.00%)	0 (0.00%)	NA
Pneumonia	0 (0.00%)	0 (0.00%)	NA
Intra-abdominal abscess	0 (0.00%)	0 (0.00%)	NA
Colitis	0 (0.00%)	0 (0.00%)	NA

[a] t test; [b] Fisher's exact test. n, number.

parison specifically to the T4 lesions as a group.[21,22] Therefore, we compared the postoperative outcomes of recovery in terms of time to first flatus, time to food intake, and length of hospital stay between cT = 4 and cT < 4 groups. Our results revealed no significant difference between the two groups.

The mERAS protocol has been implemented in our hospital since June 2016. Regarding the outcome of ED visit within 3 days of discharge, 1 of the 32 patients (3.13%) in the cT = 4 group and no patient in the cT < 4 group exhibited this outcome (p = 1.0). The cause of the 3-day ED visit was wound infection and discharge. A Canadian group reported that an average of 20% of their patients with CRC in their ERAS program had an ED visit within 30 days of discharge,[23] most commonly caused by surgical site and urinary tract infections. In our patients, the complication rate was relatively low, and the cause of the ED visit is consistent with those of the Canadian study.

Amri et al. reported that surgical site infection rates were significantly higher among patients with an operation time longer than 140 min than among those with shorter operation times (p = 0.05). Our operation time was approximately 200 min in both the cT = 4 and cT < 4 groups, with no significant difference between the groups. Although our operation time was more than 140 min, we still maintained low infection rates. This could be partly explained by the results of Li et al., who revealed that patient compliance may affect the outcome of surgical site infection.[24]

Regarding 14-day readmission, our data revealed that no patients in either group required readmission for further management in the postoperative period. This finding clearly demonstrates that the implementation of mERAS in patients with clinical stage T4 cancer did not increase complications, with each element of the mERAS program playing an essential role.

Overall, the implementation of the mERAS protocol for patients with clinical stage T4 cancer in a community hospital seems comparably feasible to the general ERAS program in terms of the length of hospital stay, 3-day ED visit, and 14-day readmission rate but requiring large-scale studies for further confirmation.

An Italian cohort study had shown the feasibility of applying ERAS protocol in patients with cT4, resulting shortened length of stay and earlier oral intake without affecting postoperative outcomes.[31] Many other studies involving patients with various T stages have demonstrated that the implementation of ERAS program provided patients with shortened length of hospital stay and without increased readmission or morbidity.[25-30] Based on our previous single-center data, colorectal cancer patients undergoing ERAS have a positive effect on the shortened length of hospital stay and is not associated with increased 14-day readmission.[32]

Applying the same protocol, the results from the present study have shown that patients with cT4 undergoing mERAS have comparable postoperative outcomes (time to food intake, hospital stay, early return to ER within 3 day and 14 day after discharge) to the control group(cT < 4) undergoing mERAS.

The present findings may serve as guidance for future clinical studies, and the implementation of ERAS for patients with clinical stage T4 colon cancer could be considered.

Limitation

More than half of the enrolled patients received right hemicolectomy with relatively low morbidity, and multi-visceral resection only accounted for 4 patients, thus more colon cancer patients are needed to demonstrate the generalized feasibility of mERAS in all levels of surgical difficulty.

Conclusion

These preliminary results reveal that mERAS is feasible for selected patients with clinical T4 colon cancer. Large-scale study is needed in future for further confirmation of its long term efficacy.

Conflicts of Interest

The authors have no conflicts of interest to declare.

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原　著

回顧性分析針對 cT4 結腸癌患者的改良術後加速康復方案的結果

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目的　使用加速術後恢復方案可降低接受結直腸手術的患者的發病率並促進恢復。患有 T4 癌症的患者經常被排除在 ERAS 方案之外，因為他們通常表現出更高的圍術期病發症。 在這項研究中，我們檢查了改良的 ERAS 方案應用於臨床分期 T4 結腸癌患者接受手術，並評估了短期結果。

方法　在這項單中心回顧性研究中，所有在 2019 年 1 月至 2020 年 11 月期間在大學附設醫院接受手術的臨床診斷為 cT1 至 cT4 的結腸癌患者均按照改良 ERAS 方案進行治療，比較短期術後結果。

結果　收入了共 50 名 pT4 期癌症患者、其中包含 32 名臨床 cT4 癌症患者和 18 名低於 T4 期 (cT < 4) 的癌症患者。兩組對固體食物的平均耐受時間和術後住院時間均無顯著差異 (分別為 $p = 0.55$ 和 $p = 0.47$)。沒有觀察到短期病發症的差異。

結論　慎選對臨床分期 T4 癌症患者使用改良的 ERAS 方案是可行的，與臨床分期低於 T4 的患者相比，這些患者的病發症發生率沒有增加，但需要更大規模研究來驗證這些結果。

關鍵詞　加速術後恢復方案、結腸癌、T4。