A meta-analysis of fast track surgery for patients with gastric cancer undergoing gastrectomy

S Chen^{1,*}, Z Zou^{2,*}, F Chen¹, Z Huang¹, G Li²

¹Zhujiang Hospital, Southern Medical University, Guangzhou, China

²Nanfang Hospital, Southern Medical University, Guangzhou, China

*S Chen and Z Zou contributed equally to this work and should be considered as joint first authors

ABSTRACT

INTRODUCTION This meta-analysis evaluated the safety and efficacy of fast track surgery (FTS) for patients with gastric cancer undergoing gastrectomy.

METHODS

Randomised controlled trials (RCTs) published between 1 January 1995 and 21 June 2013 comparing FTS with conventional perioperative care for patients with gastric cancer undergoing gastrectomy were identified in the PubMed, Embase™ and Cochrane Library databases, and were analysed systematically using RevMan software (Nordic Cochrane Centre, Copenhagen, Denmark).

RESULTS

Seven RCTs (524 patients) were analysed. Compared with conventional perioperative care, FTS treatment with/without laparoscopy was associated with shorter postoperative hospitalisation, less hospitalisation expenditure (both $p < 0.00001$), less pain and better quality of life. Short-term morbidity and readmission rates did not differ between treatments. No incidents of death occurred during the short-term follow-up period.

CONCLUSIONS

In patients with gastric cancer undergoing gastrectomy, the FTS pathway reduces the length and cost of postoperative hospitalisation while maintaining short-term morbidity, readmission and mortality rates comparable with those of conventional care.

KEYWORDS

Gastric cancer – Gastrectomy – Fast track surgery – Meta-analysis

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CORRESPONDENCE TO

Zonghai Huang, E: drhuangzonghai@163.com

Gastric cancer is the fourth most common cancer worldwide and the second leading cause of cancer related deaths in the world.¹ Surgery has been the cornerstone of gastric cancer treatment. The fast track surgery (FTS) pathway, also known as enhanced recovery after surgery (ERAS), was initiated in 1995 by Bardram *et al.*² FTS is a multidisciplinary approach aiming to accelerate recovery, reduce complications, minimise hospital stay and reduce healthcare costs, all without compromising patient safety. The FTS pathway has been used successfully in urological,^{3,4} orthopaedic,⁵ gynaecological^{6,7} and, especially, colonic^{8,9} settings.

For colorectal surgery, a working group developed and modified a consensus guideline for FTS programmes in 2009.¹⁰ These programmes addressed 20 issues including preadmission counselling, preoperative preparation, use of standard intraoperative protocols and prophylaxis, and postoperative care. Most recommendations were based on grade A evidence. However, no consensus guideline has been developed for gastric surgery although surgeons have attempted to introduce slightly modified FTS programmes for patients undergoing such surgery.

Several small randomised controlled trials (RCTs)^{11–17} and retrospective studies^{18,19} have documented the benefits and safety of FTS programme implementation in patients with gastric cancer undergoing gastrectomy. Conversely, other retrospective studies^{20,21} have questioned these assertions and use of the FTS pathway in this patient group has not been systematically reviewed. In order to evaluate the safety and efficacy of the FTS pathway, we performed a meta-analysis of RCTs, comparing this programme with conventional perioperative care for patients with gastric cancer undergoing gastrectomy.

Methods

All RCTs comparing the FTS pathway with conventional perioperative care for patients with gastric cancer undergoing gastrectomy were identified by searching the PubMed, Embase™ and Cochrane Library databases. RCTs published in any language between 1 January 1995 (the year when Bardram *et al* introduced the FTS concept)² and 21 June 2013 were considered for inclusion. The following MeSH

(Medical Subject Headings) and free text terms were used: “fast track”, “enhanced recovery”, “accelerated rehabilitation”, “multimodal perioperative care”, “enhanced recovery after surgery”, “ERAS”, “gastrectomy”, “gastr*”, “gastric resection” and “stomach”.

The reference lists of relevant articles and previous meta-analyses were searched to identify additional relevant articles. Authors’ names were entered as search terms in the PubMed database to check for additional studies. Trials were also identified using the ‘related articles’ function in PubMed.

Inclusion and exclusion criteria

RCTs included in the meta-analysis met the following criteria: (1) comparison of the FTS pathway with standard care for patients with gastric cancer undergoing elective gastrectomy; (2) reporting of at least one relevant outcome (length of primary postoperative hospital stay, hospitalisation expenditure; and/or short-term morbidity, readmission; and/or mortality rates); and (3) clear documentation of a multimodal FTS pathway composed of at least seven elements. Given the lack of a consensus guideline for FTS programme implementation in patients undergoing gastric surgery, we made the arbitrary decision that such programmes should include at least 7/20 items addressed in the guidelines published by a working group related to FTS.¹⁰ This number of FTS elements was selected because fewer elements might represent ‘modern’ traditional care.

When two articles reported on the same clinical trial, the publication providing the most information was selected. Non-randomised studies, case-controlled trials, cohort studies, retrospective studies and other studies that did not fulfil the inclusion criteria were excluded.

Outcome measures

The primary endpoints were the length of primary postoperative hospital stay and hospitalisation expenditure. The secondary endpoints were short-term morbidity, readmission and mortality rates.

Method of review

This meta-analysis was performed in accordance with the recommendations of the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement.²² Two reviewers evaluated all retrieved studies independently to determine selection, assess study quality and extract data. Disagreements were resolved through discussion and consensus of the study team.

Two reviewers independently assessed RCT quality and risk of bias using tools provided by the Cochrane Collaboration.²³ The reviewers examined randomisation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, baseline comparability of groups, completeness of outcome data and selective outcome reporting. Baseline comparability of groups was assessed using six matching criteria: age, sex, body mass index (BMI), ASA (American Society of Anesthesiologists) grade or Eastern Cooperative Oncology Group score, type of reconstruction and pathological TNM (tumour, lymph

nodes, metastasis) stage. Baseline incomparability was defined as non-matching in at least three of these six criteria.

The risk of bias in each domain was categorised as low, high or unclear. Trials with high risk of bias in at least four of seven domains were not included in the meta-analysis.

Statistical analysis

Statistical analyses were performed using RevMan version 5.0 (Nordic Cochrane Centre, Copenhagen, Denmark). Weighted mean differences (WMDs) with 95% confidence intervals (CIs) were calculated for continuous variables (length of postoperative hospital stay and hospitalisation expenditure) and odds ratios (ORs) with 95% CIs were calculated for dichotomous variables (short-term morbidity, readmission and mortality). A random effects model was used to pool studies with significant heterogeneity, as determined by the chi-squared test ($p \leq 0.10$) and the inconsistency index ($I^2 \geq 50\%$). Quality of life data could not be pooled because of incompatibility in measurement among studies but they are presented descriptively.

Sensitivity analysis was also performed by excluding one trial at a time to assess its effect on the overall estimate. Bias exploration using a funnel plot was attempted but was not possible because of the small number of trials included in this review. Subgroup analyses were performed of: 1) FTS versus conventional care with/without laparoscopy, to explore the role of laparoscopy in FTS for patients undergoing gastrectomy, and 2) FTS versus conventional care in patients undergoing total, distal, proximal or mixed gastrectomy, to explore the role of the extent of gastric resection in FTS.

Results

Of the 413 citations generated by the initial literature search, 7 RCTs with 524 patients were included in the meta-analysis (Fig 1, Table 1).^{11–17} Regarding the methodological quality of the RCTs, all seven showed low to moderate overall risks of bias (Fig 2). Sealed envelopes were used for allocation in one trial¹² but the exact allocation sequence was not reported. Randomisation methods were adequately reported in five trials,^{11–13,16,17} but were not specified in two trials.^{14,15} Adequate methods of allocation concealment were reported in four trials.^{11,13,16,17} No study used blinding of surgeons and patients because of the design of the FTS pathway, and only two trials used blinding of assessors.^{15,17} All included trials had low risks of bias owing to incomplete data and selective reporting.

Matching criteria used in the RCTs are shown in Table 1. One trial matched patients only according to age, sex and BMI,¹⁴ and was therefore classified as having a high risk of baseline incomparability.

Table 2 lists the FTS pathway components of the guidelines¹⁰ used in the RCTs. The study conducted by Hu *et al* had four arms,¹⁵ which we divided into two studies: Hu Open 2012 (FTS vs conventional perioperative care after open surgery) and Hu Lap 2012 (FTS vs conventional perioperative care after laparoscopy). Disparities were found

between the guidelines and the studies. Long acting opioids were avoided in all studies but only one study used midthoracic epidural and continuous epidural local anaesthetic.¹⁴ Infiltration of surgical wounds with local anaesthesia was used in two studies.^{16,17} One study used intermittent pneumatic compression, rather than heparin (as recommended), for prophylaxis against thromboembolism.¹⁶ Two studies used transperitoneal jejunum nutrient canals.^{11,15}

Length of primary postoperative hospital stay

All seven RCTs reported this outcome measure^{11–17} but data from only five trials were available for meta-analysis.^{11–15,16,17} Postoperative hospital stays were significantly shorter for patients receiving FTS treatment than for those receiving conventional perioperative care (WMD: -2.62 days; 95% CI: -3.59–1.65 days, $p<0.00001$), with significant heterogeneity among studies ($I^2=71\%$, $p=0.009$) (Fig 3).

Hospitalisation expenditure

Six articles reported hospitalisation expenditure.^{11,15–17} Meta-analysis demonstrated that expenditure was significantly lower for the FTS group than for the conventional perioperative care group (WMD: -0.39×10^4 Chinese yuan, 95% CI: -0.52 – -0.26×10^4 Chinese yuan, $p<0.00001$), with significant heterogeneity among studies ($I^2=57\%$, $p=0.03$) (Fig 4).

Short-term morbidity, readmission and mortality rates

Postoperative morbidity rates were reported in all seven studies.^{11–17} Meta-analysis demonstrated comparable postoperative morbidity between patient groups (OR: 0.82, 95% CI: 0.40–1.66, $p=0.58$), with significant heterogeneity among studies ($I^2=57\%$, $p=0.02$) (Fig 5). Readmission rates, reported in four studies,^{12,14,16,17} were also comparable (OR: 2.01, 95% CI: 0.36–11.29, $p=0.43$), with no significant heterogeneity among studies ($I^2=0\%$, $p=0.85$) (Fig 6). No death occurred during the follow-up period in any RCT.

Quality of life

Wang *et al*¹⁴ and Kim *et al*¹⁶ found that the FTS pathway was significantly superior to the conventional care system, in terms of quality of life at discharge and two weeks thereafter respectively. Wang *et al*¹⁴ and Feng *et al*¹⁷ reported lower pain intensity in the FTS group than in the conventional care group on postoperative days 1–5, as measured with a visual analogue scale. Kim *et al* reported similar pain intensities in both groups but less need for additional pain control in the FTS group.¹⁶

Table 1 Characteristics of studies included in the meta-analysis

Publication	Sample size		Approach	Matching criteria*	Follow-up duration
	Fast track	Conventional			
He, 2010 ¹¹	41	41	Open	1, 2, 5, 6	0 days
Liu, 2010 ¹²	33	30	Open	1, 2, 3, 4, 5, 6	30 days
Tang, 2010 ¹³	21	21	Open	1, 2, 5, 6	0 days
Wang, 2010 ¹⁴	45	47	Open	1, 2, 3	28 days
Hu (Open), 2012 ¹⁵	21	22	Open	1, 2, 3, 5, 6	28 days
Hu (Lap), 2012 ¹⁵	20	22	Lap	1, 2, 3, 5, 6	28 days
Kim, 2012 ¹⁶	22	22	Lap	1, 2, 3, 4, 5, 6	14 days
Feng, 2013 ¹⁷	59	60	Open	1, 2, 3, 4, 5, 6	28 days

Open = open gastrectomy; LAP = laparoscopic gastrectomy
 *1 = age; 2 = sex; 3 = body mass index; 4 = American Society of Anesthesiologists grade / Eastern Cooperative Oncology Group score; 5 = type of reconstruction; 6 = pathological TNM (tumour, node, metastasis) stage

Sensitivity and subgroup analyses

Sensitivity analysis determined that no single RCT significantly affected the overall results of the meta-analysis. Subgroup analyses of FTS versus conventional care with/without laparoscopy yielded similar results (Figs 3–6). Subgroup analyses of FTS versus conventional care focusing on the extent of gastric resection also yielded similar results for postoperative hospitalisation, hospitalisation expenditure and short-term readmission rates although the short-term morbidity showed some differences. The short-term morbidity was significantly less for patients who received FTS treatment than for patients who received conventional perioperative care in the total gastrectomy subgroup. However, this parameter was comparable for the distal gastrectomy subgroup and the mixed gastrectomy (including distal, total and proximal gastrectomies) subgroup. Although there was a selection bias (only one trial

was included in the total gastrectomy subgroup),¹⁷ the results suggest that patients with gastric cancer undergoing a total gastrectomy might also benefit from the FTS pathway.

Discussion

The results of our meta-analysis of seven RCTs suggest that the implementation of the FTS pathway significantly reduces the length of postoperative hospital stay and hospitalisation expenditure for patients with gastric cancer undergoing gastrectomy. At the same time, it maintains comparable short-term morbidity, readmission and mortality rates.

Nevertheless, the FTS pathway should be applied selectively in this patient group as not all patients will benefit. Most RCTs included in the present meta-analysis excluded patients with contraindications to early postoperative discharge or optimised measures. These trials were conducted in patients in good physical health. Patients were excluded if they exhibited malnutrition, pregnancy, ASA grade >2, or any important vital organ co-morbidity such as cardiac, lung, hepatic or renal disease. These patients might have been excluded because these conditions could impede a fast recovery, because of ethical review considerations or because of the possibility of poor patient compliance. The studies also excluded patients with conditions impeding fast recovery, such as those who had undergone preoperative radiotherapy/chemotherapy^{11,15–15,17} or who had diabetes mellitus (DM).^{11,15,14,16,17} As our understanding of surgical pathophysiology improves and the FTS procedure is further developed, FTS could probably be applied safely in these critically ill patients in the near future.¹⁷

Preoperative chemoradiotherapy for gastric cancer can be delivered safely and is well tolerated, with acceptable rates of perioperative morbidity and mortality.^{24,25} A meta-analysis from 2013 demonstrated that neoadjuvant chemotherapy for gastric cancer does not increase treatment related morbidity or mortality.²⁶ The FTS pathway could therefore be applied cautiously in patients who have undergone preoperative chemoradiotherapy.

DM is a major risk factor in patients undergoing surgery that contributes to the development of postoperative nosocomial infection. The incidence of such infection after elective gastrectomy was significantly greater in patients with DM (especially long-term DM) than in non-diabetic patients.²⁷ Recent RCTs demonstrated that intensive glucose control significantly reduced short-term morbidity in non-diabetic²⁸ and diabetic²⁹ patients undergoing gastrectomy for gastric cancer. As the FTS pathway can reduce insulin resistance and stress, we believe that it could also benefit patients with DM if implemented carefully. Other situations in which the FTS pathway is potentially inapplicable may require specific consideration.

Another concern with FTS pathway implementation is that it may make patients physically and psychologically uncomfortable. Despite this, patients have been found to welcome some measures such as the avoidance of routine gastric tube use and early reintroduction of oral intake.¹²

Table 2 Enhanced recovery after surgery (ERAS) pathway components applied in the included trials

ERAS component	He, 2010 ¹¹	Liu, 2010 ¹²	Tang, 2010 ¹³	Wang, 2010 ¹⁴	Hu (Open), 2012 ¹⁵	Hu (Lap), 2012 ¹⁵	Kim, 2012 ¹⁶	Feng, 2013 ¹⁷
Preadmission information and counselling	✓	✓	✓	✓	✓	✓	✓	✓
Preoperative bowel preparation	✓	✓	✓	✓	✓	✓	✓	
Preoperative fasting and carbohydrate loading	✓	✓	✓	✓	✓	✓	✓	✓
Preanaesthetic medication				✓				
Prophylaxis against thromboembolism							✓	
Antimicrobial prophylaxis								✓
Standard anaesthetic protocol				✓				
Prevention and treatment of postoperative nausea and vomiting		✓						
Laparoscopy assisted surgery						✓	✓	
Surgical incisions	✓	✓	✓	✓	✓			
Nasogastric intubation	✓	✓	✓	✓	✓	✓	✓	✓
Prevention of intraoperative hypothermia	✓	✓	✓				✓	✓
Perioperative fluid management	✓	✓	✓	✓	✓	✓		✓
Drainage of peritoneal cavity following anastomosis	✓	✓	✓	✓	✓	✓	✓	✓
Urinary drainage	✓	✓	✓	✓	✓	✓	✓	✓
Prevention of postoperative ileus				✓		✓	✓	
Postoperative analgesia				✓				
Postoperative nutritional care		✓		✓	✓	✓	✓	✓
Early mobilisation	✓	✓	✓	✓	✓	✓	✓	✓
Audit	✓	✓	✓	✓	✓	✓	✓	✓

Improved quality of life has been detected in FTS groups.^{14,16} Some patients with histories of similar surgical procedures have expressed their amazement at the fast recovery and early postoperative discharge achieved by FTS implementation.¹² Satisfaction and improved quality of life related to this treatment course have also been reported in patients undergoing gynaecological³⁰ and hepatic³¹ surgery. These outcomes suggest the amenity of implementing the FTS pathway in gastric surgery settings.

One obstacle of FTS pathway implementation in patients undergoing gastric surgery is the lack of a consensus guideline. For open colorectal surgery, a midline or transverse incision of minimal length is recommended. The use of a minimal abdominal incision in open gastric surgery was reported in five trials; an epigastric midline incision that did not pass over the umbilicus was described in two of these trials. The best way to minimise the incision may require further discussion. Although not recommended,¹⁰ the use of a transperitoneal jejunum nutrient canal was reported in two studies. This invasive procedure should not be used because it may impede rapid recovery, and early oral feeding has been demonstrated to be safe and highly effective in reducing the length of hospital stays.³²

Based on the consensus guidelines,³³ the FTS protocol is subject to evolution of clinical implementation and component modification. The pattern of this evolution in the last decade suggests that the omission, replacement or modification of individual components to achieve better outcomes can be challenging. Although the FTS pathway significantly reduces the length of postoperative hospital stay and hospitalisation expenditure, compliance with its protocol in daily

clinical practice worldwide is not optimal.³⁴ Considering the multidisciplinary nature of FTS, cooperation among anaesthetists, nurses, physiotherapists, outpatient caregivers and general practitioners is mandatory to further improve implementation (and thereby also the outcomes and success) of FTS protocols.

Study limitations

This meta-analysis had some limitations. First, the sample of RCTs was small and the meta-analysis was limited by the presence of bias in all included studies. Second, the studies showed significant heterogeneity in the length of postoperative hospital stay, hospitalisation expenditure and postoperative morbidity. On the other hand, this heterogeneity probably represents an acceptable degree of diversity in medical and economic status in different global regions. For example, Feng *et al* noted that patients worried about their safety after discharge owing to the traditional belief that surgery could cause great damage.¹⁷ In addition, the cost of the same medical service differs among regions. Such factors are likely to be responsible for the heterogeneity observed. However, individual FTS groups showed improvements in length of postoperative hospital stay and hospitalisation expenditure, and no difference in postoperative complications from conventional care groups.

Conclusions

The results of this meta-analysis suggest that the FTS pathway with/without laparoscopy reduces the length of postoperative hospital stay and hospitalisation expenditure

without compromising patient safety. It therefore appears superior to conventional perioperative care. Nevertheless, further studies are needed to confirm these findings.

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