Optimizing strategies in gastrointestinal surgery

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Gastrointestinal motility recovers faster after laparoscopy and fast track care in patients undergoing co-locionic surgery
Abstract

Background
Postoperative ileus characterized by delayed gastrointestinal (GI) transit and is a major determinant of recovery after colorectal surgery. Both laparoscopic surgery and fast track multimodal perioperative care have been reported to improve clinical recovery, i.e. earlier occurrence of flatus and defecation and tolerance of food. However, objective measures supporting faster GI recovery are lacking. The aim of this study was to objectively assess, using a scintigraphic technique, which perioperative strategy, laparoscopic or open surgery combined with fast track or standard care, leads to a faster recovery of the gut after colonic surgery.

Methods
Patients requiring elective colonic surgery were enrolled in the Academic Medical Center as part of the LAFA (LAParoscopic in combination with FAst track multimodal management is the best perioperative strategy in patients undergoing colonic surgery) multicenter trial. Colonic transit and gastric emptying were scintigraphically assessed from day 1 to 3. Colonic transit at day 2 and 3 was represented as geometrical center (GC) of activity (segment 0=small intestine, 1=proximal colon, 2=distal colon, 3=toilet). Secondary endpoints were time to toleration of solid food and/or bowel movement, and time until (ready for) discharge.

Results
In total 93 patients participated. The median colonic transit at day 3 of patients undergoing laparoscopic/fast track care (GC: 2.6 (2.0-2.9)) was significantly faster, compared to laparoscopic/standard (GC: 2.2 (1.6-2.5), P=0.044), open/fast track (GC: 2.0 (1.6-2.4), P=0.010), and open/standard group (GC: 1.3 (1.0-1.5, P<0.001). Multivariate regression analysis showed that both laparoscopic surgery and fast track care were significant independent predictive factors of improved colonic transit, resulted in significantly shorter time until toleration of solid food and bowel movement and faster clinical recovery.

Conclusions
These data demonstrate that colonic transit recovers fastest after laparoscopic surgery embedded in the fast track program, providing objective data that this combination leads to faster recovery of GI motility and concomitant enhanced clinical recovery.
**Introduction**

Each patient undergoing an abdominal surgical procedure will develop a transient episode of impaired gastrointestinal (GI) motility or postoperative ileus (POI). Importantly, POI is the single most important determinant of hospital stay after abdominal surgery and consequently significantly contributes to postoperative morbidity and hospitalization costs.\(^1\,^2\) Laparoscopic surgery and the implementation of an enhanced recovery after surgery (ERAS) program, also referred to as ‘fast-track’ (FT) perioperative care are the two most important recent advances in modern surgical care. Both have been reported to be safe and effective and to result in a shorter hospital stay with earlier recovery of GI function\(^3\,^6\) and less morbidity compared to open colorectal surgery and standard care.\(^7\,^10\)

FT programs in colonic surgery were introduced to reduce surgical stress response, organ dysfunction and morbidity, thereby promoting a faster recovery after surgery.\(^11\,^12\) This multimodal perioperative care strategy constitutes a multidisciplinary approach involving dieticians, nurses, surgeons and anaesthesiologists. It mostly focuses on fluid restriction, optimized analgesia, early oral nutrition and early mobilization.\(^6\,^13\,^14\) Similarly, faster postoperative clinical recovery has been reported following laparoscopic procedures most likely due to decreased tissue trauma compared to open procedures.\(^15\) It should be emphasized though that most studies assessing POI have used rough clinical parameters such as return of bowel sounds and time to first flatus or defecation as primary outcomes. These parameters are not only difficult to assess accurately, but it is also questionable to what extent they reflect restoration of GI motility. For example, the occurrence of first flatus may rather reflect emptying of rectal gas rather than recovery of colonic transit. To date, only two clinical studies comparing laparoscopic and open colectomies objectively measured postoperative GI motility and at best showed only a modest increase in the recovery of GI motility.\(^16\,^17\) With regard to the comparison between the current standard approach and the FT care concept, there are no clinical controlled trials providing objective measures on postoperative bowel recovery. Therefore, the question whether laparoscopic surgery and/or FT care lead to a faster recovery of GI motility measured by postoperative GI transit remains unanswered.\(^10\,^18\) Hence, our aim was to objectively assess using a scintigraphic technique which perioperative strategy, laparoscopic or open surgery combined with FT or standard care, leads to a faster recovery of the gut after colonic surgery.
Methods

Patients enrolled in the Academic Medical Center Amsterdam as part of the LAFA (LAParoscopy in combination with FAST track multimodal management is the best perioperative strategy in patients undergoing colonic surgery) multicenter trial were eligible for this study. Patients between 40 and 80 years of age, with an American Society of Anesthesiologists Physical Health status (ASA-PS) status < IV, were invited to participate if they were to undergo elective segmental colectomy for histologically confirmed adenocarcinoma or adenoma without evidence of metastatic disease. Exclusion criteria were prior midline laparotomy, unavailability of a laparoscopic surgeon, emergency surgery, or a planned stoma.

The study was registered under NTR1884 and was conducted in accordance with the principles of the Declaration of Helsinki and according to the CONSORT statement. The protocol was approved by the independent medical ethics review board of the Academic Medical Center Amsterdam, the Netherlands.

Study design

A 2 x 2 balanced factorial block design was used to randomize patients to laparoscopic or open colectomy, and to the FT program or standard care. This resulted in four treatment groups: (I) laparoscopic colectomy with FT care (Lap/FT), (II) laparoscopic colectomy with standard care (Lap/Standard), (III) open colectomy with FT care (Open/FT), and (IV) open colectomy with standard care (Open/Standard). All procedures were performed by one of three staff surgeons with a fellow and/or a resident. Patients and nursing staff were routinely informed about the perioperative care program, i.e. FT care or standard care, but were blinded to the type of surgical intervention, i.e. laparoscopic or open surgery by covering the abdomen with a large dressing.

In order to avoid cross-over treatment of FT and standard care by the nursing staff, patients were admitted either to a ward providing FT care or a ward providing standard care, depending on randomization. Nursing and medical staff working on the FT care ward were already familiar with FT care prior to this study. The principles of the standard care and FT multimodal management are described in detail elsewhere.

Twenty-four hours after surgery, patients underwent a solid gastric emptying test (99mTc labelled pancake, 115 Kcal) directly followed by the ingestion of 60 ml of indium-111 labelled water to assess colonic transit on postoperative day 2 and 3 (see section Gastrointestinal transit studies for details). During hospital admission, patients were visited at least once daily by a trial nurse and/or a research physician for clinical evaluation (i.e., diet, first bowel movement, nausea and vomiting). Clinical symptoms of upper and lower GI motility were evaluated via self-designed questionnaires. Patients were assisted to fill in this self-assessment sheet daily at the time of the scintigraphical scan until discharge. Until discharge, nursing staff reported daily on the patient’s progress, i.e. intake, passage of stool, and predefined discharge criteria were checked.

Outcomes

The primary outcome of efficacy was postoperative GI transit on postoperative day 1 to 3. GI
transit endpoints were: (I) colonic transit on day 3, depicted as geometrical center of intracolonic mass 48 hours postprandially of 111In-DTPA labeled water; (II) gastric retention at 24 hours after surgery, formulated as the percentage of 99mTc labelled pancake present in the stomach two hours after ingestion.

The secondary endpoints of this study were: (I) time until first bowel movement in hours after surgery; (II) time until first tolerance of solid food in hours after surgery; (III) the composite outcome of time to tolerate solid food and bowel movement; (IV) postoperative hospital stay, i.e. days until discharge; (V) time until ready for hospital discharge in hours after surgery. Patients were daily questioned about the occurrence and severity of nausea, vomiting, and abdominal bloating. All patients were discharged if they complied with the following predefined discharge criteria: (1) adequate pain control with paracetamol and/or non-steroidal anti-inflammatory drugs (2) ability to tolerate solid food (3) absence of nausea (4) passage of first flatus and/or first stool (5) mobilization as preoperative, and (6) acceptance of discharge by the patient. Time until ready for discharge was defined as the time when patients were able to tolerate solid food without reversal to enteral fluids, were without complications, and pain was adequately controlled with oral analgetics.

Gastrointestinal transit studies

On postoperative day 1, patients underwent a solid gastric emptying test. Two hours after ingestion of a 99mTc labelled pancake (115 Kcal), a 5-min acquisition was performed in a 128 matrix with the patient in a supine position using a single head gamma camera (Siemens Orbi-tet, or Diacam, Siemens, Hoff man Estates, IL) fitted with a medium energy collimator. The relative gastric content of the pancake 2 hours after ingestion was calculated as previously described.20 Briefly, to depict the percentage of activity present in the stomach compared with the total activity in the abdominal region of interest, the counts in the stomach were divided by the counts in the complete abdominal region, corrected for background.

Directly after completion of the gastric emptying test patients were asked to drink 60 ml of tap water labeled with 4 MBq 111In-DTPA (DiethyleneTriaminePentaAcetate, Covidien, Petten, The Netherlands). A cobalt marker was placed on the iliac crest for anatomical reference and a baseline scan was performed to determine total amount of indium activity present in the abdomen 5 minutes after ingestion. To determine colonic transit, two 5-min acquisitions were performed 24 and 48 h after ingestion of the radiolabelled water using the same single head gamma camera.

To enable calculation of colonic transit, the gut was subdivided into three segments (i.e., 0 = small intestine; 1 = proximal colon; 2 = distal colon; 3 = stool). The center of mass model21 was applied expressing colonic transit at 24 and 48 hours postprandial as geometrical center (GC) of activity. The primary variable of interest in overall colonic transit was the GC at 48 hours. The GC is the weighted average of counts in the different colonic regions: proximal colon, distal colon and stool. Quantification of the counts in each region was performed using a Hermes Gold software program (Hermes Medical Solutions, Stockholm, Sweden). At any time, the portion of colonic counts in each colonic region (corrected for background activ-
ity and isotope decay) was multiplied by the corresponding weighting factors as follows: GC = \(\%\) proximal colon \(x\) 1 + \(\%\) distal colon \(x\) 2 + \(\%\) stool \(x\) 3)/100. Thus, a high GC implies faster colonic transit. A GC of 0 implies that none of the isotope has reached the colon, and a GC of 3 implies that all isotope is in the stool. The amount of 111In-DTPA tracer defecated before day 4 was computed by subtraction of decay corrected abdominal counts on day 3 from total abdominal counts on day 1. Interpretation and calculation of gastric retention and colonic transit was performed blinded by two researchers independent from each other (research physician S.v.B. & staff physician of the Nuclear Medicine Department R.J.B.) on a Hermes workstation.

Sample size calculation and statistical analysis
Since resumption of colonic motility occurs on postoperative days 3 through 5 and typically is the rate-limiting factor for the resolution of ileus (reviewed in\(^{22}\)), the colonic transit on day 3 was used as the primary efficacy parameter. Sample size calculation was based on earlier studies on GI transit after abdominal surgery\(^{16,20}\) and indicated that 18 patients per group were required to identify a >15% significant (P<0.05) difference in colonic transit on day 3 between the different treatment modalities, providing 80% power.

Per protocol analysis was applied on all data as this study was designed and powered to detect a difference in postoperative GI transit between patients who actually received the treatment of interest and had no major surgical complications of the intestinal tract.

Data were presented as means ± standard deviations or as medians and interquartile ranges according to data type. For dichotomous outcomes, treatment groups were compared by means of the Chi-square test or Fisher’s Exact test. The Kruskal-Wallis test and Mann-Whitney U tests were used for continuous, not normally distributed outcomes. For continuous normally distributed data, the ANOVA test was used. Multiple linear regression was used to analyze the effect of laparoscopy, FT care and the combination of both on the primary and secondary endpoints. As the measurements of gastric emptying and clinical parameters (except time until defecation) were skewed, linear regression analysis of these endpoints was carried out after logarithmic transformation of the dependent variable. Statistical analysis was performed using SPSS for Windows version 17 (SPSS Inc. Chicago, III., USA). A two-sided P-value < 0.05 was considered to be statistically significant.

Results

Patients
Between October 2005 and August 2009 a total of 93 patients were randomly assigned to one of the four treatment groups. Fifteen patients (n=1 Lap/FT; n=3 Lap/Standard; n=6 Open/FT; n=5 Open/Standard) were withdrawn for various reasons: two had resection of the small intestine, one a delirium, one abdominal dehiscence, four had metastasis at time of admission, five had a protocol violation and two withdrew informed consent. GI transit was assessed in 78 patients. Seven of these developed a paralytic POI requiring surgical intervention within the first five days: three Lap/FT patients (two internal herniation & one adhesion); one Lap/
Standard patient (anastomotic leakage); one Open/FT patient (anastomotic leakage); two Open/Standard patients (intraperitoneal bleeding & adhesion). Therefore, data from 71 patients without major surgical complications were available for per protocol analysis.

In one patient laparoscopy had to be converted to open colectomy because of the extent of tumour invasion. Baseline characteristics and surgical aspects did not differ significantly between the four treatment groups, except duration of surgery (P<0.001, Table 1).

**Table 1** Baseline characteristics and surgical aspects of the included patients per group

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<th>Laparoscopy &amp; Standard care (n = 17)</th>
<th>Open &amp; Fast Track (n = 18)</th>
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*Values are mean ± standard deviation / BMI = Body Mass Index / ASA = American Society of Anesthesiologists / IQR = inter-quartile range / *ANOVA test / *Chi-square test / *Kruskal-Wallis test

**Gastrointestinal transit**

**Colonic transit**

The median calculated GC of activity at day 2 are shown in Figure 1a. Colonic transit at day 2 was significantly faster in the Lap/FT patients (2.2 (1.8-2.6)) compared to the Lap/Standard (1.3 (1.2-2.0), P=0.005), Open/FT (1.5 (1.2-1.9), P=0.002), and Open/Standard patients (1.1 (1.0-1.4), P<0.001). These data indicate that most of the radiolabelled material was still located in the proximal part of the colon at day 2 in the latter three groups, while in the Lap/FT group it had already moved to the distal part of the colon.
On postoperative day 3, most of the Indium was still present in the proximal colon in the Open/Standard group, but had moved into the distal colon in the other three groups. The median GC for patients in the Lap/FT (2.6 (2.0-2.9)) was significantly higher, compared to the Lap/Standard (2.2 (1.6-2.5), P=0.044), Open/FT (2.0 (1.6-2.4), P=0.010), and those in the Open/Standard group (1.3 (1.0-1.5), P<0.001).

**Figure 1** Postoperative gastrointestinal transit
Scintigraphical evaluation of gastrointestinal transit of an In-111 labelled non-caloric liquid test-meal and gastric emptying of a 99mTc labelled pancake 24 hrs after surgery. Lines represent inter-quartile-ranges in corresponding treatment groups. Mann-Whitney U test. *P <0.05, **P<0.001

Colonic transit on day 3 was significantly influenced by both laparoscopy (B=0.64; CI: 0.36-0.92, P<0.001; i.e. laparoscopic surgery would lead to an increase in the GC of 0.64) and FT care (B=0.53; CI: 0.24-0.81, P<0.001; i.e. leading to an increase in the GC of 0.53 compared to patients receiving standard care). The combination of both did not add any benefit.

Colonic transit is considered to mainly determine clinical recovery. The latter (i.e. time until ready for discharge) correlated significantly with colonic GC on day 3 (r = -0.56, P<0.001; Spearman’s rank correlation). As depicted in Figure 1b, the median percentage of 111In-DTPA tracer defecated 48 hours after intake was 70% (36-49) in the Lap/FT treated group com-
pared to 37% (0-58), 26% (0-57) and 0% (0-0) in the Lap/Standard, Open/FT and Open/Standard treated groups respectively, showing a significant difference of the Lap/FT treated patients with the Open/FT group (P=0.043) and the Open/Standard group (P=0.001).

**Figure 1b** Amount of $^{111}$In-DTPA tracer defecated before day 4, depicted as median percentage of In-$^{111}$ defecated on day 3

**Figure 1c** Gastric retention determined 2 hr postprandial, depicted as median percentage in stomach compared to total abdominal region corrected for background


**Gastric retention day 1**

The residual gastric content two hours after ingestion of the pancake varied from almost complete emptying to gastric stasis with more than 99% of the radiolabelled pancake still present in the stomach. The median gastric retention did not differ between groups (P=0.61) (Figure 1c). Gastric retention was 70% (IQR: 36-94), 81% (34-95), 58% (26-71), 58% (31-100) in patients treated with Lap/FT, Lap/Standard, Open/FT and Open/Standard respectively.

**Clinical evaluation**

**Symptoms of upper and lower GI motility and time until (ready for) discharge**

Visual-analogue scores for nausea and bloating were comparable in the four groups at day 1 (P=0.735 and P=0.359, respectively). Median time until first defecation and tolerance of solid food, length of hospital stay, and ready for discharge were significantly shorter for patients who underwent Lap/FT treatment compared to the other groups (Figure 2). In a second analysis patients with a major surgical complication (n=7) were included and similar differences between groups were found. Linear regression analysis showed that laparoscopic resection and FT care both independently resulted in a significantly shorter time until first defecation, tolerance of solid food, first defecation & tolerance of solid food, length of stay and time until ready for discharge.

There was no significant difference between the groups in readmission rate (P=0.850) and overall morbidity (P=0.217) until 30 days after surgery.

Overall compliance of surgical, anesthesiological and nursing care personnel with the multimodal perioperative rehabilitation pathway was very good. Intra-operative fluid loading was similar (P=0.092) and restricted in all four treatment groups with a median of 2.0 (IQR: 1.3-3.0) liter.

**Figure 2** Clinical (secondary) endpoints

Lines represent inter-quartile-ranges in corresponding treatment groups. Per protocol analysis. Mann-Whitney U test. *P<0.05, **P<0.001

**Figure 2a** Hrs until first defecation
Figure 2b Hrs until first tolerance solid food

Figure 2c Hrs until first defecation & tolerance solid food

Figure 2d Days until discharge
The results of this study provide objective data indicating that laparoscopic surgery and FT care improve recovery of GI transit associated with faster clinical recovery compared to open colectomy and standard care. In a multivariate analysis, the present study shows that both are significant predictors of improved colonic transit, and reduced time to tolerance of solid food and bowel movement. These data suggest that laparoscopic resection embedded in a FT program leads to the most optimal recovery of GI transit.

In our study clinical hallmarks were not the primary outcome measures for POI as these are non-specific. Parameters such as nausea, vomiting and tolerance of solid food strongly depend on patient reporting, whereas first passage of stool or flatus may simply reflect rectal emptying and therefore not necessarily inform on recovery of effective GI contractile activity. For this reason nuclear scintigraphy was used to assess postoperative GI motility in a detailed and objective manner.

In the present study gastric retention on day 1 did not differ significantly between groups. A possible explanation for the discrepancy between gastric emptying and the time until ready for discharge could be a difference in the dosage of opioids or anti-emetics between the groups before day 1. However, there was no difference in analgesia or dosage of anti-emetics in this period. Therefore, it is more likely that the time frame in which the beneficial effect of laparoscopy and FT care on GI motility can be detected starts after day 1. This indicates that gastric emptying, in contrast to colonic transit, is not a good parameter to predict clinical recovery.

The study of Basse et al, is the only study that evaluated recovery of GI transit after open and laparoscopic colectomy. They used scintigraphy in patients who underwent elective
laparoscopic or open colonic resection within a FT program, but did not address the question what the individual contribution of laparoscopic surgery and/or FT was on GI transit. Their results demonstrated no significant difference in the amount of $^{111}$In-tracer defecated, but showed a significantly higher colonic transit 48 hours after surgery in the laparoscopic group. Based on these results Basse et al. concluded that there was no significant difference between an open and laparoscopic approach. However it is likely that the sample size was too small to find a difference in amount of $^{111}$In-tracer defecated within the first 48 hours after surgery. As the amount of $^{111}$In-tracer defecated is not only dependent on colonic transit, but also whether or not rectal emptying of rectal $^{111}$In-tracer has occurred and therefore may be less precise in reflecting recovery of GI transit. Secondly, determining the amount of $^{111}$In-tracer defecated within only the first 48 hours postoperatively might be too short since colonic motility is impaired between 48-72 hours after surgery. We found a significantly higher colonic transit and amount of $^{111}$In-tracer defecated before day 4 after laparoscopic surgery compared to open colonic resection with FT rehabilitation. In addition, our finding that there was a clear difference in the amount of $^{111}$In-tracer defecated between patients in the FT care and standard care groups confirms the beneficial effect of FT care on GI transit. These scintigraphical data were consistent with the results on the clinical outcome measures and of previous randomized clinical trials, confirming in an objective manner that laparoscopic surgery and FT care fasten postoperative bowel motility.

The pathophysiological mechanisms involved in POI are still not completely understood, but recent studies have shown the importance of inflammation of the intestinal muscularis resulting from surgical handling. The faster clinical recovery observed after laparoscopic surgery compared with open surgery could be explained by decreased tissue trauma with concomitant decreased mast cell activation leading to attenuated intestinal inflammation and thus a quicker GI recovery. The beneficial effect of the FT program may not only be explained by the set of FT elements actually applied but also by the discriminating aspect of the FT program that the perioperative care is protocolized. For example, the protocol precluded the discussion of if and when the patient could mobilize after surgery, or the time of removal of the epidural. Thus, the fact that the rehabilitation process is always implemented in the same way can be an important explanation for the success of the FT program. Further study is required to distinguish which of the FT elements have the greatest impact upon POI.

Limitations of this study were the omission of baseline GI transit measurements. This design would have allowed comparison before and after surgery in each individual patient, possibly reducing the variability and increasing the power of the study. However such a design was not possible as this would place too high a burden on patients and logistics. Second, with regard to the (secondary) clinical endpoints total blinding for the type of surgery was difficult to achieve by an opaque abdominal dressing as the majority of the patients could not resist looking under the abdominal dressing. Wound inspection was not a limiting factor as this was not carried out until the day of discharge, but obviously only in those patients without wound complaints or complications.
In conclusion, these data demonstrate that colonic transit recovers fastest after laparoscopic surgery embedded in the fast track program, providing objective data that this combination leads to faster recovery of GI motility and concomitant enhanced clinical recovery.

**Acknowledgment**

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