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Original Article

Fast-track in open intestinal surgery: Prospective randomized study (Clinical Trials Gov Identifier no. NCT00123456)

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SUMMARY

Background: Studies have shown the value of using fast-track postoperative recovery. Standard procedures (non-fast-track strategies) remain in common use for perioperative care. Few prospective reports exist on the outcome of fast-tracking in Central Europe. The aim of our study was to assess the effect and safety of our own fast-track protocol with regard to the postoperative period after open bowel resection.

Patients and methods: One hundred and five patients with ASA score I–II scheduled for open intestinal resection in the period April 2005–December 2007 were randomly selected for the fast-track group (FT) and non-fast-track group (non-FT). A designed protocol was used in the FT group with the emphasis on an interdisciplinary approach. The control group (non-FT) was treated by standard established procedures. Postoperative pain, rehabilitation, gastrointestinal functions, postoperative complications, and post-op length of stay were recorded.

Results: Of 105 patients, 103 were statistically analyzed. Patients in the FT group ($n = 51$) and non-FT group ($n = 52$) did not differ in age, surgical diagnosis, or procedure. The fast-track procedure led to significantly better control of postoperative pain and faster restoration of GI functions (bowel movement after 1.3 days vs. 3.1, $p < 0.001$). Food tolerance was significantly better in the FT group and rehabilitation was also faster. Hospital stay was shorter in the FT group – median seven days (95% CI 7.0–7.7) versus ten days (95% CI 9.5–11.3) in non-FT ($p < 0.001$). Postoperative complications within 30 postoperative days were also significantly lower in the FT group (21.6 vs. 48.1%, $p = 0.003$). There were no deaths and no patients were readmitted within 30 days.

Conclusions: Following the FT protocol helped to reduce frequency of postoperative complications and reduced hospital stay. We conclude that the FT strategy is safe and effective in improving postoperative outcomes.

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1. Introduction

Advances in perioperative care have often been described in the literature over the past 10 years, with emphasis on the positive effect of enhanced perioperative care on results of surgical treatment.[1–8] A combination of perioperative interventions, the aim of which is to reduce postoperative stress, frequency of postoperative complications, and length of hospital stay, is usually called accelerated postoperative rehabilitation or fast-track. It is basically a multidisciplinary perioperative care strategy in which anesthesiologists, surgeons, dieticians, and physiotherapists participate.[9,10] Education of the patient during postoperative care is also crucial as

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Abbreviations

ASA	American Society of Anesthesiologists Physical Status
FT	Fast-track
PCA	Patient-controlled analgesia
VAS	Visual analog scale
NGT	Nasogastric tube
D0	Day of surgery
D1–5	Postoperative day 1–5
GI	Gastrointestinal
IBD	Inflammatory bowel diseases
CD	Crohn's disease
UC	Ulcerative colitis
FAP	Familial adenomatous polyposis
EBM	Evidence-based medicine

well as their active participation in the process of postoperative recovery. Fast-track postoperative care is derived from evidence-based medicine as an alternative to the dogma of empirical non-evidence-based procedures. A large number of surgical departments, however, continue to apply standard procedures.[11]

The aim of our prospective randomized study was to prove that our fast-track protocol was safe, improved the patient's analgesic care, enabled faster restoration of gastrointestinal (GI) functions, improved postoperative results, and shortened length of hospitalization in comparison with the standard care. The study aim was also to see whether significant reduction of length of hospital stay could be achieved in Central Europe, where there is a tradition of much longer length of hospital stay.

2. Patients and method

This prospective, monocentric, unblinded, randomized study included all patients scheduled for open intestinal resection, with or without stomy, during the period April 2005–December 2007. All eligible patients were enrolled in the study if they were in the age group 18–70 years and were scored ASA I–II. It was presumed that selection of patients with low polymorbidity would lead to better cooperation and easier interdisciplinary coordination during introduction of the new method and therefore patients scored ASA III–IV were excluded. Procedures were performed by specialists in open colon and rectal surgery. Patients who had had pelvic radiation and those having multi-organ resections were excluded as well as those with cancer and pregnant women. Patients fulfilling inclusion criteria and consenting to participate in the study were randomized into the fast-track group (53 patients) and into the control group – non-fast-track group (52 patients) – by an independent physician and nurse at the time of admission for surgery. Simple unrestricted randomization using the standard envelope method was performed. Numbered envelopes containing a sequence of included patients determined their random distribution into the FT and non-FT groups. The sequence was prepared in advance by a statistician. According to the envelope content the patient was assigned to one of the monitored groups on the day of admission, i.e. the day prior to surgery.

Two patients from the FT group were excluded owing to protocol failure and they were not analyzed (in one case, the anesthesiologist did not follow the protocol during anesthesia; in the other, a PCA pump and scheduled medication were not available). Three patients in whom early repeated surgery was necessary were included in the analysis in terms of the intention-to-treat principle. A total of 51 patients were analyzed in the FT group and 52 patients in the control non-FT group (Fig. 1).

Patients in the FT group were informed prior to surgery about perioperative anesthesia and analgesic care by an anesthesiologist who was involved with the fast-track protocol. PCA (patient-controlled analgesia) pump training was conducted and the system of pain assessment was explained by means of the visual analog scale (VAS-0–10, 0 = no pain, 10 = maximum pain). These patients were similarly instructed in this perioperative period by the physiotherapist, dietician, and surgeon. Thoracic epidural catheter (Th10–12) was inserted prior to surgery in this group. Patients underwent bowel preparation by mechanical orthograde lavage only if rectal surgery was planned. The FT group patients had a normal oral intake during the day before surgery until 2 p.m. and a light dinner on the eve of surgery. Then they were advised to increase fluid and carbohydrate cocktail intake (400–800 ml of 12.5% carbohydrate solution, Nutricia preOp, Nutricia Ltd). Fluid intake was stopped two to four hours prior to surgery. Anesthesia consisted of O_2/air and desflurane by use of the low flow method with exclusion of N_2O with standard introduction without special premedication (propophol 2–3 mg/kg, cisatracurium 0.15 mg/kg, suphentanyl 0.5–1 μg/kg). Twenty minutes prior to the end of surgery 10 μg suphentanyl (loading dose) was dispensed into the epidural catheter and continued by PCA pump (ropivacaine 0.2% 48 ml + suphentanyl 10 μg, at rate 5 ml/h) with the possibility of bolus dose on days 0–3. PCA epidural analgesia was combined with intravenous paracetamol and diclofenac or metamizol in the postoperative period. Pain monitoring with VAS was recorded hourly for the first 24 h and then every four hours. When the epidural analgesia failed, continuous subcutaneous analgesia was used. Immediately after postoperative stabilization patients were encouraged to exercise in bed as well as out of it. Apart from fluids a semi-solid and solid diet was offered to patients from the day of surgery (Day 0) according to their tolerance. A nasogastric tube (NGT) was inserted into patients during surgery only at the surgeon's or anesthesiologist's request. Intra-abdominal drains were selectively inserted into patients with extensive intra-abdominal procedure and in case of diffuse bleeding; drains were removed on the first postoperative day. An urinary catheter was inserted during surgery only in the case of minor pelvis surgery, fistulization into the urinary bladder or at the request of the surgeon or anesthesiologist when the operation lasted more than three hours. Patients were discharged from hospital if they fulfilled all the discharge criteria: their oral intake was higher than 2000 ml/day; when GI functions restored; pain was controlled by oral analgesics; and patients had no signs of infection or other complications and were content to be discharged.

Patients randomized into the non-FT group were educated in the standard manner. They had orthograde mechanical bowel preparation and an enteral feeding tube was inserted if they agreed to this process. They fasted from the midnight before surgery. The type of anesthesia and analgesic care were determined by the anesthesiologist. Introduction of the epidural catheter was also left to the anesthesiologist's discretion. Postoperative analgesia comprised continuous epidural analgesia by local anesthetics combined with morphine or subcutaneous morphine. Both methods were supplemented by bolus administration of metamizol or diclofenac. Insertion of an NGT, intra-abdominal drains and urinary catheter was routine. Postoperative oral intake and rehabilitation (exercising) proceeded in the standard manner on the day of surgery. Discharge from the hospital depended on the patient's condition and on the agreement of the surgeon, without special criteria. Patients in the study were monitored by a special nurse and by two independent physicians. This included demographic data, weight, BMI prior to surgery, nutritional markers, length and

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