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Enhanced Recovery after Elective Colorectal Surgery – Reasons for Non-Compliance with the Protocol

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Key Words
Enhanced recovery · Colorectal surgery · Compliance

Abstract
Background/Aims: Enhanced recovery after surgery (ERAS) protocols for elective colorectal surgery reduce the intensity of postoperative complications, hospital stays and costs. Improvements in clinical outcome are directly proportional to the adherence to the recommended pathway (compliance). The aim of the present study was to analyze reasons for the non-compliance of colorectal surgeries with the ERAS protocol. ***Methods:*** A consecutive cohort of patients undergoing elective colorectal surgery was prospectively analyzed with regards to the surgery's compliance with the ERAS protocol. The reason for every single protocol deviation was documented and the decision was categorized based on whether it was medically justified or not. ***Results:*** During the 8-month study period, 76 patients were included. The overall compliance with 22 ERAS items was 76% (96% in the preoperative, 82% in the perioperative, and 63% in the postoperative period). The decision to deviate from the clinical pathway was mainly a medical decision, while patients and nurses were responsible in 26 and 14% of the cases, respectively. However, reasons for non-compliance were medically justified in 78% of the study participants. ***Conclusion:*** 'Non-compliance' with the ERAS protocol was observed mostly in the postoperative period. Most deviations from the pathway were decided by doctors and in a majority of cases it appeared that they were due to a medical necessity rather than non-compliance. However, almost a quarter of deviations that were absolutely required are still amenable to improvement.

Introduction

Enhanced recovery after surgery (ERAS) is a multimodal evidence-based approach that optimizes the perioperative management of patients [1–3]. Those pathways are considered standard of care in colorectal surgery, as they have been shown to successfully improve postoperative recovery and reduce complications, length of stay in hospital [4, 5] as well as overall costs [6]. Clinical outcomes are closely associated with compliance to the ERAS pathway [7], as increasing ERAS compliance was correlated with fewer complications and shorter primary hospital stay [8]. Sustainability of ERAS pathways is dependent on the continuous monitoring of compliance with the proto-

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col [9]. This study detects and corrects deviations from evidence-based protocols, which might be deleterious to the patients. It is thus important not only to report application of the protocol (yes/no) but also to identify problem areas and analyze the underlying reasons.

Therefore, the aim of our present study was to analyze within an established ERAS protocol as to (i) who decided on deviations from the standardized pathway and (ii) whether those decisions were medically justified or not.

Methods

Since the implementation of a standardized ERAS protocol for all elective colorectal surgery procedures at Lausanne University Hospital in 2011 [6], demographic and surgical information along with information on perioperative care items and clinical outcome were systematically entered into a prospective database (EIAS®). A dedicated ERAS nurse was in charge of data management. While compliance for every individual care item was meticulously recorded, reasons responsible for deviations were not routinely documented.

The present study prospectively analyzed non-compliances of consecutive patients undergoing elective colorectal surgical procedures within an established colorectal ERAS pathway at our institution during an 8-month period from August 24, 2012 until March 25, 2013. Elective colorectal surgery comprised of any colorectal resection as well as stoma procedures performed during a planned hospital admission.

The Institutional Review Board approved the study and all patients provided written consent before surgery. The study was conducted in accordance with the STROBE criteria (http://strobe-statement.org/) and registered under www.researchregistry.com (UIN: 771).

ERAS Pathway

The ERAS Society guidelines recommendations for colorectal surgery constitute the ground of our institutional ERAS protocol (table 1) and the updated versions were published recently for colorectal surgery [2, 3].

Outcome Measures

Compliance or non-compliance with the standardized ERAS protocol was individually assessed for each surgical procedure for each patient. Overall compliance as well as compliance in the preoperative, perioperative and postoperative periods was also reported. In case of non-compliance, the decision to deviate from the clinical pathway was made by one of the following people: surgeon, anesthetist, nurse or patient. This assessment was based on the reported decisions transcribed in the patient's medical and nurse boards. The respective protocol deviations were discussed with those concerned and classified on the basis of whether they were medically justified or not. Any controversy was resolved by the institutional ERAS core group (V.A., M.H., and C.B.).

Statistical Analysis

The compliance was obtained as the number of items successfully applied divided by the 22 items. The compliance for each item was calculated as the number of compliant patients divided by the total number of patients. Descriptive statistics for categorical variables were reported as number and percentage, while continuous variables were reported as median and interquartile range or means and SD as appropriate. Data analysis was performed using GraphPad Prism 5.0 (GraphPad Software, La Jolla, USA).

Results

Patients

Within an 8-month period, 76 consecutive patients undergoing elective colorectal surgery were included in the present prospective audit. Demographic and surgical details of this consecutive cohort are displayed in table 2.

Compliance to the ERAS Protocol

The overall compliance of elective patients to the ERAS protocol was 76%. Preoperative measures were applied with a compliance of 96%, while intraoperative and postoperative measures were followed with 82 and 63%, respectively. Compliance with individual care items is shown in figure 1. The overall quantum of missing information was 1%.

Who Was Responsible for Non-Compliance?

The doctors (surgeons 21% and anesthetists 34%) were chiefly responsible for non-compliance. In 26% of deviations, patients refused to follow recommendations, while in 14%, nurses accounted for the deviations. In 6% of deviations combined decision-making was observed, while in 5%, those who were mainly responsible for non-compliance could not be clearly identified. Those responsible for non-compliance are displayed for each individual item in figure 2.

True Non-Compliance or Medical Necessity?

Overall, deviations from the ERAS protocol were evaluated as medically justified in 78% of cases. For the remaining 22%, no good clinical reason could be identified upon careful assessment of the charts and discussion with the caretakers; those deviations were therefore considered true non-compliance. Typical examples for well-founded modifications of the intraoperative care pathway included the use of epidural analgesia, the no-routine use of abdominal drains and the use of postoperative nausea and vomiting (PONV) prophylaxis. Problematic items were the avoidance of long-term sedative, the use of postoperative analgesia and the timing to stop the epidural analgesia (fig. 3).

Table 1. Items of the institutional ERAS protocol for elective colorectal surgery

Education	Patient's preadmission counseling + written information
Bowel preparation	Avoidance of bowel preparation
Carbohydrate drinks	800 ml on evening, and 400 ml 2 h before surgery
Sedative	No preoperative long-acting sedative premedication
Thrombo-prophylaxis	LMW heparin 12 h before surgery, IPC
Antibiotic prophylaxis	Cefuroxime 1.5 g + metronidazole 500 mg 30 min before incision
Epidural analgesia	Thoracic epidural analgesia for laparotomy. Epidural or PCA for laparoscopy
PONV prophylaxis	Droperidol 1 mg at induction, ondansetron 4 mg ± bethametasone 4 mg at the end of operation for Apfel score >2
Warming	Hypothermia prevention with active warming (air blanket)
Nasogastric tubes	No routine postoperative nasogastric tube
Abdominal drains	No routine abdominal drain
Systematic laxatives	Oral magnesium hydroxyde
Postoperative analgesia	Epidural or PCA. Paracetamol, ibuprofen, and oxycodone-naloxone only for breakthrough pain
Nutrition	Normal diet at will from the day of surgery
Postoperative fluids	Cristalloids 500 ml during the first 24 h than stop
Oral fluids	Free fluid 4 h after surgery
Mobilization at all on day of surgery	Rising from bed 4 times more than 30 min (to walk, or to sit in chair counts as mobilising, but not sitting on the edge of bed)
Bladder catheter	Removal on POD 1
Energy POD 1	2 oral nutritional supplements (300 kcal/unit) per day
Mobilization at 1st POD	At least 6 h per day
Stop epidural analgesia	Removal of thoracic epidural analgesia or PCA at POD 2
30 days follow up	Postoperative control after 30 days

LMW = Low molecular weight; IPC = intermittent pneumatic compression; PCA = patient-controlled analgesia; POD = postoperative day.

Table 2. Demographics and surgical characteristics of patients undergoing elective colorectal surgery

Characteristics	n = 76
Age, years*	59 (18)
Sex ratio, M:F	41:35
ASA grade, n	
I–II	62
III–IV	14
Diagnosis, n	
Neoplasia	53
Diverticular disease	18
Inflammatory disease	5
Surgical approach, n	
Laparoscopic	34
Open	38
Converted	4

* Values calculated as mean (SD).
ASA = American Society of Anesthesiologists.

Discussion

The present analysis shows that the evaluation of compliance with the ERAS protocol is of importance and emphasizes 2 aspects: the majority of deviations from an ideal protocol are observed during the postoperative course and deviations are mostly based on well-founded medical decisions. In contrast, 22% of true non-compliances were not justified and clearly showed that despite an established ERAS protocol there is further room for improvement in perioperative care.

The monitoring of compliance with regard to the ERAS protocol is essential in order to improve clinical outcome [8]. Comparing our present study with other studies could be difficult because of the difference in the items as well as due to the difference in the number of items, which ranged from 4 to 14 in a systematic review

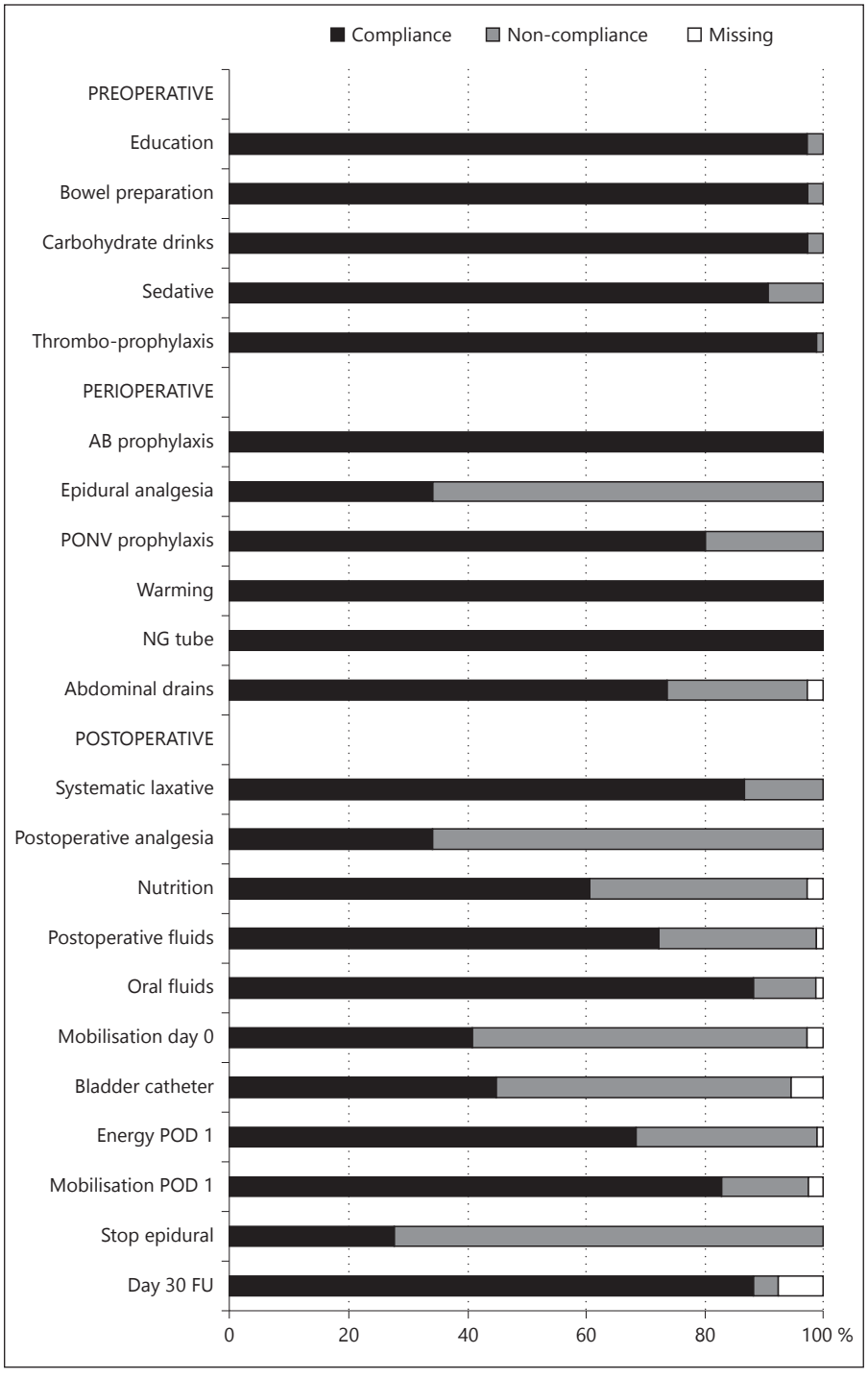

Fig. 1. ERAS protocol compliance. AB = Antibiotic; NG = nasogastric; POD = postoperative day; FU = follow up.

out of 22 validated ERAS items [10]. The reported compliance rates compare favorably with those of the previous published studies, especially for the pre- and perioperative period [8, 11]. In spite of the potential confounding effect of postoperative recovery and the occurrence of complications on compliance to postoperative items [8], postoperative items were also reported and analyzed.

Some problematic items in the perioperative and postoperative phases were observed and deserve further discussion. The item 'epidural analgesia' with a compliance

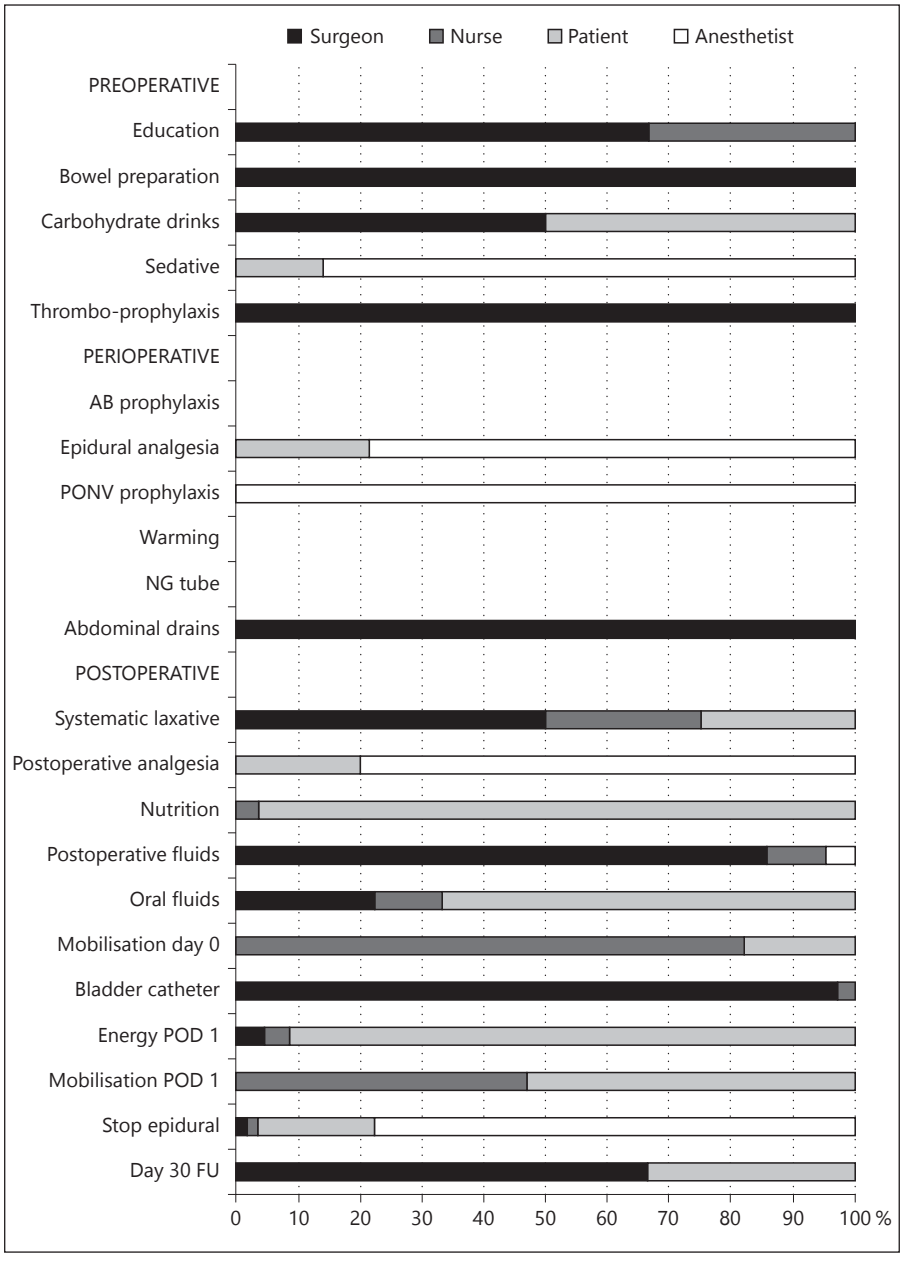

Fig. 2. Responsible of non-compliance. For abbreviations refer fig. 1 legend.

of about 34% was artificially low in our study compared to other studies because of an ongoing controlled randomized trial comparing epidural versus patient-controlled analgesia for laparoscopic colorectal surgery [12]. In line with ERAS recommendations and previous data [13], we follow a no-routine-drain policy in our department. However, low rectal resections or heavily contaminated surgical fields constitute accepted indications for surgical drains for a limited duration [3]. The results of the GRECCAR V trial (NCT01269567) are eagerly awaited and based on these results, the ERAS guidelines is expected to be revised accordingly. A high level of non-compliance for PONV prophylaxis could be explained by the fact that the protocol for PONV prophylaxis was adapted during the time of the present study. At the beginning of study, the ERAS guidelines were strictly followed, based on the use of Apfel score [14] for the calculation of PONV risk with the administration of PONV prophylaxis for Apfel score higher than 2. After the first half of the study period, up to 35% of PONV were ob-

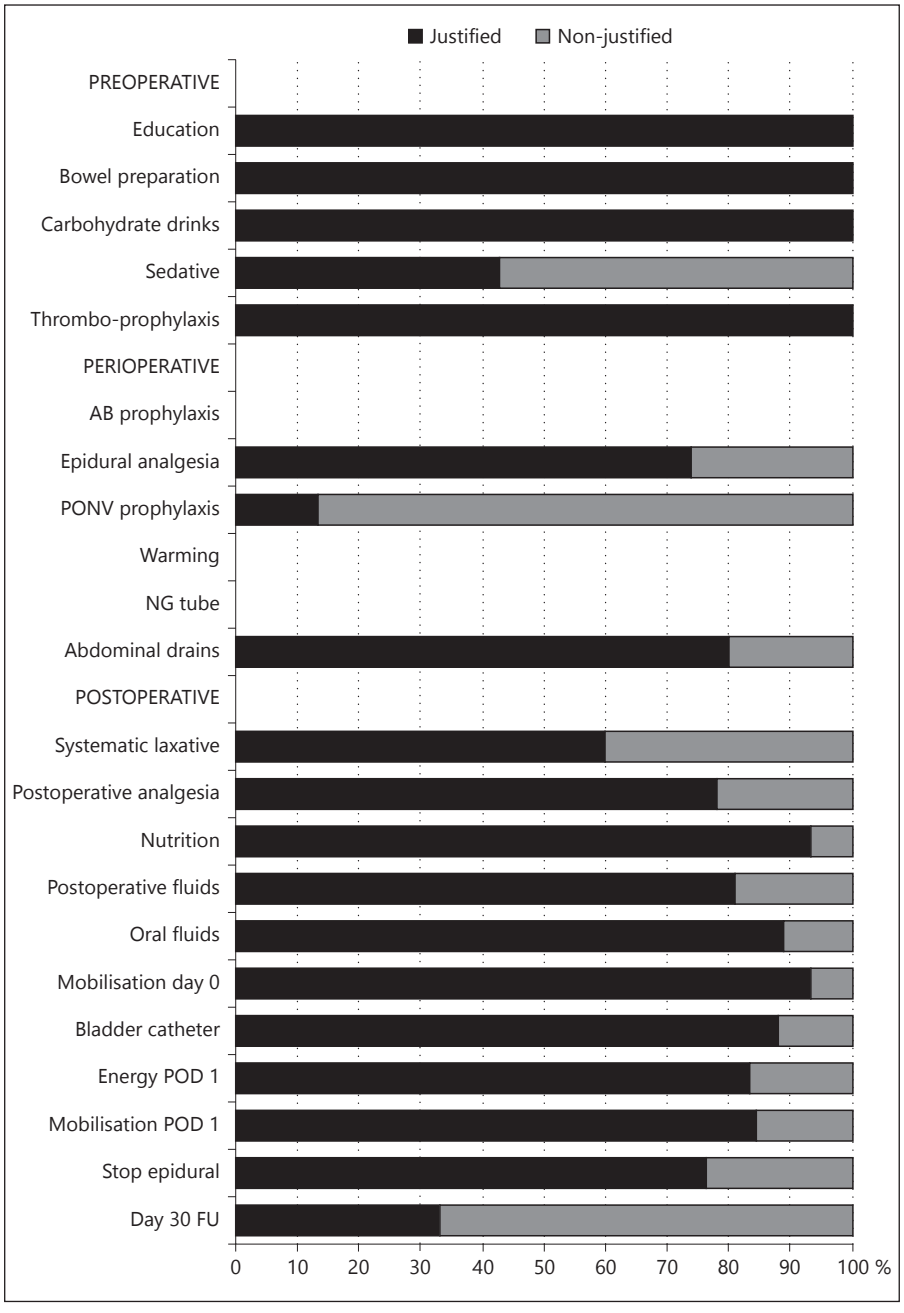

Fig. 3. Justification of non-compliance. For abbreviations refer fig. 1 legend.

served. This was discussed in the regular ERAS team meeting and it was decided that a PONV prophylaxis be given systematically to all patients with a drop of PONV to 10%.

While the ERAS protocol is overall a comprehensive bundle of potentially beneficial measures, perioperative care should not be regarded as a rigid system. The physician remains in charge and needs to conform to or modify the foreseen pathway according to the individual needs and actual clinical situation of every single patient. In fact, 78% of the deviations were found to be an utterly required deviation of the pathway from a medical point of view and in the patient's best interest. So it should not be surprising that the surgeon or the anesthetist who was in charge of the surgery was mainly responsible for initiating protocol deviations. Patients were mostly non-compliant for items concerning early food intake like supplements, oral fluids and energy at first postoperative day. Another example

was the patient's mobilization. We observed that those who were responsible for protocol deviation were both nurses and patients. This could be explained by the fact that often in the postoperative period, patients have some hypotension and may be symptomatic, thereby preventing their mobilization. A previous study that assessed how patient factors influence compliance identified male gender, age above 75 and American Society of Anesthesiologists 3/4 as independent predictors for non-compliance to most postoperative items [15].

Several limitations of this study need to be addressed. The current data reflect our institutional experience and cannot be generalized to other hospitals. The study sample is rather small but still sufficient to fulfill the aims and answer the questions of this prospective analysis. Obviously, there is no objective criterion to label whether clinical decisions were medically justified or not. However, a careful joint analysis of the ERAS team appeared to be a good and reliable approach to this important subject. Despite these limitations, to the best of our knowledge, this study is the first prospective one that has assessed the reasons and causal factors for non-compliance with the ERAS protocol.

In summary, high compliance with the ERAS protocol can be achieved in all phases of perioperative care. The postoperative period, however, seems to be more subject to variation and close observation is warranted to adjust patient care if medically indicated. The compliance or adherence to ERAS protocol should be monitored and reported in every scientific study to enhanced recovery. Having said this, if the ERAS protocol does not fit a few individual patients perfectly, it still is suitable for a majority of them.

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Disclosure Statement

The authors have no conflicts of interest to declare.

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