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ORIGINAL ARTICLE

Variation in care for surgical patients with colorectal cancer: protocol adherence in 12 European hospitals

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Abstract
Purpose Surgical care for patients with colorectal cancer has become increasingly standardized. The Enhanced Recovery After Surgery (ERAS) protocol is a widely accepted structured care method to improve postoperative outcomes of patients after surgery. Despite growing evidence of effectiveness, adherence to the protocol remains challenging in practice. This study was designed to assess the adherence rate in daily practice and examine the relationship between the importance of interventions and adherence rate.
Methods This international observational, cross-sectional multicenter study was performed in 12 hospitals in four European countries. Patients were included from January 1, 2014. Data was retrospectively collected from the patient record by the local study coordinator.
Results A total of 230 patients were included in the study. Protocol adherence was analyzed for both the individual interventions and on patient level. The interventions with the highest adherence were antibiotic prophylaxis (95%), thromboprophylaxis (87%), and measuring body weight at admission (87%). Interventions with the lowest adherence were early mobilization—walking and sitting (9 and 6%, respectively). The adherence ranged between 16 and 75%, with an average of 44%.
Conclusion Our results show that the average protocol adherence in clinical practice is 44%. The variation on patient and hospital level is considerable. Only in one patient the adherence rate was >70%. In total, 30% of patients received 50% or more of the key interventions. A solid implementation strategy seems to be needed to improve the uptake of the ERAS pathway. The importance-performance matrix can help in prioritizing the areas for improvement.

Keywords ERAS · Colorectal surgery · Care pathways · Protocol adherence · Importance-performance analysis

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Introduction

Over the last decade, surgical care for patients with colorectal cancer has become increasingly standardized. The use of structured care methods, such as care pathways and protocols, has helped in standardizing (not only) colorectal cancer (CRC) surgery. The Enhanced Recovery After Surgery (ERAS) protocol [1] is a widely accepted structured care method to improve postoperative outcomes of patients after surgery. This protocol aims to optimize interventions in the perioperative care (pre-, per-, and postoperative phase), to decrease postoperative morbidity, by enhancing patients' recovery, and thus shorten length of stay (LOS) [1–4]. The ERAS protocol has

recently been described as a "true revolution in colorectal surgery," highlighting its importance in today's surgical care [3]. Even more, evidence regarding its safety and effectiveness is still published nowadays.

Despite the growing evidence, adherence to the ERAS protocol remains insufficient in daily practice. Adherence rate, or protocol adherence, is defined as the percentage of protocol elements (interventions) delivered to an individual patient. Protocol adherence ranging from 45 to 90% has been reported in the literature, illustrating the difficulty to implement an ERAS protocol [5–8].

Recently, a "dose-effect" relationship between protocol adherence and patient outcomes has been suggested: the more protocol elements are applied, the better the patient outcomes, with an adherence of >70% showing improved outcomes [4, 9]. Therefore, it is important to assess the level of adherence, not only in study settings but in daily practice.

The purpose of this study was to assess colorectal units' adherence rate in daily practice. Two major objectives have been defined: (1) to describe protocol adherence for perioperative care, in colorectal cancer surgery, and (2) to study the relationship between adherence to the individual protocol elements ("key interventions") and the importance (strength) of key interventions.

Methods

Population

This international observational, cross-sectional multicenter study was performed in 12 hospitals in four European countries: Belgium, France, Germany, and the Netherlands. The study was supervised by the European Pathway Association (E-P-A, www.e-p-a.org), an international not-for-profit organization aiming to increase and disseminate knowledge of care pathways. Three hospitals in each country were included in the study using purposive sampling. Purposive sampling is a non-probability sampling technique, in which known characteristics of the population are used to construct the sample [10]. The goal was to obtain a sample with a mix of academic/teaching versus non-teaching and small versus large hospitals, to provide a representation of different characteristics of current healthcare systems.

Within the participating hospitals, consecutive patients were included. Inclusion criteria were (1) scheduled admission for colorectal cancer surgery (open or laparoscopic) and (2) adults (≥18 years). Exclusion criteria were (1) emergency (not planned) admission for colorectal cancer surgery and (2) severe dementia (DSM IV) or severe concomitant disease that may affect very short-term outcome (life expectancy less than 3 months).

The local study coordinator was instructed to collect the data from the patient record, for 20 consecutive patients admitted from January 1, 2014, using a standardized data extraction form. If data were not available or retrievable in the patient record, this was marked as "no information available." The requested data were retrospectively collected by the local study coordinator.

Ethical approval for this study was obtained with the ethical committee of the University Hospital Leuven (S57152 (ML11311)). Based on the study protocol, all hospitals provided written agreement of the local study coordinator and approval of the local ethical committee.

Variables

Demographic data and data on the perioperative care (see Table 1), as well as data on time intervals and the following outcomes: length of stay (LOS) (total hospital stay and stay on ICU), morbidity (defined as readmission rate and reintervention rate), and time of first flatus and first stool, and 31-day mortality were recorded. Protocol adherence was measured based on the care elements (or key interventions) from the ERAS protocol. A number of interventions (e.g., measuring C-reactive protein (CRP), albumin) not included in ERAS protocol, but relevant for the patient group, were also studied based on the outcomes of a previous literature review [11]. Where clinically relevant, adherence to specific interventions (e.g., use of drain) was assessed for patients with colon or rectal cancer. In these cases, patients with tumors in the colorectal joint were analyzed as colon cancer patients.

Statistical analysis

Data were recorded using MS Excel®. Analyses were performed using MS Excel® and visualizations were made in MS Excel® and statistical package R version 3.2.5, using easyGgplot2.

Continuous data are reported as mean and standard deviation (SD) or median and interquartile range (IQR); dichotomous data are presented as count and percentage. The relationship between strength of the key interventions and adherence is presented by using an importance-performance matrix, as used in similar research [12]. The importance dimension is defined by the strength of the key interventions. To determine the strength of each key intervention, the levels of evidence as reported in the ERAS protocol were converted to points. Three levels of evidence are distinguished [1]: low (1 point), moderate (2 points), and high (3 points), and two grades of recommendations: weak (1 point) and strong (2 points). Subsequently, the strength of the key intervention is defined as the sum of the points. A cutoff point was defined as ≥3 points, in order to include key interventions with a strong recommendation, even if the evidence was low. The performance dimension is defined by the adherence rate. This was

measured per key intervention as the number of patients that received the intervention (numerator) / the number of patients for whom the intervention was indicated (denominator), resulting in a percentage between 0 and 100%. A cutoff of ≥70% was used, based on thresholds in previous studies showing an effect on outcomes with a compliance of 70% or higher [4, 9]. Combining the importance dimension and performance dimension forms a matrix consisting of four quadrants (see Fig. 1). The top 2 quadrants signify important interventions, with a high adherence rate (top-right) and a low adherence rate (top-left). The bottom 2 quadrants signify the less important interventions, with high adherence rate (bottom-right) and low adherence rate (bottom-left). The variation between and within hospitals is visualized by boxplots.

Results

Hospital and patient characteristics

The 12 participating hospitals were divided equally over the countries (see "Acknowledgements"). One was an academic hospital, six were teaching hospitals, and five were non-teaching hospitals. The number of beds ranged between 145 and 1995. The number of admissions for colorectal cancer (CRC) surgery in 2014 ranged between 65 and 340.

The 12 hospitals provided data on 230 patients. One hospital provided data on 12 patients, of which two proved to be duplicates. All other hospitals provide data on 20 consecutive patients as required. The patient characteristics are summarized in Table 1. The mean age of the patients was 69.4 years, and 44% was female. The majority of patients had colon cancer (61%), and laparoscopic surgery was performed in 45% of the cases (Table 1). Outcomes are reported in Table 2. The average LOS was 13.8 days. Overall 31-day mortality was 1.7%, and reintervention and readmission rates were 9 and 12%, respectively (Table 2).

Adherence to versus strength of the perioperative key interventions

Table 3 summarizes all key interventions, with their level of adherence and strength. The table shows the observed variation in adherence, ranging between 95% (antibiotic prophylaxis) and 6% (early mobilization: sitting the evening of surgery). The interventions with the highest adherence rate were widely accepted surgical and anesthesiological practices, such as antibiotic and thromboprophylaxis and no prolonged preoperative fasting. The lowest adherence rates were found in postoperative interventions, e.g., early mobilization, early nutrition, and the use of mid-thoracic analgesia. The adherence to nutritional screening, including measuring body weight, is noteworthy. Adherence to measuring body weight at the start of the care process (normal body weight, day of admission) was 70%. At discharge, it was 31%. Nutritional screening was carried out in 59% of patients. However, if patients were at risk, only in one out of four patients a nutritional care plan was implemented.

Figure 1 shows the relationship between the strength of the recommendation and the adherence to the key interventions in the importance-performance matrix. There were six

Table 1 Patient characteristics (n = 230)

Age (in years) (mean ± std. dev)	69.36 ± 11.96
Male (*N*, %)	130 (56%)
Female (*N*, %)	100 (44%)
Comorbidities (*N*, %)	
Hypertension	119 (52%)
Cardiovascular disease	46 (20%)
Coronary disease	44 (19%)
Diabetes	43 (19%)
Pulmonary disease	33 (14%)
Liver disease	11 (5%)
Renal failure	6 (3%)
Location of tumor (*N*, %)	
Colon	141 (61%)
Rectum	56 (24%)
Colorectal joint	27 (12%)
Missing data	6 (3%)
ASA classification[a] (*N*, %)	
I	29 (13%)
II	132 (58%)
III	56 (25%)
IV	9 (4%)
Type of surgery (*N*, %)	
Open	75 (33%)
Laparoscopic	103 (45%)
Laparoscopic converted to open	37 (16%)
Missing data	15 (7%)

[a] American Society of Anesthesiologists

Table 2 Patient outcomes (n = 230)

Indicator	
Length of stay (in days) (mean ± std. dev)	13.76 ± 12.29
Number of days on ICU (mean ± std. dev)	1.96 ± 6.19
31-day mortality (*N*, %)	4 (1.7%)
Reintervention rate (*N*, %)	20 (9%)
Readmission rate (*N*, %)	27 (12%)
Postop day of first flatus[a] (mean ± std. dev)	2.76 ± 2.93
Postop day of first stool[b] (mean ± std. dev)	3.29 ± 2.15

[a] Reported in 67 patients, from nine hospitals

[b] Reported in 124 patients, from 12 hospitals

Table 3 Adherence to the perioperative interventions

Number	Intervention	Performance *n*/*N* (%)	Hospital median (Q1–Q3)	Level of evidence[a]	Grade of recomm[a]	Strength[b]
01	Antibiotic prophylaxis	219/230 (95%)	98% (90–100)	High	Strong	5
02	Thromboprophylaxis—low molecular weight heparin	200/230 (87%)	90% (84–100)	High	Strong	5
03	Measuring body weight—day of admission	200/230 (87%)	90% (86–95)	Low	Strong	3
04	Paracetamol/novaminsulfon	187/230 (81%)	90% (79–96)	Moderate	Strong	4
05	Measuring body weight—pre-surgery	181/230 (79%)	88% (68–96)	Low	Strong	3
06	No prolonged fasting—solid up to 6 h before surgery	166/230 (72%)	88% (65–96)	Moderate	Strong	4
07	Measuring Body weight—day of surgery	161/230 (70%)	70% (64–81)	–	Weak	1
08	Measuring CRP level at discharge	157/226 (69%)	68% (54–90)	–	Strong	2
09	Skin cleansing with chlorhexidine	156/210 (68%)	100% (14–100)	High	Strong	5
10	No/selective bowel preparation colon/colorectal tumor	112/168 (67%)	74% (67–92)	High	Strong	5
11	Screening of nutritional status	135/230 (59%)	75% (21–100)	Low	Strong	3
12	No nasogastric tubes (incl. removal before reversal of anesthesia)	132/230 (57%)	48% (29–86)	High	Strong	5
13	Preadmissions counseling—patient received information leaflet	129/230 (56%)	88% (38–95)	Low	Strong	3
14	Measuring CRP level at admission	126/230 (55%)	70% (23–88)	–	Strong	2
15	No drains colon/colorectal tumor	82/168 (49%)	62% (27–75)	High	Strong	5
16	Thromboprophylaxis—well-fitting stockings	108/230 (47%)	19% (0–86)	High	Strong	5
17	No prolonged fasting—fluid up to 2–3 h before surgery	104/230 (45%)	50% (0–86%)	Moderate	Strong	4
18	No opiates (oral, intramuscular, or intravenous)	104/230 (45%)	53% (29–96)	Low	Strong	3
19	Preadmissions counseling—leaflet discussed (partly) with team member	102/230 (44%)	45% (0–88)	Low	Strong	3
20	Postoperative counseling—patient received information leaflet	88/230 (38%)	38% (0–66)	Low	Strong	3
21	Early removal of catheter (postop days 0–2)	73/215 (34%)	34% (23–42)	Low	Strong[c]	3 (2)
22	No/selective bowel preparation rectal tumor	18/56 (32%)	37% (22–57)	?[d]	Strong	2
23	Prevention of nausea and vomiting—screening for risk factors	73/230 (32%)	10% (0–54)	Low	Strong	3
24	Prevention of nausea and vomiting—if at risk: prophylaxis	62/192 (32%)	26% (4–69)	Low	Strong	3
25	Antibiotic prophylaxis—repeated dose if surgery prolonged	19/59 (32%)	16% (0–64)	High	Strong	5
26	Measuring Body weight—at discharge	71/226 (31%)	20% (19–46)	–	Strong	2
27	Prevention of nausea and vomiting—if at risk: antiemetic's	57/192 (30%)	21% (0–64)	Low	Strong	3
28	No drains rectal tumor	16/56 (29%)	25% (0–36)	High	Strong	5
29	Avoidance of salt and water overload—IV drip (removal postop days 0–3	65/230 (28%)	30% (19–36)	High	Strong	5
30	Early oral nutrition—solid start postop day 0 or 1	61/230 (27%)	20% (9–51)	Low[e]	Strong	3
31	Screening of nutritional status—if at risk: nutrition assessment	46/180 (26%)	19% 4–68)	Low	Strong	3
32	Fluid and carbohydrate loading	60/229 (26%)	0% (0–32)	Low	Strong	3
33	Screening of nutritional status—if at risk: nutrition care plan	44/180 (24%)	19% (0–73)	Low	Strong	3
34	Postoperative counseling—leaflet discussed (partly) with team member	55/230 (24%)	8% (0–22)	Low	Strong	3
35	Measuring albumin level at admission	52/230 (23%)	8% (0–18)	–	Strong	2
36	Early oral nutrition—fluid start day of surgery	51/230 (21%)	28% (5–31)	Low	Strong	3
37	Non-opioid oral analgesia/NSAIDs	49/230 (21%)	13% (4–26)	Moderate	Strong	4
38	Measuring body weight—31-day follow-up	41/225 (19%)	13% (0–30)	–	Strong	2
39	Mid-thoracic epidural anesthesia/analgesia	41/230 (18%)	0% (0–30)	High	Strong	5
40	Measuring albumin level at discharge	30/230 (13%)	0% (0–13)	–	Weak	1
41	No premedication	30/230 (13%)	3% (0–21)	High	Strong	5
42	Early mobilization—walking postop day 1	20/230 (9%)	5% (0–16)	Low	Strong	3

Table 3 (continued)

Number	Intervention	Performance *n*/*N* (%)	Hospital median (Q1–Q3)	Level of evidence[a]	Grade of recomm[a]	Strength[b]
43	Early mobilization—sitting evening of surgery	14/230 (6%)	5% (0–10)	Low	Strong	3
44	Calculate CRP/albumin ratio at admission	0/230 (0%)	–	–	Weak	1
45	Calculate CRP/albumin ratio at discharge	0/230 (0%)	–	–	Weak	1

[a] Based on ERAS protocol

[b] Strength: Level of Evidence 1–3 points, grade of recommendation 1, 2 points, strength = sum (e.g., measuring body weight at admission: low evidence (1 point), strong recommendation (2 points), strength is 3)

[c] Weak when epidural is used

[d] ERAS only states high level of evidence for colonic, no level of evidence for rectal

[e] Effect: low; safety: high

interventions in the top-right quadrant (importance: strength ≥3 and adherence ≥70%): antibiotic prophylaxis, thromboprophylaxis (LMWH), measuring body weight (day of admission and normal), administering paracetamol/novaminsulfon, no prolonged preoperative fasting. In total, there were 29 interventions in the top-left quadrant (importance, strength ≥3 and adherence <70%) (e.g., no use of nasogastric tubes, no use of drains, early oral nutrition). These interventions are strongly recommended, but are used in a relative low percentage of patients, suggesting possible underuse.

The interventions in the bottom-left quadrant, totaling nine interventions (e.g., no/selective bowel preparation (rectal tumors), measuring body weight at discharge and follow-up), are less important interventions (strength <3), with a low adherence rate (<70%). The bottom-right quadrant includes only one intervention (measuring body weight at day of surgery). This intervention is weakly recommended (strength <3) and used in a high percentage of patients (70%).

Protocol adherence and variation

In this analysis, only the key interventions with a strength level of at least 3 were included, since these are considered the most important interventions (see Fig. 1). The overall protocol adherence (patient level) ranged between 16 and 75% (median 44%). No patient received all key interventions, and only one patient received care with an adherence of more than 70%, the cutoff described by Gustafsson et al. [4]. In total, only 30% of patients received 50% or more of the key interventions.

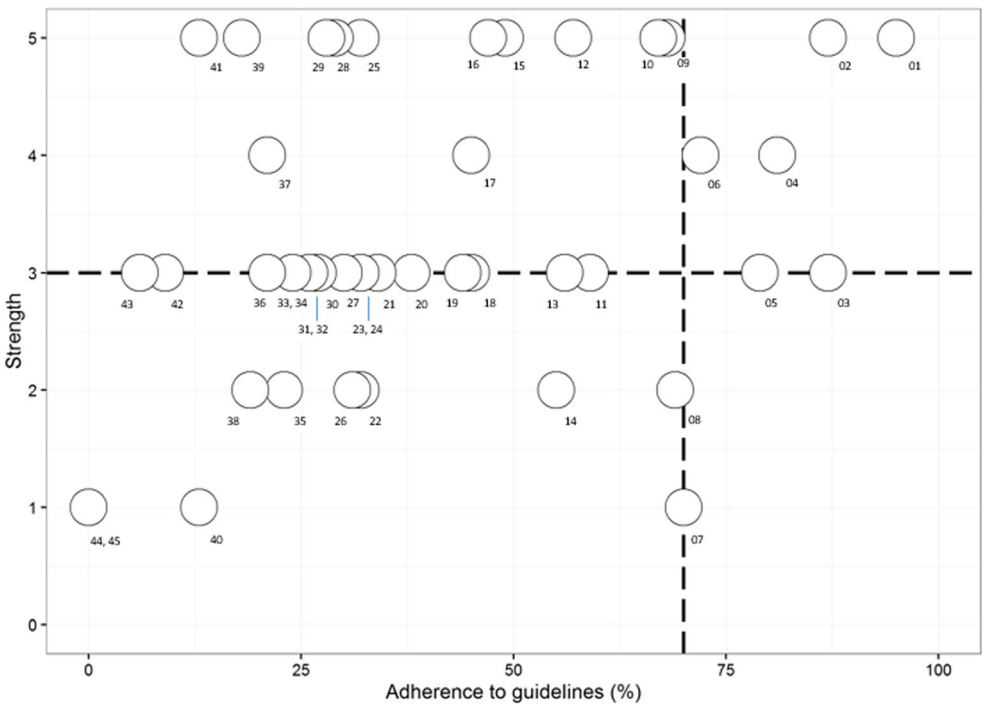

Fig. 1 Importance-performance matrix for the CRC pathway interventions. The numbers in Fig. 1 correspond to the numbers in Table 3, identifying the key interventions. *Upper right quadrant*: correct use; *upper left quadrant*: underuse; *lower right quadrant*: overuse; *lower left quadrant:* correct use (low priority interventions)

Figure 2 compares the performance per hospital in a box plot. The figure shows that there was considerable variation between and within the hospitals: the median scores of the participating hospitals ranged from 58 to 35%.

Discussion

Our data shows the baseline level of adherence to ERAS elements in 12 European hospitals in four countries with departments dedicated to colorectal surgery. A wide variability between the hospitals was observed regarding the implementation of all single ERAS elements. Even within the hospitals, there is considerable variation. The "whiskers" in Fig. 2, signifying the variation within a hospital (minimum–maximum score), were very long, notably so in hospitals 2, 8, 10, and 12. Overall, the present study shows an average protocol adherence rate of 44%. This is comparable with data published in the "Quality of healthcare study" in 2003, which is regarded as a benchmark study on recommended care. This paper states that patients receive on average 55% of recommended care [13]. The study also included colorectal cancer (54% adherence rate). Since this study was published in 2003, ERAS has become the standard of care for perioperative management of colorectal cancer surgery. While the "Fast Track" ERAS program was originally designed for colorectal surgery, protocols have since then been established for gastrectomy, pancreatectomy, cystectomy, and other procedures. ERAS represents a multimodal treatment bundle including items with different grades of evidence from prospective randomized studies [1]. The idea behind this bundle is that all interventions in the bundle should be performed, to improve patients' outcome. A long-term cohort study showed that the adherence to an ERAS protocol may be associated with improved 5-year cancer-specific survival after colorectal cancer surgery. This study included 911 consecutive patients undergoing major colorectal cancer surgery. In total, 30% of patients had an adherence rate ≥70% to ERAS interventions. For this group, the risk of cancer-specific death was reduced by 42%, compared to the group (of patients) with an adherence rate <70% [4]. The authors clearly state that there is a strong association between protocol adherence and survival, but that this may not be a cause-and-effect relationship. Nor did their study provide evidence on the mechanism behind the reported effect. A possible explanation given by the authors is that protocol adherence reduces the metabolic stress response, which in turn reduces tumor recurrence [4].

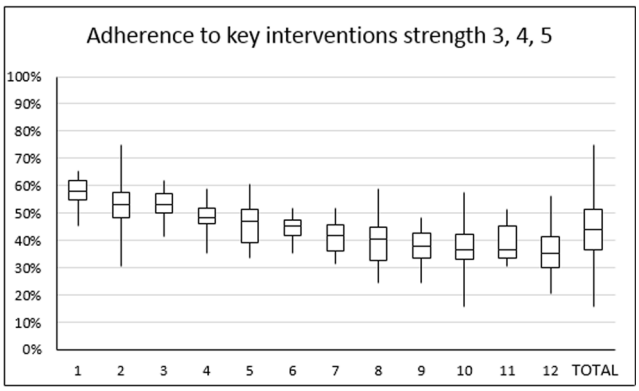

Fig. 2 Variation between and within hospitals: percentage of documented key interventions the patient received. Numbers *1–12* represent the individual hospitals in descending order of median adherence rate; the final *box* represents the total/benchmark with all 230 patients

The necessity of some interventions, not supported by good evidence, is arguable. However, the results show a very low adherence to three strongly recommended key interventions of the ERAS protocol in all participating colorectal units. Early oral nutrition (fluid start day of surgery), mid-thoracic epidural anesthesia/analgesia, and early mobilization (sitting evening of surgery and walking postop day 1) were documented in a small fraction of patients. This is much lower than expected by the results of previous studies [3–7, 9]. However, there may be traditional and/or practical barriers for these interventions. Fasting is a surgical "tradition" promoting "safer" healing of any gastrointestinal anastomosis. Epidural analgesia means the introduction of modern techniques of regional analgesia. Early mobilization could be a challenge for the workload of restricted nursing staff capacities.

Implementation strategies for guidelines and treatment protocols are an important issue worldwide for the improvement of clinical care. Implementation is a central element in the Medical Research Council (MRC) framework for process evaluations of "complex interventions." This framework links the *outcomes* of implementation efforts to *mechanisms* in daily practice, within the *context* (organization, society) [14]. Implementation of a guideline or protocol such as ERAS is a complex intervention and can be influenced by elements in the *context*. For example, the availability or lack of qualified community nurses and home care staff may influence the protocol adherence. *Organizational features*, such as resources, and *mechanisms* in daily practice such as hierarchy, training, etcetera, could also influence the implementation of and adherence to ERAS protocol. These concepts (context, mechanism, outcome) reflect the previously mentioned practical barriers of tradition (mechanisms), introduction of modern techniques (context), and workload for nurses (context). The ERAS Society is providing support for implementation of the ERAS protocol. Another relevant implementation resource is the International Consortium for Health Outcome Measures (ICHOM) Standard Set for colorectal cancer. This document provides recommendation or indicators to measure the outcomes that matter most to persons with colorectal cancer [15, 16]. Finally, the development and implementation of care pathways can be a strategy to bring evidence to practice. A recent systematic review defines care pathways as one of the proven interventions to reduce adverse events in surgery [17]. A

recent meta-analysis by Song et al. on the effects of clinical pathways for patients with gastrointestinal cancer shows a reduction in expenditure and average length of stay and higher patient satisfaction [18].

This study comes with strengths and some limitations. First of all, there might be selection bias, taking into account the limited number of patients included in every single hospital. This may not represent each hospital reliably. However, this study is focused on identifying process improvement opportunities, taken the resource and time constraints in the participating hospitals into account. A number of 20 patients have been suggested as sufficient in previous care pathway research and method papers [19–21].

The purposive sampling of the hospitals could have led to a positively biased selection of hospitals, with a focus already on structured (surgical) care for colorectal cancer patients. The inclusion of the patients was performed by local research coordinators and not under control of the authors. This could have led to an over estimation of the protocol adherence.

A final limitation of the study is the retrospective design with some shortages in clinical documentation. Our data shows a median under-documentation of 20%. It is interesting to note that the level of documentation is higher in interventions with the higher strength. This could mean that these interventions are considered more important and are documented with greater attention. Because of the under-documentation, the results of our study may *underestimate* the ERAS protocol adherence. However, our study shows a comparable or even lower adherence rate than published in the "Quality of healthcare study" [13]. This makes us quite confident of the representativeness of our data.

If we assume the positive scenario that key interventions are performed, but not documented, the level of adherence would be approximately 20% higher. This percentage is certainly debatable. Moreover, a mean adherence of 44% as found in our study +20% documentation bias is still below the 70% cutoff point from the Gustafsson et al. 2016 study [4]. Apart from the problem in determining the true adherence, the documentation shortages represent a potential or actual quality problem in daily practice, in terms of continuity and coordination of care.

We believe that our results provide a great opportunity for hospitals to learn from each other. Improvement priorities can be identified using the importance-performance method. Care pathways can be used as a method to implement the evidence-based key interventions in daily practice. Because adherence to the evidence seems so challenging in daily practice, we suggest to evaluate not only the effect of implementation on adherence and patient outcome but also the process of implementation. This could help in designing a practical and effective implementation strategy.

Conclusion

The goals of this study were to examine the adherence to the individual protocol elements ("key interventions") and the relationship between the importance (strength) of key interventions and the adherence rate, and to describe protocol adherence and variation for perioperative care in colorectal cancer surgery. Our data shows that the average protocol adherence in clinical practice is 44%. The variation within and between hospitals is considerable. Only in one patient the adherence rate was >70%. In total, only 30% of patients received 50% or more of the key interventions. This could mean a serious threat to quality of care, because patients are undertreated. A solid implementation strategy to bring evidence into practice seems to be needed to improve the uptake of the ERAS pathway. The importance-performance matrix can help in prioritizing the areas for improvement.

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Conflict of interest AW has received lecturers' honoraria from Baxter, B.Braun, Berlin-Chemie, Fresenius Gabi, Lilly, Medtronic, Nestlé, and Nutricia, and has received research grants from Baxter and Danone. The other authors declare that they have no conflict of interest.

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