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Original Research

Do we really need the full compliance with ERAS protocol in laparoscopic colorectal surgery? A prospective cohort study

Magdalena Pisarska [a, *], Michał Pędziwiatr [a], Piotr Małczak [a], Piotr Major [a], Sebastian Ochenduszko [b], Anna Zub-Pokrowiecka [a], Jan Kulawik [a], Andrzej Budzyński [a]

[a] 2nd Department of General Surgery, Jagiellonian University Medical College, Kopernika 21, 31-501 Kraków, Poland
[b] Department of Oncology, University Hospital Krakow, Śniadeckich 10, 31-501 Kraków, Poland

HIGHLIGHTS

- Very high compliance with ERAS protocol is achievable in a significant proportion of patients..
- It strongly correlates with surgical outcomes such as morbidity, readmissions and length of hospital stay.
- It has also significant impact on improvement in recovery parameters.

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ABSTRACT

Background: Although the relation between adherence to the ERAS protocol and clinical outcomes was extensively studied, there is still ongoing discussion on the need and feasibility of full compliance in laparoscopic colorectal surgery. In this study, we aimed to verify whether a strict adherence to the protocol (>90%) leads to further improvement in clinical outcomes compared to high (70–90%) and low (<70%) compliance groups.

Materials and methods: The analysis included consecutive prospectively registered patients operated laparoscopically for colorectal cancer between January 2012 and December 2015. Patients were divided into three groups depending on the compliance with the ERAS protocol: <70% (Group 1), 70–90% (Group 2), >90% (Group 3). The measured outcomes were: complication rate, readmission rate, recovery parameters (tolerance of early oral diet on 1st postoperative day and mobilization of a patient on the day of surgery), length of stay (LOS).

Results: Group 1 consisted of 70, Group 2 of 65 and Group 3 of 116 patients. There were no statistical differences between the groups based on demographic parameters, stage of cancer and operative parameters (operative time, blood loss, conversion rate). The overall compliance with the protocol in the study group was 85.6 ± 11.9%. There was a significant decrease in complication rate with increasing compliance (35.7% vs. 36.4% vs. 16.4%, $p = 0.0024$) and severity of complications according to the Clavien-Dindo classification ($p = 0.0198$). Moreover, we observed differences in recovery parameters between the groups: tolerance of oral diet on the 1st postoperative day (52.8% vs. 79.5% vs. 87.9%, $p < 0.0001$), mobilization of a patient on the day of surgery (68.6% vs. 92.3% vs. 99.1%, $p < 0.0001$), respectively. We also observed that with compliance increase, the median LOS decreased (6 vs. 4 vs. 3 days, $p < 0.0001$).

Conclusion: Full implementation of the ERAS protocol significantly improves short term outcomes both in comparison to the high- and low-compliant groups.

1. Background

The benefits of introducing the Enhanced Recovery After Surgery protocol into colorectal surgery are well documented in the literature. They include reducing morbidity rate and the length of hospital stay [1,2].

* Corresponding author. Department of Endoscopic, Metabolic and Soft Tissue Tumors Surgery, Kopernika 21, 31-501 Kraków, Poland. Tel.: +48 609 852 680.
E-mail address: magdalena.pisarska@uj.edu.pl (M. Pisarska).

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In fact, achieving full protocol compliance is impossible in the majority of patients. Therefore, the mean compliance rate varies between 60% and 80%, even in centres that use it on a routine basis [4,5]. It has been clearly shown that adherence to the protocol is strongly correlated with surgical outcomes such as morbidity rate, readmission rate and shortened length of hospital stay [2,6,7]. This confirms the thesis that more is better, yet it remains unknown whether full protocol compliance is truly necessary because most of the studies do not distinguish patients with full compliance. This prompted us to conduct an analysis to determine the impact of full compliance to the protocol on short-term results.

2. Objectives

In this study we aimed to answer the question whether the strict adherence to the protocol (>90%) leads to further improvement of clinical outcomes comparing to high (70–90%) and low (<70%) compliance groups.

3. Material and methods

3.1. Inclusion and exclusion criteria

The analysis included consecutive patients electively operated for colorectal cancer since January 2013 to July 2016.

Inclusion criteria were: age above 18 years, histopathologically confirmed colorectal adenocarcinoma, laparoscopic resection of the colon and/or rectum, perioperative care based on the ERAS protocol.

Exclusion criteria were: initially open or emergency surgery, patients treated with transanal endoscopic microsurgery (TEM) or transanal total mesorectal excision (TaTME) techniques, multivisceral resection, concomitant inflammatory bowel disease, intensive care unit stay directly after surgery. Patients flow through the study is presented in Fig. 1.

In all patients, the 16-item ERAS protocol was applied (Table 1). Prior to admission, every patient was consulted at least once by anaesthetist and at least twice by a surgeon in out-patient clinic. For each patient a risk of malnutrition was assessed and if needed a nutritional support was being introduced (14 days prior to surgery). Additionally, patients were advised to quit smoking, stop drinking alcohol and start physical exercises adjusted to their physical status before admission. All procedures were performed by high-volume surgeons.

All patients were actively mobilized by the nursing staff on the day of surgery (independent sitting up, a short walk to the toilet). In all patients, oral diet was introduced in the evening on the day of the operation with fluids and oral nutritional supplements.

Compliance was calculated as the number of pre- and intraoperative interventions fulfilled from the 16-element protocol used in the clinic. For the purpose of further analysis, patients were divided into three groups depending on the compliance with the ERAS protocol: Group 1 included patients with compliance less than 70%, Group 2 between 70% and 90%, and Group 3 more than 90%.

We analysed demographic parameters such as sex, age, BMI, ASA (American Society of Anaesthesiologists) physical status, the presence of preoperative comorbidities, type of surgery and stage of cancer according to American Joint Committee on Cancer. Moreover, operative time, intraoperative blood loss and conversion rate were analysed.

3.2. Outcome measures

The primary outcomes were: morbidity and readmission rate. Complications were graded according to the Clavien-Dindo classification. Readmissions were defined as hospitalization related to the surgery within 30 days after discharge.

The secondary outcomes were postoperative recovery parameters: early mobilization, early introduction of oral feeding, need for opioids within the first 24 h after the procedure and length of stay (LOS).

3.3. Statistical analysis

All data were collected prospectively and entered in a digital database. Statistical analysis was performed with Statsoft STATISTICA v.12. The results are presented as mean ± standard deviation (SD), median and interquartile range (IQR), when appropriate. Tests were selected depending on the type of the variables. For the qualitative variables the chi-square test was used. In cases of quantitative variables, where no normal distribution was observed, we used the Kruskal–Wallis test. To compare the two groups, when non-normally distributed quantitative variables were present, the U Mann-Whitney test was used. Data were considered statistically relevant with $p < 0.05$.

3.4. Ethical approval

The study was approved by the local Ethics Review Committee (approval number KBET/53/B/2014), and has been performed in accordance with the ethical standards laid down in the 1964 Helsinki Declaration and its later amendments. Written informed consent was obtained from all patients before surgery.

4. Results

Group 1 included 70 patients, Group 2–65 patients, and Group 3–116 patients. No statistically significant differences between groups were observed for demographic parameters such as sex, age, BMI, ASA scale, comorbidities, localization and stage of the tumour according to the AJCC classification. The median operative time (180 vs. 190 vs. 180 min., p = 0.1593) and intraoperative blood loss (50 vs. 100 vs. 70 ml, p = 0.0667) in groups were similar. Although there was a difference in conversion rate between groups 8.6% vs. 3.1% vs. 1.7%, it was not statistically significant (p = 0.0808). Demographic and intraoperative parameters are presented in Table 2.

Complications occurred in 67 (26.7%) patients. There was a statistical difference in postoperative morbidity rate between Groups 1, 2 and 3 (35.7% vs. 35.4% vs. 19%, $p = 0.0024$), and its severity according to the Clavien-Dindo classification ($p = 0.0198$). Readmission rate was similar in groups (8.6% vs. 4.6% vs. 6.9%, $p = 0.6469$). Furthermore, comparison of patients in Group 2 (compliance 70%–90%) with Group3 (compliance > 90%) showed a decrease in complication rate ($p = 0.0042$) and its severity according to the Clavien-Dindo classification ($p = 0.0174$), but not in readmission rate ($p = 0.5296$).

There were also significant differences in recovery parameters such as tolerance of an oral diet on the 1st postoperative day (52.8% vs. 78.5% vs. 87.9%, $p < 0.00001$) and mobilization of a patient on the day of surgery (68.6% vs. 92.3% vs. 99.1%, $p < 0.00001$) (see Fig. 2). Comparison of patients in Group 2 and 3 showed no significant differences in the use of opioids ($p = 0.1242$), toleration of oral diet on the first postoperative day ($p = 0.0965$) and time to first flatus ($p = 0.9131$). We noticed that there was a greater proportion of mobilized patients in Group 3 compared to Group 2 (p = 0.0149). The postoperative outcomes are presented in Table 3.

We observed a statistically significant difference between Group 1, 2 and 3 in median LOS (6 vs. 4 vs. 3 days, $p < 0.00001$). Patients in

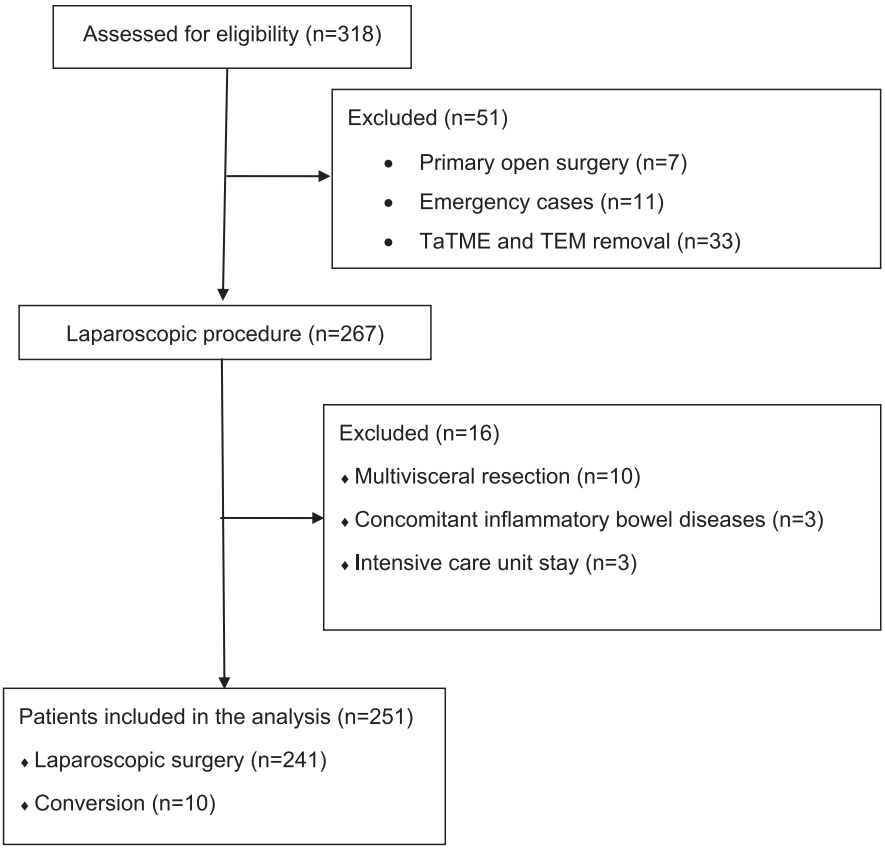

Fig. 1. Patients flow through the study.

Table 1
ERAS protocol used in our department.

1. Preoperative counselling and patient's education
2. No bowel preparation (oral lavage in case of low rectal resection with TME and defunctioning loop ileostomy)
3. Pre-operative carbohydrate loading (400 ml of Nutricia preOp® 2 h prior surgery)
4. Antithrombotic prophylaxis (Clexane® 40 mg sc. starting in the evening prior surgery)
5. Antibiotic prophylaxis (preoperative Cefuroxime 1,5 g + Metronidazole 0,5 g iv 30–60 min prior surgery)
6. Laparoscopic surgery
7. Balanced intravenous fluid therapy (<2500 ml intravenous fluids during the day of surgery, less than 150 mmol sodium)
8. No nasogastric tubes postoperatively
9. No drains left routinely for colonic resections, one drain placed for <24 h in case of TME
10. TAP block and standard anesthesia protocol
11. Avoiding opioids, multimodal analgesia (oral when possible - Paracetamol 4 × 1g, Ibuprofen 2 × 200 mg, Metamizole 2 × 500 mg, or Ketoprofen 2 × 100 mg)
12. Prevention of postoperative nausea and vomiting (PONV) (Dexamethasone 8 mg iv., Ondansetron 8 mg iv., Metoclopramide 10 mg iv.)
13. Postoperative oxygenation therapy (4–6 l/min)
14. Early oral feeding (oral nutritional supplement 4 h postoperatively - Nutrcia Nutridrink® or Nestlé Impact®, light hospital diet and oral nutritional supplements on the first postoperative day, full hospital diet in the second postoperative day)
15. Urinary catheter removal on the first postoperative day
16. Full mobilization on the first postoperative day (getting out of bed, going to toilette, walking along the corridor, at least 4 h out of bed)

Group 1 had a two times longer LOS in comparison with Group 3. Comparison of patients in Group 2 and 3 showed no significant decrease in LOS ($p = 0.0767$).

5. Discussion

This study shows that the improvement of compliance to the ERAS protocol results in better treatment results and convalescence parameters. This benefit is observed also when groups with high and very high compliance rate are compared. Previous studies showed that using the ERAS protocol is beneficial for the patients; however, the difference was shown between groups of patients with relatively low and high compliance rates. Its introduction not only shortens LOS and enhances convalescence, but also reduces the morbidity rate [4,8]. It is not associated with a higher readmission rate in that group of patients. LAFA study showed that combining the ERAS protocol with laparoscopy works synergistically, significantly reducing morbidity rate and speeding up the convalescence process [9]. It was also confirmed in subsequent meta-analyses [4,10].

Guidelines for Perioperative Care in Elective Colonic and Rectal Surgery: Enhanced Recovery After Surgery (ERAS) Society Recommendations describe a twenty-element protocol for colorectal surgery [11,12]. Despite that, centres which are routinely using the

Table 2
Demographic analysis of patient groups.

Parameter	Group 1 < 70%	Group 2 70–90%	Group 3 > 90%	*p* value
Number of patients, n	70 (27.9%)	65 (25.9%)	116 (46.2%)	–
Females, n (%)	28 (40%)	33 (50.8%)	54 (46.6%)	0.4432
Males, n (%)	42 (60%)	32 (49.2%)	62 (53.4%)	
Mean age, years ± SD	67.6 ± 11.3	64.7 ± 12.8	66 ± 12.6	0.5404
BMI, kg/m^2 ± SD	25.6 ± 4.3	25.8 ± 4.8	27.1 ± 5.5	0.2071
ASA 1, n (%)	2 (2.9%)	1 (1.5%)	2 (1.7%)	0.1969
ASA 2, n (%)	39 (55.7%)	46 (70.8%)	69 (59.5%)	
ASA 3, n (%)	29 (41.4%)	16 (24.6%)	41 (35.3%)	
ASA 4, n (%)	–	2 (3.1%)	4 (3.5%)	
Any comorbidity	58 (82.9%)	43 (66.2%)	87 (75%)	0.0806
Cardiovascular	31 (44.3%)	17 (26.2%)	39 (33.6%)	0.0823
Hypertension	38 (54.3%)	30 (46.2%)	66 (56.9%)	0.3750
Diabetes	15 (21.4%)	11 (16.9%)	16 (13.8%)	0.4078
Pulmonary disease	11 (15.7%)	4 (6.2%)	15 (12.9%)	0.1789
Renal disease	5 (7.1%)	5 (7.7%)	10 (8.6%)	0.9325
Liver disease	4 (5.7%)	2 (3.1%)	6 (5.2%)	0.7274
AJCC Stage I, n (%)	20 (28.6%)	26 (40.0%)	37 (31.9%)	0.4745
AJCC Stage II, n (%)	17 (24.3%)	18 (27.7%)	38 (32.8%)	
AJCC Stage III, n (%)	20 (28.6%)	15 (23.1%)	28 (24.1%)	
AJCC Stage IV, n (%)	13 (18.5%)	6 (9.2%)	13 (11.2%)	
Colon, n (%)	39 (55.7%)	42 (64.6%)	79 (68.1%)	0.2351
Rectum, n (%)	31 (44.3%)	23 (35.4%)	37 (31.9%)	
Formation of stoma	14 (20%)	16 (24.6%)	21 (18.1%)	0.5679
Mean operative time, min.± SD	185 ± 73.8	197.3 ± 61.0	193.3 ± 50.9	0.1593
Median operative time, min.(IQR)	180 (130–220)	190 (160–240)	180 (160–230)	
Mean intraoperative blood loss, ml ± SD	109.9 ± 137.2	117.6 ± 80.1	97.2 ± 84.1	0.0667
Median intraoperative blood loss, ml (IQR)	50 (50–100)	100 (50–200)	70 (50–150)	
Conversion, n (%)	6 (8.6%)	2 (3.1%)	2 (1.7%)	0.0808

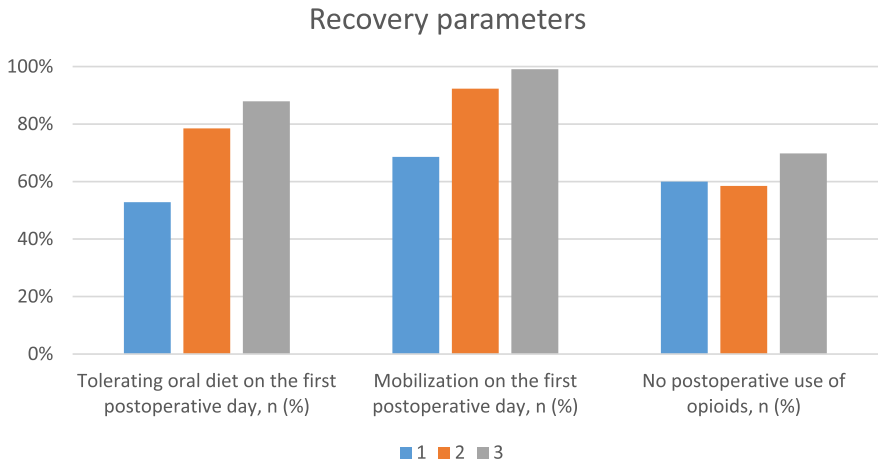

Fig. 2. Recovery parameters in analysed groups.

Table 3
Postoperative outcomes in analysed groups.

Parameter	Group 1 < 70%	Group 2 70–90%	Group 3 > 90%	*p* value
Tolerating oral diet on the first postoperative day, n (%)	37 (52.8%)	51 (78.5%)	102 (87.9%)	<0.0001
Mobilization on the first postoperative day, n (%)	48 (68.6%)	60 (92.3%)	115 (99.1%)	<0.0001
No postoperative use of opioids, n (%)	42 (60.0%)	38 (58.5%)	81 (69.8%)	0.2142
Time to first flatus, days ± SD	2.19 ± 1.58	1.28 ± 1.67	1.36 ± 2.44	<0.0001
Patients without complications, n (%)	45 (64.3%)	42 (64.6%)	97 (83.6%)	0.0024
Patients with complications, n (%)	25 (35.7%)	23 (35.4%)	19 (16.4%)	
Clavien-Dindo 1, n (%)	13 (18.6%)	14 (21.5%)	8 (6.9%)	0.0198
Clavien-Dindo 2, n (%)	4 (5.7%)	4 (6.2%)	4 (3.5%)	
Clavien-Dindo 3, n (%)	8 (11.4%)	4 (6.2%)	5 (4.3%)	
Clavien-Dindo 4, n (%)	–	1 (1.5%)	–	
Clavien-Dindo 5, n (%)	–	–	2 (1.7%)	
Mean length of hospital stay, days ± SD	7.81 ± 6.80	4.94 ± 3.66	4.54 ± 4.45	<0.0001
Median length of hospital stay, days (IQR)	6 (4–8)	4 (3–6)	3 (2–5)	
Readmission, n (%)	6 (8.6%)	3 (4.6%)	8 (6.9%)	0.6469

ERAS protocol vary in the number of elements implemented. Delaney et al. mentioned 4 elements, whereas Wang et al. and Khoo et al. state 8 cardinal elements [13–15]. Only part of studies regarding compliance to the ERAS protocol reported more than 10 elements [1,16,17]. Actually, we did not find a centre which reported using all elements from the guidelines as a routine practice. The protocol we have used in colorectal surgery since 2012 consists of 12 elements, which is above the mean number of elements included in systematic reviews [18]. Although many authors suggest that compliance affects treatment results, little is known about the influence of the number of used elements. The next issue involves the method of measuring compliance rate. Gustafsson et al. in his study used only preoperative elements, which were staff dependent [6]. Pędziwiatr et al. assessed it using both pre- and postoperative components [19]. Thorn et al. divided components into passive and active when analysing the short-term outcomes. He demonstrated that poor compliance with active but not passive elements of the programme was significantly associated with major morbidity [20]. A thorough analysis and interpretation of such results is not fully possible due to reporting technique.

Another issue is the difference in defining compliance to the protocol, which is determining cut off points for analysed parameters. Balanced fluid therapy is a great example. Gustafsson et al. consider balanced fluid therapy when perioperative fluids do not exceed 3000 ml in the case of colon resection and 3500 ml in the case of rectum resection [6]. The same element is interpreted in a different fashion by other authors – Wang considers intravenous infusion of 1500 ml Ringer's lactate in early postoperative care as compatible with the ERAS protocol [14]. In our studies, balanced intravenous fluid therapy is defined as less than 2500 ml of intravenous balanced crystalloids during the day of surgery.

Similar differences apply to defining early oral nutrition and patient mobilization. In some studies oral diet introduced on the day of surgery is considered as “according to protocol”, whereas other authors report “according to protocol” when diet is expanded on day 1 or day 2. Early mobilization is also subjectively determined by the authors. Some consider it as sitting in a chair, whereas other as being out of bed for several hours or walking a certain distance on their own. Thus these are not standardized endpoints, with a rather subjective accuracy, resulting in possible high risk of bias when trying to assess overall unified compliance rate.

It seems that despite the definition, the improvement of the ERAS protocol compliance provides better short-term treatment results, which is suggested by multi-centre ERAS compliance study group [2]. Furthermore, in our study we showed that it is still beneficial to improve compliance from high to very high, resulting in: morbidity rate reduction and improvement of some convalescence parameters. Unfortunately, some clinical situations do not allow full protocol realization due to medical considerations (e.g. bowel preparation in case of intra-operative colonoscopy in search for tumour, prolonged urinary catheter after partial bladder resection, increased fluid requirements in patients with PONV, no intention of mobilization in patients with move impairment prior to surgery, nasogastric tube placement and oral diet cessation in patients with PPOI). Post-operative complications and lack of consent for some protocol elements are other reasons influencing the ERAS compliance rate. It is worth mentioning that ERAS can be modified depending on clinical requirements and centre capabilities.

Until now there have been studies with the sole aim of determining which protocol element plays a crucial part in improving treatment results. Although it has been proven that each and every one has a positive impact on convalescence, there is a group with a particularly high influence. It is known that laparoscopy allows better outcomes with and without ERAS [1]. Additionally, balanced fluid therapy as a single element lowers the morbidity rate, shortens LOS or decreases time to first flatus [21,22]. A preoperative carbohydrate loading improves outcomes only in the case of major abdominal surgeries [23,24]. Currently, it is believed that the outcome improvement is not an effect of one particular element, but rather an aggregation of marginal gains. Therefore, although it is not always possible to fully adhere to the protocol, efforts should always be made to do so. Even though it is not always statistically possible to present every single protocol element as beneficial, as a whole they are proven to work, which is clearly confirmed in our analysis.

One of the limitations of our study is that we only analysed short term results, up to 30 days after surgery. In a recently published study, Gustafsson et al. showed that the 5-year survival rate in colorectal cancer is greater by 42% in groups with >70% compliance in comparison to <70%. At the same time the authors stated that adherence of >80% and >90% was not associated with further outcome improvement [3]. This is one of the first reports on this subject and even though it is based on a high population number, the matter still requires further studies. Although ERAS protocol was approved and implemented, we have noticed that in some cases adherence to all protocol elements was impossible without any particular reason. Such deficiencies in the implementation of the protocol are incidental and it does not seem that any particular surgeon/anaesthetics this affected. In fact, ERAS is routinely implemented in all our patients irrespective of the age, stage of cancer or other factors (ASA, comorbidities, type of surgery etc.). Therefore, we claim that all indeed go through ERAS pathway. However, we don't consider it another surgical dogma and allow for deviations from the pathway in certain clinical situations as mentioned above. This may result in differences compliance rates. In summary, we try to follow the pathway but agree that sometimes it is clinically justified not to adhere to each ERAS point. Another limitation of our study is the design as a single centre study. Our material involved a relatively limited number of patients. Moreover, the ERAS protocol is currently part of our routine perioperative care independently of the type of surgery and operated organ, and it is possible that the results of similar studies in other centres with worse protocol performance could be different.

6. Conclusion

An increase in compliance to the ERAS protocol from high to very high/full is associated with further improvement in short-term outcomes. Full protocol adherence reduces morbidity rate and has a positive impact on specific convalescence parameters, while maintaining comparable LOS.

Ethical approval

The local independent ethics committee of the Jagiellonian University, Krakow (KBET/53/B/2014) approved the study.

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Author contribution

Magdalena Pisarska - Study conception and design, Acquisition of data, Analysis and interpretation of data, Drafting of manuscript, Critical revision of manuscript.

Michał Pędziwiatr – Study conception and design, Drafting of

manuscript, Critical revision of manuscript.

Piotr Małczak – Drafting of manuscript, Critical revision of manuscript.

Piotr Major – Acquisition of data, Analysis and interpretation of data.

Sebastian Ochenduszko – Acquisition of data, Analysis and interpretation of data.

Anna Zub-Pokrowiecka – Acquisition of data, Analysis and interpretation of data.

Jan Kulawik – Acquisition of data, Analysis and interpretation of data.

Andrzej Budzyński – Study conception and design, Critical revision of manuscript.

Conflict of interest statement

The Authors declare no conflict of interest.

Trial registry number – ISRCTN

The study is not an RCT. Research registry 1779.

Guarantor

Magdalena Pisarska, MD.
Michał Pędziwiatr, MD Ph.D.
Andrzej Budzyński, Prof.
2nd Department of General Surgery, Jagiellonian University, Krakow, Poland.
Department of Endoscopic, Metabolic and Soft Tissue Tumors Surgery.
Kopernika 21, 31-501 Kraków, Poland.
Tel. +48 608 55 23 23.
Email: magdalena.pisarska@uj.edu.pl.

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