

Contents lists available at [ScienceDirect](http://ScienceDirect.com)

International Journal of Surgery

journal homepage: www.journal-surgery.net

Original research

Early implementation of Enhanced Recovery After Surgery (ERAS[®]) protocol – Compliance improves outcomes: A prospective cohort study



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H I G H L I G H T S

- Implementation of ERAS protocol reduces postoperative complications and shortens length of stay.
- Introducing the ERAS protocol is however a gradual process.
- It is possible only through close cooperation, continuous education and evaluation.

A R T I C L E I N F O

Article history:

Received 17 February 2015

Received in revised form

29 March 2015

Accepted 28 June 2015

Available online 29 July 2015

Keywords:

Enhanced recovery after surgery

Laparoscopy

Colorectal cancer

Length of stay

A B S T R A C T

Enhanced Recovery After Surgery protocol in colorectal surgery allows shortening length of hospital stay and reducing complication rate. Despite the clear guidelines and conclusive evidence their full implementation and putting them into daily practice meets certain difficulties, especially in the early stage.

The aim of the study was to analyse the course of implementation of the ERAS protocol into daily practice on the basis of adherence to the protocol.

Group included 92 patients (43F/49M) with colorectal cancer submitted to laparoscopic resection during the years 2013–2014. Perioperative care in all of them based on ERAS protocol consisting of 16 items. Its principles and discharge criteria were based on the guidelines of the ERAS Society guidelines. The entire analysed group of patients was divided into 3 subgroups (30 patients) depending on the time from ERAS protocol implementation. We analysed the compliance with the protocol and its influence on length of hospital stay, postoperative complications and readmission rate in different subgroups.

The average compliance with the protocol differed significantly between groups and was 65% in group 1, 83.9% in group 2 and 89.6% in group 3. The compliance with subsequent protocol elements was different. The length of stay and complication rate was statistically different in analysed subgroups. The whole group demonstrated an inverse correlation between compliance and length of stay.

This analysis leads to the conclusion that the introduction of the ERAS protocol is a gradual process, and its compliance at the level of 80% or more requires at least 30 patients and the period of about 6 months. The initial derogation from the assumed proceedings is inevitable and should not discourage further action. Particular emphasis in the initial stage should be put on continuous training of personnel of all specialties and continuous evaluation of the results.

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1. Introduction

The advantages of the Enhanced Recovery After Surgery

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protocol in colorectal surgery are now very well documented in literature [1–4]. These include shorter hospital stay and reduced number of postoperative complications [5]. Randomized controlled trials confirmed the safety of ERAS programmes [6–10]. In 2013, guidelines on perioperative care for patients after resection of the colon and rectum were published [2,3]. Despite the clear guidelines and conclusive evidence on the legitimacy of their use, their full implementation and putting them into daily practice meets certain difficulties [11–13]. Firstly, their interpretation leaves a wide margin of discretion, which makes the individual elements of the protocol, and their number vary depending on the surgical department size and profile [14–16]. Secondly, effective implementation of ERAS requires close collaboration of a multidisciplinary team consisting of surgeons, anaesthetists, nurses, physiotherapists and dieticians. The specificity of a comprehensive approach to perioperative care leads to a situation when individual member breaking out from a large team can prevent the protocol's full implementation [12]. It turns out that even in hospitals where the ERAS protocol has been implemented for some time, adherence to some of its elements is incomplete [17,18]. Although there are several studies on the compliance with ERAS programmes, little attention was paid to the analysis of the early stages after introducing it into general practice.

2. Aim

The aim of the study was to analyse the course of implementation of the ERAS protocol into daily practice on the basis of adherence to the protocol. We assessed if compliance influences the length of hospital stay (LOS), postoperative complications and readmission rate.

3. Methods

Our department is a university tertiary referral medical center. We are mostly involved in elective treatment of abdominal surgical diseases. 80% of all procedures are performed laparoscopically (colorectal, gastric, pancreatic, bariatric, hepatobiliary, splenic and adrenal surgery). We perform about 100 colorectal procedures a year, and minimally invasive access is a method of choice in case of large bowel pathology. At the beginning of 2013, it was decided to introduce the ERAS protocol for general practice in patients after colorectal surgery. At the moment it is also routinely used in patients operated due to pathology of the stomach, pancreas, liver and due to morbid obesity.

The study included patients with colorectal cancer submitted to laparoscopic resection during July 2013 and June 2014. Perioperative care in all of them based on ERAS protocol consisting of 16 items (Table 1). Its principles and discharge criteria were based on the guidelines of the ERAS Society guidelines [2,3].

Before the implementation, an independent ERAS coordinator, not involved directly in the treatment process was appointed, and a series of trainings for the team was started. Further analysis excluded patients with distant metastases and patients in whom in addition to colorectal resection another multiorgan surgery was performed due to stage of the disease. The group also excluded patients with rectal cancer operated using the experimental hybrid TaTME technique (Transanal Total Mesorectal Excision), since it was introduced relatively recently. The entire analysed group of patients was divided into 3 subgroups depending on the time from ERAS protocol implementation.

The coordinator was responsible for the prospective collection of data while running a continuous audit and analysis of the results every 30 consecutive patients. After his report, and after identifying problems encountered during the implementation of the ERAS

protocol, additional training for staff was conducted, at the same time expanding the team and appointing the ERAS nurse responsible e.g. for preparing patients to stay in the hospital, care during their stay, stoma care education, assistance in complying with the protocol, and, after discharge from hospital, monitoring all patients via telephone. Currently, the team responsible for monitoring the implementation of the protocol consists of 10 people (5 surgeons, 2 anaesthetists, 2 nurses, physiotherapist and a dietician).

While assessing compliance, two parameters were analysed: the percentage of the entire protocol implementation for each patient, and the degree of implementation of each of its elements in certain periods of time (30 consecutive patients). For most elements a simple assessment was possible, based on a yes/no answer. The implementation of the item involving no bowel preparation consisted in the lack of bowel preparation in the case of surgery of the colon and upper part of the rectum, and preparation in the case of total mesorectal excision (TME) with defunctioning loop ileostomy. In the case of restrictive fluid therapy, the cut-off point was less 2500 ml intravenous fluids on the day of surgery. In case of opioids, the element was considered implemented if no opioid were administered postoperatively. The use of epidural anaesthesia (which was used mainly in the initial period) or transversus abdominis plane (TAP) block instead (used routinely in later stages) was treated equivalently.

Primary outcome was the compliance with the protocol and its influence on length of hospital stay, postoperative complications and readmission rate in different subgroups. A complication was defined using the Clavien-Dindo classification. Readmission was identified as any patient rehospitalisation within 30 days of surgery after discharge.

3.1. Statistical analysis

Due to the lack of normal data distribution with a normal distribution when comparing groups in terms of measurable and ordinal data, the Kruskal–Wallis analysis of variance test was used. Comparing groups in terms of nominal data was done using the chi-square test. The relationship between the compliance with the protocol and LOS was examined using Pearson's correlation. Statistical significance is accepted at $p < 0.05$.

All patients were informed about the study and gave their consent before including in the study group. The study obtained the ethical approval from the local Ethics Review Committee and has been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments.

4. Material

During the study period 104 patients underwent colorectal resection for cancer. 12 of them did not meet the inclusion criteria (Fig. 1).

The study group consisted of a total of 92 patients (43 women, 49 men); the mean age was 66.6 years (27–94 years). 62 patients had colonic and 30 rectal resection. Patients were divided into 3 groups: group 1 included the first 30 patients operated on after the introduction of the ERAS protocol, group 2 included another 30 patients operated on after the second cycle of training, and group 3 consisted of 32 patients after the next audit. Demographic characteristics and the types of procedures performed in the subgroups are presented in Table 2.

Subgroups were comparable to each other in terms of age, gender, body mass index (BMI), ASA (American Society of Anaesthesiologists), physical status, operative times, and the types of procedures performed (colon/rectum). We noticed however that there was a significant difference in intraoperative blood loss

Table 1
ERAS protocol used in our unit.

1. Preoperative counselling and patient's education
2. No bowel preparation (oral lavage in the 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 (placed for <24 h in case of TME)
10. TAP block
11. Avoiding opioids, multimodal analgesia (oral when possible - Paracetamol 4 × 1 g, Ibuprofen 2 × 200 mg, Metamizole 2 × 2.5 g, 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, 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 mobilisation on the first postoperative day (getting out of bed, going to toilette, walking along the corridor, at least 4 h out of bed)

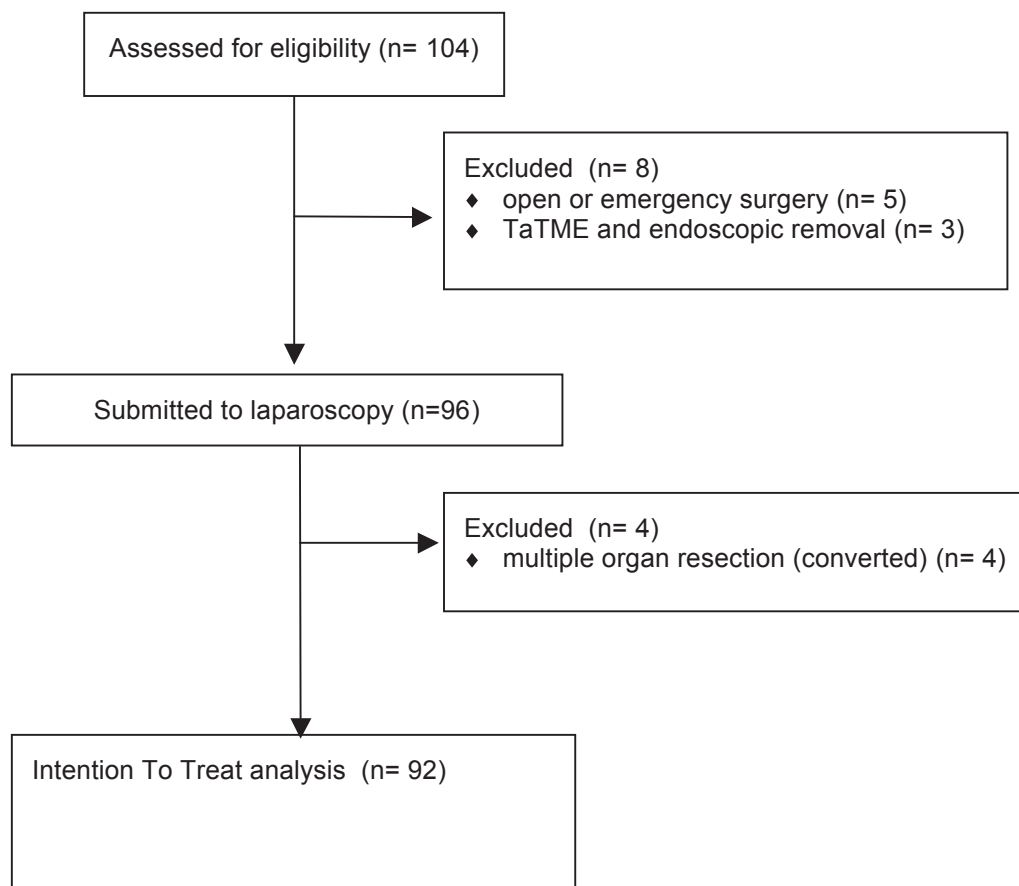


Fig. 1. ITT flow-chart.

between groups ($p = 0,0419$).

5. Results

The average compliance with the protocol differed significantly between groups and was 65% in group 1, 83.9% in group 2 and 89.6% in group 3 ($p < 0.0001$, Fig. 2).

A thorough analysis of implementation of the various elements of the ERAS protocol in subsequent periods is presented in Fig. 3.

While assessing the implementation of subsequent protocol elements, 3 groups of them were distinguished. The first group included: preoperative counselling, antithrombotic prophylaxis,

antibiotic prophylaxis, laparoscopy and avoiding nasogastric tubes. They were fully implemented from the very beginning, as they were the routine proceedings before the introduction of ERAS. Another group consisted of elements whose relatively good implementation already took place after the first audit, and did not change significantly after the second one. These include: no bowel preparation, preoperative carbohydrate loading, restrictive fluid therapy, PONV prophylaxis and early removal of catheters. The last group consists of elements that were introduced gradually, and a high percentage of implementation was only achieved in the last stage: no drains, no opioids, use of epidural/TAP-block analgesia, postoperative oxygen therapy, early oral nutrition, and early

Table 2
Demographic characteristics of patient groups.

Parameter	Group 1	Group 2	Group 3	Overall	p value
number of patients	30	30	32	92	–
females	14	9	20	43	0.0372
males	16	21	12	49	
mean age (years)	63.7	66.6	69.5	66.6	0.6387
BMI (kg/m ²)	26.2	25.5	26.0	25.9	0.3471
ASA 1	3	0	0	3	0.0271
ASA 2	18	20	17	55	
ASA 3	9	10	11	30	
ASA 4	0	0	4	4	
Procedures performed on:	Group 1	Group 2	Group 3	Overall	
colon	20	19	23	62	0.7692
rectum	10	11	9	30	
mean operative time (min.)	161	171	181	173	0.2940
mean intraoperative blood loss (ml)	63.7	98.3	72.4	76.7	0.0419

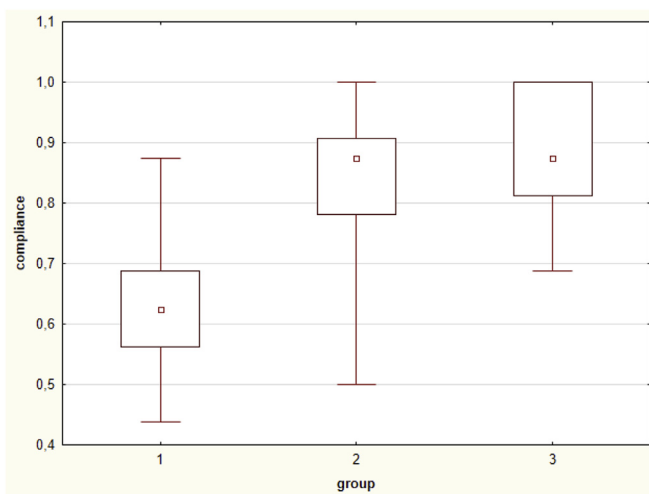


Fig. 2. The average compliance in different patient groups.

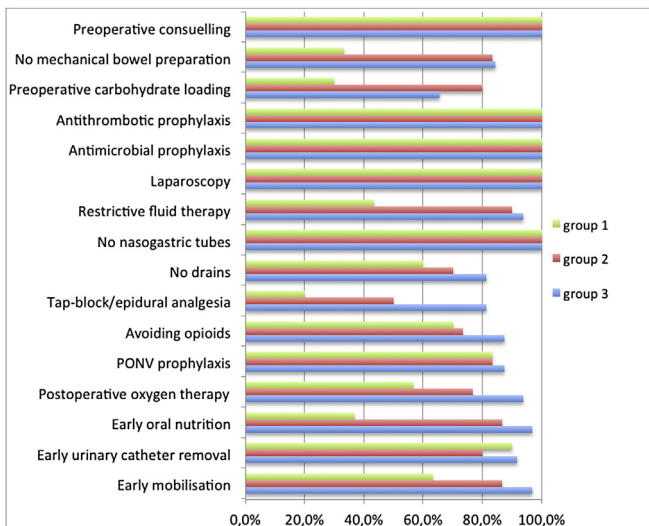


Fig. 3. Compliance in the individual elements of ERAS protocol.

mobilisation. Some elements (no bowel preparation, urinary catheter removal, no opioids, restrictive fluid therapy) have also been identified, which have failed to fully implement in all patients

despite all efforts.

The median LOS in group 1 was 5 days; in group 2–5 days; in group 3 - 3 days. Statistically significant differences were found between the groups ($p = 0.014$). Figs. 4 and 5 show the trend lines for the duration of hospital stay in consecutive patients and compliance.

It shows that the curve length of stay in the second period (patients 30–60) flattens. Similarly, the compliance trend line also flattens between 30 and 60 patient, when it starts to reach a value of 80%. Furthermore, the whole group demonstrated an inverse correlation between compliance and length of stay (Fig. 6).

Perioperative complications in group 1 were noted in 56% of patients; in group 2, 43% of patients; in group 3, 9.4% of patients. There is a statistically significant difference between groups 1 and 3 ($p < 0,0001$) and groups 2 and 3 ($p = 0.002$). There was no mortality within 30 days of surgery. The analysis of complications is shown in Table 3.

Readmission was necessary in a total of 9 patients (9.8%) (in 3, 4, and 2 patients in groups 1, 2 and 3 respectively). No significant differences between the groups were observed in this regard ($p = 0,5712$). 8 readmitted patients were treated conservatively, and one patient required reoperation in the sixth postoperative day because of diffuse peritonitis and intra-abdominal abscess.

6. Discussion

Introducing the ERAS protocol is possible and allows improving the results of treatment; it is however a gradual process. The workflow we have adopted, relying on the appointment of an ERAS coordinator combined with constant auditing and analysis of the results as well as the creation of a multidisciplinary ERAS team,

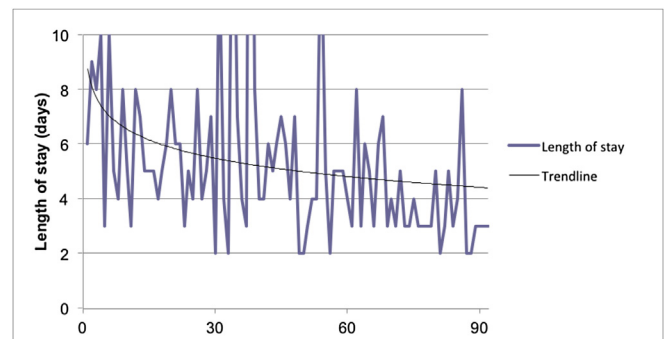


Fig. 4. Length of hospital stay in subsequent patients.

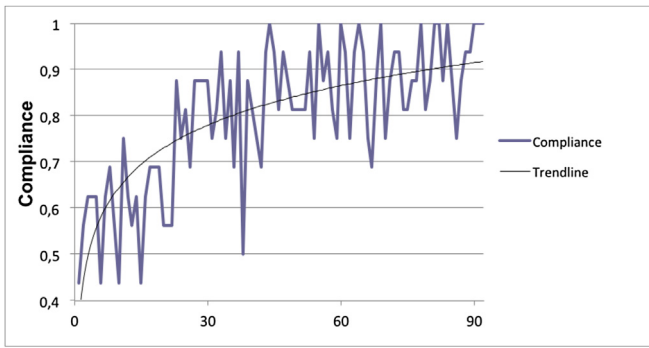


Fig. 5. Compliance with the protocol in subsequent patients.

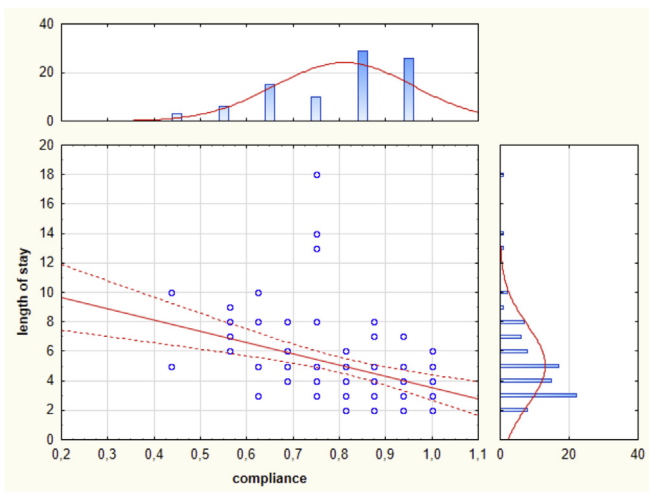


Fig. 6. Correlation between compliance and LOS.

Table 3
Complications in the study group.

Clavien-Dindo	Group 1	Group 2	Group 3	Overall
grade 1	14 (46.6%)	4 (13.3%)	3 (9.9%)	21 (22.8%)
grade 2	1 (3.3%)	4 (13.3%)	0	5 (5.4%)
grade 3a	0	2 (6.6%)	0	2 (2.2%)
grade 3b	2 (6.6%)	3 (9.9%)	0	5 (5.4%)
	Group 1	Group 2	Group 3	Overall
complicated	17 (56.7%)	13 (43.3%)	3 (9.4%)	33 (35.9%)
not complicated	13 (43.3%)	17 (56.7%)	29 (90.6%)	59 (64.1%)

allows achieving a high compliance in a relatively short time. We observed a rapid increase in the average number of implemented items, especially after the period covering the first 30 patients. In the second period, LOS and compliance curves were flattened (at the level of approximately 80%), which leads to the conclusion that, in our unit, this is the rough number of patients (for about 5–6 months) necessary to assimilate the new guidelines for staff conduct.

Not all elements could be introduced immediately; also, the implementation rate of changes differed depending on the element. Those of them that were part of the traditional perioperative care did not pose significant difficulties and were fully implemented from the beginning. Another group of ERAS elements has been identified, in which a high compliance was achieved relatively quickly (second group of analysed elements). We believe

that this was possible thanks to the cooperation of a motivated, coherent team of specialists from different groups: surgeons, anaesthetists, nurses, dieticians, physiotherapists, and social workers [19]. It is known that such approach significantly improves the overall perioperative care [20]. According to Carter and Kennedy, the most effective way to make changes in perioperative care is to establish a new protocol, build a multidisciplinary team responsible for its implementation, and appoint a person responsible for the continuous monitoring of the effects [19]. Our observations are in line with these assumptions. We believe that a successful introduction of the ERAS protocol was possible only through close cooperation, continuous education and evaluation of results. The size of the team is also significant, as is the profile of the hospital treating patients. While analysing multicentre results from Spain, Arroyo noted that the introduction of the ERAS protocol was much slower and more difficult in large multi-profiled centres compared to smaller departments similar to ours [21]. Some components of the ERAS protocol encountered difficulties in their implementation, which were overcome thanks to auditing and training. This situation may have been affected by factors such as the habit of traditional approach, lack of skills (e.g. in the case of TAP-block), fear of new and unproven workflows. Therefore, we decided to hold some additional information meetings following the analysis of the initial results, as well as further (very promising) results of the treatment, which contributed to the increase in trust for the new protocol. This naturally resulted in an improvement in adherence. What is also noteworthy, in a major part of items compliance, although high in the last period, does not reach 100%. The explanation of this phenomenon may be the fact that in some clinical situations, it is necessary to waiver from strict ERAS protocol. This is dictated by a more rational and safer approach. For instance, the need for bowel preparation in case of small lesions requiring precise location during intraoperative colonoscopy, or the need to leave the catheter in the urinary bladder after suturing the injured ureter. Moreover, the occurrence and severity of postoperative complications significantly affect the compliance.

The three groups we analysed were comparable in terms of demographics, operative times and types of surgery. Although there was a difference in mean intraoperative blood loss between them, in our opinion it was not clinically relevant. We found that the introduction of the ERAS protocol reduced postoperative complications and shortened LOS. Gustafsson has shown that the key element for the improvement of these parameters is to increase compliance [22]. Ferocci and Alcantara-Moral reached similar conclusions [23,24]. It is also important to monitor the results of treatment and the quality of implementation of the protocol on a regular basis, even despite its proper functioning. This issue is raised by Cakir et al. who showed that, despite the relatively high compliance in the first period, it was declining in subsequent years, which automatically translated into the results of treatment [25].

Undoubtedly, the success of the protocol depends on doctor-patient cooperation as well as appropriate preoperative education. Doing so speeds up the rehabilitation and motivates patients to a faster recovery [26,27]. One also cannot forget about ensuring the continuity of care after early discharge from hospital. In our unit, an ERAS nurse calls the patients on the first and third day after discharge. In addition, we have created a special 24/7-telephone number for all patients; they can contact our department in the case of alarming symptoms.

The introduction of new treatment regimens may be difficult, particularly in the surgical environment. The typical behaviour involves the fear of an increased complication and readmission rates, especially if LOS is shortened [16]. Favourable changes in treatment results already between the first and second groups were undoubtedly a strong argument in internal discussions on the

legitimacy of the use of the ERAS protocol. Moreover, Kehlet and Wilmore noted that despite the existence of strong evidence of benefit from the use of ERAS, its full introduction into daily practice usually occurs slowly, hence the need for a process of gradual changes that will allow the environment to get used to this type of procedure. The support of the persons responsible for the management of medical units and adoption of comprehensive guidelines by scientific societies are also significant [28]. In our country, the ERAS protocol is virtually unknown in the surgical and anaesthesia communities. Therefore, some believe that introducing a multi-element protocol may be more of a revolution than an evolution in perioperative care. The greatest difficulty lies in revising the many years of traditional patterns and dogmas [29]. This may be aided by clear guidelines supported by strong scientific evidence [30]. Staff should be fully trained prior to the introduction of the ERAS protocol, preferably with a multidisciplinary series of meetings to discuss any issues that may arise during the introduction phase.

This analysis leads to the conclusion that the introduction of the ERAS protocol is a gradual process, and its compliance at the level of 80% or more requires at least 30 patients and the period of about 6 months. The initial derogation from the assumed proceedings is inevitable and should not discourage further action. Particular emphasis in the initial stage should be put on continuous training of personnel of all specialties and continuous evaluation of the results. Using own observations and results, combined with other research studies and their presentation during regular multidisciplinary meetings can influence the attitudes of staff and accelerate the adoption of the changes. This easily translates into improving the adherence to the protocol and better outcomes.

Ethical approval

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

Sources of funding

The publication of this paper was supported by the Faculty of Medicine, Jagiellonian University Medical College, Leading National Research Centre (KNOW) 2012–2017.

Author contribution

Michał Pędziwiatr – Study conception and design, Acquisition of data, Analysis and interpretation of data, Drafting of manuscript, Critical revision of manuscript.

Mikhail Kisialewski – Acquisition of data, Analysis and interpretation of data, Drafting of manuscript, Critical revision of manuscript.

Mateusz Wierdak - Acquisition of data, Analysis and interpretation of data.

Maciej Stanek - Acquisition of data, Analysis and interpretation of data.

Michał Natkaniec –, Analysis and interpretation of data Drafting of manuscript Acquisition of data, Critical revision of manuscript.

Maciej Matłok – Study conception and design, Drafting of manuscript, Critical revision of manuscript.

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

Piotr Małczak – Analysis and interpretation of data.

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

Conflicts of interest

All authors declare no conflict of interest.

Guarantor

The Guarantor is the one or more people who accept full responsibility for the work and/or the conduct of the study, had access to the data, and controlled the decision to publish.

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Acknowledgement

The publication of this paper was supported by the Faculty of Medicine, Jagiellonian University Medical College, Leading National Research Centre (KNOW) 2012–2017.

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