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High compliance to ERAS protocol does not improve overall survival in patients treated for resectable advanced gastric cancer

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Abstract

Introduction: The ERAS (Enhanced Recovery after Surgery) protocol revolutionized perioperative care for gastrointestinal surgical procedures. However, little is known about the association between adherence to the ERAS protocol in gastric cancer surgery and the oncological outcome.

Aim: To explore the relation between adherence to the ERAS protocol and the oncological outcome in gastric cancer patients.

Material and methods: We performed a retrospective analysis of a prospectively collected database of patients treated for gastric cancer between 2013 and 2016. All patients were treated perioperatively with a 14-item ERAS protocol. Every patient underwent regular follow-up every 3 months for 3 years after surgery. 80% compliance to the ERAS protocol was the goal during perioperative care. Based on the level of compliance, patients were divided into group 1 and group 2 (compliance of $\geq 80\%$ and $< 80\%$, respectively).

Results: Compliance to the ERAS protocol was not a risk factor for diminished overall survival – probability of 3-year survival was 63% in group 1 and 56% in group 2 ($p = 0.75$). The proportional Cox model revealed that only stage III gastric cancer was a risk factor of poor prognosis in patients operated on for gastric cancer (HR = 7.89, 95% CI: 2.96–20.89; $p = 0.0001$).

Conclusions: High adherence to the ERAS protocol did not improve overall survival in our 3-year observation. Only the stage of the disease, according to the AJCC classification, was identified as a risk factor for poor prognosis.

Key words: enhanced recovery after surgery, gastric cancer, gastrectomy, laparoscopy, adherence.

Introduction

Minimally invasive surgery and the ERAS (Enhanced Recovery after Surgery) protocol revolutionized perioperative care for gastrointestinal surgical procedures [1–4]. While the most extensive research involved colorectal diseases, ERAS was found to be beneficial in other branches of surgery [5, 6]. Its ap-

plication diminished postoperative morbidity and reduced hospital length of stay [6]. In 2014 the ERAS Society published its guidelines for perioperative care after gastrectomy [7]. Many versions of the ERAS protocol, however, are still being used in different surgical departments [6, 8]. Nevertheless, the main elements of the ERAS protocol remain common [6]. Many authors report that introduction of the

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ERAS protocol improves the short-term outcomes as well as compliance to its elements [9]. However, the ERAS protocol is not as commonly used in gastric surgery. Studies on long-term outcomes in this field are lacking, too [10]. The advances in surgical technique currently are marginal; therefore we should investigate meticulously other items contributing to final outcomes of gastric cancer surgery [11]. Recently, several papers revealed that compliance to the ERAS protocol may affect long-term survival in patients with cancer [12, 13], which is the most objective benchmark in assessment of oncological treatment. The reason for this association is still under investigation. So far, no such influence has been investigated regarding gastric cancer surgery.

Aim

To evaluate whether adherence to the ERAS protocol affects survival in patients undergoing gastric cancer surgery.

Table I. ERAS protocol used in our department

1. Preoperative counseling and patient's education
2. Pre-operative carbohydrate loading (400 ml of Nutricia preOp 2 h prior to surgery)
3. Antithrombotic prophylaxis (Clexane 40 mg s.c. starting in the evening prior to surgery)
4. Antibiotic prophylaxis (preoperative ceftriaxone 2 g i.v. 30–60 min prior surgery)
5. Laparoscopic surgery
6. Balanced intravenous fluid therapy (< 2500 ml of intravenous fluids during the day of surgery, less than 150 mmol sodium)
7. No nasogastric tubes postoperatively
8. No drains left routinely
9. TAP block and standard anesthesia protocol
10. Avoiding opioids, multimodal analgesia (oral when possible – paracetamol 4 × 1 g, ibuprofen 2 × 200 mg, metamizole 2 × 500 mg, or ketoprofen 2 × 100 mg)
11. Postoperative oxygenation therapy (4–6 l/min)
12. Early oral feeding (oral nutritional supplement 4 h postoperatively – Nutricia Nutridrink or Nestlé Impact, light hospital diet and oral nutritional supplements on the first postoperative day, full hospital diet on the second postoperative day)
13. Urinary catheter removal on the first postoperative day
14. 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)

Material and methods

We performed a retrospective analysis of a prospective collected database of patients treated for gastric cancer between 2013 and 2016. In 2012 laparoscopic total gastrectomy became the method of choice in gastric cancer. Qualification for preoperative chemotherapy was performed based on ESMO guidelines [14]. All patients were treated perioperatively with a 14-item ERAS protocol (Table I).

Every patient underwent regular follow-up every 3 months for 3 years after surgery. It included general check-up and computed tomography imaging for recurrence and distant metastasis evaluation.

Operative technique

All patients underwent D2 gastrectomy with spleen preservation in the laparoscopic approach. Reconstruction of the digestive tract was done with the Roux-en-Y approach. The esophago-jejunal anastomosis was carried out with a linear 45 mm GIA stapler and jejuno-jejunal anastomosis. In both anastomoses the common orifice was closed by a hand-sewn suture. No routine drainage of the peritoneal cavity was used.

Inclusion criteria

Inclusion criteria were: 18 years old, histologically confirmed gastric adenocarcinoma, procedure performed with a laparoscopic approach (gastrectomy with D2 lymphadenectomy), and follow-up of at least 12 months. Patients with stage IV cancer according to the AJCC classification, patients operated initially with an open approach and patients after conversion, patients who died within 30 days after the initial procedure, and patients requiring multivisceral resections and patients with locally inoperable cancer were all excluded from the analysis.

Outcome measures

For the study purposes, patients were divided into two groups depending on their compliance to the ERAS protocol. Patients with compliance of equal to or more than 80% formed group 1. Patients with compliance of less than 80% represented group 2. We did not include postoperative elements of the ERAS protocol in the adherence calculation. As a result, compliance to the ERAS protocol was calculated by dividing the number of components fulfilled by 11.

The primary outcome was 3-year overall survival. The secondary outcomes were perioperative complications, length of stay, and recovery parameters.

Ethical approval

The study was approved by the local Ethics Review Committee (approval number 1072.6120.225.2017). All procedures were performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments.

Statistical analysis

All data were analyzed with StatSoft Statistica v.13 (StatSoft Inc., Tulsa, OK, USA). The results are presented as mean \pm standard deviation (SD), median and interquartile range (IQR), and hazard ratio (HR) with 95% confidence intervals (CI) when appropriate. The study of categorical variables used the χ^2 test of independence. The Shapiro-Wilk test was used to check for normal distribution of data and Student's test was used for normally distributed quantitative data. For non-normally distributed quantitative variables, the Mann-Whitney *U* test was used. For the purposes of further analysis, the entire group of patients was divided into subgroups depending on compliance with the ERAS protocol (< 80% and \geq 80%). This was the target compliance with the ERAS protocol in our department. Survival data were analyzed according to the Kaplan-Meier method. The log-rank test was used to detect differences between groups. Univariate and multivariate analysis was performed using Cox proportional hazards. The variables with $p < 0.05$ were included in the model. Results were considered statistically significant when the p -value was found to be less than 0.05.

Results

During the study period, 97 patients with gastric cancer underwent total gastrectomy. Eventually, 78 patients were included in the analysis (51 males and 27 females). Mean age was 61.2 ± 10.7 years. Mean compliance to the ERAS protocol in the whole group was 75.6%.

Group 1 (patients with compliance > 80%) included 34 patients and group 2 (patients with compliance < 80%) included 44 patients. The groups did not differ in terms of sex, age, BMI, ASA class

and comorbidities. Both groups were also similar in terms of stage of the disease. Forty-six (58%) patients required adjuvant chemotherapy; the number of individuals was not statistically different between groups. The data are summarized in Table II.

A subgroup analysis demonstrated that the patients in group 1 and group 2 did not statistically differ in terms of 3-year overall survival (Figure 1).

Patients in group 1 required shorter length of stay in the hospital (mean: 6.0 ± 4.1 days vs. 10.4 ± 13.3 days; $p = 0.0052$). However, multivariate regression analysis revealed that only complications were a risk factor for prolonged hospitalization ($\beta = -0.68$; 95% CI: $(-0.95, -0.42)$; $p < 0.001$). Patients with high compliance had a lower complication rate (20.6% vs. 29.5%), although the result did not reach statistical significance.

Univariate analysis of overall survival identified only stage III AJCC as a risk factor of poor prognosis in patients operated on due to gastric cancer (HR = 7.89, 95% CI: 2.96–20.89; $p = 0.0001$; Table III).

According to Kaplan-Maier curves, probability of 3-year overall survival for group 1 was 63% and 56% (12/44) for group 2 (Figure 2). These two groups did not differ statistically significantly ($p = 0.75$).

Kaplan-Maier curves show decreased probability of overall survival in patients with stage III AJCC, which is 28 in 3-year observation (Figure 3). In patients with stage I and II overall survival was 87% ($p < 0.001$).

We also analyzed the influence of complications on overall survival. There were no statistically significant differences between groups of patients with no complications, patients with Clavien-Dindo I–II complications and patients with Clavien-Dindo III–IV complications ($p = 0.22$).

Discussion

Our study showed that compliance to the ERAS protocol positively impacts short-term outcomes, but it does not influence 3-year survival. The only factor that worsens the patient's prognosis is the stage of the disease. This is to our best knowledge the first study investigating this problem.

Compliance to ERAS seems not to influence patient survival. Our findings are contrary to Gustafsson *et al.*, who observed improved long-term outcomes in colorectal cancer surgery in patients with high compliance to the ERAS protocol [12]. Pisarska

Table II. Demographic analysis of patient group

Parameter	Total	Group 1	Group 2	P-value
Number of patients, <i>n</i>	78	34	44	–
Females, <i>n</i> (%)	27 (34.6)	10 (29.4)	17 (38.6)	0.3939
Males, <i>n</i> (%)	51 (65.4)	24 (70.6)	27 (61.4)	
Age, mean ± SD [years]	61.2 ±10.7	61.1 ±10.3	61.3 ±11.2	0.9466
BMI, mean ± SD [kg/m ²]	25.7 ±4.1	25.5 ±3.7	25.9 ±4.4	0.7772
ASA 1, <i>n</i> (%)	1 (1.3)	1 (2.9)	–	0.5581
ASA 2, <i>n</i> (%)	62 (79.5)	27 (79.4)	35 (79.5)	
ASA 3, <i>n</i> (%)	14 (17.9)	6 (17.6)	8 (18.2)	
ASA 4, <i>n</i> (%)	1 (1.3)	–	1 (2.3)	
Any comorbidity, <i>n</i> (%)	53 (67.9)	26 (76.5)	27 (61.4)	0.1525
Cardiovascular, <i>n</i> (%)	19 (24.4)	8 (23.5)	11 (25)	0.8806
Hypertension, <i>n</i> (%)	28 (35.9)	11 (32.4)	17 (38.6)	0.5654
Diabetes, <i>n</i> (%)	9 (11.5)	2 (5.9)	7 (15.9)	0.1553
Liver disease, <i>n</i> (%)	5 (6.4)	1 (2.9)	1 (2.3)	0.8536
Operative time, median (IQR) [min]	307.4 ±90.9	275 (242–332)	300 (240–355)	0.6511
Intraoperative blood loss, median (IQR) [ml]	317 ±272.6	200 (200–300)	200 (150–500)	0.4491
Conversion, <i>n</i> (%)	3 (3.8)	1 (2.9)	2 (4.5)	0.7149
Neoadjuvant treatment, <i>n</i> (%)	53 (67.9)	24 (70.6)	29 (65.9)	0.6599
Adjuvant treatment, <i>n</i> (%)	46 (59)	19 (56)	27 (61)	0.8037
AJCC Stage 0, <i>n</i> (%)	5 (6.4)	2 (5.9)	3 (6.8)	0.7004
AJCC Stage I, <i>n</i> (%)	22 (28.2)	11 (32.4)	9 (20.5)	
AJCC Stage II, <i>n</i> (%)	20 (25.6)	7 (20.6)	11 (25)	
AJCC Stage III, <i>n</i> (%)	31 (39.7)	14 (41.2)	21 (47.7)	
Tumor grade G1, <i>n</i> (%)	1 (1.3)	–	1 (2.3)	0.5329
Tumor grade G2, <i>n</i> (%)	46 (59.0)	21 (61.8)	25 (56.8)	
Tumor grade G3, <i>n</i> (%)	31 (39.7)	13 (38.2)	18 (40.9)	
Time to first flatus, mean ± SD [days]	2.6 ±1.2	2.6 ±0.9	2.6 ±1.4	0.9874
Patients without complications, <i>n</i> (%)	58 (74.4)	27 (79.4)	31 (70.7)	0.3656
Patients with complications, <i>n</i> (%)	20 (25.6)	7 (20.6)	13 (29.5)	
Clavien-Dindo 1, <i>n</i> (%)	3	2 (5.9)	1 (2.3)	0.4358
Clavien-Dindo 2, <i>n</i> (%)	6 (7.7)	1 (2.9)	5 (11.4)	
Clavien-Dindo 3, <i>n</i> (%)	7 (9.0)	2 (5.9)	5 (11.4)	
Clavien-Dindo 4, <i>n</i> (%)	3 (3.8)	1 (2.9)	2 (4.5)	
Length of hospital stay, mean ± SD [days]	8.3 ±10.1	6.0 ±4.1	10.4 ±13.3	0.0052
Length of hospital stay, median (IQR) [days]	6 (4–8)	5 (4–6)	7 (5–8)	
Readmission, <i>n</i> (%)	11 (14.1)	6 (17.6)	5 (11.4)	0.4319

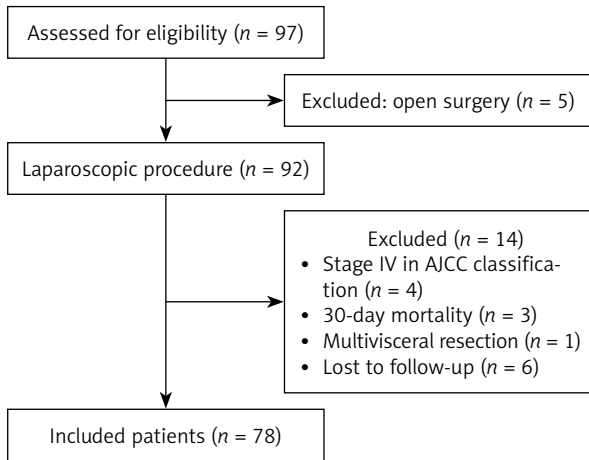


Figure 1. Patients flow through the study

et al. also found benefit of adherence to the ERAS protocol, observing better overall survival in patients with at least 80% compliance [13]. However, it is not easy to explain the why ERAS could possibly improve oncological outcomes. Asklid *et al.* reported that balanced fluid therapy in the perioperative course also could improve 5-year survival [15]. The topic is still under investigation, and it is highly likely that better survival is a consequence of many marginal gains in the perioperative period.

The ERAS protocol improves short-term outcomes, diminishing the rate of postoperative complications [16–18]. Some authors suggest that complications may negatively impact long-term survival [19]. Wang *et al.* performed a meta-analysis in which they found that postoperative complications

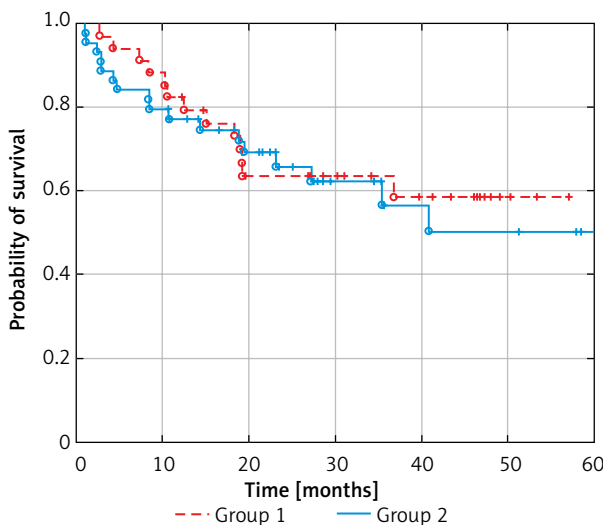


Figure 2. Kaplan-Meier survival estimates according to ERAS protocol adherence

Table III. Univariate analysis of overall survival

Parameter	HR (95% CI)	P-value
Sex (female vs. male)	1.13 (0.52–2.48)	0.7534
Age (< 65 vs. ≥ 65 years)	1.01 (0.47–2.16)	0.9781
BMI (< 25 vs. ≥ 25 kg/m ²)	0.49 (0.22–1.07)	0.0729
ASA scale (I–II vs. III–IV)	1.42 (0.61–3.37)	0.4229
Neoadjuvant treatment (yes vs. no)	1.09 (0.49–2.45)	0.8255
Cardiovascular disease (no vs. yes)	1.35 (0.59–3.09)	0.4812
Hypertension (no vs. yes)	0.88 (0.40–1.97)	0.7659
Diabetes (no vs. yes)	0.77 (0.18–3.28)	0.7283
Liver disease (no vs. yes)	1.02 (0.58–1.28)	0.4334
Renal disease (no vs. yes)	1.27 (0.46–1.72)	0.7318
Adherence to ERAS (< 80%)	0.83 (0.37–1.85)	0.6620
AJCC (I–II vs. III)	7.87 (2.96–20.89)	< 0.0001
Adjuvant chemotherapy	2.5 (0.51–12.32)	0.2500
Duration of the surgery (< 300 vs. > 300 min)	0.81 (0.38–1.71)	0.5715
Intraoperative blood loss (< 200 vs. > 200 ml)	1.58 (0.21–2.02)	0.6113
Postoperative complications (no vs. yes)	1.79 (0.79–3.99)	0.1571

correlate with poor survival in patients with stage II and III of the disease [20]. However, in patients with stage I complications it had no impact on the

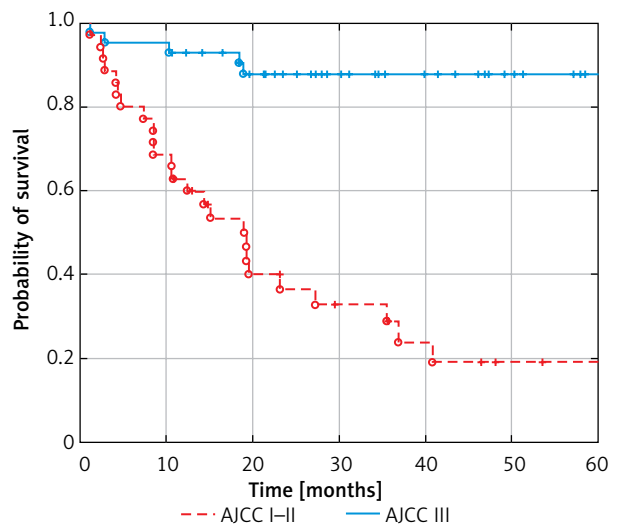


Figure 3. Kaplan-Meier survival estimates according to stage of the disease

oncological outcomes [20]. On the other hand, Climent reported the following risk factors for worse survival: male gender, stage III of the disease and D1 lymphadenectomy; complications however were not associated with worse long-term prognosis [21]. In our study, only stage III cancer was a risk factor for poor survival. However, we did not assess the type of lymphadenectomy, because D2 lymphadenectomy in our unit is performed routinely.

Patients with high compliance had a significant shorter length of stay in comparison to those with low compliance. This result are in line with many other studies, as shortening of LOS is one of the main benefits of the ERAS protocol reported in the literature. Li *et al.* in their meta-analysis of 6 randomized control trials confirmed the benefit also for patients undergoing gastrectomy for gastric cancer [22].

What is important is that the ERAS protocol has many different modifications. Implemented protocols vary, including between 12 and 25 elements [23–25]. In our department we use a 14-element protocol for gastric cancer, and 16 elements for colorectal procedures [13, 26]. However, most of the elements are common for all ERAS protocols.

In our study we decided not to include postoperative elements in ERAS adherence calculation. Also, in our high compliance group, we observed a significantly shorter length of hospital stay. Moreover, we observed fewer Clavien-Dindo II–IV complications in the high compliance group, although the data did not reach statistical significance. On the other hand, Aarts *et al.* found that postoperative components have the strongest impact on overall result [27]. Having said that, they still underline the significance of preoperative elements. Kehlet also stresses that core elements of ERAS improve the final outcomes [28]. We focused on pre- and intraoperative elements of ERAS, because they are mostly staff-dependent. Moreover, these elements influence the compliance with postoperative elements, which in this situation could be regarded as an outcome. It is also worth remembering that not only perioperative care but also proper surgical technique with D2 lymphadenectomy and neoadjuvant treatment are the basis of a good final outcome.

There are some limitations of our study. Firstly, our sample size is fairly small and some subgroups might be underpowered for adequate statistical analysis, especially in patients with Clavien-Dindo grade III and IV complications. Secondly, we also

used the national personal identification number database to gather data on overall survival, which allows us to access only date of death but not information whether the death was cancer-specific. Next, the impact of the learning curve of laparoscopic gastrectomy has to be taken into consideration due to the complexity of the procedure requiring a significant number of cases for proficiency [29]. That could be a possible source of bias in the early stages of the study. Finally, we do not have complete information about adjuvant therapy, since some of our patients chose the treatment in other oncological centers.

Conclusions

High adherence (80% and higher) to the ERAS protocol does not improve overall survival in our 3-year observation. Only the stage of the disease according to the AJCC classification was identified as a risk factor for poor prognosis.

Conflict of interest

The authors declare no conflict of interest.

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