

THE USE OF THE ENHANCED RECOVERY AFTER SURGERY (ERAS) PROTOCOL IN PATIENTS UNDERGOING LAPAROSCOPIC SURGERY FOR COLORECTAL CANCER – A COMPARATIVE ANALYSIS OF PATIENTS AGED ABOVE 80 AND BELOW 55

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Age is one of the principal risk factors for colorectal adenocarcinoma. To date, older patients were believed to achieve worse treatment results in comparison with younger patients due to reduced vital capacity. However, papers have emerged in recent years which confirm that the combination of laparoscopy and postoperative care based on the ERAS protocol improves treatment results and may be particularly beneficial also for elderly patients.

The aim of the study was to compare the outcomes of laparoscopic surgery for colorectal cancer in combination with the ERAS protocol in patients aged above 80 and below 55.

Material and methods. The analysis included patients aged above 80 and below 55 undergoing elective laparoscopic colorectal resection for cancer at the ²nd Department of General Surgery of the Jagiellonian University. They were divided into two groups according to their age: ≥ 80 years of age (group 1) and ≤ 55 years of age (group 2). Both groups were compared with regard to the outcome of surgery: length hospital stay, complications, hospital readmissions, degree of compliance with the ERAS protocol, and recovery parameters (tolerance of oral nutrition, mobilisation, need for opioids, restored gastrointestinal function).

Results. Group 1 comprised 34 patients and group 2, 43 patients. No differences were found between both groups in terms of gender, BMI, tumour progression or surgical parameters. Older patients typically had higher ASA scores. No statistically significant differences were found with regard to the length hospital stay following surgery (5.4 vs 7 days, $p=0.446481$), the occurrence of complications (23.5% vs 37.2%, $p=0.14579$) or hospital readmissions (2.9% vs 2.4%). The degree of compliance with the ERAS protocol in group 1 and 2 was 85.2% and 83.0%, respectively ($p=0.482558$). Additionally, recovery parameters such as tolerance of oral nutrition (82.4% vs 72.1%, $p=0.28628$) and mobilisation (94.1% vs 83.7%, $p=0.14510$) within 24 hours of surgery did not differ among the groups. However, a smaller proportion of older patients required opioids in comparison with younger patients (26.5% vs 55.8%, $p=0.00891$).

Conclusions. Similar levels of compliance with the ERAS protocol may be achieved among patients aged ≥ 80 and younger patients. When laparoscopy is combined with the ERAS protocol, age does not seem to be a significant factor that could account for worse outcomes. Therefore, older patients should not be excluded from perioperative care based on ERAS principles.

Key words: ERAS protocol, fast track protocol, postoperative care, colorectal cancer, colorectal surgery, advanced age, laparoscopic surgery

The constantly increasing incidence of colorectal cancer in developed countries is inextricably linked with the population's increased life expectancy: advanced age is one of the principal risk factors for adenocarcinoma (1, 2). It is estimated that in the near future even 35-45% of new cases of colorectal cancer will affect patients above 80 years of age (3). Elderly patients constitute a special group because their vital capacity is reduced which negatively affects treatment outcomes (4). Therefore, strong emphasis is placed on reducing the injury caused by surgery. Earlier studies confirmed that older patients could benefit particularly from minimally invasive techniques; in this age group, these techniques are also associated with less pain, a quicker return to activity, less complications and shorter hospitalisation periods (5, 6, 7).

For over a decade, more and more hospitals have been routinely using the Enhanced Recovery After Surgery (ERAS) protocol. As shown by recent meta-analyses, this procedure is associated with a significantly reduced risk of complications (even up to 40%) and shorter hospitalisation (in the case of both open and laparoscopic surgery) (8, 9). Opponents argue that not all patients are suitable candidates for the ERAS protocol (10). Meanwhile, some papers have also highlighted the possibility of using this protocol in older patients (11-14). However, the cut-off point adopted by most of these papers was the age 65 threshold; in light of the current demographic situation among patients with colorectal cancer, this may obviously distort results and lead to conflicting conclusions. Consequently, this study aimed to assess the possibility of implementing the ERAS protocol in combination with laparoscopic surgery in patients above 80 years of age in comparison with patients who are relatively very young according to colorectal cancer epidemiology.

This study aimed to compare the outcomes of laparoscopic surgery for colorectal cancer in combination with the ERAS protocol in patients aged above 80 and below 55.

MATERIAL AND METHODS

The analysis was performed on consecutive patients who underwent elective laparoscopic large bowel resection due to cancer at the 2nd

Department of General Surgery of the Jagiellonian University Medical College between January 2012 and September 2015. All data were collected prospectively and the results were subsequently analysed. The inclusion criteria were: age over 80 or under 55, elective laparoscopic surgery for verified colorectal adenocarcinoma and perioperative care based on the ERAS protocol. It was based on the guidelines developed by the ERAS Society concerning perioperative care after colorectal surgery (15, 16). Patients who were initially operated on using open approach or undergoing emergency surgery, patients who underwent multiorgan resection, and patients with rectal cancer undergoing transanal total mesorectal excision (TaTME) or transanal endoscopic microsurgery (TEM) were excluded from the study. Patients with concomitant inflammatory bowel diseases and patients in whom the ERAS protocol could not be implemented (e.g. patients who were admitted to the intensive care unit immediately admitted surgery) were also excluded.

For the purpose of the analysis, patients were divided into two groups depending on age. Older patients (>80 years of age) constituted the first group while younger patients (aged <55) were included in the second group.

The endpoints included: length of hospital stay (LOS), complication rate (based on the Clavien-Dindo classification), 30-day readmission rate, and degree of compliance with the protocol. The latter was calculated similarly to Gustafsson et al. based on the presence or lack of 13 elements of perioperative care which were at the discretion of the consultant surgeon (17). Additionally, the postoperative recovery period was assessed based on the following parameters: tolerance of oral nutrition within 24 hours of surgery (oral nutrition was implemented in all patients in the evening of the day of surgery), patient mobilisation within 24 hours of surgery (ability to sit without help, short walk to the toilet: all patients were actively mobilised by the medical personnel on the day of surgery), ability to pass flatus, and the need for opioids in the first 24 hours after surgery. Hospital discharge criteria included full mobilisation, good tolerance of oral nutrition, no need for intravenous fluid and drug administration, and lack of complications. All cases of hospitalisation within 30 days of discharge from hospital after surgery were considered as readmission.

The study was approved by the Ethical Review Committee of the Jagiellonian University. All procedures were applied in accordance with the ethical standards laid out in the 1975 Declaration of Helsinki and its subsequent revisions.

Statistical analysis was performed with Statsoft STATISTICA version 10. Qualitative variables were analysed using the chi-square test. In the case of quantitative variables, the Mann-Whitney U test was used to assess the statistical significance of factors once normal distribution in groups was disproved. When normal distribution was proved, calculations were made using the student's t-test for independent samples. The adopted statistical significance threshold was $p < 0.05$.

Material

During the analysed period of time, a total of 297 colorectal cancer patients were operated on in our Department. Of those, 17 patients who received emergency surgery or in whom the procedure was initially performed using the open approach, and 22 rectal cancer patients who received TEM or TaTME surgery were excluded from the study. 10 patients were excluded from further analysis due to multiorgan resection. Moreover, 168 patients aged 55-80 were also excluded (fig. 1).

Ultimately, 34 patients were included in group 1 and 43 patients were included in group 2. Table 1 shows demographic data and surgical parameters in both groups. The mean age in group 1 was 84.4 years and in group 2, 47.7 years. Statistically significant differences were found in the distribution of surgical risk according to ASA classification in both groups. No other differences were found between the groups in terms of other demographic data such as gender, BMI or tumour progression. The groups varied significantly in terms of the type of surgery. Right hemicolectomy was the most common surgical procedure in group 1 (44.1%) while low anterior resection was most common in group 2 due to tumour location (39.6%). The mean operative time and intraoperative blood loss were similar in both groups. In comparison with group 1, stoma was performed significantly more often in group 2 which was undoubtedly associated with the type of surgical procedure (32.6% vs 11.8%, $p = 0.0277$).

RESULTS

The median LOS was 5 days and was the same for both groups ($p = 0.446481$). Table 2 shows an analysis of the occurrence and type of complications; no statistically significant difference was found between both groups

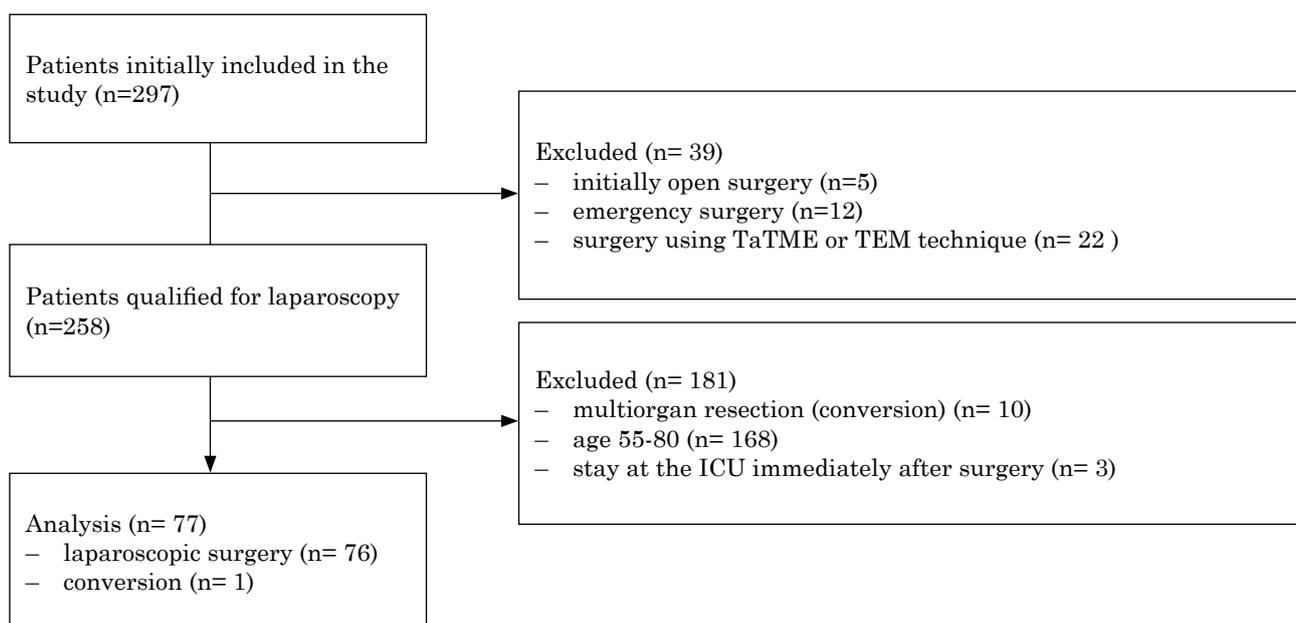


Fig. 1. Patients included in the analysis

Table 1. Demographic and surgical characteristics

Parameters	Group 1 ≥80 years of age	Group 2 ≤55 years of age	p value
Number of patients, n (%)	34	43	-
Women, n (%)	12 (35,3%)	20 (46,5%)	0,31993
Men, n (%)	22 (64,7%)	23 (53,5%)	
Mean age, years ± SD	84,4±3,5	47,7±7,4	-
Median age, years (IQR)	83 (82-87)	50 (44-54)	-
BMI, kg/m ² ± SD	25,4±4,1	26,6±5,4	0,315575
ASA 1, n (%)	-	3 (7%)	<0,00001
ASA 2, n (%)	5 (14,7%)	38 (88,4%)	
ASA 3, n (%)	25 (73,5%)	2 (4,6%)	
ASA 4, n (%)	4 (11,8%)	-	
AJCC stage I, n (%)	13 (38,2%)	18 (41,9%)	0,321020
AJCC stage II, n (%)	12 (35,3%)	9 (20,9%)	
AJCC stage III, n (%)	4 (11,8%)	11 (25,6%)	
AJCC stage IV, n (%)	5 (14,7%)	5 (11,6%)	
Right hemicolectomy, n (%)	15 (44,1%)	12 (27,9%)	0,01379
Left hemicolectomy, n (%)	2 (5,9%)	1 (2,3%)	
Sigmoid resection, n (%)	11 (32,4%)	10 (23,3%)	
Low anterior rectal resection, n (%)	3 (8,8%)	17 (39,6%)	
Hartmann's procedure	3 (8,8%)	1 (2,3%)	
Abdominoperineal amputation of the rectum, n (%)	-	2 (4,6%)	
Conversion, n (%)	1 (2,9%)	-	-
Stoma, n (%)	4 (11,8%)	14 (32,6%)	0,02770
Mean operative time, min ± SD	173±54,2	188,2±57,8	0,273679
Median operative time, min (IQR)	180 (135-210)	180 (150-220)	
Mean blood loss, ml ± SD	93,1±96,8	72,3±63,5	0,447263
Median blood loss, ml (IQR)	50 (30-100)	50 (50-100)	

(23.5% vs 37.2%, $p=0.19454$). No differences were also found in the 30-day hospital readmission rate (2.9% vs 2.4%).

Analysis of particular elements of perioperative care showed that the of compliance with the ERAS protocol in group 1 and 2 was 85.2 ± 14.3 and 81.5 ± 14.1 , respectively ($p=0.482558$). Figure 2 shows the performance

of the 13 elements of the ERAS protocol that were used to assess protocol compliance in both groups.

No differences were found in recovery parameters such as patient mobilisation and tolerance of oral nutrition during the first 24 hours within surgery in both groups (tab. 3). However, a smaller proportion of older patients required

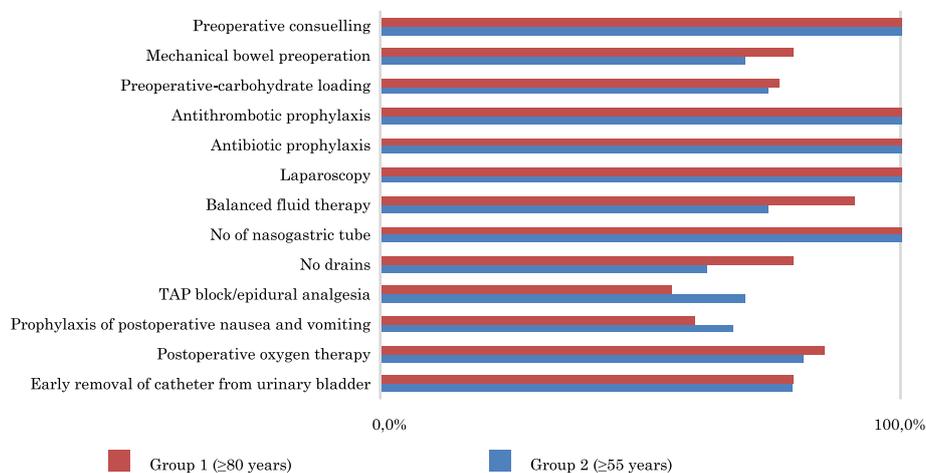


Fig. 2. Compliance with elements of ERAS protocol in our Department

Table 2. Postoperative results

Parameters	Group 1 ≥ 80 years of age	Group 2 ≤ 55 years of age	p value
Mean LOS, days \pm SD	5,4 \pm 5	7 \pm 7,4	0,446481
Median LOS, days (IQR)	5 (3-7)	5 (3-8)	
Readmissions, n (%)	1 (2,9%)	1 (2,4%)	-
Complications, n (%)	8 (23,5%)	16 (37,2%)	0,19454
Clavien-Dindo 1, n (%)	5 (14,7%)	9 (20,9%)	0,14579
Clavien-Dindo 2, n (%)	3 (8,8%)	2 (4,7%)	
Clavien-Dindo 3, n (%)	-	5 (11,6%)	

Table 3. Convalescence parameters

Parameters	Group 1 ≥ 80 years of age	Group 2 ≤ 55 years of age	p value
Compliance with the ERAS protocol, % \pm SD	85,2 \pm 14,3	83 \pm 14,1	0,482558
Tolerance of oral nutrition within 24 hours of surgery, n (%)	28 (82,4%)	31 (72,1%)	0,28628
Mobilisation within 24 hours of surgery, n (%)	32 (94,1%)	36 (83,7%)	0,14510
No need for opioids, n (%)	25 (73,5%)	19 (44,2%)	0,00891
Time to first flatus, days \pm SD	1,8 \pm 1,2	1,6 \pm 0,9	0,32451

opioids in comparison with younger patients (26.5% vs 55.8%, $p=0.00891$). Time to first flatus was restored after 1.8 and 1.6 days in group 1 and 2, respectively ($p=0.32451$).

DISCUSSION

The results of this analysis of patients in whom laparoscopic surgery and the ERAS protocol used show that short-term treatment outcomes (median LOS, complication and readmission rates, compliance with the ERAS protocol, and recovery period) in patients above 80 are similar to those of younger patients (≤ 55 years of age).

Although elderly patients (>80 years) constitute a relatively large group of patients with colorectal cancer (even 1/3 of all cases), it turns out that a smaller proportion of these patients compared with younger individuals are operated on (18). Only 54-87% of patients aged 75-85 undergo surgery while as many as 1/3 of patients with confirmed colorectal cancer above the age of 85 receive no treatment whatsoever and typically die of complications of the underlying disease (gastrointestinal obstruction, tumour perforation or bleeding) (19). The primary cause of this situation is the belief in the risk associated with surgery that is brought up by the surgeon or patient's family but is not always justified (20). The reasoning behind

this belief is that vital capacity is reduced in elderly patients and any existing concomitant diseases may be risk factors for adverse events (21). Another argument that is brought up is convalescence in the case of complications. This is why it is now widely accepted that the quality of perioperative care is best measured by the postoperative recovery parameters (22). When analysing these in our study, we found no differences in the mobilisation during the first 24 hours after surgery or in the tolerance of oral nutrition. The time to first flatus was similar in both groups. The authors of other papers concerning this topic reached similar conclusions (23, 24). There are thus grounds to believe that age is not necessarily the most important factor that hinders the return to full activity following laparoscopic colorectal surgery. On the other hand, some papers suggest that older patients may need more time to full mobilisation, but this period is longer on average by 1 day (25). Moreover, in our material the complication rate was observed to be higher in the younger group but this difference was not statistically significant. A complication rate of 30% is similar to other findings where patient groups undergoing laparoscopy and the ERAS protocol were extensively analysed and no age-dependent differences were found (13, 25-27). It is worth highlighting that the implementation of ERAS is associated with a reduction in nonsurgical complications even

by 40% while preserving patient safety and without any increase in readmission rate (8, 28, 29). Appropriate preparation for surgery is absolutely essential. All of our patients are required to increase physical activity prior to surgery to improve their performance after surgery. Additionally, we use nutrition intervention (oral dietary supplements) 2 weeks before the planned operation. After surgery, all patients are mobilised by the medical personnel and family within several hours after surgery. It is our belief that procedures aimed at early mobilisation reduce complication rates, especially respiratory complications.

Treatment outcomes are influenced mostly by the degree of compliance with the ERAS protocol (17, 30, 31). Although it is usually impossible to implement all elements in every patient, protocol compliance at 80% significantly reduces the risk of complications, accelerates the recovery of gastrointestinal functions, shortens length of hospital stay and decreases readmission rate as well as the rate of readmission. ERAS opponents argue that protocol compliance in the initial phase of its implementation may be challenging and that it may not be used in all patients. Elderly patients are shown as one example (10). Our analysis showed that some deviations from the protocol may truly be the case in the initial phase of implementing the protocol into daily practice which result from the learning curve of the new perioperative care. This period lasts about 6 months or 40 patients (31). However, in our study the compliance with the protocol was high and did not differ according to patient age. No differences were also observed in the performance of particular elements. Logically thinking, abandoning some elements of traditional perioperative care may be associated with particular benefits in the general state of older individuals: no intestinal preparation (avoidance of electrolyte imbalance and dehydration), reduced opioid doses (reduced risk of postoperative confusion), lack of drains, early removal of catheters (better mobilisation) and balanced fluid therapy (reduced risk of oedema). It may therefore be assumed that the argument about the challenges of treating patients in accordance with the ERAS concept is, in this case, unjustified.

Despite the fact that the LOS is currently not considered the best parameter to assess recovery it has been included in our analysis. The differ-

ence in the mean and median in the younger group was caused by the fact that two patients were hospitalised longer due to anastomotic leakage which was treated with Endo-SPONGE®. The lack of statistically significant differences in the median LOS of both groups may have two causes. Elderly people often depend on the help of family. When caretakers are informed early of the date of discharge from hospital, the subsequent days may be planned and discharge and care for the patient during the first days after surgery are easier. Although this was not the subject of our analysis, we suspect that the inclusion of this aspect in determining the discharge criteria could have led to the shortening of the LOS. According to Rumstadt et al., difficult social conditions and the lack of support after discharge are the second most common cause of prolonged LOS (after complications) (24). A review of literature concerning treatment outcomes in elderly patients in combination with the ERAS protocol age was found not to influence the LOS in 7 out of 11 papers, while according to the remaining 4 papers elderly patients remained in hospital 1-2 days longer (14). On the other hand, younger patients underwent low anterior resection with ileostomy significantly more often. This procedure and stoma are well-known causes of prolonged LOS (32).

This study has some limitations that are typical for single-centre studies. Moreover, the ERAS protocol is currently part of our routine perioperative care independently of the type of surgery and operated organ and consequently protocol compliance is high. It is possible that the results of similar studies in other centres with worse protocol performance could be different. Additionally, laparoscopy is the method of choice in virtually all colorectal procedures performed in our centre. This may also influence treatment outcomes, especially since open procedures are known to be associated with different results in older patients. It is also worth highlighting that our study focused only on short-term treatment outcomes within 30 days of surgery.

CONCLUSIONS

Our results show that the use of the ERAS protocol in combination with laparoscopic colorectal surgery in patients aged above 80 is safe and allows to achieve satisfactory results

which are similar to the results obtained in young individuals. The compliance with particular protocol elements does not differ with age, neither does recovery after surgery. Therefore, older patients should not be excluded from care based on ERAS principles.

Moreover, due to the fact that these patients constitute a significant proportion of those operated, and this proportion will continue to increase in the coming years, more studies are recommended that will help improve treatment outcomes in this particular age group.

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Received: 28.10.2015 r.

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