

Sustainability Audit of an Enhanced Recovery Program in Colorectal Surgery Consolidated after 5 Years of Implementation: A Comparison of Two Cohorts

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Received: 12 Aug 2024

Accepted: 04 Sep 2024

Published: 10 Sep 2024

J Short Name: AJSCCR

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Citation:

Julio Bel Diaz. Sustainability Audit of an Enhanced Recovery Program in Colorectal Surgery Consolidated after 5 Years of Implementation: A Comparison of Two Cohorts. *Ame J Surg Clin Case Rep.* 2024; 8(2): 1-10

Keywords:

Colectomy; Enhanced Recovery After Surgery; Laparoscopy; Length of Stay; Postoperative Complications

1. Abstract

1.1. Introduction

The main objective of the study is to analyze the compliance of each strategy and the overall compliance of an ERAS program in Colorectal Surgery, 5 years after its implementation. Secondary objectives include studying the incidence of postoperative complications (PO) (classified according to the Clavien-Dindo classification), healthcare-associated infections (HAIs), functional recovery, length of stay, and readmission during this period.

1.2. Methodology

Comparison of two prospective cohorts of patients undergoing scheduled Colorectal Surgery at Puerta de Hierro Hospital; the first cohort (ERAS) includes patients operated on during the period immediately after the protocol implementation (January 2017 to June 2018), and the second cohort (ERAS 5) includes those operated on 5 years after the implementation (January 2022 to June 2022).

1.3. Results

A significant increase in overall compliance was observed (88.2% vs 84.2%, $p < 0.01$). When adjusting the outcomes for the surgical approach, a statistically significant reduction in HAI (Healthcare-Associated Infections) was observed (9% vs 25.2%, $p < 0.01$), although no differences were observed in the rest of the complications. There was an acceleration in functional recovery and a decrease in hospital stay, although statistical significance was not reached. The readmission rate remained unchanged.

1.4. Conclusion

After 5 years of implementing an ERAS protocol in Colorectal

Surgery at our hospital, we have managed to maintain overall compliance, significantly reduce HAIs, and not worsen our outcomes regarding postoperative complications (PO), functional recovery, length of stay, and readmission.

2. Introduction

Enhanced Recovery After Surgery (ERAS) programs have revolutionized the field of surgery. They are evidence-based perioperative strategy protocols with a common goal of reducing perioperative inflammation and facilitating functional recovery. These programs have demonstrated a reduction in postoperative complications and hospital stay, proving to be economically efficient. However, there is less evidence regarding their long-term outcomes [1]. To consider an ERAS protocol properly implemented and to achieve positive outcomes, not only is a suitable design crucial, but also high compliance. 2 Therefore, conducting audits 3-6 years post-implementation and providing feedback to the team becomes essential for maintaining effectiveness [3-7]. The proper conduct of systematic audits remains one of the most significant barriers encountered by all groups. Given that 5 years have passed since the implementation of the Enhanced Recovery After Surgery (ERAS) program in Colorectal Surgery (CCR) at our hospital, and we are uncertain about the current compliance and outcomes, we conducted an audit to compare two time points: the immediate implementation of the program and the consolidation phase (5 years later). The main objective of the study is to analyze the compliance of each strategy, as well as the overall compliance, of the ERAS protocol after 5 years of implementation. Secondary objectives include studying the incidence of postoperative complications (PO) (categorized ac-

ording to the Clavien-Dindo classification)8, transfusion, the incidence of Healthcare-Associated Infections (HAIs), and surgical site infection (SSI). Additionally, we examine the average length of stay, readmission, and functional recovery over this time period. Functional recovery is assessed by criteria for discharge on the 5th day or earlier. The study also looks into the median length of stay and readmission over this time.

3. Methods

3.1. Study Design

The study is a comparison of two prospectively collected cohorts, including all patients undergoing scheduled Colorectal Surgery at Puerta de Hierro Majadahonda University Hospital (HUPH). The first cohort (ERAS cohort) includes patients operated on from January 2017 to June 2018 (immediately after protocol implementation), and the second cohort (ERAS 5 cohort) includes patients operated on between January and June 2022 (coinciding with the 5th year of protocol implementation). Both study groups followed the same ERAS protocol, comprising 21 perioperative strategies based on international ERAS guidelines and RICA guide recommendations.9,10 The only difference is our protocol recommends mechanical bowel preparation for all colorectal surgeries, while guidelines reserve it for rectal surgery. In order to compare results with other series, it is considered that colorectal surgery receiving bowel preparation does not comply with this strategy. After ethics committee approval, the study was conducted following the principles of the Helsinki Declaration. The manuscript follows STROBE recommendations for observational studies [11].

3.2. Inclusion and Exclusion Criteria

Inclusion criteria were: 1) Scheduled colorectal surgery with abdominal approach; 2) Signed informed consent for data collection;

3) No exclusion criteria for following an ERAS protocol: no emergency surgeries, patients under 18, or dependent patients, and no type I diabetes mellitus. Exclusion criteria were: 1) Transanal surgery; 2) Lack of signed informed consent; 3) Meeting any exclusion criteria for following an ERAS program.

3.3. Studied Variables

All variables collected for the study were extracted from patients' medical records and anesthesia charts, both in a computerized manner, and recorded through the Piscis® and Selene® programs. Demographic variables such as age, gender, anesthetic risk (measured by the ASA scale), CR-POSSUM prognostic index, and surgical variables such as type of surgery, approach, or duration were recorded. The compliance with each of the 21 strategies that make up the ERAS protocol at HUPHM was analyzed, including overall compliance (expressed on a percentage scale of the number of fulfilled strategies relative to the total; considering 100% compliance if all strategies were met). All postoperative complications were documented (organized according to the CD classification), individually and grouped, including the incidence of perioperative transfusion and Healthcare-Associated Infections (HAI) (all infections that a patient can develop as a result of care received in the hospital or any other healthcare setting, contracted more than 48 hours after admission; for surgical patients, the timeframe extends up to 3 months after surgery or up to 1 year in the case of bone or joint surgery) [12]. Lastly, functional recovery (meeting discharge criteria by the 5th day or earlier (Table 1)), the percentage of patients discharged on or before the 5th day, the days of hospital stay, and readmission, were recorded. All these results were adjusted based on the type of surgical approach to identify if this variable acted as a confounding factor in our data.

Table 1: Eras Protocol at Huphm.

	ERAS (n=313)	ERAS 5 (n=105)	p
Gender (n)			
Male	191 (61%)	54 (51,4%)	<i>0,84</i>
Female	122 (39%)	51 (48,6%)	
Age (years)	67[57-73]	67[53-75]	<i>0,98</i>
BMI (Kg/m²)	26,2[23,8-28,6]	24,9[22,4-28,2]	<i>0,12</i>
ASA (n)			
I-II	226 (72,2%)	77 (73,3%)	<i>0,82</i>
III-IV	87 (27,8%)	28 (26,7%)	
POSSUM f	9[7-10]	9[7-10]	<i>0,24</i>
POSSUM Q	7[7-8]	7[7-8]	<i>0,44</i>
Mortality (%)	1,9[1,3-3,5]	2,3[1,3-6,1]	<i>0,35</i>

Type of Surgery (n)			
Oncological	267 (85,3%)	78 (74,3%)	
IBD (Inflammatory Bowel Disease)	29 (9,3%)	17 (16,2%)	0,07
Diverticulitis	19 (3,2%)	7 (6,7%)	
Others	7 (2,2%)	3 (2,9%)	
Rectal Surgery (n)	78 (24,9%)	26 (24,8%)	0,97
Minimally Invasive Surgery (n)	179 (57,2%)	87 (71,4%)	0,009
Surgery Duration (minutes)	180[125-239]	175[135-214]	0,61
Conversion to Open Surgery (n)	34 (10,9%)	14 (13,5%)	0,48
Postoperative Stoma (n)	64 (20,5%)	17 (16,2%)	0,34

Eras Protocol

Perioperative strategies:

- ERAS information and advice on healthy habits
- Nutritional optimization
- Preoperative respiratory physiotherapy
- Anemia optimization
- Bowel preparation and oral antibiotic therapy
- Carbohydrate drinks before surgery
- Minimally invasive surgery
- No placement of drains
- Antibiotic prophylaxis
- Compliance with DVT prophylaxis
- Multimodal and preventive analgesia
- Analgesic protocol
- No placement of nasogastric tube
- Restrictive fluid therapy / Goal-directed fluid therapy
- Normothermia
- Prophylaxis for postoperative nausea and vomiting (PONV)
- Early removal of urinary catheter (UC)
- Early discontinuation of fluid therapy
- Glucose control
- Early oral tolerance
- Early mobilization

Discharge criteria in HUPHM ERAS protocol:

- Ambulation
- Pain controlled with oral analgesia
- Correct bowel transit (passes stool and/or gas, absence of nausea, tolerates solids)
- Completion of stoma self-care
- Plasma levels of C-reactive protein (CRP) < 50 mg/dL

3.4. Statistical Analysis

Categorical variables were presented as absolute and relative frequencies; numerical variables as mean and standard deviation (SD), or median and percentiles 25 and 75 (p25-p75), depending on the normality assumption assessed using the Shapiro-Wilk test. The association of categorical variables was studied using Pearson’s chi-square test or Fisher’s exact test, as appropriate. Continuous numerical variables were compared using Student’s t-test or Mann-Whitney U test based on their distribution. In case of

imbalance between the baseline characteristics of both groups, adjustment was made for those variables in a multivariable logistic regression or linear regression model, as appropriate. The odds ratio (OR) will be presented as the effect measure in logistic regression, the coefficient in case of linear regression, and the marginal prediction adjusted by the model. The significance level was set at 0.05. For multiple comparisons, the Bonferroni correction was applied. The statistical package used was Stata v.17.

4. Result

No patient loss occurred, with a total of 418 patients included in both cohorts: 313 in the ERAS group and 105 in the ERAS 5 group. There are no significant differences in demographic and surgical variables (Table 2), except for a higher use of minimally invasive surgery in the ERAS 5 cohort compared to the ERAS cohort (71.4% vs. 57.2%, $p = 0.009$). Out of the 21 strategies, compliance increased in 14, decreased in 6, and remained the same in 1. There was a significant increase in nutritional optimization, respiratory physiotherapy, minimally invasive surgery, the use of perioperative multimodal analgesia, and postoperative nausea and vomiting (PONV) prophylaxis according to the Apfel scale. However, a significant decrease was observed in the avoidance of nasogastric tube (NGT) placement and restrictive or goal-directed fluid therapy. Overall compliance was slightly higher in the ERAS 5 group (84.2% vs. 88.2%, $p = 0.003$) (Table 3). In the univariable analysis, a decrease was observed in the incidence of postoperative

complications for each type of the CD classification, except for CD I. There was also a decrease in transfusion and HAIs, globally and for each of its subtypes. The decrease in HAIs (25.6% vs. 8.6%, $p < 0.01$), surgical site infection (18.2% vs. 6%, $p < 0.01$), and transfusion (10.6% vs. 3.8%, $p = 0.034$) is statistically significant (Table 4, Figure 1). Upon adjusting these results for surgical approach, a decrease in the transfusion percentage is still observed, although significance is lost. Additionally, belonging to the ERAS 5 group reduces the probability of developing an HAI by 71% ($p < 0.01$). The average hospital stay has decreased by 1 day between both groups (6 days in the ERAS group and 5 days in the ERAS 5 group, $p = 0.051$). Functional recovery and the proportion of patients discharged on or before the 5th day were higher in the ERAS 5 cohort (although none of these differences reached significance). Upon adjusting these results for surgical approach, the differences are maintained but remain non-significant. The incidence of readmission was similar, without reaching statistical significance.

Table 2: Demographic and Surgical Variables.

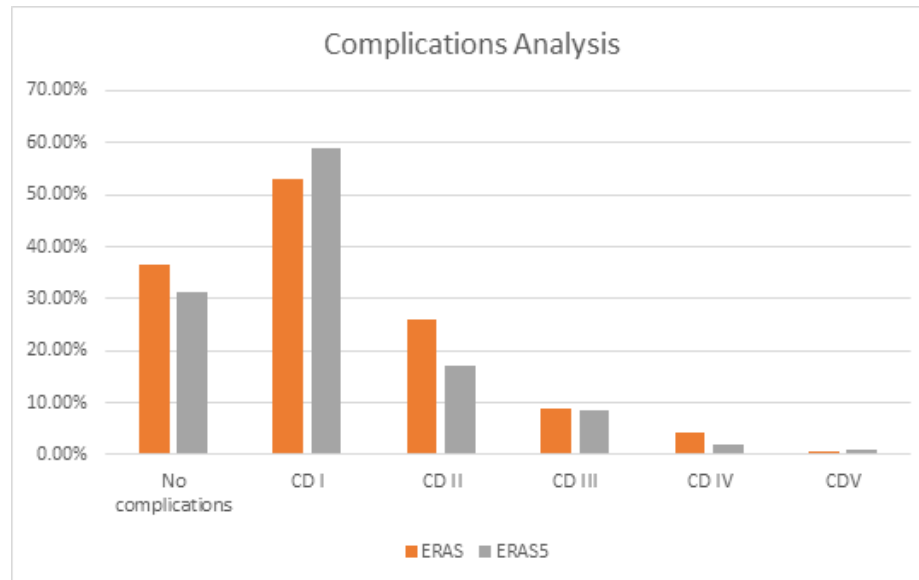
	ERAS (n=313)	ERAS5 (n=105)	p
Information (n)	313 (100%)	105 (100%)	0,99
Nutritional optimization (n)	37 (11,8%)	18 (17,1%)	0,02
Respiratory physiotherapy (n)	215 (68,7%)	96 (91,4%)	0,04
Anemia optimization (n)	66 (47,1%)	27 (67,5%)	0,08
Bowel preparation (n)	52 (16,8%)	22 (19,1%)	0,43
Carbohydrate drinks (n)	269 (86,8%)	97 (67,5%)	0,12
Minimally invasive surgery (n)	179 (57,2%)	87 (71,4%)	0,009
No placement of drains (n)	267 (85,3%)	86 (81,9%)	0,41
Antibiotic prophylaxis (n)	303 (97,4%)	105 (100%)	0,097
Compliance with DVT prophylaxis (n)	300 (96,8%)	103 (98,1%)	0,49
Multimodal analgesia (n)	294 (93,9%)	104 (99,1%)	0,03
Analgesic protocol (n)	254 (81,4%)	96 (87,6%)	0,14
No placement of nasogastric tube (n)	306 (98,1%)	98 (83,3%)	0,02
Restrictive fluid therapy (n)	295 (97,7%)	94 (89,5%)	0,0004
Normothermia (n)	302 (97,7%)	101 (96,2%)	0,39
Prophylaxis PONV (n)	271 (88%)	104 (99%)	0,0007
Early removal of UC (n)	225 (71,9%)	69 (65,7%)	0,23
Early discontinuation of fluid therapy (n)	223 (74,3%)	94 (81,7%)	0,21
Glucose control	200 (64,5%)	96 (83,4%)	0,06
Early oral tolerance (n)	289 (92,33%)	102 (97,1%)	0,08
Early mobilization (n)	271 (87,7%)	94 (89,5%)	0,62
Overall compliance (%)	84,2[75-89,5]	88,2[82,4-94,1]	0,003

Table 3: Strategies.

	ERAS (n=313)	ERAS5 (n=105)	Adjusted Odds Ratio (95% CI)/Coefficient	p
No complications (n) <i>Adjusted Predicted Value*</i>	114 (36,4%) 37%	33 (31,4%) 30%	 0,72 (0,44; 1,17)	0,35 0,184
Complications according to Clavien-Dindo (n)				
CD I	166 (53%)	62 (59%)		0,28
CD II	81 (25,9%)	18 (17,1%)		0,07
CD III	28 (8,95%)	9 (8,6%)		0,91
CD IV	13 (4,2%)	2 (1,9%)		0,28
Exitus/CDV <i>Valor predicho ajustado para CD III/IV/V*</i>	2 (0,7%) 9,7%	1 (1%) 1,4%	 1,21 (0,56; 2,66)	0,74 0,622
Transfusion (n) <i>Adjusted Predicted Value*</i>	33 (10,6%) 10,1%	4 (3,8%) 4,41%	 0,39 (0,14; 1,17)	0,034 0,094
HAIs (n) <i>Adjusted Predicted Value*</i>	80 (25,6%) 25,2%	9 (8,6%) 9%	 0,29 (0,14; 0,60)	0,002 0,001
Pneumonia	4 (1,2%)	1 (0,95%)		0,79
Urinary Tract Infection	10 (3,8%)	1 (0,95%)		0,13
Surgical Wound Infection	57 (18,2%)	7 (6%)		0,002
Bacteremia	9 (2,8%)	0 (0%)		0,07
Meets criteria for discharge on 5th day (n) <i>Adjusted Predicted Value*</i>	162 (51,9%) 52,8%	68 (64,8%) 62,1%	 1,50 (0,93; 2,41)	0,07 0,093
Stay less than 5 days (n) <i>Adjusted Predicted Value*</i>	126 (40,3%) 41,2%	53 (50,5%) 47,5%	 1,32 (0,83; 2,09)	0,067 0,240
Average Length of Stay (days) <i>Adjusted Predicted Value*</i>	6[5-11] 9,55	5[5-10] 8,01	 -1,54 (-3,85; 0,76)	0,051 0,189
Readmission (n) <i>Adjusted Predicted Value*</i>	16 (5,1%) 5,1%	6 (5,7%) 5,9%	 1,17 (0,44; 3,09)	0,82 0,756

*Adjusted Predicted Value: Predicted value for each group, adjusted in the multivariable model for the type of surgical approach (minimally invasive surgery).

Figure 1: Postoperative Complications.



5. Discussion

Currently, there are numerous publications that demonstrate the positive outcomes of implementing ERAS programs; however, literature regarding the compliance of such programs and their long-term results is more limited. Auditing is an essential part of any ERAS program, and this article presents the results of an audit after 5 years of implementing our protocol. 13 After an initial implementation phase, the natural evolution of ERAS programs involves a decline in overall compliance, resulting from new barriers such as team apathy and lack of leadership. These characteristics of the consolidation phase also make it challenging for systematic audits to be conducted correctly.^{9,14,15,16} In our study, not only has compliance not decreased, but there is a sustained high compliance in both groups, exceeding the 80% considered essential for properly implemented ERAS protocols. Our data surpass the national and European averages (64% and 57%, respectively) [17,18]. Our ERAS program was implemented in 2017 with very positive results.^{3,19} In the course of these 5 years, we have not been able to address some of our organizational shortcomings (such as holding institutionalized regular meetings, having an ERAS coordinator nurse, continuous access to data, etc.) [19, 20]. However, we have managed to overcome certain barriers, such as maintaining a well-coordinated multidisciplinary team despite rotations in the anesthesia and nursing teams, and sustaining a high level of commitment and motivation through a training program on ERAS fundamentals and the communication of our own results (as recommended by guidelines). Another facilitating factor has been the establishment of other ERAS programs in the hospital, fostering a growing ERAS culture. Audits not only monitor outcomes but also identify areas for improvement in our clinical practice, being essential for maintaining healthcare quality. The first improvement point we observed in our study is the lower compliance with certain strategies, which could have been associated with a higher

number of complications; for example, increased placement of nasogastric tubes (NGT) and drains or delayed removal of urinary catheters (UC) could translate into an increase in the incidence of HAIs. The second improvement point is the low compliance with some strategies (even though they have increased over time in our series), such as nutritional optimization and anemia optimization. Malnutrition and anemia are conditions associated with increased morbidity and mortality in surgical patients [21-24]. The increase in CD I complications has allowed us to identify a significant rise in the proportion of phlebitis (third improvement point). Thanks to this identification, we have modified our nursing care protocol for venous access. A fourth improvement point is that setting the discharge goal on the 5th day may seem late (current guidelines recommend the 4th day). During the protocol design 5 years ago, we decided to set it on the 5th day to encourage the team’s confidence in protocol-based work and ERAS programs [3, 10, 25, 26]. Once the initial implementation phase was overcome, and given the low readmission rate, the protocol was updated, and the discharge goal was set as the 4th day [17, 18]. It is true that our groups are not homogeneous due to the higher proportion of minimally invasive surgery in the ERAS 5 group. However, as this is one of the main strategies of ERAS protocols, we should also view this difference as an achieved goal within ERAS protocol compliance. There are numerous publications demonstrating the association between the use of laparoscopic techniques and a lower proportion of complications, faster functional recovery, and shorter hospital stay [27, 28]. In fact, this same research group has already confirmed the use of these techniques as an independent factor associated with functional recovery [3]. For this reason, we decided to adjust our results based on the proportion of minimally invasive surgery. When observing a noticeable (though not significant) reduction in CD II complications in the descriptive analysis, we decided to individually study HAI and transfusion, noting a statistically significant

decrease in both in the univariable analysis. The loss of statistical significance for the transfusion variable, after performing the adjusted analysis, could be due to the loss of statistical power or the interaction of minimally invasive surgery as a confounding factor; it would be necessary to expand the groups to clarify it. The low value of the odds ratio (OR), along with minimal variation during adjustment, leans us more towards the first possibility. The same does not happen with HAI, so belonging to the ERAS 5 group decreases the chances of having an HAI by 71%, regardless of the type of surgical approach. We are especially proud of this result, as our results in 2015, specifically those related to Surgical Site Infections (SSI), considered an index of quality in colorectal surgery 29, reached alarming figures and were the main driving force behind the creation of the ERAS program in our hospital.³⁰ The improvement in our results regarding HAI has not stopped after the implementation phase but continues to improve considerably over these first 5 years; probably because, despite improvement after the implementation of the ERAS program, we still had a high incidence of HAI and SSI. In the ERAS 5 group, we observe HAI and SSI figures similar to those of other series [17, 18]. We continue to maintain hospital stays below the national average 17, and we believe that this parameter has room for improvement if all patients who achieve functional recovery actually receive discharge (there is a 23% of patients who achieve functional recovery but do not receive discharge on the 5th day). This study has the limitations inherent in an observational study. Although the difference in sizes between groups may be noteworthy, we ruled out the possibility of reducing the ERAS group to avoid reducing statistical power. We decided to include all cases of colorectal surgery regardless of the cause of the surgery, to give external validity to our results (this is the real population undergoing colorectal surgery in any hospital every day). However, despite not reaching statistical significance, there is an important difference between the two groups in this regard, which may have influenced results such as the incidence of HAI, SSI, and length of stay. Although it is not the objective of the current study, in future studies, we could create subgroups by the cause of surgery to determine their influence. As an audit of the program, we can ensure that it has fulfilled its objectives: we have been able to analyze our results, identifying areas for improvement and providing us with the opportunity to enhance the quality of our care. It is essential to disseminate these results to encourage other groups to audit their ERAS programs, both externally and internally, to keep our multidisciplinary team cohesive and motivated.

5. Conclusion

There was observed maintenance of a high degree of overall protocol compliance since its implementation.

A decrease in the incidence of all types of postoperative complications grouped by CD (except CDI), transfusion, HAI, and SSI was observed. When adjusting these results for the surgical approach, belonging to the ERAS 5 group decreases the chances of develop-

ing HAI by 71%.

Functional recovery has increased, hospital stay decreased by one day, and the proportion of readmissions remained stable.

This audit has allowed us to identify several areas for improvement.

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