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Implementation and Early Results on an Enhanced Recovery Program in Esophageal Surgery

Deswysen Y[1]*, Piraux E[2], Lecourt E[3], Robu BC[4], Dujardin M[5] and Leonard D[6]

[1]Upper Gastro-Intestinal Surgical Unit, Cliniques Universitaires Saint-Luc, UCL, Brussels, Belgium

[2]Pôle de Neuro-musculo-Skeletal Lab, Pôle de Pneumologie, ORL and Dermatologie, Institut de Recherche Expérimentale et Clinique, Clinical Neuroscience, Institute of Neurosciences, Haute Ecole Leonard de Vinci, Parnasse-Isei, Secteur Kinésithérapie, Cliniques Universitaires Saint-Luc, UCL, Brussels, Belgium

[3]Dietetic Department, Cliniques Universitaires Saint-Luc, UCL, Brussels, Belgium

[4]Anesthesia Departement, Cliniques Universitaires Saint-Luc, UCL, Brussels, Belgium

[5]UpperGastro-Intestinal Surgical Unit, Nursing Department, Cliniques Universitaires Saint-Luc, UCL, Brussels, Belgium

[6]Colorectal Surgical Unit, Cliniques Universitaires Saint-Luc, UCL, Brussels, Belgium

***Corresponding author:**

Yannick Deswysen,
Service de Chirurgie et Transplantation Abdominale, Cliniques universitaires Saint-Luc, Université Catholique de Louvain 10, Avenue Hippocrate, B-1200 Bruxelles, Belgium

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1. Abstract

1.1. Background: Esophageal surgery remains the main treatment for esophageal cancer. Despite constant improvements, morbidity of esophagectomy remains high. For several years, enhanced rehabilitation programs have been used to reduce the impact of surgery on the patients to support a faster recovery.

This study analyses the first results of newly implemented enhanced program after esophagectomy within the framework of an academic center.

1.2. Materials and Methods: Between June 2019 and November 2021, 40 patients with esophageal disease requiring esophageal surgery were included in this study. Our enhanced recovery program includes 23 specific measures validated in multidisciplinary consultation, spread over the pre-, intra- and postoperative period. Compliance to the ERP, severe postoperative complications (Dindo/Clavien III/IV), mortality, intensive care unit discharge, start of refeeding, hospital stay and readmission were compared into the two groups.

1.3. Results and Conclusions: Regarding inclusive criteria, 40 patients underwent esophageal surgery. 20 patients were included in the enhanced recovery program (ERP) and 20 patients, studied retrospectively, underwent conventional care. Demographic data were comparable in the two groups of patients operated mainly for cancer (92.5%). Overall compliance was 81.7%. First mobilisation was significantly earlier in the ERP group (POD 1.1+/-0.2 vs POD 3.0+/-3.0 SD $p<0.05$). Enteral nutrition, liquid and solid food intake occurred earlier for patients in the ERP compared with the control group (POD 1.4+/-1.9 VS POD 2.2 +/-1.9 SD $p<0.05$; POD 3.6+/-1.3 vs 4.2+/-1.4 SD $p<0.05$; POD 5.0+/-0.9 VS POD 6.0+/-1.4 SD $p<0.05$, respectively). The hospital stay was significantly reduced from 13.4+/- 6.5 SD days in the retrospective cohort to 10.2+/-5.0 SD days after ERP implementation. No significant difference was found in intensive care stay, morbidity, mortality and readmission rate.

Enhanced recovery program after esophagectomy benefits patients care resulting in better outcomes. Although with some limitations, the first experience in our academic centre demonstrates the feasibility of such care program. Future prospective studies should be proposed to validated this new standard of care.

2. Introduction

Although surgery remains the treatment of choice in esophageal cancer, esophageal surgery is characterized by significant morbidity. In view of the literature, perioperative morbidity is still range from 17-49% [1, 2].

In recent decades, the improvement on the surgical procedure and the perioperative management of patients with esophageal cancer have reduced this morbidity while maintaining similar oncological efficacy.

The concept of fast-track surgery was developed by Henrik Kehlet in the 90' and was based on the improvement of perioperative management. It evolved towards the concept of enhanced recovery after surgery (ERAS) now proposed as standard of care in many areas of surgery. These protocols are based on specific pre- intra – and postoperative measures with the aim of reducing surgical stress, accelerate recovery after surgery and reduce postoperative complications.

Although largely supported by evidence-based data in many surgical fields, the adaptation of these protocols in esophageal surgery remains poor and its legitimacy unclear. No consensus on the clinical enhanced recovery pathway has been established until now and strong evidence is lacking in the current literature.

The aim of this study is to analyse the implementation and the first results of a recovery program after esophagectomy in a single belgian academic centre.

3. Materials and Method

The study was approved by our Ethics Committee of the Cliniques universitaires Saint-Luc and Université catholique de Louvain (2023/23JAN/038).

From June 2019 to November 2021, patients undergoing elective esophageal resection were enrolled in this retrospective analysis.

Since June 2020, a 23-items enhanced recovery program was proposed to all elective patients. This protocol was elaborated and validated by a multidisciplinary team dedicated to esophageal surgery according to the ERAS recommendations [3]. Table 1, shows the different items include in our program spread over the pre-, intra- and postoperative period.

Inclusion criteria of our program were elective esophageal resection for adult patients. Exclusion criteria were all contraindication for surgery according to the World Health Organization (WHO) physical status of IV, emergency surgery, mental illness, and patient's refusal.

Medical data of each patient was collected in an electronic database at our academic centre, retrospectively for the non-ERP-group and prospectively for the ERP-group. Data recorded included age, sex, BMI, WHO score, primary diagnosis, stage of tumor when applicable, surgical procedure type, postoperative outcomes including major postoperative complications (grade III/IV according Dindo-Clavien's complications) within postoperative period, 30 and 90 days, time to first ambulation, time to first clear liquid diet, time to the first solid diet, time to the last surgical drain removal, intensive care length of stay, hospital length of stay, readmission rate.

Statistical analyses were performed with JMP software. Continuous variables were presented as mean and standard deviation (SD), data for categorical variables were presented as frequencies as percentages and statistical tests ANOVA and Chi Square were also used. The P values <0.05 were considered statistically significant.

Table 1: Patient characteristics

Variables	ERAS group	Control group	p value
Number	*20*	*20*	
Age (years)	66.0 +/- 12.8	61.2 +/- 12.1	NS
Men	14 (70,0)	12 (60,0)	NS
BMI (kg/m²)	27.5 +/- 3.8	27.1 +/- 6.2	NS
WHO status 0	13 (65,0)	8 (40,0)	NS
I	6 (30,0)	10 (50,0)	NS
II	1 (5,0)	2 (10,0)	NS
III	0	0	NS
IV	0	0	NS
Oncological surgical indication	19 (95,0)	18 (90,0)	NS
Histological type Adenocarcinoma	16 (84,2)	14 (77,8)	NS
Squamous carcin	2(10,5)	3 (16,7)	NS
GIST	1 (5,3)	0 (0)	NS
Other	0 (0)	1 (5,6)	NS
Pathological tumor stage			
0	5 (26,3)	3 (16,7)	NS
I A	0 (0)	0 (0)	NS
I B	1 (5,3)	6 (33,3)	NS
II A	3 (15,8)	2 (11,1)	NS
II B	5 (26,3)	2 (11,1)	NS
III A	0 (0)	1 (5,6)	NS
III B	2 (10,5)	4 (22,2)	NS
III C	0 (0)	0 (0)	NS
IV	3 (15,8)	0 (0)	NS

Data are mean SD and numbers (percentage) as appropriate

4. Results

A total of 52 consecutive patients were analysed between June 2019 and November 2021. As shown in the flowchart, 12 patients were excluded regarding the exclusion criteria. The ERP group included 20 patients who benefited from the recovery programs. The non-ERP group included 20 patients operated before June 2020 according to standard care (Figure 1).

Table 2 presents the demographics of the two groups. Both groups underwent similar surgical procedure with similar anaesthetic methods and analgesia. There was no significant difference in the population characteristic regarding the age, the sex, the BMI and the tumor stage.

Regarding our primary outcome, the overall compliance with ERP protocol was 87.1%.

In ERP group, the time to first ambulation after surgery was significantly reduced (POD 1.1+/-0.2 vs POD 3.0+/-3.0 mean SD, $p<0.05$) and the first enteral, liquid and oral solid diet occurred earlier in the ERP group than in the non-ERP group (POD 1.4+/-1.9 vs POD 2.2+/-1.9 mean SD, $p<0.05$; POD 3.6+/-1.3 vs 4.2+/-1.4 SD $p<0.05$ and POD 5.0+/-0.9 vs POD 6.0+/-1.4 mean SD, $p=0.03$). The hospital stay was significantly reduced from 13.4+/-6.5 SD days in the retrospective cohort to 10.2+/-5.0 SD days after ERP implementation. No difference was found in the intensive care length of stay and last surgical drain removal.

Regarding major postoperative complications (Dindo-Clavien III/IV), no significative difference was found between the two groups although there was a trend of lower morbidity in the ERP group (25.0% vs 5.0% $p=0.6$). One patient developed anastomotic leakage postoperatively compared with 2 in the control group. All were managed by endoscopy or delayed refeeding without need of surgical reintervention. One patient was readmitted in the ERP group for infectious reason. No patient was readmitted for surgical complications (Table 3-5).

Table 2: Esophageal ERAS protocol in CUSL

Preoperative measures • Information to patient, family and family doctor • Nutritional status asssessment • Preoperative nutritional support • Immunonutrition • Alcohol-smoking cessation
Physical and respiratory training Peroperative measures • Premedication • Breaking fast • No intestinal preparation • Thromboprophylaxis • Fight against hypothermia • Pain management • Fluids management • Surgical approach • Type of surgical reconstruction
Surgical drainage Postoperative measures • Pain management • Prevention of nausea and vomiting • Fluids management • Renutrition • Vesical catheter • Prevention of postoperative ileus • Mobilisation

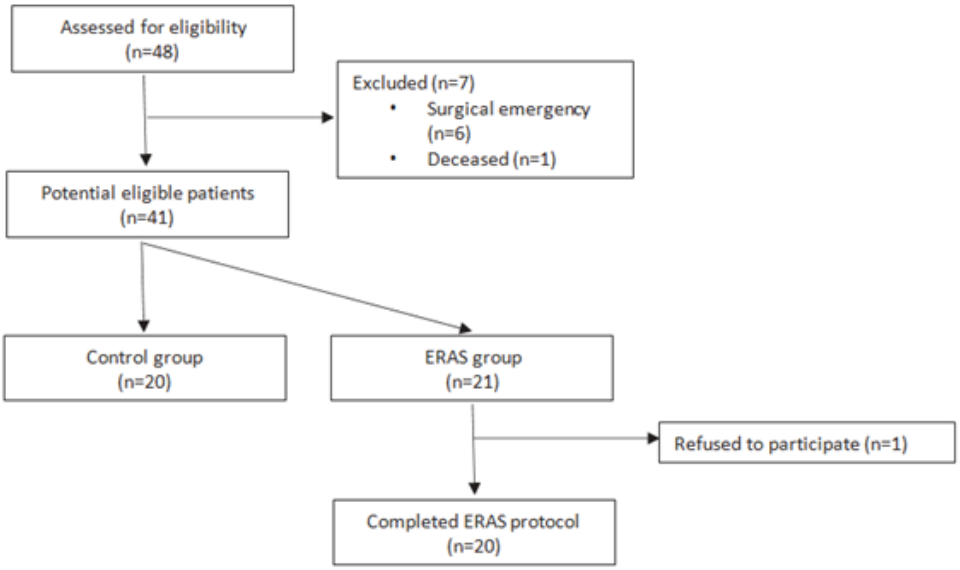

Figure 1: Flow chart

Table 3: compliance with ERAS measures

Preoperative measures	**Compliance %**
Information to patient, family and	100
family doctor	
Nutritional status assessement	100
Preoperative nutritional support	100
Immunonutrition	95
Alcohol-smoking cessation	100
Physical and respiratory training	100
Peroperative measures	
Premedication	60
Breaking fast	100
No intestinal preparation	100
Thromboprophylaxis	100
Fight against hypothermia	100
Pain management	100
Fluids management	100
Mini-invasive surgical approach	85
Type of surgical reconstruction (stomach)	80
Surgical drainage	80
Postoperative measures	
Pain management	100
Prevention of nausea and vomiting	100
Fluids management	100
Early refeeding (POD1)	100
Vesical catheter removal (POD2)	85
Prevention of postoperative ileus	100
Early mobilisation (POD1)	95
Overall compliance	81.7

Table 4: ERAS protocol outcomes

Variables	**ERAS group**	**Control group**	**p value**
Number	*20*	*20*	
Completed protocol	20 (100)		
Start refeeding (POD)			
Enteral nutrition	1.4 +/- 1.9	2.2 +/- 1.9	<0.05
Liquid oral nutrition	3.6 +/- 1.3	4.2 +/- 1.4	<0.05
Solid oral nutrition	5.0 +/- 0.9	6.0 +/- 1.4	<0.05
BladerKT removal	2.7 +/- 1.7	5.5 +/- 3.9	<0.05
Nasogastric tube removal	2.2 +/- 1.1	3.4 +/- 1.1	<0.05
Last surgical drainage	5.2 +/- 2.6	6.3 +/- 4.6	0.6
First mobilisation (POD)	1.1 +/- 0.2	3.0 +/- 3.0	<0.05
Intensive care discharge (POD)	1.6 +/- 1.7	2.9 +/- 2.7	0.07
Hospital discharge (POD)	10.2 +/- 5.0	13.4 +/- 6.5	<0.05
At POD 8 or before	8 (40.0)	1 (5.0)	<0.05

Data are mean SD and numbers (percentage) as appropriate

Table 5: Surgical morbi-mortality

Variables	**ERAS group**	**Control group**	**p value**
Numbers	*20*	*20*	
Mortality POD 30	1 (5.0)	1 (5.0)	NS
POD 90	2 (10.0)	1 (5.0)	NS
In hospital morbidity	1 (5.0)	5 (25.0)	NS
Pneumonia	1 (5.0)	4 (20.0)	NS
ARDS	0	1 (5.0)	NS
Fistula	1 (5.0)	2 (10.0)	NS
Readmission	1 (5.0)	0 (0)	NS
SARS-2 infection	1 (5.0)	0 (0)	NS

Data are mean SD and numbers (percentage) as appropriate. Morbidity is based on Dindo-Clavien grade III/IV.

5. Discussion

Surgical resection is the mainstay of the curative treatment of localized and locally advanced esophagogastric cancer, alone or in combination with neoadjuvant chemoradiation or chemotherapy [4, 5]. Esophagectomy is a complex and invasive procedure and its morbidity remains high. The incidence of complications has been previously reported to reach up to 75% [6]. In 2019, the Esophageal Complications Consensus Group reported a morbidity rate of 59% after esophagectomy for cancer. Severe complications (Dindo-clavien ≥ IIIb) occurred in 17.2% of patients [1]. Complications influence significatively hospital stay [7], cancer survival [8], recurrence [9], and quality of life [10]. Hence, strategies to reduce the impact of surgery with the aim of improving postoperative outcomes are of considerable importance.

First described by Henrik Kehlet in 1997 for colorectal surgery [11], the concept of enhanced rehabilitation after surgery evolved over the years into a multidisciplinary approach including all actors of the perioperative patient's care. This approach aims to optimize pre-, intra- and postoperative patient management by applying standardized procedures and integrating evidence-based principles in the clinical practice. Major principles include (i) the physical and nutritional preparation for surgery in the preoperative period; (ii) surgical and anaesthesia techniques to reduce the impact of the surgical trauma on patient's homeostasis in intraoperative period; (iii) optimized pain management, early mobilisation and appropriate early refeeding after surgery [12, 13].

Nevertheless, development of ERP protocol after esophagectomy remain limited and ERP shows heterogenous results mainly because of the absence of a common and uniform program. Until 2018 and ERAS Society guidelines for esophageal surgery [3], no standardized guidelines were available. Retrospective studies reported a positive impact of ERP protocol in term of morbidity, mortality and length of stay in esophageal surgery [14]. Few randomized trials are available and only analysed very specific aspects of such program as nutrition or physical exercise.

In fact, we know the impact of ensuring a nutritional support for patients with esophageal cancer throughout the treatment. It can reduce weight and muscle loss, decrease LOS and incidence of complications, and improve oncologic outcomes [15, 16]. Malnutrition should be screened as soon as possible along the treatment strategy and nutritional therapy should be initiated accordingly [16].

One key element of ERP's success is a quick functional recovery after surgery. Mobilization should be started on the day of the surgery and progressively increase to achieve an acceptable level of autonomy [17]. A recent randomized study including 250 patients in a physical enhanced recovery program in esophageal cancer showed a significant improvement in the length of stay but no data were available on postoperative complications [18]. However non-surgical complications and pulmonary complications seem to improve in a systematic review in 2017 by Pisarska et al even though studies included in this analysis were of low quality with high risks of bias [19].

More recently, several teams have introduced prehabilitation, a program that aims to optimize patients before surgery by exercise reconditioning, nutritional support and psychological care. Patients undergoing prehabilitation showed an improve of functional capacity before and after esophagectomy [20] or a reduction in postoperative pulmonary complication [21], suggesting that the optimization of physical capacity in the preoperative period could add benefits for patient's outcomes. Feasibility of such preoperative program beneficed from a high recruitment rate, retention and satisfaction without exercice-related adverse events [22]. Based on these results, prehabilitation is becoming the new key element of ERP.

In this prospective monocentric study, we reported our first experience of ERP implementation including prehabilitation for patients who underwent an esophagectomy. The implementation of a new protocol and preservation of a maximum adhesion to it should remain the ongoing mission of the ERP team [23]. For this purpose, we created a dedicated group of medical and paramedical actors and developed a program including 23 items based on literature and guidelines. Modification of habits in daily practices requires a lot of energy to convince of the benefit of such program. But quickly, team spirit and adapted communication allowed the development of collaboration in the staff. Once drafted and distributed, our recovery program was applied in daily practice. Each actor in patient care has been empowered enabling the success of ERP.

All consecutive patients with esophageal or eso-gastric junction pathology were enrolled regarding the inclusion criteria. In this study, the overall compliance rate was 81.7%. However, compliance with individual items of the ERP protocol was variable. Patient's education, nutritional assessment and support, anaesthesiologic approach, avoidance of bowel preparation or pain management were associated with high compliance close to 100%. The lower compliance rate was found for bladder catheter removal, perhaps due to the reluctance to remove it in case of epidural anaesthesia. Other studies observed differences in compliance to ERP items demonstrating the difficulties to apply enhanced recovery program to every surgical patient [24, 25].

The rate of major complications (Dindo-Clavien IIIb/IV) was chosen as one of the main outcome parameters. Although there is an improvement on the complication rate, no significant difference has been demonstrated both in terms of morbidity and mortality. These findings seem to be in line with the results of the literature although some improvement in major postoperative complications have been described [26]. Regarding postoperative complications and ERP, a recent meta-analysis observed a decreased rate of lung infection (RR=0.50, 95%CI: 0.33 to 0.75), postoperative length of stay (MD=-2.53, 95%CI: −3.42 to −1.65) but no significant

difference in surgical site infection (P=0.42), postoperative anastomotic leakage (P=0.45), and readmissions rate (P=0.31) [27].

There are several typical limitations for a single-centre study. The number of patients included in the analysis is limited. Many items present in the ERP were already used routinely in our practice and management of esophagectomy. Thus, it is probably more difficult to show statistical differences between the 2 groups of patients. But giving our encouraging results, the implementation of such program remains useful to improve perioperative care and surgical complications without compromising safety and quality.

Our first experience in enhanced recovery program for patients undergoing esophagectomy demonstrate the feasibility of such a clinical pathway. Implementation of ERP protocol requires large efforts of organization and collaboration from the various care actors. Future randomised large studies using standardized ERAS guidelines are needed.

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