

The “Lazio Network” experience. The first Italian regional research group on the Enhanced Recovery After Surgery (ERAS) program.

A collective database with 1200 patients in 2016-2017



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The “Lazio Network” experience. The first Italian regional research group on the Enhanced Recovery After Surgery (ERAS) program: a collective database with 1200 patients in 2016-2017

AIM: *Enhanced Recovery After Surgery (ERAS) guidelines represent one of the most important steps forward in colorectal surgery in the last ten years. Despite the well-known and demonstrated positive impact on the clinical outcomes that this pathway provides, a cultural revolution in patient management is needed. This is not easy to obtain, especially in small and peripheral centers. In Italy, the diffusion of minimally invasive surgery and “fast-track” perioperative management of the patient is rapidly spreading, even in the central and southern regions. However, in these regions, the percentage of laparoscopic colorectal procedures is dramatically less than in the north of Italy. In this context, the idea of a research group based in Rome focused on the development and spreading of ERAS protocols in the Lazio Region was developed.*

METHODS: *A research group, based in Rome, was founded in December 2016 to evaluate the diffusion of the ERAS program over the main colorectal centers of the region. This “Lazio Network” began with a group of surgeons and anesthesiologists from 5 hospitals. After one and half years, the project now includes 17 hospitals in the region. A multi-center database was created, including consecutive patients who underwent laparoscopic colorectal resection following the ERAS program in the participating centers between January 2016 and December 2017.*

RESULTS: *Data for more than 1200 patients were collected over the observed period. The rate of minimally invasive surgery was higher compared to the regional rate (90% vs. 30%), adherence to the ERAS pathway was around 60% of the items per patient. A clinical study will result from this database. The objective is to evaluate the mean number of ERAS items applied, the most common and uncommon items applied and the influence of this application on the clinical outcomes.*

CONCLUSIONS: *The adoption of the ERAS program is rapidly increasing even in central Italian regions, even though the total rate of minimally invasive surgery procedures still low. Benefits in terms of clinical outcomes will be evaluated from the analysis of a multi-center database of patients treated between January 2016 and December 2017, including more than 1200 patients.*

KEY WORDS: Colorectal surgery, ERAS guidelines, Fast track surgery

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Introduction

The ERAS pathways of perioperative management form an evidence-based model that can decrease surgical stress and improve postoperative recovery. It is a multimodal

program where surgical techniques and technologies need to be combined with multiple non-surgical items and interventions, often counter to old clinical dogmas¹. Evidence-based guidelines regarding multiple branches of surgery have been developed and published by “ERAS Society”², and applications of these pathways have demonstrated reduced perioperative complications, length of hospital stay and overall costs³. Therefore, the benefits of this protocol have already been demonstrated and now their dissemination is needed.

Currently, the exact situation regarding the spread of ERAS protocols across countries, regions and hospitals is not well documented. Unfortunately, the diffusion of the application of ERAS protocol is slow and often difficult because it is often necessary to apply these evidence-based items and interventions against old surgical dogmas.

In a situation of cost control in the health system globally, due to the aging population and the increasing need of treatments for old and multimorbid patients, applications of ERAS protocols can reduce costs for the sanitary system, in combination with better outcomes and satisfaction for the patients.

In Italy, the diffusion of minimally invasive surgery and “fast-track” perioperative management of the patient is rapidly spreading, even in the central and southern regions. In these regions, the rate of laparoscopic colorectal procedures is dramatically less when compared to the north of Italy. In the region of Lazio, the percentage of laparoscopic colorectal resections is around 30%, compared to a mean percentage of 50-60% in the northern Italian regions⁴.

In this context, the idea of a research group based in Rome and focused on development and dissemination of ERAS protocols in the Lazio Region was born.

PROJECT DEVELOPMENT

A research group – the “Lazio Network” – based in Rome, was founded in December 2016 by a group of surgeons and anesthesiologists from 5 hospitals. The main reason was to evaluate the diffusion of the ERAS program over the main colorectal centers of the Lazio Region and start a collaboration to increase the application of the protocols across colorectal centers.

In monthly meetings, each center shared their experience on the ERAS protocol with the other centers, including the goals, difficulties and doubts. The audit helped each center to gain experience and knowledge.

In early 2017, the research group opened up to other participants, in order to start a collaboration between as many centers as possible; by March 2018, the Network encompassed 17 hospitals in the region, including peripheral hospitals. The increase in participating centers over time is detailed in Fig. 1.

From the beginning, it was clear that the project needed not only collaboration between surgeons and anesthesiologists, but teamwork in order to follow the patient along every moment of his/her hospitalization. Every center selected a team of surgeons, anesthesiologists, nutri-

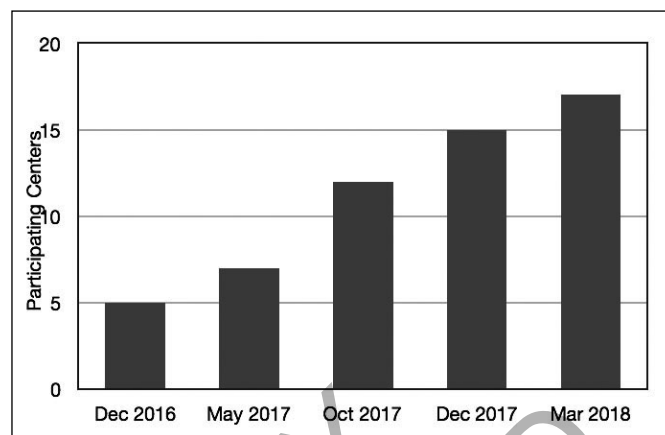


Fig. 1: Participating centers.

tionists and nurses, who focused on the diffusion and standardization of the ERAS program in the hospital.

In early 2017, the Network began a regional study in order to analyze the application rate of the ERAS program and its outcomes in the Lazio Region. To facilitate this, every center collected data to form a common, shared database. The database was never used to compare the results between hospitals but to compile as much data as possible and analyze the results across the Lazio region. Only 10 centers of the network participate to the clinical study including patients operated in 2016 and 2017.

Material and Methods

Eligible patients were those who underwent colorectal procedures, with a “fast track” perioperative approach, for both malignant and benign disease between January 2016 and December 2017. The majority of the participating centers, at that time, had no real internal ERAS protocol, and instead used to apply as many items of the protocol as possible in the context of, so-called, “fast track” surgery. The database included 94 items per patient, divided into demographical data, preoperative clinical data, intraoperative data and postoperative data. The items selected covered the entire hospitalization of the patient, including surgical data, anesthesiological data, nutritional data and clinical data.

To minimize bias in terms of item application, a consensus guideline was developed to create cutoffs to consider every item applied or not. At the end of 2017 every item of the ERAS pathway was evaluated by the Network and added to a shared protocol that is going to be used from 2018 on by all centers.

The items were divided into preoperative assessment, anesthesiologic protocol, surgical protocol, postoperative management and discharge⁵. Quantitative data were reported as medians (range). Qualitative data were reported as number of patients (percentage of patients). Given the descriptive aim of this study, no inferential statistics were performed.

This study was first approved by the institutional Ethics Committee of *Fondazione Policlinico Universitario A. Gemelli* of Rome (Protocol number 000767418) and then approved by the Institutional Ethics Committee of every participating center. The study was registered on ClinicalTrials.gov in November 2017 with registration number NCT03353311.

It is conducted according to the declaration of Helsinki; informed consent was obtained from all patients.

Results

In January 2017, the participating centers started collecting data on patients undergoing colorectal procedures in the observed period. Therefore, patients operated in 2016 were recorded retrospectively, patients operated in 2017 were recorded prospectively.

Data from 1223 patients were collected over the period of observation.

Among the operated patients, 133 patients (11.7%) underwent open surgery and 10 patients (0.8%) underwent robotic surgery, whereas most of the patients underwent laparoscopic surgery (993 cases, 87.4%), as summarized in Table I. The types of surgical procedures are summarized in Table II.

Based on the collective database, 18 items of the ERAS pathway were collectable. The collectable items are summarized in Table III.

All the selected items were standardized following ERAS guidelines with the approval of all participating centers to obtain a uniform application across all the centers. Preoperative bowel preparation and abdominal drainage were not considered for patients undergoing rectal resec-

TABLE I - Surgical technique (n=1136)

Open surgery (n, %)	133 (11.7)
Robotic surgery (n, %)	10 (0.8)
Laparoscopic surgery (n, %)	993 (87.4)
Complete laparoscopic	959 (84.4)
Converted	44 (4.5)

TABLE II - Surgical procedures (n=1136)

Ileocecal resection (n, %)	20 (1.8)
Right hemicolectomy (n, %)	361 (31.8)
Transverse resection (n, %)	32 (2.8)
Splenic flexure resections (n, %)	28 (2.5)
Left hemicolectomy and sigmoidectomy (n, %)	330 (29.0)
Rectal resection (n, %)	207 (18.2)
TaTME (n, %)	46 (4.0)
Miles (n, %)	29 (2.5)
Other (n, %)	83 (7.3)

tions as there is no strict opinion on these two items for rectal surgery.

Out of 18 possible items, a median of 17 items (range 10-18) were collected in the patients of this series, whereas a mean of 11 items (range 2-16) were applied following the ERAS guidelines, as detailed in Table IV.

Clinical results of the population in terms of intraoperative data and postoperative short-term outcomes are being processed and will be presented in the second half of 2018.

TABLE III - Collectable Items

Item	Definition
Preoperative counseling	Received multidisciplinary preoperative counseling
Prehabilitation and informative booklet	Received a preoperative informative booklet with details on the prehabilitation, surgical procedure and postoperative care
Preoperative bowel preparation	No preoperative mechanical bowel preparation (rectal resections excluded)
Preoperative nutritional evaluation	Preoperative counseling with a nutritional care specialist to plan preoperative and postoperative nutrition
Preoperative fasting	Food allowed up to 6 hours prior to surgery, clear fluids up to 2 hours
Postoperative nausea and vomiting (PONV) prevention	Pharmacological administration to prevent postoperative nausea
Preoperative antimicrobial prophylaxis	Antibiotic prophylaxis prior to surgery
Prophylaxis against thromboembolism	Thromboembolism prophylaxis with low-molecular-weight heparin
Multi-modal anesthetic protocol	Application of new anesthesiological technique together with classical anesthesiological strategies
Prevention of intraoperative hypothermia	Active warming during surgery
Minimally invasive surgery	Laparoscopy or robotic surgery
Abdominal drainage	Avoid abdominal drain placement (rectal resections excluded)
Perioperative fluid management	Postoperative fluids < 1ml/hr/kg
Postoperative analgesia	Avoid use of Morphine or opioids drugs
Nasogastric intubation	Removal of nasogastric intubation before leaving the operating room
Early mobilization	Autonomous mobilization within 24 hours
Urinary drainage for 1-2 days	Removal of urinary drainage within 48 hours
Early oral feeding	Feeding with solid food within 48 hours

TABLE IV - ERAS Items (n=1136)

ERAS items collectable (n)	18
ERAS items collected (median, range)	17 (10-18)
ERAS items applied (median, range)	11 (2-16)

Discussion

Evaluating the diffusion and application of the ERAS protocol is challenging and the results are not easy to analyze. There are two main problems: the application of the enhanced recovery protocols are often different from center to center, depending on the experience and the confidence of the surgical team; furthermore, a real system, provided and managed by the Italian sanitary system, to collect data on this field, does not exist.

In order to overcome these problems, in 2016, the "PeriOperative Italian Society" (POIS) ⁷ started collecting data in a collective database, and in 2017 it published the first reports on the application of the ERAS protocol in high-risk patients ⁸ and on the impact of laparoscopy on adherence to an enhanced recovery pathway ⁹.

Nevertheless, the data collection primarily involved hospitals in northern Italy where there is wider diffusion of minimally invasive surgery ⁴, as well as the application of Enhanced Recovery Pathways.

In order to enhance uptake in central Italy, a project to evaluate the ERAS protocol application in Lazio region was initiated; indeed, adherence to the program has been demonstrated to be a key point to have the better clinical outcomes ¹⁰.

The decision to start a regional research group arose from two considerations. A regional project provides motivation to surgeons, anesthesiologists, specialists in clinical nutrition and caregivers to participate actively, and compare habits, experiences and results in periodical meetings. Another key factor is the regional management of the sanitary system in Italy, whereby the participating centers may be able to obtain more resources and facilities from the regional government if involved in regional initiatives.

The Lazio Network is a success in both these regards. The research group grew rapidly in a very short period, with periodical meeting involving specialists from all hospitals; moreover, the government of Lazio Region already expressed satisfaction with this project in scientific congresses during 2017.

In 2015, in the Lazio region, a total of almost 3500 patients underwent colorectal resection for cancer, including elective and emergency procedures ¹¹. Over 2 years we could expect 7000 patients in total. This group collected data of 1223 patients, around 17% of all the patients operated in our region during the 2-year period. An interesting point is the high rate of minimally invasive procedures of this database. The mean rate of minimally invasive colorectal surgery in Lazio region is 30% but the rate in this clinical study is around 90%. This

is related, probably, with the propensity of surgeon using modern surgical approach, such as laparoscopy or robotics, to apply a modern perioperative management of the patients.

In the collective database not all of the classical ERAS Program Items ⁶ were included in order to overcome the possibility of bias from a non-homogeneous evaluation of the single items in different hospitals.

Working together, sharing results and showing to the other centers that the application of an Enhanced Recovery Pathway is safe and effective is the only way possible to spread this cultural revolution. Even if most surgeons are very receptive to new technologies and technical improvements, they are still very reticent to accept a cultural revolution on the side of patient management, as it requires overcoming established surgical dogmas.

The benefits of ERAS protocol has been demonstrated in previous studies: it offers better clinical outcomes and potentially high cost-savings due to a shortened postoperative length of stay and fewer postoperative complications ¹²⁻¹³. The aim of this research group is to extend these benefits to the Lazio Region, offering better clinical outcomes and cost-savings for the entire regional health system.

Conclusions

The adoption of the ERAS program is rapidly increasing even in central Italian regions, even though the rate of minimally invasive surgery procedures still being low. Benefits in terms of clinical outcomes will be evaluated from the analysis of a multi-center database of more than 1200 patients treated between January 2016 and December 2017.

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Riassunto

Le linee guida ERAS rappresentano uno dei più importanti passi avanti in chirurgia coloretale degli ultimi dieci anni. Nonostante i gli evidenti e dimostrati benefici che questo percorso può generare sugli outcomes clinici, è necessaria una rivoluzione culturale riguardo alla gestione clinica del paziente. Questo non è facile da ottenere, specialmente nei piccoli ospedali periferici. In Italia la diffusione della chirurgia mini-invasiva e della gestione clinica dei pazienti secondo una cosiddetta "fast-track" sono in rapida diffusione. Questo sta avvenendo anche nelle regioni del centro e del sud, nonostante in quest'ultime la percentuale di interventi di chirurgia coloretale mini invasivi sono drammaticamente minori rispetto al nord Italia.

In questo contesto è nato a Roma il progetto "Lazio Network", un gruppo di ricerca la cui finalità è quella dello sviluppo e diffusione dei protocolli ERAS nella Regione Lazio.

Il gruppo di ricerca è nato nel Dicembre del 2016 con il progetto iniziale di valutare la diffusione dell'applicazione del protocollo ERAS nei principali centri di chirurgia coloretale della Regione. Il "Lazio Network" nasce dalla collaborazione di chirurghi, anestesisti ed infermieri di 5 ospedali di Roma. Dopo solo un anno e mezzo il gruppo contava la partecipazione di 17 ospedali della Regione Lazio.

E' stato quindi creato un database online multicentrico includendo tutti i pazienti sottoposti a chirurgia resetti-

va coloretale, in un contesto di percorso ERAS dal Gennaio 2016 al Dicembre 2017. Questo progetto ha permesso di raccogliere ed analizzare i dati di oltre 1200 pazienti.

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