

Utility of 'Enhanced Recovery of Surgery (Eras)' Guidelines for Elective Digestive Tract Surgeries

^{1*}Geeta Sundar, ²K. Jayarama Shenoy

1 – Resident, Department of General Surgery, Kasturba Medical College, Mangalore, Manipal Academy of Higher Education, Karnataka

2 – Professor, Department of General Surgery, Kasturba Medical College, Mangalore, Manipal Academy of Higher Education, Karnataka

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ABSTRACT

AIMS AND OBJECTIVES

To determine whether ERAS guidelines, can be adapted in a local setting for elective digestive tract surgeries and to study its outcomes.

METHODOLOGY

After institutional ethical approval, the observational cohort was selected from hospitals affiliated to the college, with the subjects being considered after adequate inclusion and exclusion criteria and divided into 2 groups as per the operating surgeon – where ERAS guidelines were followed vs the group where the standard hospital protocols were followed. The elective surgeries included colorectal, pancreatic, small bowel, gastric resection and anastomosis.

Details of the peri-operative care were noted in each group and utmost compliance for the ERAS guidelines as feasible in the local setup was tried. Every patient was followed up till the day of their discharge. Primary outcome was length of hospital stay. Secondary outcomes were the ERAS strategies across the peri-operative period.

SPSS IBM software v22.0 was used. Mean, mode, SD, IQR range were calculated, Chi Square test, Mann-Whitney U test used, with p value <0.05 as significant.

RESULTS AND CONCLUSION

Between the 2 groups, age, demographic characters were identical; Whipples procedure (16.7%), Anterior resection (15%), Right colon surgery (26.5%), gastrectomy (20.2%) were most commonly performed; gastric cancer more prevalent in controls, vs rectal cancer more in cases, periampullary and colon cancer distributed uniformly among the 2 groups.

Time to mobilization, post-operative removal of abdominal drains, Ryle's tube & Foley's catheter, enteral feeding, post-operative need for intravenous fluids were all faster in the ERAS group with statistical significance (p value <0.05). Length of

hospital stay was significantly shorter in the ERAS group.

We noted statistical significance on multiple parameters of ERAS, so conclude that implementing ERAS strategies can definitely enhance overall recovery.

KEYWORDS :ERAS guidelines, digestive tract surgeries, elective surgeries, hospital stay, recovery

I. INTRODUCTION

The concept of 'fast-track' surgery was first introduced by Henrik Kehlet in the 1990's, who explained that by employing certain practices they could reduce the hospital stay following colonic surgery.¹

The ERAS Study Group, was what it was called back in 2001, when a group of European academic surgeons developed certain new notions to allay approaches for enhanced care. They believed it was the quality of care that mattered more than how fast the care was given, which was based on the physiology of the body's response to surgical stress. In 2005, The ERAS Society was founded to target ongoing education and learnings in ERAS for colonic surgery to implement models for practices across the world. Since then, it has seen many modifications. These principles are tailored around evidence-based elements that will reduce the surgical stress, preserve the physiology of the body mechanisms.^{10, 12}The core concept of ERAS adapts to explain that the metabolic response to stress encompasses - mental, cognitive, physiological, metabolic, homeostatic, physical aspects, which can be lowered by understanding how to control stress. Because, if left unchecked, the very same stress can cause complications, organ dysfunction, morbidity, mortality.^{1,12}

ERAS guidelines depict a transfer in the course of giving care and includes certain protocols that reduce surgical stress, help alleviate return to baseline following surgical stress and plays an important role in preserving physiology. Each step



in the entire care with ERAS assures towards a larger goal of enhanced recovery for the patient.^{1, 7,}

Research has shown that with increased compliance to the guidelines, the lower is the rate of the complications as noted. The ERAS society has in the last decade published modifications of their guidelines to suit different surgical procedures involving abdomen, thorax, urological, gynaecological, cardiac, bariatric, breast surgeries and research has shown that there has been improvement in daily practice and restoration of health.^{1, 4, 6, 12, 14}

Whilst the ERAS protocols are largely surgical and managed by a surgeon, the multidisciplinary approach is the corner stone to its functionality. Right from when a patient arrives to an out-patient clinic, to intraoperatively adjusting the fluid loss and influx to postoperatively deciding on analgesia administration, the anesthesia team perform key roles. Similarly, internists, intensivists, nutritionists, physiotherapists, nursing team and psychologists all play stark parts into ensuring a smooth hospital transit for the patient.^{1, 7, 8, 12}

Age comes with decreased reserve to battle surgical stress, and worsened with the presence of comorbid conditions, especially obesity, diabetes, cardiac disease, cancer. Studies have shown that effect of these, affect the patients in the post-operative healing, immunity and recoup. Pre-operative anxiety, depression implicate into increased pain, delayed healing and greater complications post-operatively.^{1, 12}

Pre-operative optimization as it's called, embarks on the ERAS guidelines, and under its umbrella comes risk assessment, stabilization of the patient, getting the comorbidities under control, smoking and alcohol cessation, counselling to prepare the patient and family/kin for the surgery to alleviate anxiety, assessment and cohesive optimization of the physical, nutritional and mental health of the patient. ^{1, 6, 12}

As mentioned above, the stress response refers to multiple circuits that are activated in the body at the hormonal, metabolic, chemical, immunological, haematological, endocrinological, inflammatory level and warrants an intense reaction with stress hormones – cortisol, growth hormones, glucagon, catecholamines, which in turn induce the let-down of the cytokines and messengers garnered for tissue injury and finally leading to consequences of these criss-cross pathways on the target organs. These pathways induce formation of reactive oxygen species that harbour radicals to impair micro-anatomical structures in the body like DNA, proteins, lipids which can worsen in patients who aren't adequately optimized, who have uncontrolled co-existing diseases, and their stress response surges creating complications.^{1, 12}

The metabolic response throws in mediators that lead to fluid and salt retention. It is associated with mechanisms by which blood shunts to vital organs, body temperature reduces to conserve oxygen, and there are nuclear level changes to proteins produced in the cell. In such a setting - increased intestinal permeability, interstitial edema, chemokines, hypercoagulability of blood causes increased risk of thrombosis and infection. ERAS principles help combat this by – ensuring patient is maintained in normothermia, normovolemia peri-operatively with allowing clear fluids till before surgery, discouraging dehydration by bowel preparation, early onset enteral feeds post-operatively.^{1,5,11,12}

The body usually performs on a balance between anabolic and catabolic measures. Any complex surgery usually inflicts chaos in this balance and causes fall out of the homeostasis leading to insulin resistance. Insulin resistance has been found to be an independent deciding factor in hospital stay. Post-operatively, after the surgical stress, protein catabolism is rampant and causes loss of protein stores in he body, which is far higher in those with insulin resistance and diabetes - this decrement of lean tissue decreases muscle strength, muscle mass, prolongs wound healing, reduced mobilization, increases risk of mechanical ventilation by impeding coughing, and results in poor rehabilitation, recovery and discharge from hospital.^{1, 12}

ERAS deals with insulin resistance by putting forth analogies of carbohydrate loading prior to procedure, epidural anaesthesia, early feeding post-op, and strict glycemic control. The idea of carbohydrate loading draws its inspiration from the fact that stress can be coped better in a fed state than in starvation. This maneuverer has been found to be effective in reducing the insulin resistance by causing an anabolic predominance in patients.^{1, 3, 12}

Tissue trauma stimulates various pathways that light up the catabolic responses in the body, which can be inhibited by advocating epidural and local blocks. Epidural anesthesia also serves to secure adequate cardiovascular, respiratory outcomes. The sooner the enteral feeds are initiated, the faster is the recovery – it hampers bowel ischemia, impairs bacterial translocation, inhibits ileus, ensures good mucosal function, reduces lean body loss, and improves health.^{1, 12}



Surgery and pain go hand-in-hand. Nociceptors are stimulated by multiple mediators activated by the process of surgery that interfere with the normal recovery. The crux for multimodal analgesia in ERAS is based on the complex system of neurohumoral pathways that create pain, which requires varied medications to act at different sites to have an effect. These approaches choose an opioid sparing plan to reduce incidence of PONV, ileus, distension and aid by reducing pain, improving wellbeing, faster mobilization, and prevent thrombosis.^{1,5, 12}

Intra-operative components of ERAS don't lag far behind on their influence to return to normal health. The more extensive the wound, the injury to the surrounding tissues, tissue handling, trauma to the vital structures, fluid loss, bleeding, the larger the inflammatory spiral of stress response; which again predisposes the person to a slow, stagnant recovery. The primary injury inflicted by surgery is due to the direct damage to the abdomen or the structures when handled. The indirect injury arises from bleeding, anesthesia techniques and drugs, physiological aspects of patient position and pneumoperitoneum. That is the reason why minimally invasive surgery, delicate tissue handling, recent advances in energy devices, laparoscopic procedures, smaller incisions and appropriate fluid management are components of accelerated recovery.^{1, 12}

It is recommended to clean the surgical site with a chlorhexidine wash, administer antibiotics prophylactically within 30 mins to 1 hour prior to the procedure, sterile precautions in operating environment, avoidance of abdominal drains, appropriate technique of wound closure, and regular sterile dressings can help reduce incidence of SSI's.^{5, 12}

Normal post-operative recovery routes a negative dip from the baseline and follows indolently back to baseline with a positive curve. The track covered depends on many factors across the 3 phases of the planned surgery and it is herein that ERAS works by uplifting the recovery process, reducing the negative dip and expediting the rehabilitation.⁹

In the post-operative phase, when the body is on its repair, the lesser the active intervention, the pronounced is the healing. It is noted that VTE prophylaxis, early stopping of IVF postoperatively, early removal of RT, Foley's (by POD-1), avoidance of abdominal drains, or early removal augments earlier mobilization, encourages quicker onset of enteral feeds to maintain bowel homeostasis, with supplementation of nutrition, prevention of ileus by chewing gum/laxatives, adequate collective analgesia, glucose control, are crucial components for reduced hospital stay and improved recovery. ^{2, 5, 6, 9, 12, 13}

II. AIM AND OBJECTIVES

The aim of this study is to determine whether ERAS guidelines, can be adapted and utilized in a local setting for elective digestive tract surgeries and to study the outcomes and impacts of such a study.

The objectives of this study are:

- 1. Primary outcome is the length of hospital stay, which is considered as the time from adequate optimization of the patient prior to the surgery till the day the patient is discharged. This entity is compared amongst the 2 groups – cases where ERAS guidelines would be followed, versus controls – where the local hospital guidelines would be followed.
- 2. Secondary outcomes aim at comparing the ERAS guidelines between the 2 groups involving peri-operative thromboprophylaxis, early (by POD-1 or 2) mobilization, enteral feeding, early removal of Ryle's Tube and Foley's catheter, time to stopping intravenous fluids post-surgery, early removal of abdominal drains, post-operative nutritional supplementation, post-operative complications.

The study wishes to record the benefits in terms of time to recovery and duration of hospitalization, early assimilation to active lifestyle by preventing prolonged immobilization.

III. METHODOLOGY

This observational cohort study included patients selected from the government and the private hospitals affiliated to Kasturba Medical College, Mangalore over 20 Months (November 2019 to June 2021)

The patients considered were those planned for one of the following elective surgeries:

- 1. Colorectal resection with anastomosis with/without Colostomy
- 2. Small Bowel resection and anastomosis
- 3. Gastrectomy and bowel anastomosis
- 4. Elective exploratory laparotomy with resection and anastomosis of bowel.
- 5. Pancreatic surgeries

INCLUSION CRITERIA

- 1. Women and men between the age group: 18-75 years
- 2. Patients giving informed consent



3. Patients undergoing elective digestive tract resection and anastomosis as mentioned above.

EXCLUSION CRITERIA

- 1. Patient who didn't give informed consent
- 2. Patients who underwent emergency surgeries
- 3. Pregnancy and lactation
- 4. Patients who had co-morbidities in uncontrolled states :
- a. Uncontrolled Diabetes with FBS >200mg/dl
- b. Ischemic Heart Disease with Ejection fraction < 50% and Hypertension with BP > 150/100
- c. Asthma requiring more than twice daily medications
- d. Seizures that are not controlled with medications
- e. Immunocompromised states those on prolonged corticosteroid therapy, HIV positive states, status post immediate chemo or radiotherapy.
- f. Poor nutritional status with reduced Hemoglobin or Albumin that requires preoperative build up.
- 5. Age group of <18 and >75 years
- 6. Given the Covid-19 pandemic, those patients who were covid positive and eventually underwent elective surgeries were also not considered.
- 7. Those patients who underwent preoperative chemo or radiotherapy at a previous setting, or those who were optimized at successive admissions for control of their comorbidities were also considered for the study, if they met the inclusion criteria and their parameters were stabilized.

The study was taken up after the Institutional Ethics committee approval. The selection of the participants was through non random sampling method.

The surgery consultants decided which group – controls or cases, the subjects were divided into and the course of the patients in both the groups was observed and studied.

Patients and bystanders who consented to participate in the study were assured and thoroughly informed about the study and were assured that it would not affect their treatment.

For all the subjects considered, general physical examination and history was elicited. The surgery that they are scheduled for was explained to them along with the reason for the surgery. ERAS guidelines applied to the cases group were also explained separately.

- 1. Patients with the above mentioned elective digestive tract surgeries were selected according to the inclusion and exclusion criteria.
- groups/categories were made Cases and Control group. Cases group represent the patients where ERAS guidelines were followed and Controls represent the patients where the ERAS guidelines were not applied and the local hospital protocols were applied.
- 3. ERAS guidelines were applied peri-operatively for the cases.
- 4. Patient were followed up till the day of discharge from the time of admission. Each surgery undergone has been treated as one single event. Data of each of the patients were collected on a proforma.
- 5. Comparisons were drawn in terms of the following –
- a) Preoperative optimization
- b) NPO for how many hours prior to surgery solids and liquids
- c) Bowel preparation if given, type and quantity
- d) Premedication if given, and what
- e) Antibiotic prophylaxis if given, and what, for how long
- f) Pre and post-op Thromboprophylaxis given or not, if given, and what
- g) Epidural anesthesia given or not
- h) Post-operative nausea and vomiting if present, and if controlled
- i) Ambulation/Mobilization started on what postoperative day
- j) Orals/Enteral feeding started when postoperatively
- k) Chewing gum and other stimulators for gut motility
- Post-operative analgesia, laxatives, prokinetics if given, type, quantity
- m) Drains if placed, how many and removed when
- n) Ryle's Tube (RT), Foley's Catheter, if placed, removed when
- o) Intravenous fluid (IVF) given for how many days post-surgery
- p) Nutritional supplementation after surgery if given, and what
- q) Post-operative glucose control
- r) Number of days of hospital stay

The end point of each exposure/control would be if – a. the patient gets discharged after the planned surgery, or b. if they have any surgical complications of anastomotic leak, sepsis, pneumonia, Covid-19, or paralytic ileus, or mortality, in which case those patients wouldn't be considered in the final analysis of the study.



However, a mention of those patients has been included in the results to conclude on those subjects who were abandoned in the course of the study.

The patients were followed up till the time of discharge. Their entire peri-operative care was observed and noted according to the guidelines of ERAS.

- 6. There was no further follow up noted after the patient was discharged after the present considered hospital stay. Hence, further information on readmission and post-operative reviews are not noted.
- 7. The hospital stay of the patients was calculated from the time of adequate preoperative optimization, till the day of discharge from the hospital.

SAMPLE SIZE CALCULATION

Sample Size Formula: $(SD^2/AD^2) * (Z (1-\alpha/2) + Z (1-\beta))^2$

 α = Significance level taken as 95% (α = 0.05)

 β =1- Power, where, Power = 90% and so β = 0.10

SD = Standard deviation

AD = Anticipated Difference between Sample Mean (Current study) and Population Mean Z represents the standard normal distribution

The minimum number of cases required as per this calculation comes to 29, and so 30 cases and controls were considered for the study and the total cohort at 60 cases.

PREOPERATIVE	GUIDELINES AS	MEASUREMENT/				
GUIDELINES	RECOMMENDED AS PER	MODULATION MADE FOR				
	ERAS	THE STUDY				
1. Preoperative	Preadmission counselling and Preadmission counselling an					
optimization	written information, nutritional	written information, nutritional				
	supplementation, smoking and	supplementation, smoking and				
	alcohol cessation	alcohol cessation				
2. NPO in hours	2 hours for clear liquids	As per the hospital anesthesia				
	6 hours for solids team protocols					
3. Carbohydrate	2 hours prior to surgery	If followed, it was noted,				
loading drink						
4. Bowel	Avoidance of bowel preparation	rel preparation Surgeon's choice of bowel				
preparation	preferable	preparation followed – electrolyte				
		solution/PEG/antibiotics				
5. Premedication	No preoperative long-acting	If given, it was noted				
	sedative					
	premedication					
6. Antibiotic	Usually given 30 mins before	Surgeon's choice of antibiotics				
prophylaxis	incision, and avoid long post-	noted as per the patient, the				
	operative course	diagnosis and surgery planned				
7. Preoperative	LMWH, intermittent pneumatic	Based on the availability of				
venous	compression	heparin/compression with				
thromboprophylaxis		stockings or crepe bandage or				
		pump				

IV. ERAS GUIDELINES DEFINITION FOR THE STUDY

INTRA	OPERATIVE	GUIDELINES AS	MEASUREMENT/		
GUIDELINES		RECOMMENDED AS PER	MODULATION MADE FOR		
		ERAS	THE STUDY		
1.	Anesthesia given	Epidural anesthesia, given or not	As per the hospital anesthesia		
			team protocols		
2.	Type of surgery	Minimally invasive than open	Surgeon's choice and experience		
			determined the surgery done.		
3.	Ryle's Tube	Avoid use, remove early	If inserted, POD of removal noted.		
4.	Abdominal	Avoid use, remove early	If inserted, POD of removal noted.		
drains			If more than one drain, mention		
			made of the same and POD of		
			removal		



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5. Maintenance	f To be maintained throughout	As per the hospital anesthesia	
normothermia	procedure	team protocols	
6. Intraoperative	Maintaining fluid balance to avoid	As per the hospital anesthesia	
Fluid Management	over or under hydration	team protocols	
administer vasopressors to support			
blood pressure control			
7. Foley's Cathete	Removal as early as possible, by POD-1	If inserted, POD of removal noted.	

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POSTOPERATIVE	GUIDELINES AS	MEASUREMENT/		
	RECOMMENDED AS PER	MODULATION MADE FOR THE		
	ERAS	STUDY		
1. Postoperative	Preferable used	If advocated, surgeon's choice noted		
laxatives		_		
2. Mobilization	As early as possible, POD-1	When started, POD noted		
started on POD				
3. Enteral feeds	As early as possible, by POD-1	When started, POD noted		
started on POD	5 1 7 5	,		
4. IVF stopped	As early as possible, by POD-1	When stopped, POD noted		
on POD				
5. Postoperative	LMWH, intermittent pneumatic	Based on the availability of		
Venous	compression	heparin/compression with stockings		
thromboprophylaxis	1 I	or crepe bandage or pump		
6. Post-	Chewing gum	If given, it was noted.		
operative Gut motility	00			
agents				
7. PONV	Multimodal approach	Drugs given noted.		
avoidance	TI TI			
8. Post-	Opioid sparing as far as possible,	Drugs given noted.		
operative analgesia	as less as possible			
given				
9. Post-	Strictly maintained with regular	Methods to control sugars noted as		
operative glucose	blood sugars and insulin/OHA's	per the hospital internal medicine		
control		team		
10. Post-	To enhance feeding with	If supplementation given, it was		
operative Nutritional	important nutrients by POD-1	noted.		
Support	_r			
~~PPoit				

Some of the ERAS parameters were followed as per the respective hospital anesthesia team and their goals for premedication/NPO to liquids and solids/need for epidural and the level of the epidural anesthesia/ intraoperative fluid management/ maintenance of normothermia/ choice of anesthesia for each of the patients in the 2 groups, was decided by the anaesthesiologist incharge and their decision was final. Hence, these followed guidelines were only documented for analysis and not elaborated.

Similarly, the guidelines for post-operative glucose control were followed according to the hospital Internal Medicine team and the sugars were managed according to the physician incharge. In most of the abdominal surgeries as observed in both groups, abdominal drains were usually placed, and in instances where it warranted more than one abdominal drain (maximum four), the drain removed the fastest amongst all the drains was considered for analysis, titled as "Drain 1 removed on POD".

Oral/enteral feeding was considered as the day when the patient first had liquids – usually sips of water – either through the RT/ feeding tube or orally.

POD – stands for Post-operative day and it includes numerical data. POD-0 refers to the day of the surgery, and the first day after surgery is 1 and so on. POD-7 would imply the 7th day after surgery.



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V. STATISTICAL ANALYSIS

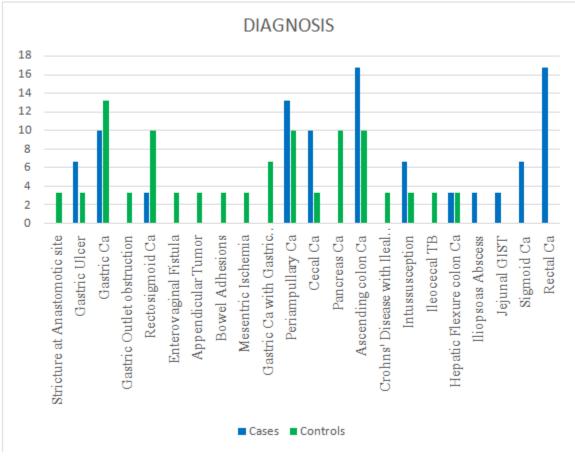
All the data collected was entered into Microsoft Excel. SPSS IBM software version 22.0 was used to perform statistical tests and graphs. According to the variable type, count, percentage, mean, quartiles, median, SD and IQR were calculated and using the Chi Square test, Mann-Whitney U test, the p value was computed.

p value <0.05 was considered significant.

Using the Spearman Rank Correlation, corelation and association, if any, between the hospital stay (in days) and the other secondary variables was identified. p value <0.05 was considered significant.

VI. RESULTS

In the age distribution, the mean and SD were almost identical between the groups -57.3 ± 12.65 years in cases, vs 54.5 ± 12.65 years in controls (p value 0.464). The controls showed an equal distribution of males and females as compared to cases. Private hospital distribution appeared to be 70% in both the groups considered. Overall, the demographics cross the 2 groups was evenly distributed.





In Figure 1, the diagnosis varied across the 2 groups, but gastric cancer was more prevalent in the controls, rectal cancer more in the cases, periampullary and colon cancer was distributed uniformly and these represented the main diagnosis in the 2 groups

On comparing comorbidities in the 2 groups showed – higher incidence in the cases at 67% vs 53% in the controls. Out of the comorbidities, Diabetes Mellitus, Hypertension

were primarily noted with Ischemic Heart Disease (IHD), Bronchial Asthma (BA) and Hypothyroidism closely following. Diabetes was noted in 40% (12 patients) of the cases, vs 26.7% (8 patients) in the controls. Hypertension was noted in 43.3% (13 patients) of the cases, vs 40% (12 patients) in the controls.

The surgery performed varied across the groups – involving surgeries on the stomach, small bowel and large bowel, and depending upon the



diagnosis, however, most of the surgeries overall included Whipple's procedure (16.7%), Anterior resection and colorectal anastomosis (15%), Right colon resection and appropriate anastomosis (26.5%), Gastrectomy and gastro-jejunostomy (20.2%). 8 out of the 60 (13%) of the overall cohort underwent laparoscopic surgeries whilst the remaining were open surgeries.

Smoking history noted was prevalent in about 1/3rd of the cases and controls. Alcohol history noted was more prevalent in the controls. Epidural anesthesia was given in 83% of the cases vs compared to 63% in controls. Preoperative venous thromboembolism was advocated in 96.7% of the cases vs only in 76.7% of the controls. Of options available, DVT pump was the most commonly used mechanism for preoperative prophylaxis, followed by mechanical prophylaxis with crepe bandage.

All patients in both groups underwent preoperative counselling. None of the patients in either cases or controls received any carbohydrate loading drink or premedication prior to the procedure. All patients in both groups received combination antibiotics preoperatively and that was continued for at least 7 days post-operatively.

Intraoperatively, every patient in both groups were kept under normothermic conditions as per the hospital anesthesia team protocols – either with warm blankets, warm fluids or external devices. Intraoperatively, fluid management was under the control of the hospital anesthesia team, was monitored and give according to their protocols. Post-operative pain management included NSAID's in all the patients in both groups, and also opioids – especially Tramadol, but there was need for escalation of pain control with other opioids in 13.3% on cases and 23.3% of controls. All patients in both groups were managed with a similar multimodal approach for prevention of PONV.

As mentioned in the methodology, we had to abandon the following cases when the patients developed complications of ileus, anastomotic leak, sepsis, pneumonia, or covid-19 –

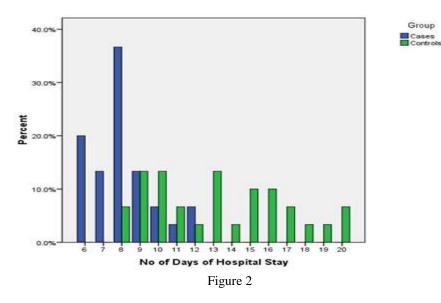
- 1. 75 y/o female, diagnosed with gastric outlet obstruction, due to gastric ca, developed anastomotic leak, burst abdomen after surgery.
- 49 y/o female, diagnosed with sigmoid colon ca, developed anastomotic leak and sepsis after surgery
- 3. 38 y/o male, diagnosed with mesenteric ischemia, was Covid positive.

Bowel preparation prior to procedure was given in 76.7% of the cases as compared to 60% in controls. In both groups the most commonly given preparation was PEG and phosphate enema. Postoperatively laxatives were given in non-colorectal surgeries in 16.7% on the cases vs 30% on the controls.

Abdominal drains were placed in all controls and almost all cases.

Surgical site infection (SSI) was observed in 16.7% of the cases as compared to 36.7% in the controls.

Post-operatively all the cases and controls received combination of nutritional supplements. In both groups, most of the patients (70%) received boosting protein powder mix with multivitamin tablets; supplementation with Albumin infusion was twice as more common in controls than the cases and only one patient in the control group received TPN.



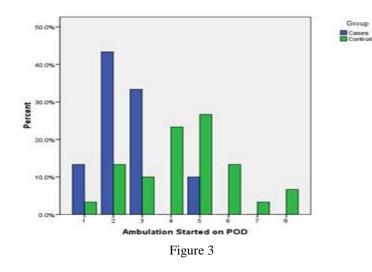


In Figure 2, when compared on the number of days of hospital stay, cases showed peak for 8 days (36.7%) followed by, 6 days (20%) and then 7 and 9 days (13.3% each), whereas, for the controls, it was distributed more evenly – across days 9, 10, 13 15, 16 (10-13%).

On comparison between the 2 groups, 8,2 days in cases vs 13,6 days in controls was the average hospital stay. The difference showed statistical significance, p value 0.001.

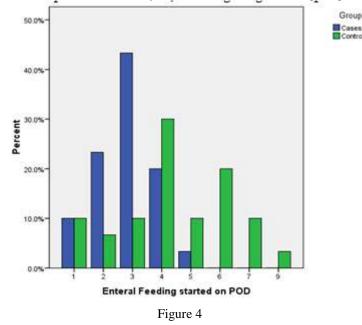
NPO to solids time was longer for controls as compared to cases. And a similar trend was observed for NPO to liquids time. Epidural was removed on POD 2 in 84% of the cases, but only in about 58% in controls, as compared to POD 3.

Considering median and IQR, cases showed 2,0 vs 2,1 in controls for POD removal of the epidural. There was no significance with respect to the p value between the groups (p = 0.057).



In Figure 3, Ambulation was started on POD 2 (43.3%), followed by on POD 3 (33.3%), whereas in the control it was distributed mainly

across POD 4-6 (13-26.7%). When compared, cases showed 2,1vs 5,2 days for start of patient ambulation, showing a significant p value of 0.001.



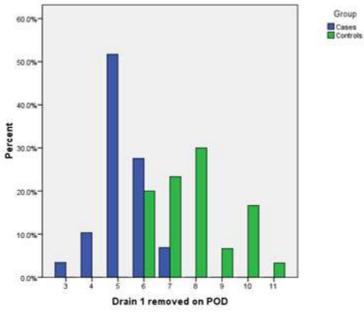
In Figure 4, Enteral feeding was started earlier in the cases group, around 43% on POD-3

and 23% POD-2 versus later on in controls on POD 4-7 (10-30%). When compared using median and



IQR, starting enteral feeds post-operatively in cases was at 3,1 vs 4,3 days in controls with a significant

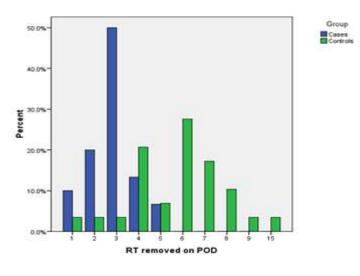
p value of 0.001.





In Figure 5, abdominal drains were removed faster on POD-5,6 in the cases group, accounting for about 79% overall, and removed later in the controls on POD-6,7,8 accounting for 73%.. Among the groups, cases showed a median of 5,1 days before the drain removal vs 8,2 in controls, with a p value 0.001 showing significance.

A second drain was placed in 6 patients in cases and most removed on POD-6 as compared to 12 patients in controls and most removed on POD-6, 7. A third drain was placed in 4 patients in the control group, and removed beyond 7 days.

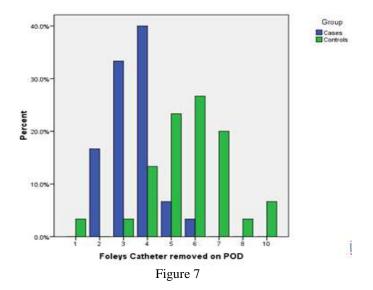




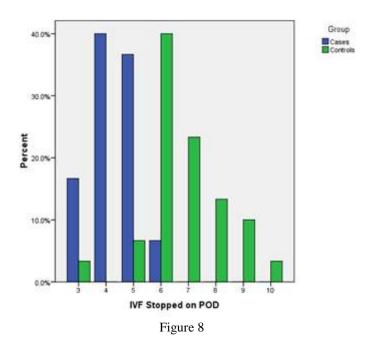


In Figure 6, Ryle's Tube was removed faster in the cases, mainly on POD-2,3 accounting for 70% of overall cases, whereas, removed later on POD-6,4,7 accounting for almost 66% in the controls group. Comparing between the 2 groups,

with cases showing a median and IQR of 3,1 vs 6,3 days postoperative for RT removal in controls, the p value was significant with 0.001.



In Figure 7, Foley's Catheter was removed faster in the cases, mainly on POD-2,3,4 accounting for 90% of overall cases, whereas, removed later on POD-5,6,7 accounting for almost 70% in the controls group. Comparing between the 2 groups, with cases showing a median and IQR of 4,1 vs 6,2 days post-operative for catheter removal in controls, the p value was significant with 0.001.



In Figure 8, Intravenous Fluids were stopped sooner in the cases, mainly on POD-4,5

accounting for 77% of overall cases, whereas, continued for longer till POD-6,7,8 accounting for



almost 67% in the controls group. Comparing between the 2 groups, with cases showing a median and IQR of 4,1 vs 7,2 days for stopping IVF post-operatively in controls, the p value was significant with 0.001.

The main outcome variable – the hospital stay in days, showed a median with IQR of -8, 2 in cases vs in controls with 13, 6 days, creating a significant difference between the 2 groups.

Variable	I able 1 N Median IQR				P-		
v ur lubic	11				ivit		Value(Mann
	Cases	Controls	Cases	Controls	Cases	Controls	Whitney test)
Age	30	30	60	55	16	19	0.464
NPO to Solids in hours	30	30	8	8	2	0	0.054
NPO to Liquids in hours	30	30	2	2	0	0	0.132
Epidural Removed on POD	25	19	2	2	0	1	0.057
Ambulation Started on POD	30	30	2	5	1	2	0.001
Enteral Feeding started on POD	30	30	3	4	1	3	0.001
Drain 1 removed on POD	29	30	5	8	1	2	0.001
RT removed on POD	30	29	3	6	1	3	0.001
Foleys Catheter removed on POD	30	30	4	6	1	2	0.001
IVF Stopped on POD	30	30	4	7	1	2	0.001
No of Days of Hospital Stay	30	30	8	13	2	6	0.001

Table 1

As per Table 1, Using the Mann-Whitney U Test, considering a significant p value of <0.05, we found that between the groups, there was significance noted in these variables in the cases as compared to the controls – Ambulation started on

OPD, enteral feeding started on POD, Drain 1 removed on POD, RT removed on POD, IVF stopped on POD, Foley's catheter removed on POD, and the overall no. of days spent in the hospital.



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No of Days of Hospital Stay							
Spearman Rank Correlation	Cases			Controls			
Variable	N	Correlation	P-Value	N	Correlation	P-Value	
Age	30	-0.257	0.170	30	-0.007	0.970	
NPO to Solids in hours	30	0.365	0.047	30	-0.145	0.444	
NPO to Liquids in hours	30	-0.104	0.586	30	-0.077	0.684	
Epidural Removed on POD	25	0.498	<mark>0.011</mark>	19	0.694	0.001	
Ambulation Started on POD	30	0.571	0.001	30	0.492	0.006	
Enteral Feeding started on POD	30	0.545	0.002	30	0.143	0.452	
Drain 1 removed on POD	29	0.650	0.001	30	0.676	0.001	
RT removed on POD	30	0.407	0.026	29	0.500	0.006	
Foleys Catheter removed on POD	30	0.322	0.083	30	0.606	0.001	
IVF Stopped on POD	30	0.712	0.001	30	0.505	0.004	

Table 2

In Table 2, using the Spearman Rank Correlation, which identifies correlation between variables, and the magnitude of the value of the correlation gives a linear relationship, considering a significant p value of <0.05, we found the following results :

- 1. The correlation of hospital stay to ambulation started on POD is higher in the cases than the controls
- 2. The correlation of hospital stay to IVF stopped on POD is also higher in cases than controls
- 3. But, when comparing RT removed on POD, Drain 1 removed on POD and Epidural removed on POD, with hospital stay, there was a greater correlation noted in the controls than cases.

VII. DISCUSSION

Implementing ERAS guidelines is protracted – the protocols are diffuse and pan across the entire perioperative timeline, requiring continuum of care and have a lot of variation in their enforcement across caregivers, across centres. In addition there is a strong need for a dedicated multidisciplinary team who can cater and execute these strategies. The awareness of fast-track surgeries is now well known worldwide and despite advancement in minimally invasive surgery, the ERAS guidelines haven't yet been accepted wholly in India.²⁶

Our study targets this gap and bridges the acceptance by showing that with similar resources in a local setting, that ERAS protocols can play a major role in the overall health and reduce morbidity. We believe that this study is one of a kind from India - there have been very few studies that have considered all the ERAS protocols and contrasted them with ongoing traditional medical practice; and aimed at exhibiting a feasible workflow for ERAS protocols in a local secondary/tertiary care setup. This study compared ERAS strategies to the pre-existing strategies followed for elective surgeries on the gastrointestinal tract. Most of our data considered is quantitative and objective.

The study was carried out during the Covid-19 pandemic, and though this brought certain challenges, we could still apply the ERAS guidelines for patient care and impress its broad scope of applicability and benefits as reflected in our results.



The prospective observational cohort studied was included from both government and private hospitals in the local setting. This distribution amongst the type of hospitals provided us with sub cohorts from among which we could compare the results and the usefulness of ERAS protocols, in government set-up could in future play an important role in defining the healthcare system of the country.

Our study found a uniform distribution of the study group based on their demographics. The study cohort had an assorted mix of diagnoses with a higher incidence of malignancy in both groups gastric cancer was more prevalent in the controls (22%), rectal cancer more in the cases (16.7%), periampullary (30%) and colon cancer (46%) was distributed uniformly and these represented the main diagnosis in the 2 groups. The surgeries performed mainly involved the pancreas, stomach, colon and rectum, and 13% of them were laparoscopically done.

In the ERAS group, early mobilization (By POD- 2 or 3), early onset of enteral feeding (by POD-2 or 3), removal of drains and tubes (POD- 5 or 6 for drains, POD- 2 or 3 for RT and Foley's catheter), decreased need for post-operative intravenous fluids (by POD- 4 or 5), early discharge from the hospital (POD-8 vs POD -13) and fewer complications was noted that was significantly different than as compared to the other group. These findings are at par with the studies in literature.^{16, 17, 19, 20, 21, 22, 23, 24, 25, 27, 28, 29} Our study didn't include follow-up of the patients beyond their discharge; each discharge was treated as a separate entity.

Hospital stay was a primary outcome – and we found that hospital stay was statistically shorter with patients in the ERAS line of treatment than the other. Again this is in line with the other studies compared. ^{16, 17, 19, 20, 21, 22, 23, 24, 25, 27, 28, 29}

As per the rules of ERAS, mechanical bowel preparation is not recommended.^{21, 30} Nonetheless, bowel preparation prior to surgery mainly colorectal surgery can play a major role in preventing infections. This concept even though reported across literature, has yet to find a place in ERAS guidelines. In our study at the advice of the operating surgeons, about a third of the patients in both arms received bowel preparation.

The need for nil oral intake prior to surgery as per ERAS follows a short overnight fast and a carbohydrate loading drink 2 hours prior to the surgery.^{26, 27}Since the timing of the surgeries were not always after an overnight fast, with the due consideration in diabetic patients, apprehension of surgery, possible aspiration chances and anesthesia team instructions, these were modified accordingly. We found that the time for the NPO status advocated for controls was longer than the cases and maybe related to observer bias.

Venous thromboembolism prevention with prophylaxis was followed peri-operatively across our cohort and ranged from mechanical sources like DVT pumps, stockings, to heparins. Postoperative pain management combined NSAID's and Opioids. All our patients received multimodalanalgesia.^{2, 7, 10, 13, 15, 22, 23}

Each of our patients received perioperative antibiotics. ERAS guidelines ^{10, 18, 10, 18, 26} recommend preoperative antibiotics given 30 mins prior to the incision, and not more than 24 hrs post-operatively; however our study showed an adjustment in this. A course of combined antibiotics usually started on the morning of the surgery day, or a few hours prior to the surgery, and continued for at least five days after surgery, which were converted to oral available forms. The operating surgeon decided which antibiotic combinations were used and for how long.

Ryle's tube (RT) and Foley's catheterization was done in all our patients across both groups. ERAS guidelines state that RT and Foley's catheter could impede early mobilization of the patient, early feeding and hinder normal gut function and hence recommends early removal of the accessory tubes.^{16, 17, 19, 20, 21, 22, 23, 24, 25, 27, 28, 29}

RT and Foley's catheter were removed earlier (by POD- 2, 3) in the patients in the ERAS group. However, we noticed some changes in the timing of their removal – a patient after Whipple's/gastric surgery would have the RT later than would a patient with colorectal surgery and similarly a patient on an epidural for pelvis surgery and anastomosis would have the Foley's catheter removed later than the one undergoing a gastric surgery without epidural.

Enteral feeding was started either orally/ through feeding tube/RT. Our study found that the patients under the ERAS group were started on feeds earlier (by POD - 2, 3) than the other group. As shown by ERAS, early feeding plays a role in early discharge of the patient by improving gut function. ^{16, 17, 19, 20, 21, 22, 23, 24, 25, 27, 28, 29}

Mobilization was planned as early as possible and was aided by the physiotherapy team. ERAS group showed earlier mobilization than the other - this might have a relation to the early removal of the accessory tubes, early enteral feeding and decreased need for post-operative intravenous fluids.



This study was underway when the Covid-19 pandemic hit. These circumstances made it difficult for the ERAS guidelines and with the prerequisite statutory restrictions of covid negative results prior to elective surgeries, and increase in emergency surgeries, there was delay in collecting data.

Our study considered patients in an indexed point frame, till their time of discharge, after which there was no follow up – about readmission, complications, morbidity or mortality.

Also, intra-operative parameters like blood loss, total time of surgery, techniques of operative surgery that play a role and influence surgical outcomes were considered, however due to the time constraints, Covid-19 situation, were not studied in detail.

The hospital stay across the 2 groups varies significantly. However, the median hospital stay in ERAS group is higher than as compared to other studies; we believe this might reflect the different diagnoses and surgeries in our cohort, in contrast to the other studies which only considered one type of diagnosis or surgery.

We conclude by stating that implementing ERAS strategies can enhance overall health for the patients. We were able to show statistical significance on multiple parameters of ERAS and future similar studies could help substantiate our findings.

VIII. CONCLUSION

The above study details the ERAS guidelines that can be used in the local setup with strong evidence for enhanced recovery with reduced morbidity and hospital stay. Thereby, reiterating the call for a change in the local protocols. We would also like to point out that in spite of the negative impact, challenges and constraints that we faced due to the Covid-19 pandemic our study has proved and opened the scope with profound impact for a wider scale of the implementation of ERAS guidelines.

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