

# **RANDOMISED CONTROL TRIAL COMPARING OUTCOMES OF ENHANCED RECOVERY AFTER BARIATRIC SURGERY(ERABS) PROTOCOL IN ROUX-EN Y GASTRIC BYPASS (RYGB) PATIENTS.**

- Speaker : Dr. Manish Khaitan
- Co-investigator: Dr. Vinay Khatri

# Warm greetings from Team Nobesity





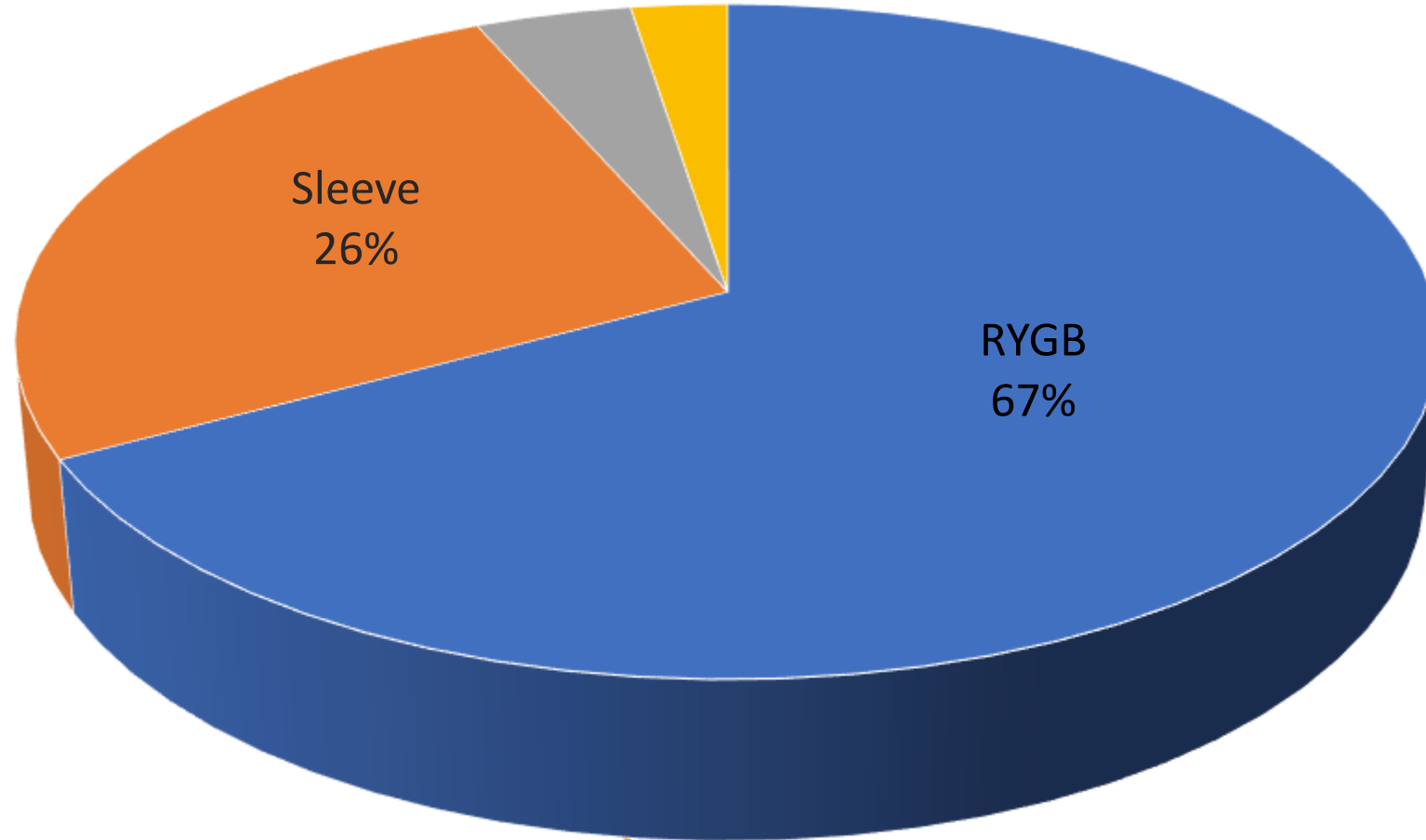
Dr. Manish Khaitan  
MBBS, MS, FIAGES, FALS, FMBS  
Director & Chief Bariatric Surgeon,  
Nobesity Bariatric Centre, Ahmedabad.

## PROFESSIONAL AFFILIATIONS

- Immediate Past President Of Obesity Surgeons Society of India (OSSI)
- Member of International Federation for Surgery of Obesity & Metabolic Disorder (IFSO)
- Member of All India Minimal Access Surgeons of India (AMASI)
- Member of Association of Surgeons of India (ASI)
- Member of Indian Association of Gastrointestinal Endosurgeons (IAGES)
- Member of Indian Medical Association (IMA)

# Case Mix

■ RYGB   ■ Sleeve   ■ OAGB   ■ Revision  
OAGB 4%   Revision 3%



# Disclosure

- No disclosures



# INTRODUCTION

- Enhanced recovery after surgery (ERAS) pathways comprises of a series of perioperative, multidisciplinary, evidence-based interventions that were developed initially for elective colorectal surgery.
- ERAS pathways aim to optimise physiological function, enhance mobilisation, reduce pain and facilitate early oral nutrition postoperatively by reducing perioperative surgical stress.
- Adopting ERAS protocol resulted in reduced morbidity, reduced hospital stay, improved patient compliance and cost-effectiveness.

- After successful application of ERAS in many surgical disciplines, in recent years ERAS is being followed in the setting of bariatric surgeries (Enhanced Recovery After Bariatric Surgery).
- Thorell et al in 2016 have published the guidelines for perioperative care in bariatric surgery as suggested by Enhanced Recovery After Surgery (ERAS) Society.
- A number of studies then evaluated the benefit of ERAS protocol in bariatric surgery. Yet, only a **few studies have been published to prove its validity and importance in RYGB in Asian subcontinent.**

- Thorell A, MacCormick AD, Awad S, Reynolds N, Roulin D, Demartines N, Vignaud M, Alvarez A, Singh PM, Lobo DN. Guidelines for Perioperative Care in Bariatric Surgery: Enhanced Recovery After Surgery (ERAS) Society Recommendations. World J Surg. 2016 Sep;40(9):2065-83. doi: 10.1007/s00268-016-3492-3. PMID: 26943657.

# AIMS & OBJECTIVES:

- To evaluate the outcomes of Enhanced recovery after Surgery (ERAS) protocol in patients of Roux-en Y Gastric Bypass.

## RESEARCH QUESTION

1. Impact of ERAS protocol on **Length of Stay (LOS)**
2. Impact of ERAS protocol on **resumption of daily routine activity.**
3. Impact of ERAS protocol on **Post Operative Nausea and Vomiting (PONV).**
4. Impact of ERAS protocol on **Post Operative Pain.**



# METHODOLOGY:

- Subjects were patients undergoing RYGB by Nobesity at KD Hospital, Ahmedabad.
- This was a **single center blinded randomized prospective trial**.
- Principal Investigator and Anesthetist were not blinded in this trial.
- Principal Investigator was involved in pre-operative counseling and optimization as per the allocated group.
- Randomization was done with the help of computer-generated randomization and patients were allocated to ERAS or Standard protocol group.
- Patients in **ERAS and Standard protocol group followed a different clinical pathway**

ERAS PATHWAY	STANDARD PATHWAY
<b><u>Pre-Operatively</u></b>	
Information and counselling regarding ERAS	Normal preoperative counseling
Solids allowed up to 6 hours before surgery	Overnight fasting
1st Pre-Surgery drink at night	--
Tab. Aprepitant 125/80 mg at night	--
Tab. Paracetamol 1 gram at night	--
Tab. Gabapentin 300mg at night	--
<b><u>On the Day Of Surgery</u></b>	
2nd Pre-Surgery drink 2 hours before surgery	--
Tab. Aprepitant 125/80 mg	--
Tab. Paracetamol 1 gram	--
Tab. Gabapentin 300mg	--
Inj. Dexamethasone 90 mins before surgery	Inj. Dexamethasone at the start or during surgery
<b><u>Intraoperatively</u></b>	
Restrictive IV fluid therapy(12-15 ml/kg/hr)	Liberal IV fluid therapy(25-30 ml/kg/hr)
Nitrous oxide as carrier gas	Nitrous oxide as carrier gas
Desflurane	Desflurane
TAP Block	No block
<b><u>Post-Operatively</u></b>	
Restrictive IV fluid therapy	Liberal IV fluid therapy
Oral Fluids started at 6 hours postoperatively	Oral Fluids started at 24 hours postoperatively
IV Fluids stopped on Post-Operative day 0	IV Fluids continued up to satisfactory oral intake

## STUDY DESIGN

- This study was a hospital based prospective study.
- Total study period- 1year

## INCLUSION CRITERIA

- All patients under the age of 60 years who underwent Laparoscopic RYGB at Nobesity at KD, Hospital during the study period.

## EXCLUSION CRITERIA

- Patients not willing for participation.
- Redo Bariatric Surgery.
- ASA grade more than III.
- Patients requiring combined procedure ( Hernioplasty, Cholecystectomy etc.)
- Patients with Chronic Renal Failure and Chronic Liver Disease.
- Patient above 60 years of age.

## OUTCOME

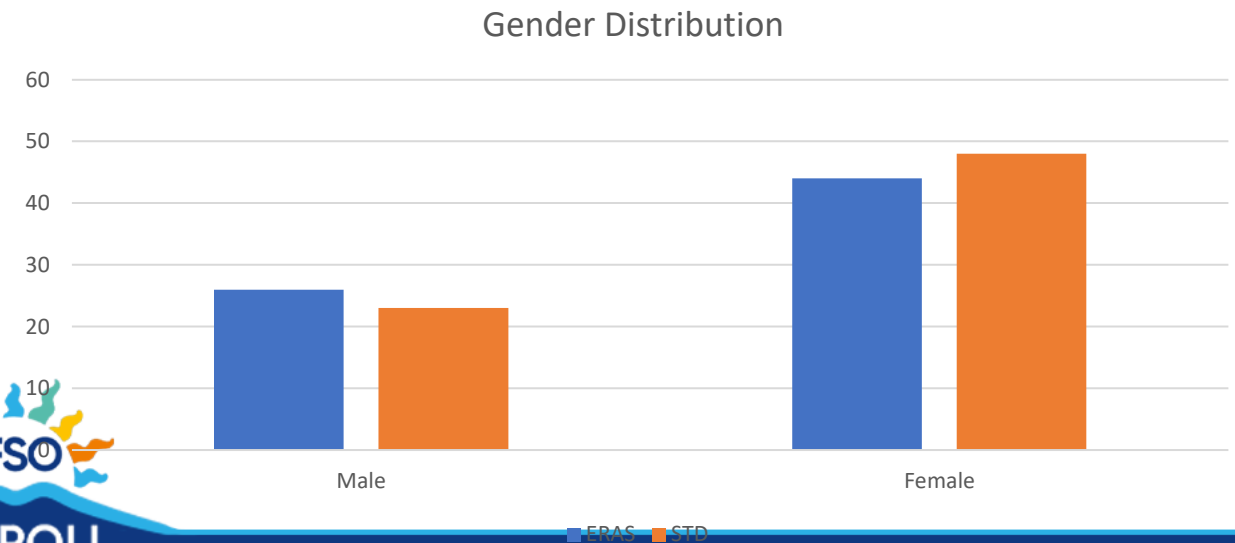
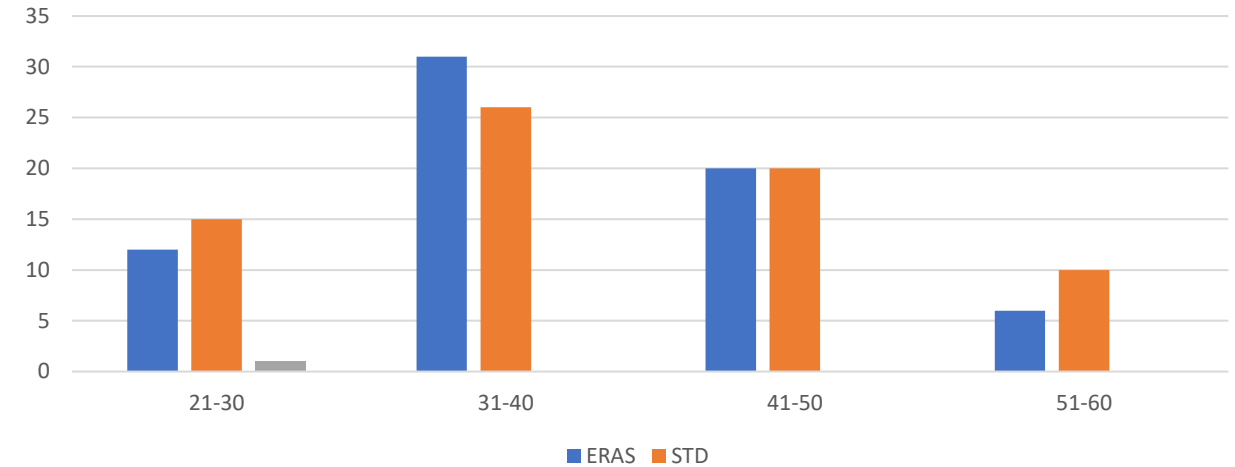
- Difference in the Length of stay (LOS) between ERAS and STD protocol group.
- Post-operative pain reduction between ERAS and STD protocol group.
- Post operative nausea and vomiting (PONV) between ERAS and STD protocol group.
- Complication rates / 30 days readmission rates between ERAS and STD protocol group.

## STATISTICAL ANALYSIS

- All the baseline demographic, clinical, preoperative and post operative data if the patients were entered inside the Microsoft Excel 2019<sup>®</sup> and descriptive statistics were analysed using SPSS 25.0, (IBM corporation<sup>®</sup>) was used. **Paired t test** was used to calculate the difference between the ERAS protocol group and Standard protocol group. P value less than 0.05 was considered as statistically significant.

# RESULTS

- A total of 140 subjects were enrolled in the study
- 70 patients were enrolled in ERAS group and 70 in Standard protocol group
- Mean age in our study was  $39.06 \pm 9.54$  years, most common age group was 31-40 years in our study.
- Gender was almost equally distributed in both the groups



- Resumption of bowel sound

	<6 hours	6-8 hours	8-16 hours
ERAS	39 (55.71%)	28	3
STANDARD	18	42 (59.1%)	11



- Passage of flatus for the first time post surgery

	<24 hours	24-30 hours	31-36 hours	37-40 hours
ERAS	9	40 (57.14%)	21	0
STANDARD	0	16	48 (67.6)	7

- Passage of faeces for the first time post surgery

	<30 hours	30-36 hours	37-40 hours	41-48 hours
ERAS	2	14	27 (38.5%)	27 (38.5%)
STANDARD	1	0	10	60 (84.5%)



# Average Post Operative Nausea and Vomiting Score (PONV)

Assessment	Score
<b>A. At 6 hours after surgery (or time of discharge if after ambulatory surgery)</b>	
Q1 Have you vomited or had dry-retching*?	
a) No	0
b) Once or twice	2
c) Three or more times	50
Q2 Have you experienced a feeling of nausea ("an unsettled feeling in the stomach and slight urge to vomit")? If yes, has your feeling of nausea interfered with activities of daily living, such as being able to get out of bed, being able to move about freely in bed, being able to walk normally or eating and drinking?	
a) No	0
b) Sometimes	1
c) Often or most of the time	2
d) All of the time	25
Q3 Has your nausea been mostly:	
a) varying ("comes and goes")?	1
b) constant ("is nearly or almost always present")?	2
Q4 What was the duration of your feeling of nausea (in hours [whole or fraction])?	__ . __ h
For Part A, if answer to Q1 = c), score A = 50; otherwise, select the highest score of Q1 or Q2, then multiply x Q3 x Q4	PONV intensity score (0-6 h) <b>A =</b>

\*Count distinct episodes: several vomits or retching events occurring over a short time frame, say 5 min, should be counted as one vomiting/dry-retching episode; multiple episodes require distinct time periods without vomiting/dry-retching

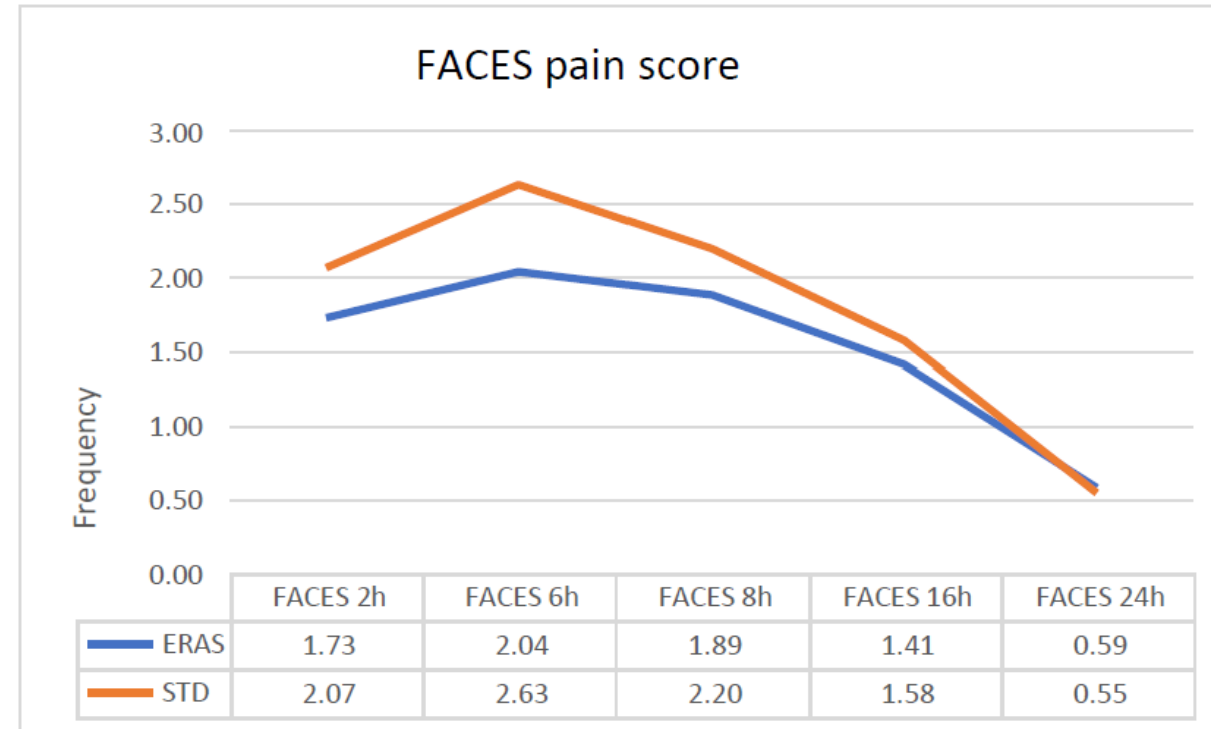
## Scoring for Clinical Importance of PONV

Total Score	Score
Clinically important PONV is defined as a total score $\geq 50$ at any time throughout the study period. Scores at 6 and 24 (and, if considered important in the clinical context, 72) hours can be added for quantification of the entire period, or sub-scales used for each period.	Final PONV intensity score (0-72 h)
<b>A + B + C =</b>	

Score	ERAS	STD
0	24 (34.2%)	13 (18.30%)
1	1	0
2	19 (27.14%)	12 (16.90%)
3	4	0
4	7	17 (23.9%)
5	3	3
6	6	2
8	2	3
10	1	1
12	1	3
14	1	1
16	1	0
18	0	2
25	0	1
26	0	3
27	0	2
28	0	2
50	0	3

- # FACES Pain Score

FACES Score	ERAS	STANDARD
2 hours	1.72 ± 1.36	2.07 ± 1.47
6 hours	2.04 ± 1.91	2.63 ± 1.72
8 hours	1.88 ± 1.60	2.19 ± 1.48
16 hours	1.41 ± 1.51	1.57 ± 1.39
24 hours	0.58 ± 0.95	0.54 ± 0.77





- Surgical Time in Minutes**

	STANDARD group(n=71)	ERAS group(n=70)	P value
<b>Mean</b>	69.97	76.75	0.002
<b>SD</b>	10.31	10.93	

P value is less than 0.05. So, statistically significant

- Patient Satisfaction Score out of 10**

	STANDARD group (N=71)	ERAS group (n=70)	P value
Mean	7.31	7.51	0.130
SD	0.772	0.694	

P value is not less than 0.05. So, not statistically significant

- **Length Of Stay in days (LOS)**

	STANDARD group(n=71)	ERAS group(n=70)	P value
<b>Mean</b>	2.56	2.29	0.0131
<b>SD</b>	0.73	0.57	

P value is less than 0.05. So, statistically significant

- **Complications**

There were no complications noted in our study and 30 days readmission rates were also zero.

# DISCUSSION

- We started this study with the aim to evaluate the outcomes of enhanced recovery after bariatric surgery (ERABS Protocol) in Roux-en-Y Gastric Bypass (RYGB) patients.
- We recruited a total of 140 subjects in the study. Mean age in our study was  $39.06 \pm 9.54$  years, most common age group was 31-40 years in our study.
- Both the groups were comparable in comorbidities. ( $p=0.213$ )

# Impact on resumption of daily routine activity

- In our study, resumption of bowel sound was seen statistically early in ERAS 7.2 hours as compared to 8.7 hours. (p=0.010).
- Early passage of first flatus postoperatively is seen in ERAS group as compared to Standard group. (p=0.048).
- Passing of first stool post operatively is seen early in ERAS group as compared to standard group. (p=0.003).
- Similarly in Study by Kim et. al reported early resumption of a regular bowel habits following surgery in ERAS group.

- Kim, J. Y., Wie, G. A., Cho, Y. A., Kim, S. Y., Sohn, D. K., Kim, S. K., & Jun, M. D. (2018). Diet modification based on the enhanced recovery after surgery program (ERAS) in patients undergoing laparoscopic colorectal resection. *Clinical Nutrition Research*, 7(4), 297-302.

# Impact on PONV score

- In our study, total PONV score for 0-6 hr and 6-24 hr in ERAS was significantly lower as compared to standard group. (p=0.000 and p=0.041, respectively).
- The PONV score for 24-48 hr in ERAS was lower as compared to standard group, but not statistically significant. (p=0.543).
- But the overall total PONV score was lower in ERAS group as compared to standard group. (p=0.003).
- A systematic review, by Parisi A and team also suggested that decrease in the incidence of PONV.
- Another meta analysis suggested that PONV were observed in 39% of the ERAS group as compared to 52.6% of the standard group.
- A previous RCT in RYGB patients by Ruiz-Tovar and colleagues reported decreased incidence of PONV 8.9% versus 2.2%.(STD vs ERAS).

- Parisi A, Desiderio J, Cirocchi R, Trastulli S. Enhanced Recovery after Surgery (ERAS): a Systematic Review of Randomised Controlled Trials (RCTs) in Bariatric Surgery. *Obes Surg.* 2020 Dec;30(12):5071-5085. doi: 10.1007/s11695-020-05000-6. Epub 2020 Sep 26. PMID: 32981000.

- Zhou J, Du R, Wang L, Wang F, Li D, Tong G, Wang W, Ding X, Wang D. The Application of Enhanced Recovery After Surgery (ERAS) for Patients Undergoing Bariatric Surgery: a Systematic Review and Meta-analysis. *Obes Surg.* 2021 Mar;31(3):1321-1331. doi: 10.1007/s11695-020-05209-5. Epub 2021 Jan 9. PMID: 33420977.

- Ruiz-Tovar J, Garcia A, Ferrigni C, Gonzalez J, Castellon C, Duran M. Impact of implementation of an enhanced recovery after surgery (ERAS) program in laparoscopic Roux-en-Y gastric bypass: a prospective randomized clinical trial. *Surg Obes Relat Dis.* 2019 Feb;15(2):228-235. doi: 10.1016/j.soard.2018.11.002. Epub 2018 Nov 14. PMID: 30606469.

# • Impact on rescue analgesia

- In our study, FACES pain score for 24 hr was reported low in ERAS group patients as compared to standard group. (p=0.001).
- Time of rescue analgesia used was more in ERAS group as compared to standard group. Where in the use of Paracetamol, tramadol, fentanyl use was lower in ERAS group.
- Similar studies which have provided data for postoperative pain scores have demonstrated improvements by use of ERAS protocols in postoperative pain management.
- Another RCT by Geubbels et al. have reported that implementation of ERAS protocol resulted in decrease in postoperative pain.
- It can be safely concluded that the adoption of ERAS seems to be related to better control of postoperative pain, as reported in the results section.

- Prabhakaran S, Misra S, Magila M, et al. Randomized controlled trial comparing the outcomes of enhanced recovery after surgery and standard recovery pathways in laparoscopic sleeve gastrectomy [J]. *Obes Surg*, 2020.
- Lemanu DP, et al. Optimizing perioperative care in bariatric surgery patients. *Obes Surg*. 2012;22(6):979–990. doi: 10.1007/s11695-012-0648-6.
- Geubbels N, Evren I, Acherman YIZ, Bruin SC, van de Laar A, Hoen MB, et al. Randomized clinical trial of an enhanced recovery after surgery programme versus conventional care in laparoscopic Roux-en-Y gastric bypass surgery. *BJS Open*. 2019;3(3):274–281.
- Mittal T, Dey A, Siddhartha R, et al. Efficacy of ultrasound-guided transversus abdominis plane (TAP) block for postoperative analgesia in laparoscopic gastric sleeve resection: a randomized single blinded case control study [J]. *Surg Endosc*. 2018;32(12):4985–9

- **Impact on Surgical Time and Patient satisfaction score**
- In our study, mean operative time was  $76.75 \pm 10.93$  minutes in ERAS group v/s  $69.97 \pm 10.37$  minutes in Standard group. This increase in operative time can be possibly explained due to TAP block time included in the ERAS group.
- In our study, patient satisfaction score was better in ERAS group as compared to standard group, although not statistically significant.
- We failed to find out any study for ERAS in bariatric surgery reporting patient satisfaction score.
- Patient satisfaction score is a good subjective marker for early recovery, less pain and good comfort.

# • Impact on Length of Stay (LOS)



- Length of hospital stay is the most sensitive marker to confirm the effectiveness of ERAS protocols.
- In our study, ERAS group had significantly lesser, average stay of  $2.29 \pm 0.57$  as compared to standard group which reported  $2.56 \pm 0.73$  days. ( $P=0.0131$ ).
- This finding was reciprocated in previous study done by Aktimur et al. which showed significant reduction in the LOS of bariatric surgery patients. It also showed decrease in 30 day postoperative re-hospital visits in ERAS patients compared with standard protocol.
- Another study by Mannaerts et al. reported shorter hospital stay with ERAS but no differences in readmission rates or postoperative complications.

- King AB, Spann MD, Jablonski P, Wanderer JP, Sandberg WS, McEvoy MD. An enhanced recovery program for bariatric surgical patients significantly reduces perioperative opioid consumption and postoperative nausea. *Surg Obes Relat Dis.* 2018;14(6):849–856.

- Mannaerts GH, van Mil SR, Stepaniak PS, Dunkelgrun M, de Quelerij M, Verbrugge SJ, et al. Results of implementing an enhanced recovery after bariatric surgery (ERABS) protocol. *Obes Surg.* 2016;26(2):303–312.

- Mannaerts GHH, Allatif REA, Al Hashmi FY, Bhosale A, Hammo AN, Isied SH, et al. First successful large-scale introduction of an enhanced recovery after bariatric surgery (ERABS) program in the Middle East: the results and lessons learned of Tawam Hospital/Johns Hopkins, a tertiary Governmental Center in the UAE. *Obes Surg.* 2019;29(7):2100–2109





- A study carried out by Thiele RH et.al reported that ERAS protocol reduces length of stay, complication rates, use of analgesia, cost of patient and increased patient satisfaction.
- Also, the meta-analysis of Singh et al. found a significant ( $P < 0.001$ ) reduction in the LOS in ERAS compared with STD (MD – 1.56 days).
- Piotr Małczak et.al reported in his meta-analysis that ERAS protocol in bariatric surgery leads to the reduction of the length of hospital stay by 2.39 days while maintaining no or low influence on morbidity.

- Thiele RH, Rea KM, Turrentine FE, et al. Standardization of care: impact of an enhanced recovery protocol on length of stay, complications, and direct costs after colorectal surgery. *J Am Coll Surg.* 2015;220:430-43

- Singh PM, Panwar R, Borle A, et al. Efficiency and safety effects of applying ERAS protocols to bariatric surgery: a systematic review with meta-analysis and trial sequential analysis of evidence. *Obes Surg.* 2017;27(2):489–501.

- Małczak P, Pisarska M, Piotr M, Wysocki M, Budzyński A, Pędziwiatr M. Enhanced Recovery after Bariatric Surgery: Systematic Review and Meta-Analysis. *Obes Surg.* 2017 Jan;27(1):226-235. doi: 10.1007/s11695-016-2438-z. PMID: 27817086; PMCID: PMC5187372.

# CONCLUSION

- Our study reported, that implementation of ERAS protocol allows a better assistance in pre and postoperative journey of patients and ensures less postoperative morbidity, quicker recovery, and reduced length of hospital stay (LOS).

## ***Strengths of our study***

- This study was first of its kind to be performed in western region of India. We have tried to evaluate the difference between the ERAS protocol versus standard protocol, by evaluating changes in LOS, PONV score, Patient satisfaction score, Patient analgesia by using FACES score, resumption of day-to-day activities, reporting of complication rates too was done in our study.

### ***Limitations of the study***

- Cost effectiveness of ERAS protocol was not evaluated.

### ***Future work***

- Does Long term Quality of life improvement vary in ERAS and Standard protocol patients ?
- Can we include patients with higher risks?

THANK YOU