

# Prospective Randomized Interventional Comparative Study to Know the Feasibility and Efficacy of Patients with and Without Eras Protocol in Urological Surgeries Under Regional Anaesthesia

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**Received Date:** April 28, 2025; **Published Date:** May 14, 2025

## Abstract

**Introduction:** ERAS is an enhanced recovery after surgery which is also known as 'Fast track surgery'. ERAS protocol are multimodal perioperative care protocols encompassing the number of modifications to existing practices by application of evidenced based medicine, all aimed at reducing the physiological and psychological insult to the patient and therefore improving their care. All these leads to early return of bowel function, improvement in cardiopulmonary function, reduce complication, early mobilization, decreases the hospital stay and early return of daily routine activities.

**Aim:** The aim was to study the feasibility and efficacy of implementing ERAS versus conventional protocol tailored for Urological surgeries coming for elective surgeries under regional anaesthesia.

**Material and methods:** In this prospective randomized interventional comparative study, 50 patients were divided into group E (ERAS) and group N (Non-ERAS) and compared the efficacy and feasibility of ERAS protocol with conventional methods like effects of preoperative counselling, fasting, carbohydrate loading, warm intravenous fluids, early resumption of enteral feeding postoperative and early removal of urinary catheter.

**Results:** We found that patients in group E had significantly less time of starting of ambulation and achievement of PADSS score of 9 with less complication. We also found that postoperative VAS score for pain assessment was significantly low in group E as compared to group N and patients in group E were more satisfied at the time of discharge from the hospital compared to group N.

**Conclusion:** ERAS protocol found to be feasible and efficacious in urological surgeries under regional anaesthesia as it leads to early recovery and shortened postoperative stay with better patient satisfaction. It should be implemented in all urological surgeries for better outcome. For the enhanced recovery programme to be effective, it needs active participation of patient, surgeon, anaesthesiologist and nursing staff.

**Keywords:** ERAS: Enhanced Recovery After Surgery; VAS: Visual Analogue Scale; PADSS: Post Anaesthesia Discharge Scoring System; ER: Enhanced Recovery

## Abbreviations

ERAS: Enhanced Recovery After Surgery; ER: Enhanced Recovery; IV: Intravenous; INJ.: Injection; MCG: Micrograms; MG: Milligrams; VAS: Visual Analogue Scale; PADSS: Post Anaesthesia Discharge Scoring System; ASA: American Society of Anaesthesiologist; PONV: Post Operative Nausea and Vomiting; PCT: Preoperative Oral Carbohydrate Treatment; ERP: Enhanced Recovery Programme; OFA: Opioid Free Anaesthesia.

## Introduction

ERAS stands for Enhanced recovery after surgery. ERAS are a multimodal perioperative care pathway [1]. Also known as “Fast track surgery”. The goal of ERAS is to enable faster and more efficient recovery using evidence-based practices and reduction in the stress response to surgery [2]. The key factors that keep patients in the hospital after surgery include the need for parenteral analgesia, intravenous fluids, lack of mobility. The protocol encompasses optimization through the preoperative, intraoperative and postoperative period. Enhanced recovery (ER) is a process which encompasses the entire clinical pathway for a surgical procedure, starting within primary care and continuing throughout the perioperative period, to post-discharge care and the return to normal function by multimodal approach. ER consists of a number of modifications to existing practice, all aimed at reducing the psychological and physiological insult to the patient and, therefore, improving their care [3]. The concept of a formal –fast-track recovery programme after major surgery was first pioneered in colorectal surgery by Kehlet H, et al. [4] and Moningi S, et al. [5] and further research was carried out over the years in different procedures like urosurgery [1], spine [6], neurosurgery [7], vascular [8], thoracic [9], cardiac [10], orthopaedic surgeries [11].

The aim was to study the feasibility and efficacy of implementing ERAS versus conventional protocol tailored for Urological surgeries coming for elective surgeries under regional anaesthesia. Primary end points were

1. The time to recovery in terms of PADSS score
2. Total length of stay in the hospital. Secondary end point were:
  - Patient satisfaction
  - Successful implementation in Urological surgery

## Materials and Methods

This Prospective randomized interventional comparative study conducted after obtaining permission from institutional review board. Randomization done using computer generated random table number of 50 patients (twenty-five in each group) who were willing to take part in the study.

All the patients stand an equal chance of getting into any group with this method.

All the patients were aware of the study and written informed consent obtained. It was a double blinded study. The study included the patients of either gender between age 18 to 65 years belonging to and ASA 1 and 2 class, who were scheduled for elective urological surgeries under regional anaesthesia. Patients with refusal to consent were excluded from study.

## Sample Size and Statistical Analysis

Total Fifty patients were recruited out of which, twenty-five in each group of ERAS and Non-ERAS groups. Randomization done using computer generated random table number of 50 patients (twenty-five in each group) who were willing to take part in the study. All the patients stand an equal chance of getting into any group with this method. Patients were allocated into 2 group like GROUP N: - The patients who followed conventional methods. GROUP E: -The patients who followed ERAS protocol.

### Conventional Protocols Which were Followed in Group N were:

- Preoperative fasting from midnight was allowed.
- Antibiotics and antiemetic prophylaxis were given.
- Neuraxial opioids for analgesia was given along with hyperbaric bupivacaine.
- Benzodiazepines and fentanyl were given after subarachnoid block had been given.
- Infusion of intravenous fluids which were at room temperature was done.
- Initiation of enteral feeding after 8 hours of surgery postoperatively was done.
- Ambulation was started from next day morning of surgery.
- Urinary catheter was removed next day postoperatively.

### The Key Elements Which were Followed in Eras Group E Includes Preoperative, Intraoperative and Postoperative Elements Preoperatively:

- Counselling was done about surgery and anaesthesia to relieve anxiety.
- Preoperative fasting for solid up to 6 hours before and liquid upto 2 hours prior to surgery was allowed.
- Carbohydrate drinks with Appy 100 ml 2 hours prior to surgery was allowed.
- Antibiotic prophylaxis was given.

### Intraoperative:

- Pre-emptive analgesia was given in the form of 1 gm paracetamol iv.
- Neuraxial opioids for analgesia was given along with hyperbaric bupivacaine.
- Benzodiazepines was avoided.
- Patients were received minimal dose of iv opioids like

fentanyl.

- Postoperative nausea vomiting (PONV) prophylaxis was given like: Inj. Ondansetron 0.1mg/kg iv Inj. Dexamethasone 0.1mg/kg iv.
- Hypothermia was avoided by using warm intravenous fluids.

#### Postoperatively:

- Early resumption of enteral feeding (after 4 hours) was started.
- Early removal of urinary catheter within 24 hours was done.
- Early ambulation was done after complete recovery from motor blockade and achievement of steady gait without dizziness.
- Patients were received multimodal oral analgesia for >1 days postoperatively with cyclooxygenase inhibitor. non-steroidal anti-inflammatory drugs.

Details of the study procedure: Patients were assessed a day prior to surgery. Detailed systemic examination was performed. Patients name, age, sex, weight registration number and diagnosis were recorded. Our study was conducted in patients undergoing urological surgeries like ureteroscopic lithotripsy, cystoscopy which was usually done in around 60 to 90 minutes. In group E, patients were informed about the study in detailed about the anaesthesia and surgery which helped them in relieving the anxiety. They were also informed about the importance of carbohydrate rich drink (100 ml Appy) prior to surgery and their effects on postoperative recovery. They had also been asked about the history of smoking and alcohol consumption and whether they have stopped as advised in outpatient clinic in both the groups. A valid written informed consent was obtained a day prior to surgery. On the day of surgery, patient's investigation rechecked and NBM status confirmed. In group E, patients were kept fasted for 6 hours for solids and allowed to take carbohydrate rich drink 100 ml two hours prior to surgery. Antibiotics prophylaxis was received. After arrival of patient in operation theatre, routine monitors (ECG, pulse oximeter, non-invasive arterial pressure) were attached and all the baseline parameters were noted. Warm intravenous fluid

started. Patient received antiemetic prophylaxis with inj. Dexamethasone 0.1mg/kg and inj. Ondansetron 0.1mg/kg iv and 1 grams of intravenous paracetamol as pre-emptive analgesia at the start of procedure. Spinal anaesthesia was given with hyperbaric bupivacaine with minimal dose of fentanyl (25 mcg) and then procedure started once the level of anaesthesia achieved. They also had been given minimal doses of fentanyl 0.05-1 mcg/kg. Patient covered with blankets and forced air warmers were used for prevention of hypothermia. After the completion of procedure patients were shifted in post anaesthesia care unit and were assessed postoperatively at every 2 hours till first 8 hours and then every 6 hourly till discharge from the hospital. patients were allowed to mobilized after complete recovery from motor blockade and steady gait was achieved without dizziness. The following parameters were noted: VAS score every 2 hourly till 8-hour, time of start of enteral feeding, time of urinary catheter removal, time of ambulation after complete recovery from motor blockade and achievement of steady gait without dizziness, time to attain PADDSS score, and patient satisfaction in terms of Likert scale. Perioperative complications in the form of nausea, vomiting, hypotension, shivering were also noted and treated symptomatically. In the group N, conventional protocols of surgery followed like patients were kept fasting from midnight. After coming to operation theatre, all the standard monitors were attached, baseline parameters were noted and intravenous fluids started which were at room temperature. Spinal anaesthesia was given with hyperbaric bupivacaine with fentanyl 25 mcg Patient had been received injection Midazolam 0.03-0.05mg/kg, inj. Fentanyl 1-2 mcg/kg iv. for sedation once the level of subarachnoid block was achieved. Patients were shifted to post anaesthesia recovery unit after completion of procedure. The same parameters were noted as above as in group E and followed till discharge from the hospital.

The following parameters were used to assess the evaluations of objectives:

Post anaesthesia discharge scoring system (PADSS) every 2 hours till achievement of score of 9:

Variable Evaluated Score

Vital Signs (stable and consistent with age and)	
Systemic blood pressure and heart rate within 20% of the preanesthetic level	2
Systemic blood pressure and heart rate 20% to 40% of the preanesthetic level	1
Systemic blood pressure and heart rate >40% of the preanesthetic level	0
Activity Level	
Steady gait without dizziness or meets the preanesthetic level	2
Requires assistance	1

Unable to ambulate	0
<b>Nausea and Vomiting</b>	
None to minimal	2
Moderate	1
Severe (continues after repeated treatment)	0
<b>Pain</b> (minimal to no pain, controllable with oral analgesics)	
Yes	2
No	1
<b>Surgical Bleeding</b> (consistent with that expected for the surgical procedure)	
Minimal (does not require dressing change)	2
Moderate (up to two dressing changes required)	1
Severe (more than three dressing changes required)	0

VAS score at the time discharge from post anaesthesia care unit:



Patient satisfaction in terms of Likert scale:

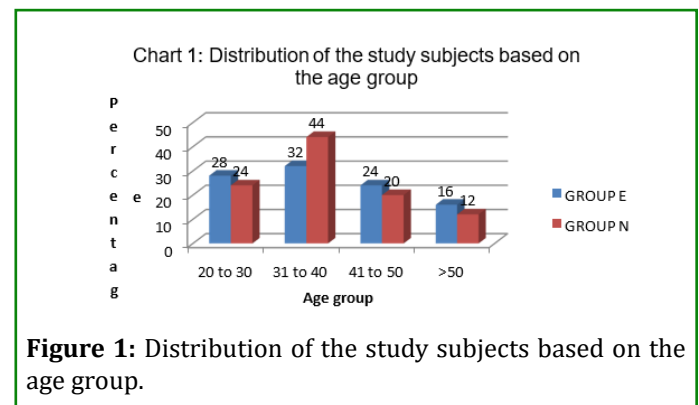
Extremely unhappy	Unhappy	Undecided	Happy	Extremely happy
1	2	3	4	5

## Results

A total of 50 patients were divided into two groups of 25 patients in each group (NON-ERAS (N) and ERAS (E)) were evaluated. Data of given manuscript represented as mean  $\pm$  SD ( $n=25$ ). All the results were analyzed statistically by unpaired t test (quantitative data) and mann whitney u test (qualitative data), wherever appropriate. In this study,  $p < 0.05$  was considered statistically significant. Demographic parameters were comparable between groups (Figures 1 and 2). ERAS group had less time of fasting (hours) till starting of procedure compared to non-eras group which was statistically significant ( $2.82 \pm 0.765$  vs  $10.12 \pm 1.21$ ) ( $p < 0.001$ ) (Table 1). Also, the time at which the feeding was resumed postoperatively was early in the ERAS group as compared to non-ERAS group which was statistically significant ( $4.44 \pm 0.87$  hours vs  $8.48 \pm 0.96$ ) (Table 2). In ERAS group, urinary catheters were removed early and patients started to ambulate early as compared to non-ERAS group (Figures 3 and 4).

Patients had good analgesia with less VAS score over the successive hours postoperatively (Figure 5) and the time to attain PADDs score of 9 were less in ERAS group than group

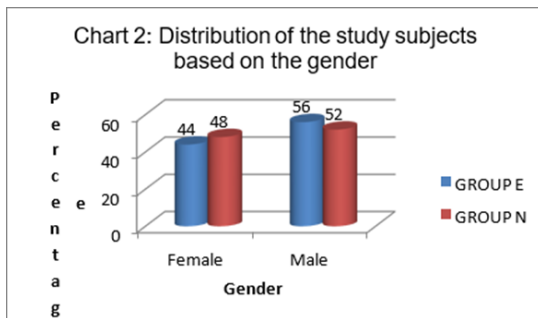
N (12.12 hours vs 21.12) (Figure 6) and this difference was statistically significant. The total length of stay was also less in group E than group N ( $25 \pm 3.52$  vs  $39.80 \pm 3.39$  hours) ( $p < 0.001$ ) (Table 3) and patients were more satisfied in group E which was evaluated by likert scale (Figure 7). There were less perioperative complications in ERAS group as compared to group N (Figure 8).



**Figure 1:** Distribution of the study subjects based on the age group.

The mean age  $\pm$ SD of the subjects in group E was  $37.92$  years  $\pm 11.11$  and among group N was  $37.36 \pm 9.90$  years and this

difference was not statistically significant.



**Figure 2:** Distribution of the study subjects based on the gender.

Among the group E, 44% were females and 56% were males. Among group N, 48% were females and 52% were males. There was no statistically significant difference between the two groups based on gender. Data represented as Mean (%),  $n=25$ ,  $p = 0.7712$ .

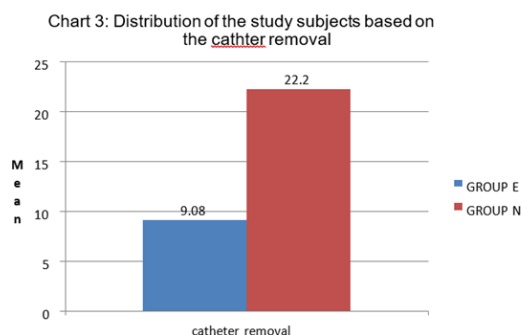
Total time of fasting till start of procedure	ERAS		Non-ERAS		P value
	Mean	SD	Mean	SD	
	2.82	0.77	10.1	1.2	<0.001

**Table 1:** Distribution of study subjects based on total time of fasting till start of procedure.

Early Resumption of Feeding	Group E		Group N		P value
	Mean	SD	Mean	SD	
	4.44	0.9	8.48	1	<0.001

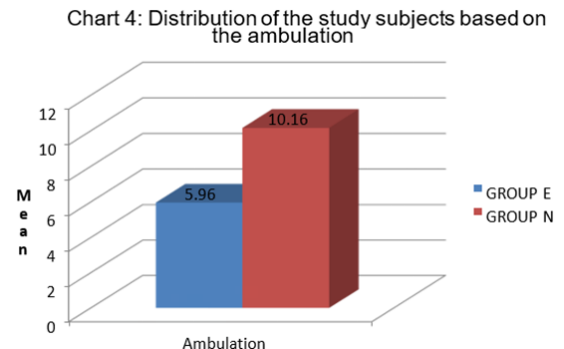
**Table 2:** Distribution of the study subjects based on the early resumption of feeding.

In group E, the catheter was removed at an average time of  $9.08 \pm 4.52$  hours and it was  $22.20 \pm 5.46$  hours group N and this difference was statistically significant.

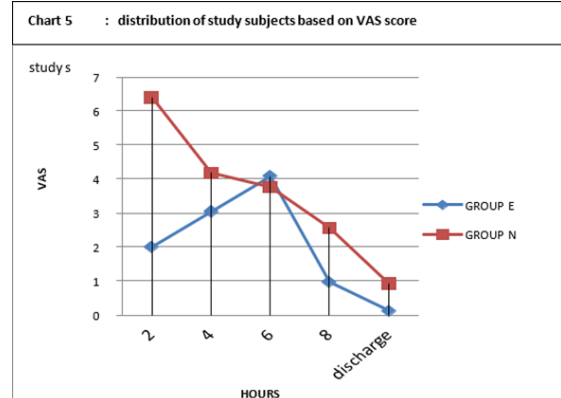


**Figure 3:** Distribution of the study subjects based on the catheter removal.

Among the group E, ambulation was at an average time of  $5.96 \pm 0.68$  hours and  $10.16 \pm 1.37$  hours in group N and this difference were statistically significant ( $P$  value  $< 0.001$ ).

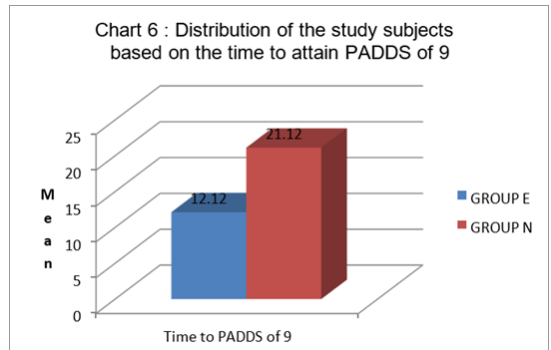


**Figure 4:** Distribution of the study subjects based on the ambulation.



**Figure 5:** Distribution of study subjects based on postoperative VAS score.

The mean VAS score of patients at 2,4,6,8 and at the time of discharge in group E were,  $2 \pm 0.76$ ,  $3.04 \pm 0.84$ ,  $4.08 \pm 0.81$ ,  $0.96 \pm 0.73$ , and  $0.12 \pm 0.33$  and in group N were  $6.4 \pm 1.15$ ,  $4.84 \pm 1.14$ ,  $3.76 \pm 0.87$ ,  $2.56 \pm 0.86$ ,  $0.92 \pm 0.75$  respectively with  $P$  value of  $<0.001$  which was statistically significant.



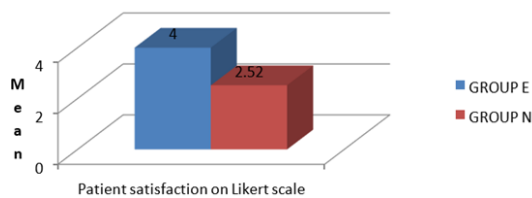
**Figure 6:** Distribution of the study subjects based on the time to attain PADDs of 9.



Total length of stay	Group E		Group N		P value
	Mean	SD	Mean	SD	
	25	3.5	39.8	3.4	

**Table 3:** Distribution of the study subjects based on the total length of stay.

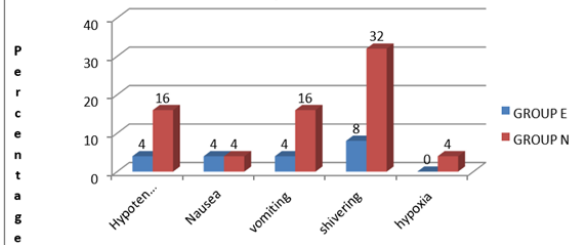
Chart 7 : Distribution of the study subjects based on patient satisfaction based on Likert scale



**Figure 7:** Distribution of the study subjects based on the patient's satisfaction of Likert scale.

Based on the Likert scale, group E had an average score of  $4 \pm 0.76$  and group N had score of  $2.52 \pm 0.65$  and this difference was statistically significant ( $p < 0.001$ ).

Chart 8: Distribution of the study subjects based on the complications



**Figure 8:** Distribution of the study subjects based on the complications.

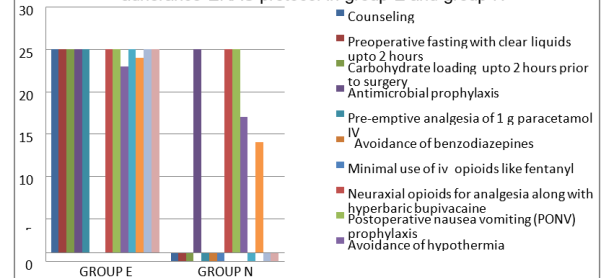
Complication	Group E		Group N		Treatment	P value
	Nor	%	Nor	%		
Hypotension	1	4	4	16	Bolus of crystalloid and vasopressor	0.161
Nausea	1	4	1	4	Antiemetics	1
Vomiting	1	4	4	16	Antiemetics	0.161
Shivering	2	8	8	32	Warm fluids, forced air warmers and blankets.	0.03
Hypoxia	0	0	1	4	Oxygen supplementation	1

**Table 4:** Distribution of the study subjects based on the complications.

Among the group E, 4% had nausea and 4% had hypotension and vomiting, 8 % had shivering and none of them had

hypoxia. Among the group N, 4% had nausea, hypoxia each, 16% had hypotension and vomiting each and 32% had shivering and 4 % hypoxia. There was no statistically significant difference in terms of all complications but was clinically significant except perioperative shivering with p value of 0.03 which was statistically significant. Hypotension and nausea and vomiting which are known haemodynamics effects of regional anaesthesia and surgical stress and was treated with bolus of crystalloid and vasopressor ephedrine as per haemodynamics and injection ondansatrom and dexamethasone with less incidence in ERAS group as compared to conventional group N. Hypoxia in non- ERAS group was due to patient underlying condition which was early treated with oxygen supplementation for short period of time. Shivering was seen in few patients in ERAS group compared to conventional group was effectively managed with use of warm fluids and forced air warmers and covering with blankets (Figure 9).

Chart 9: Graphical presentation of no. of patients to adherence ERAS protocol in group E and group N



**Figure 9:** Graphical presentation of no. of patients to adherence ERAS protocol in group E and group N.

## Discussion

Enhanced Recovery after Surgery (ERAS) protocols are rapidly becoming the standard of care for patients undergoing elective surgery. It helps in fast recovery as well as decreases the postoperative length of stay (LOS) by decreasing the morbidity. Enhanced recovery includes modification to existing practices from preoperative to postoperative care using evidence-based approach. It is also shown to be associated with reduced hospital costs, and increased patient satisfaction [1]. Surgical stimulus produces varieties of stress responses by activation of sympathetic nervous system resulting in metabolic, hormonal, hematological and immunological changes which affect the postoperative recovery and length of stay in the hospital [12]. Catabolic effect of stress response leads to increase utilization of proteins, increase gluconeogenesis and glycogenolysis [1]. Enhanced recovery pathway aimed at attenuating these responses to surgery and improving the postoperative outcome and decreasing the morbidity.

This is a prospective randomized interventional comparative study enrolling total 50 patients who were posted for elective urological surgeries under regional anaesthesia. Patients were randomized into two groups using computer generated random table numbers. Statistical analysis was done by unpaired t test (quantitative data) and mann whitney u test (qualitative data), wherever appropriate and P value < 0.05 considered statistically significant. Out of two groups, one was ERAS group (E) in which enhanced recovery protocols followed (who received carbohydrate loaded drink. Appy 2 hours prior to surgery) and the other group was non-ERAS group (N) which is followed by conventional standard methods of midnight fasting policy.

Patients in group E were kept fasting of 6 hours for solids and allowed to take carbohydrate clear drink (Appy 100 ml) 2 hours prior to surgery. They also received antibiotics and antiemetic prophylaxis and pre-emptive analgesia in the form of inj. paracetamol 1 gm iv. Measures were taken to prevent hypothermia by infusing warm intravenous fluids. In the postoperative period, enteral feeding started early (after 4 hours), urinary catheter removed within 24 hours and early ambulation was initiated after complete recovery from motor blockade and attainment of steady gait without dizziness. Patients in group N were kept fasted from midnight prior to surgery and intravenous benzodiazepines and fentanyl were given. Advised about oral intake after 8 hours of surgery. Urinary catheters were removed on next day of surgery and mobilization was also initiated on next day of surgery. Data from both the groups were collected, analyzed and compared.

In our study, demographic data were compared. The mean age of cases studied in group E and group N was  $37.92 \pm 11.11$  years and  $37.36 \pm 9.90$  years respectively. The minimum . maximum age range in group E and group N was 24-60 years and 25-50 years respectively. The distribution of mean age of cases studied did not differ significantly between two study groups (P value>0.05) (Figure 1). The gender distribution of patients in the study was almost equal among both the groups. 56% were males and 44% were females in group E and 52% were males and 48% were females in group N. This difference was not statistically significant (P > 0.05) (Figure 2). In our study, the mean weight of patients in group E was  $58.08 \pm 7.29$  and in group N was  $57.92 \pm 6.89$  respectively with p value of 0.93 which had statistically no significant difference. In our study of 25 cases studied in E group, 64% belonged to ASA Grade I, 36% belonged to ASA Grade II. Of 25 cases studied in N group, 60% belonged to ASA Grade I, 40% belonged to ASA Grade II. The distribution of ASA grades among the cases studied did not differ significantly between two study groups (P value>0.05).

Preoperative counselling has been shown to be effective in patients recovery and outcomes. It helps in decreasing the

stress response to surgery and anaesthesia, reduced post-surgical complications, potential savings in resource use, reduced morbidity, early discharge from hospital, earlier return to normal activities of daily living and increased patient satisfaction<sup>13-16</sup>. In our study, patients in ERAS counselled additionally about the procedure, importance of preoperative fasting, carbohydrate loading, cessation of smoking, alcohol and their effects on postoperative recovery and outcome of surgery. In our study, patients were advised about cessation of smoking and alcohol consumption in outpatient clinic. In our study, total 5 patients were giving history of smoking in group E out of which 3 patients stopped it 4 weeks prior to surgery and 2 had stopped 24 hours prior to surgery. As compared to this, total 6 patients were giving history of smoking in group N out of which 2 patients had stopped 4 weeks prior to surgery and 4 were had 24 prior to surgery. Smoking cessation linked to preventing postoperative pulmonary complication, infection and helps in early recovery. One patient in group N which was having COPD and didn't stopped smoking found to be showed one episode of hypoxia which was treated by 100% oxygen at 6 litre /min and nebulization with salbutamol given perioperatively.

The effects of counselling on surgical stress response and anxiety was also shown by study of Klopfenstein CE, et al. [13]. "Anesthetic assessment in an outpatient consultation clinic reduces preoperative anxiety" in which two groups of 20 patients was studied who underwent elective surgery i.e. Transurethral resection of prostate or bladder resection. They found that an anaesthetic assessment in an outpatient consultation clinic reduces preoperative anxiety, when compared with an assessment on the evening before surgery (P value <0.01). Grover M [14] also claims ERAS principles as a dramatic advance in perioperative practice in influencing outcomes and acknowledges the important contribution of preadmission counselling in the preoperative phase of managing colorectal surgical patients.

Earlier there was concept of midnight preoperative fasting prior to surgery for patient safety to prevent risk of regurgitation of gastric contents and subsequent pulmonary aspiration [7]. But now newer concept of preoperative fasting and with carbohydrate loading upto 2 hours prior to surgery in ERAS does not increase any risk of regurgitation and pulmonary aspiration. It also relieves postoperative hunger, decreases the chances of intraoperative hypotension [7]. It does not cause increase PH of gastric contents and significantly lower gastric volume. In our study, patients in group E were kept fasted for 6 hours for solids and allowed to take carbohydrate clear fluids (100 ml Appy) 2 hours prior to surgery and in group N patients were kept fasted from midnight. Mean time of fasting till start of procedure was  $2.82 \pm 0.765$  hours in group E and  $10.12 \pm 1.21$  hours in group

N which was statistically significant ( $p < 0.001$ ) (Table 1).

In our study, in group E, there were less episodes of hypotension, nausea vomiting, patients were less hungry, thirsty and had more level of satisfaction (Figure 6). In contrast, prolonged time of fasting in group N resulted in increases hunger, thirst, tiredness, patient discomfort which delayed postoperative return of bowel function and increased chance of complication like hypotension, nausea & vomiting because of increase gastric fluid volume and low gastric PH.

Our results are in also parallel with the study of Hausel J, et al. [15] who studied the effects of preoperative oral fluids in which 252 ASA 1-2 patients were randomized into carbohydrate (CHO), placebo and overnight fasting group. They have found that the carbohydrate treated group was less hungry and less anxious than both the other groups ( $P < 0.05$ ) and in the Fasted group, there were increased hunger, thirst, tiredness, weakness, and inability to concentrate increased which also shown in our study. It was concluded from the study that CHO significantly reduces preoperative discomfort without adversely affecting gastric contents and there were no adverse effects recorded from taking this drink in the preoperative period. Our study finding is also supported by study of Awad S, et al. [16]. A meta-analysis of randomized controlled trials on preoperative oral carbohydrate treatment (PCT) in elective abdominal surgeries which found that it reduces length of stay reduced postoperative insulin resistance with no effects on in-hospital complications over control. In our study, 1 out of 25 patients (4%) had hypotension in group E as compared to group N in which was in 4 out 25 patients (16%) (Figure 8). Hypotension was treated by giving around 200-250 ml bolus of crystalloid and injection ephedrine 6 mg iv. also.

In our study, all the patients in ERAS group received inj. Dexamethasone 0.1mg/kg in addition to inj. ondansetron 0.1 mg/kg as compared to non-ERAS group patients who only received inj. ondansetron 0.1 mg/ kg alone. It was found in our study that; incidence of nausea was 1 out of 25 (4%) in each group. vomiting was seen in 1 out of 25 (4%) in group E and in 4 out of 25 patients (16%). They responded to symptomatic treatment. This difference was not statistically significant but was clinically significant (Figure 8). Postoperative nausea and vomiting (PONV) are the most common complications after surgery with increased risk specially with urological and gastrointestinal surgeries. It delays the recovery and discharge. Multiple factors lead to nausea vomiting in perioperative period like female, young age, hypotension anaesthetic drugs, opioids use [17]. Therefore, nausea and vomiting prophylaxis is of important factor for early recovery. Dexamethasone is potent steroid which prevents vomiting by central neurological effect, and it also has anti-inflammatory effects.

Identical results were seen in study TC DREAMS [18], "Dexamethasone versus standard treatment for postoperative nausea and vomiting in gastrointestinal surgery: randomised controlled trial (DREAMS Trial), which studied the effect of 8 mg intravenous dexamethasone as compared to standard care for prevention of nausea vomiting. They found that addition of a single dose of 8 mg intravenous dexamethasone at induction of anaesthesia significantly reduces both the incidence of postoperative nausea and vomiting at 24 hours and the need for rescue antiemetics for up to 72 hours in patients undergoing large and small bowel surgery, with no increase in adverse events ( $p$  value 0.003).

In our study, patients had been given minimal doses of intravenous fentanyl (0.5-1 mcg/kg) in group E as compared to group N which received fentanyl (1-2mcg/kg) like conventional methods. The mean of fentanyl dose given in group E was  $35.60 \pm 10.93$  mcg and group N was  $78.20 \pm 16.00$  mcg and this difference was statistically significant ( $P$  value  $< 0.001$ ). Fentanyl was received for sedation and analgesia. These results were alike with results of study done by Lasala JD, et al. [19]. "Decreased intraoperative opioid consumption following institution of enhanced recovery program in open gynaecologic surgery." Implementation of an ERP in open gynaecologic oncologic surgeries resulted in a 61% reduction in intraoperative, a substantial decrease in opioids use with no change in pain scores ( $p < 0.0001$ ) This in contrast with Soffin EM, et al. [17] study . "Opioid-free anesthesia within an enhanced recovery after surgery pathway for minimally invasive lumbar spine surgery", who found that there was a clinically significant decrease in time to readiness for discharge from the PACU associated with OFA (37 minutes), although this was not statistically significantly different.

In our study, in addition inj. Paracetamol 1 gm intravenously were given in group E as pre-emptive analgesia as well as to reduce the dose of opioid like fentanyl which shown to be effective in adequate perioperative analgesia and its effectiveness was measured by VAS score every 2 hours till discharge and helps in relieving anxiety. All these leads to early ambulation and recovery and discharge from hospital. In our study, the mean VAS score of patients postoperatively at 2,4,6,8 hours and at the time of discharge in group E were  $2 \pm 0.76$ ,  $3.04 \pm 0.84$ ,  $4.08 \pm 0.81$ ,  $0.96 \pm 0.73$ , and  $0.12 \pm 0.33$  and in group N were  $6.4 \pm 1.15$ ,  $4.84 \pm 1.14$ ,  $3.76 \pm 0.87$ ,  $2.56 \pm 0.86$ ,  $0.92 \pm 0.75$  respectively with  $P$  value of  $< 0.001$  which was statistically significant (Figure 5). In our study, patients in group E were required rescue analgesia with paracetamol after around 6 hours postoperatively at vas score of 4 and in group N, it was required after 2 hours at Vas score of 6. An adequate pain relief is a one of the important criteria of post anaesthesia discharge scoring system, therefore it helps in early discharge from the hospital, improve surgical outcome



and increases patient satisfaction level.

Identical results were seen in study of Bhattacharya D, et al. [20] Intravenous paracetamol infusion can prolong duration of spinal anaesthesia inpatients undergoing major gynecological surgeries done in 100 patients which found that in paracetamol group, rescue analgesia was required after 8 hours a VAS score of 4 and in control group, it was required after 4 hours at VAS score of 4 ( $p < 0.001$ ) They have concluded that intravenous paracetamol infusion prolonged the duration and intensity of spinal anaesthesia. Improvement in VAS score in group E was also with analgesic effect of iv dexamethasone. This was supported by similar results of study done by Waldron NH, et al. [21]. "Impact of perioperative dexamethasone on postoperative analgesia and side-effects," which found that single i.v. perioperative dose of dexamethasone had small but statistically significant analgesic benefits.

In our study, warm intravenous fluids were infused to patients in ERAS group, intraoperative and postoperative shivering occurred in 2 patients (12 %) in group E and 8 patients (32%) in group N which was statistically significant difference with P value  $< 0.05$  (Figure 8) This is similar to study Camus Y, et al. [22] conducted a study — "The effects of warming intravenous fluids on intraoperative hypothermia and postoperative shivering during prolonged abdominal surgery" our study results was found to be similar ( $p < 0.05$ ) with this study which concluded from the study that infusion of warmed fluids helps to prevent hypothermia and reduces the incidence of postoperative shivering.

In our study, the time at which feeding was resumed was  $4.44 \pm 0.87$  hours in group E and  $8.48 \pm 0.96$  hours in group N with P value of  $< 0.001$  which was statistically significant difference (Table 2) In enhanced recovery, early resumption of feeding after surgery is an important tool to early postoperative recovery, healing of wound, early discharge and prevention of complication like paralytic ileus. it was possible as surgeries were done under regional anaesthesia and was not related to gastrointestinal system. Our study findings were resembling the findings of Osland E, et al. [23] study — Early versus traditional postoperative feeding in patients undergoing resectional gastrointestinal surgery, they found 45% statistically significant reduction in postoperative complication ( $P = 0.01$ ) and result in reduced length of stay. Therefore, it was concluded from the study that early postoperative nutrition is associated with significant reductions in total complications compared with traditional postoperative feeding practices and does not negatively affect outcomes such as resumption of bowel function, or hospital length of stay.

In our study, mean time of urinary catheter removal was  $9.08 \pm 4.52$  hours in group E as compared to group N in which it was

$22.20 \pm 5.46$  hours with statistically significant difference of p value of  $< 0.001$  and no incidence of postoperative urinary retention and urinary catheter tract infection were seen (Figure 3).

This finding was parallel with Wiener JG, et al. [24] — Early removal of catheters in an Enhanced Recovery Pathway (ERP) with intrathecal opioid injection does not affect postoperative urinary outcomes. They have found that mean time to Foley catheter removal was significantly lower in the ERP cohort compared to non-ERP patients ( $p < 0.01$ ). The median surgical length was significantly longer for the non-ERP cohort ( $p < 0.01$ ). Our study results were dissimilar to study of Coyle D, et al. [25] — "Early post-operative removal of urethral catheter in patients undergoing colorectal surgery with epidural analgesia" who found that there is increased risk of developing POUR in the presence of epidural analgesia, independent of the timing of urinary catheter removal ( $p > 0.05$ ).

Early mobilization is considered an important component of ERPs. In our study, mobilization was done after complete recovery of motor blockade and achievement of steady gait without dizziness. In our study, mean time of for ambulation of patients in group E were  $5.96 \pm 0.68$  hours and in group N were  $10.16 \pm 1.37$  hours with P value of  $< 0.001$  which was statically significant (Figure 4). Fiore JF, et al. [26] showed similar results — "Ensuring early mobilization within an enhanced recovery program for colorectal surgery" it was found that staff-directed facilitation of early mobilization increased out-of-bed activities during hospital stay but did not improve outcomes. Our study results were in contradiction to study of Zhang L, et al. [27] — Early mobilization of critically ill patients in the intensive care unit found that early mobilization decreased the incidence of weakness at ICU discharge, increases the incidence of patients who able to stand or walk but rate of adverse event and 28-day mortality was increased but was not statistically significant. In our study, mean  $\pm$ SD of time to attain post anaesthesia discharge scoring system (PADSS) score of 9 was  $12.12 \pm 2.19$  hours in patients with group E and  $21.12 \pm 3.06$  hours in group N which showed statistically significant difference ( $P < 0.001$ ) (Figure 6). Palumbo Pet, et al. [28] in their study — Modified PADSS (post anaesthetic discharge scoring system) for monitoring outpatients discharge also found that PADSS is an efficient evaluation of criteria for safe discharge. Trevisani L, et al. [29] in their study — "Post-Anaesthetic Discharge Scoring System to assess patient recovery and discharge after colonoscopy" found that Recovery from sedation was faster in PADSS-group than in Control group ( $58.75 \pm 18.67$  min versus  $95.14 \pm 10.85$  min, respectively;  $P < 0.001$ ). Therefore, they inferred from this that PADSS is a safe as the clinical assessment and allow for early discharge. This contrasts with systematic review done by Phillips NM, et al.

[30] —post-anaesthetic discharge scoring criteria|| in which they formulated that post-anaesthetic care unit discharge assessment criteria needs using further investigation using sound methodology especially regarding patient outcomes.

In our study, patients' satisfaction level was noted in terms of likert scale and we found that group E had an average score of  $4 \pm 0.76$  and group N had score of  $2.52 \pm 0.65$  and this difference was statistically significant ( $p < 0.001$ ) (Figure 7). It shows that patients were more satisfied in group E as compared to group N in terms of better pain management, were less anxious, less hungry and thirsty.

Our study results were similar to results of Machin JT, et al. [31] — "Patient satisfaction with the use of an enhanced recovery programme for primary Arthroplasty" found that the mean patient satisfaction score of 4.07 for speed of recovery in the ERP group was significantly higher than the SCP group's score of 3.68 ( $p = 0.037$ ). In our study, mean total length of stay was  $25 \pm 2.52$  hours in group E and  $39.8 \pm 3.98$  hours in group N with P value of  $< 0.001$  which was statistically significant (Table 3). Our study results were similar to study Agarwala S, et al. [32] — Decreasing hospital length of stay and enhancing recovery in Total Knee Arthroplasty suggested that multimodal interdisciplinary protocol to achieve early mobilization, better pain scores and minimize complications, resulting in overall reduced length of stay.

Our study results were resembling to results of study of Dunkman WJ, et al. [33] — "Impact of an enhanced recovery pathway on length of stay and complications in elective radical cystectomy" They found a significant reduction in length of stay associated with implementation of an enhanced recovery program for radical cystectomy. Arumainayagam N, et al. [34]- in their study —Introduction of an enhanced recovery protocol for radical cystectomy found that the introduction of an ERP was associated with significantly reduced hospital stay, with no deleterious effect on morbidity or mortality [35,36]. After assessing all the parameters of enhanced recovery, it shows that implementation of ERAS in urological surgeries under regional anaesthesia has significant results in terms of better pain management, less incidence of complications like nausea, vomiting, hypotension, perioperative shivering, decrease the length of stay in hospital, increases level of patient's satisfaction and improvement of surgical outcome by decreasing complication [37,38].

## Conclusion

ERAS protocol found to be feasible and efficacious in urological surgeries under regional anaesthesia as it leads to early recovery and shortened postoperative stay with better patient satisfaction. It should be implemented in all urological surgeries for better outcome. For the enhanced recovery

programme to be effective, it needs active participation of patient, surgeon, anaesthesiologist and nursing staff.

## Limitations

The study has several limitations that warrant consideration. First, it was conducted with a relatively small sample size from a single-center setting, which may limit the generalizability of the findings. Larger, multicentric studies are essential to validate and extrapolate these results.

## Acknowledgements

Not applicable.

## Funding

The authors received no financial support for the research, authorship, and/or publication of this article.

## Data Availability

All data are publicly available or listed in the results of the paper.

## Declarations

### Ethical approval

Ethical approval from our hospital institutional Ethics Committee was obtained prior to initiation of the research work. This study was approved by the Ethics Committee decision no: EC/160/2017. All procedures followed were in accordance with the ethical standards of the responsible committee.

### Informed consent

Informed consent was obtained from all patients included in the study

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