ORIGINAL ARTICLE

A Randomized Control Study on the Effectiveness of Enhanced Recovery after Surgery (ERAS) Protocol with Conventional Protocol in Total Laparoscopic Hysterectomy

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Abstract

Aim: The present study was aimed to evaluate the effectiveness of enhanced recovery after surgery protocol (ERAS) vs conventional protocol in decreasing the duration of hospital stay after total laparoscopic hysterectomy. It also aims to assess the postoperative complications, compliance, patient comfort, and surgeon satisfaction among the ERAS and conventional protocol in total laparoscopic hysterectomy.

Materials and methods: The present randomized controlled study was conducted by the Department of Obstetrics and Gynaecology at JSS Hospital, Mysuru, over a period of 1 year 18 months. A total of 120 patients scheduled for a laparoscopic hysterectomy with salpingectomy or salpingo-oophorectomy for a benign disease were included in the research and were randomized into ERAS ($n = 60$) and conventional protocol groups ($n = 60$). Both the ERAS protocol and the control group received care in accordance with accepted protocol.

Results: In the present study, the mean VAS score in the ERAS study group was found to be 2.4 ± 0.6, and in the control group, is 4.6 ± 0.8 with a mean difference of 2.1 and *p*-value of less than 0.05. The mean total duration of hospital stay (in days) among the patients in the ERAS group is 1.6 ± 0.3 days. In the control group, is 4.4 ± 0.5 days with a mean difference of 2.8 days and a *p*-value of less than 0.05. None of the ERAS group patients had been readmitted to the EMD.100% of the patients in both the groups, are satisfied with the outcome of the surgery.

Conclusion: The ERAS protocol implementation in laparoscopic hysterectomy procedures has resulted in decreased length of total duration of hospital stay and high patient satisfaction with no change in postoperative complications and readmission rates.

Keywords: Conventional protocol, Duration of hospital stay, ERAS protocol, Gynecology, Laparoscopic hysterectomy.

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Introduction

Enhanced recovery after surgery (ERAS) is a multidisciplinary strategy with a broad focus on enhancing postoperative results. The purpose of ERAS pathways is to preserve normal physiology during surgery in order to improve patient outcomes while reducing postoperative problems and readmissions.

In the past few years, the focus has been on aiming for shorter hospital stay following surgery so as to reduce the economic burden and improve the experience of patients which helps patients to recover sooner and return to normal life as early as possible.[1,2]

Enhanced recovery after surgery is often termed as "rapid recovery program," "multimodal perioperative management," or "fast-track program." The primary pathologic factor causing postoperative morbidity and organ dysfunction is surgical stress.[3] The comprehensive feature of the ERAS protocol was intended to incorporate the patient's whole journey throughout the perioperative period by integrating a number of modalities and therapies using an evidence-based methodology.[2]

Preoperative fasting time reduction, nausea and vomiting control, optimal fluid management, reduced nasogastric tube use, opioid-sparing analgesia, early mobilization, early enteral nutrition, antithrombotic and antimicrobial prophylaxis, and patient counseling about surgery and postoperative recovery are all ERAS components.[4]

Traditional methods support the use of catheters, nasogastric tubes, drains, oral intake restrictions, and ambulation. These are gradually declining in favor because there is no evidence from science to back up the practice.

Every year, more than 234 million major surgical procedures are performed worldwide, and despite improvements in anesthesia and surgical care, the morbidity rate following abdominal surgery is still high. With the intention of reducing the loss of functional ability and hastening the healing process, the ERAS clinical pathways have been developed to enhance the standard of perioperative care.[5]

The ERAS protocol aims to minimize surgery-related morbidities, lower the risk of complications and readmissions, lessen

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postoperative pain and painkiller use, raise patient satisfaction, and shorten hospital stays. There has been a desire for research into ERAS in gynecological procedures due to its successful use in colorectal surgery and other disciplines. Additionally, revised recommendations have been made for postoperative care for those who underwent gynecologic surgery.[6,7]

Data on the success of the ERAS program in gynecological operations, particularly benign surgery, are few. In order to assess the postoperative result in ERAS against traditional procedure in complete laparoscopic hysterectomy, we undertook this study as an institutional experience.

Objectives

To determine the effectiveness of ERAS protocol in decreasing the length of hospital stay after laparoscopic hysterectomy.

Materials and Methods

The present randomized control trail was conducted by the Department of OBG at JSS Medical College Hospital from November 2020 to June 2022 among the subjects who were scheduled for laparoscopic hysterectomy with salpingectomy or salpingo-oophorectomy for benign condition.

A total of 120 study subjects were selected for the purpose of the study with 60 subjects in each group. The sample size was estimated considering SD of post-op hospital stay as 3 hours in each group, and study to be sensitive enough to detect at least 1 hour difference in hospital stay with 5% alpha error and 95% power, as 58 in each group, considering the dropouts the sample size included was 60 in each group.

The sample size was calculated as follows:

$$= \frac{2S_p^2\left[Z_{1-\alpha/2} + Z_{1-\beta}\right]^2}{\mu_d^2}$$

$$S_p^2 = \frac{S_1^2 + S_2^2}{2}$$

where S_1 = SD in the first group, S_2 = SD in the second group, $Z\alpha$ = Mean difference between the groups, Z_β = Significance level, p = Power

Inclusion Criteria

- Patients undergoing total laparoscopic hysterectomy for benign gynecological disorder operated by same surgeon, who fall under ASA grade I and grade II categories.

Exclusion Criteria

- Infected masses
- Immunocompromised patients
- Gynecological malignancies
- Age > 70 years

Methodology

Women planned for laparoscopic hysterectomy for benign conditions at JSS Mysuru, Gynecology OPD were told about the research.

Which includes two types of protocols: ERAS and conventional

Those willing and consenting to be a part of the study are selected

The patients are randomly allocated into two groups via the sealed opaque envelope technique

Study group are those that follow the ERAS protocol

Control group are those that follow the conventional protocol

The patients were explained about the study which included two types of protocols:

1. ERAS protocol for laparoscopic hysterectomy
2. Conventional protocol for laparoscopic hysterectomy

Before starting the study the informed consent was taken from all the study subjects. The patients were randomly allocated into two groups using sealed opaque envelope technique.

a) Study group (S) $n = 60$
b) Control group (C) $n = 60$

Prior to surgery, preoperative interviews and physical and gynecological tests were conducted with women who had their eligibility examined. Women in the study group (S) get care in accordance with ERAS procedure, whereas those in the control group (C) receive care in accordance with standard practice.

Assessment of postoperative complications is done within 1 week of surgery in both the groups. Patient and surgeon satisfaction questionnaire is taken after the surgery in both the groups

Data were gathered and entered into the MS Excel spreadsheet that was already developed. The Windows version 21.0 of the SPSS application was used to conduct the statistical analysis. Bar charts were used to graphically express qualitative data, which was displayed as proportions and pie diagrams. Mean and standard deviation were used to display quantitative data. For the significance of qualitative data, the Chi-square test/test Fisher's was employed, while the student's t test was utilized to determine the degree of significance for quantitative data. Statistics were judged significant-values are considered significant at $p < 0.05$.

Results

The age-group ranged from 35 to 68 years with a standard deviation of ± 7.8. In study group, most patients were aged between 41 and 45 years (25%) and the least in 66–70 years (3.3%). Similarly, in Control group, most patients lie in the age-group of 51–55 years (33.3%) and least in 61–65 years (3.3%) (Table 1).

The mean BMI in Study group is 25.35 ± 2.763, and in Control group is 25.1 ± 2.141 with a mean difference of 0.1 and p-value of 0.704 there does not exist significant difference in mean BMI between two groups.

In the ERAS group, the average preoperative hospital stay is 7.8 ± 2.0. hours. In the control group, the patients' mean duration (hours) is 30.07 ± 4.41 with the mean difference of 22.17 and a p-value was found to be less than 0.05. Among the control group,

the mean fluid administration of the study subjects was found to be 968.33 ± 133.393 mL with the mean difference value of 489.167 mL and a *p*-value was found to be less than 0.05. The mean fluid requirement (in mL) during the postoperative period among the study subjects in the ERAS group was found to be 471.67 ± 150.808 mL. In the control group, the mean fluid requirement of the patients is 1328.33 ± 324.738 mL with a mean difference of 856.667 mL and a *p*-value was found to be less than 0.05.

The mean CO_2 pressure (mm Hg) during the intraoperative period among the study subjects in the ERAS study group was found to be 12.37 ± 0.66 mm Hg. The mean CO_2 pressure in the control was found to be around 14.0 ± 0 mm Hg with a mean difference of 1.6 mm of Hg and *p*-value was found to be less than 0.05 (Table 2).

The mean doses of postoperative rescue analgesia among the participants in the study group is 1 ± 0.2. In the control group, mean doses of postoperative rescue analgesia is 2 ± 0.3, with a mean difference of 1 and a *p*-value was found to be less than 0.05. The mean VAS score among the patients in the ERAS group is 2.4 ± 0.6, and in the control group, the mean VAS score is 4.6 ± 0.8 with the mean difference of 2.1 and *p*-value was found to be less than 0.05. The mean fluid requirement (in mL) during the postoperative period among the study subjects in the ERAS group was found to be 471.67 ± 150.808 mL. In the control group, the mean fluid requirement of the patients is 1328.33 ± 324.738 mL with a mean difference of 856.667 mL and a *p*-value was found to be less than 0.05. The mean duration of post-op catheter removal (in hours) among the patients in the ERAS group is 6.70 ± 1.02 hours. In the control group, the duration of post-op catheter removal is 10.45 ± 1.04 hours with the mean difference of 3.7 hours and a *p*-value was found to be less than 0.05. The mean duration of post-op time for ambulation (in hours) among the patients in the ERAS group is 5.80 ± 1.05 hours. In the control group, the post-op time to ambulation duration is 9.80 ± 1.3 hours with the mean difference of 4 hours and a *p*-value was found to be less than 0.05. Patients in the ERAS group had an average postoperative hospital stay of 1.1 days with a standard deviation of 0.3 days. The length of the post-op hospital stay in the control group was 3.1 ± 0.3 days, with the mean difference of 1.9 days and a p-value was found to be less than 0.05. The patients in the ERAS group had an average hospital stay of 1.6 ± 0.3 days. The duration of hospital stay is 4.4 ± 0.5 days in the control group with the mean difference of 2.8 days and a *p*-value was also found to be less than 0.05. The mean postoperative analgesia requirement (days) in the study group is 2.5 ± 0.8. In the control group, the mean post-op analgesia requirement of the patients is 5 ± 0 days with a mean difference of 2.4 days and the *p*-value was found to be less than 0.05 (Table 3).

In the study group, most participants had no shoulder pain (86.7%), and 13.3% had shoulder pain. Similarly, 81.7% of the participants had no shoulder pain in the control group, while 13.3% had shoulder pain.

In the ERAS group, most patients had no vault infection (98.3%), and 1.7% had vault infection. Similarly, 96.7% of the patients had no vault infection in the control group, while 3.3% had. In the study group, most participants had no abdominal wall wound infection (100%). Similarly, in the control group, none of the participants had

Table 1: Intergroup comparison of baseline characteristics among the groups

	ERAS group (n = 60)		*Control group (n = 60)*		
Age (years)	*Frequency*	*%*	*Frequency*	*%*	*p-value*
35–40	9	15.0	17	28.3	0.06
41–45	15	25.0	5	8.3	
46–50	12	20.0	12	20.0	
51–55	14	23.3	20	33.3	
56–60	6	10.0	3	5.0	
61–65	2	3.3	3	5.0	
66–70	2	3.3	0	0.0	

Table 2: Intergroup comparison of clinical parameters in pre- and intraoperative period

	Study group (n = 60)		*Control group (n = 60)*				*Mann–Whitney U-test*
	Mean	*Std dev*	*Mean*	*Std dev*	*Mean difference*	*t-value*	*p-value*
Preoperative hospital stay (hours)	7.85	2.007	30.07	4.437	22.17	35.36	<0.001*
Fluid administered intraoperative (mL)	479.17	101.80	968.33	133.39	–489.167	–22.5	<0.001*
Intraoperative CO_2 pressure (mm Hg)	12.37	0.663	14.00	0.000	–1.633	–19.08	<0.001*

*$p < 0.05$

Table 3: Intergroup comparison of clinical parameters in postoperative period

	Study group (n = 60)		*Control group (n = 60)*		*Mean*		*Mann–Whitney U-test*
	Mean	*Std dev*	*Mean*	*Std dev*	*difference*	*t-value*	*p-value*
Postoperative rescue analgesia	1	0.2	2	0.3	1.0	39	0.002*
Post-op pain (VAS)	2.43	0.647	4.60	0.807	–2.167	–16.224	<0.001*
Fluid requirement postoperatively in mL	471.67	150.808	1328.33	324.738	–856.667	–18.5	<0.001*
Postoperative removal of catheter in hours	6.70	1.062	10.45	1.048	–3.750	–19.46	<0.001*
Postoperative time for ambulation in hours	5.80	1.054	9.80	1.312	–4.000	–18.40	<0.001*
Postoperative hospital stay in days	1.142	0.3201	3.125	0.3973	–1.9833	–30.11	<0.001*
Total duration of hospital stay	1.617	0.3836	4.417	0.5381	–2.80	–32.81	<0.001*
Requirement of postoperative analgesia (days)	2.57	0.890	5.00	0.000	–2.433	–21.17	<0.001*

*$p < 0.05$

Table 4: Comparison of complication among the study subjects in both the groups

	Study group (n = 60)		*Control group (n = 60)*		
	N	*%*	*N*	*%*	*p-value*
Shoulder pain					
Yes	8	13.3	11	18.3	0.453
No	49	86.7	52	81.7	
Vault infection					
Yes	1	1.7	2	3.3	0.559
No	59	98.3	58	96.7	
Abdominal wall wound infection					
Yes	0	0.0	0	0.0	0.559
No	60	100.0	60	100.0	
Readmission to EMD					
Yes	0	0.0	2	3.3	0.559
No	60	100.0	58	96.7	

abdominal wall wound infection. None of the ERAS group patients had been readmitted to the EMD. Similarly, in the control group, most patients were not readmitted to the EMD (96.7%), and 3.3% had been readmitted to the EMD (Table 4).

In the ERAS group, 98.3% of patients thought the material was of high quality, while only 1.7% did not. Similarly, 98.3% of the patients liked the quality of the information provided in the control group, while 1.7% did not like it. In the ERAS group, most patients liked staying in the gynecological ward (98.3%), and 1.7% did not. Similarly, 95% of the patients liked staying in the gynecological ward in the control group, while 5% did not like it. In the study group, most patients did not have additional visits to a doctor (96.7%), and 3.3% had additional visits. Similarly, 96.7% of the patients did not have additional doctor visits in the control group, while 3.3% had additional visits. And 100% of the patients in both the groups, that is, study and control groups are satisfied with the outcome of the surgery. In the study group, the surgeon was comfortable with anesthesia given to patients. Similarly, 96.7% of the time surgeon was comfortable with anesthesia given to patients in the control group, while 3.3% were uncomfortable (Table 5).

In the study group, surgeon felt abdominal distension was sufficient (98.3%), and 1.7% did not feel sufficient abdominal distension. the surgeon felt abdominal distension was sufficient during surgery in the control group. The surgeon in both the groups, that is, study and control groups was satisfied with the relaxation during the surgery (Table 6).

Table 5: Distribution of the study subjects based on the patient satisfaction score

	Study group (n = 60)		*Control group (n = 60)*		
	N	*%*	*N*	*%*	*p-value*
Do you like the quality of the information?					
Yes	59	98.3	59	98.3	1
No	1	1.7	1	1.7	
Do you like staying in the gynec ward?					
Yes	59	98.3	57	95.0	0.309
No	1	1.7	3	5.0	
Did you have additional visits to a doctor?					
Yes	2	3.3	2	3.3	1
No	58	96.7	58	96.7	
Are you satisfied with the outcome of your surgery?					
Yes	60	100.0	60	100.0	
No	0	0.0	0	0.0	
Were you comfortable with the anesthesia?					
Yes	60	100.0	58	96.7	0.154
No	0	0.0	2	3.3	

Table 6: Distribution of the study subjects based on the doctor satisfaction

	Study group (n = 60)		*Control group (n = 60)*		
	N	*%*	*N*	*%*	*p-value*
Was the abdominal distension sufficient during surgery?					
Yes	59	98.3	60	100.0	0.315
No	1	1.7	0	0.0	
Was there sufficient relaxation during the surgery					
Yes	60	100.0	60	100.0	
No	0	0.0	0	0.0	

Discussion

The traditional method of postoperative treatment has likely been in use for many years out of habit and without any scientific support. As shown in other specialty procedures, the ERAS process is said to be superior to the traditional method. With regard to a total laparoscopic hysterectomy, our goal was to determine the cause of this outcome. The discussion is based on the fact that identical findings have been made in research using a number of different samples.[8]

The age range in the current research was 35–68 years with a standard deviation of 7.8. In the study group, patients range in age from 41 to 45 years old (25% of patients) to 66 to 70 years old (3.3% of patients). Similarly, in the Control group, most patients lie in the age-group of 51–55 years (33.3%) and least in 61–65 years (3.3%). Jimenez et al.[9] reported that the mean age of the study subjects was found to be 42.97 ± 7.88 in ERAS group and in control group it was 43.07 ± 9.51. Age-groups were insignificant between both the groups.

The study found that the mean hospital stay preoperatively (hours) in the ERAS group was 7.8 ± 2.0 and in control group was 30.07 ± 4.41 with a *p*-value less than 0.05. There was a decreased length of preoperative hospital stay in the study group as those patients were admitted on the day of surgery, which did not affect postoperative complications and readmission rates.

The mean BMI in study group is 25.35 ± 2.763, and in the control group is 25.1 ± 2.141 with a mean difference of 0.1 and *p*-value of 0.704, which is in accordance with the study of Jimenez et al. The mean BMI of ERAS group was 25.83 ± 3.66, and in the control group, it was 26.60 ± 5.14.[6]

The mean doses of postoperative rescue analgesia among the participants in the study group is 1 ± 0.2 hours. In the control group, mean doses of postoperative rescue analgesia is 2 ± 0.3, with the mean difference of 1 and a *p*-value of less than 0.05, the study shows that there were more rescue analgesic doses in control group than the study group this may be due to addition of regional anesthesia in the study group which demanded fewer rescue analgesia doses and aided in faster recovery and early ambulation.

All the ERAS and control group patients were given intraoperative analgesia. The mean VAS score among the patients in the ERAS group is 2.4 ± 0.6, and in the control group is 4.6 ± 0.8 with the mean difference of 2.1 and *p*-value of less than 0.05, which shows the statistical significance. The visual analog score (VAS) was lower in patients handled with ERAS protocols than in patients managed with traditional protocols following both laparotomy and laparoscopic procedures, which is comparable to the research by Abdelrazik and Sanad.[10]

The mean duration of post-op catheter removal (in hours) among the patients in the ERAS group is 6.70 ± 1.02 hours. In the control group, it is 10.45 ± 1.04 hours with the mean difference of 3.7 hours and a *p*-value of less than 0.05, which shows statistical significance, which aid in early ambulation postoperatively and decreases the chance of urinary tract infections, which is in line with the study of Han-Geurts IJ et al.[11] where the ED group subjects had significant correlation with shorter duration for urinary catheter required (1 vs 39 days, $p < 0.001$).

The mean duration of post-op time to ambulation (in hours) among the patients in the ERAS group is 5.80 ± 1.05 hours. In the control group, it is 9.80 ± 1.3 hours with the mean difference of 4 hours and the *p*-value was found to be less than 0.05. Early catheter removal decreased postoperative fluid administration, low pain scores aid in early ambulation of patient in the study group, In 2008, during the early stages of ERAS, Chase et al.[12] examined their ERAS program in 880 laparoscopically operated gynecologic cancer patients, which included early eating, early ambulation, and quick conversion to oral analgesics. According to their findings, ERAS decreased postoperative hospitalization without raising the risk of serious consequences.

The patients in the ERAS group had an average hospital stay of 1.6 ± 0.3 days. Among the study subjects in the control group, the mean duration of hospitalization was 4.4 ± 0.5 days with the mean difference of 2.8 days and the *p*-value was found to be less than 0.05. Factors like admission on the day of surgery, no bowel preparation preoperatively, zero fluid balance therapy, decreased administration of postoperative fluids, early removal of catheter, early ambulation all of these contribute to decreased length of hospital stay in the study group. It is true that there have been clinical trials to test these methods, but they have mostly been utilized for oncological surgery, and the outcomes have been mixed.

Similar to our study, Ferrari et al. found that the ERAS procedure resulted in a shorter hospital stay than the usual protocol. A clinical experiment was conducted by Yilmaz et al. to assess abdominal hysterectomy with a shorter hospital stay.[13] A clinical trial by the Olga Kilpios group investigated laparoscopic hysterectomy in the ERAS group; however, it only looked at how long patients stayed in the hospital and how often they used opioids. Compliance is not evaluated, and other ERAS components are not considered.[8] Seven of the eight studies that included length of hospital stay (LOHS) found that LOHS was lower in the ERAS group.[14,15]

In the study group, most participants had no shoulder pain (86.7%), and 13.3% had shoulder pain. Similarly, 81.7% of the participants had no shoulder pain in the control group, while 13.3% had shoulder pain. This finding may be due to reduced intraoperative carbon dioxide pressure in study group compared with control group.

Postoperative complications like vault infection, abdominal wall wound infection, perioperative bleeding did not show any statistical significance between the two groups, suggesting implementation ERAS protocol showed no change in postoperative complications between the two groups. Even while Jimenez et al. found no statistically significant difference in the number of complications, there did seem to be a trend toward less problems in the ERAS group (6% vs 20%, $p = 0.1$).[9]

Nilsson et al. focused on the risk variables for complications after hysterectomy using an ERAS approach. Their research revealed that while postoperative infections and complications were frequent, serious problems were very few. Strong risk factors for postoperative complications were obesity and prior laparotomy, which is in line with the results of other research on benign hysterectomy.

None of the ERAS group patients had been readmitted to the EMD. Similarly, in the control group, most patients were not readmitted to the EMD (96.7%), and 3.3% had been readmitted to the EMD. No discernible difference in readmission rates was seen between the two groups was identified in the study by Bahadur et al. which was comparable to our study findings.[15]

The majority of the data and methods are obtained from studies and protocols carried out in other surgical specialties, despite the fact that ERAS protocols are quickly becoming the new standard for the treatment of gynecological surgery. Additionally, research comparing these techniques in gynecological surgery is often observational in nature and/or contrasts the ERAS group with backward control groups.[16,17] The use of observational studies, which have a significant risk of bias, is the major issue in gynecological surgery, as stated by de Groot et al. in their review and meta-analysis of published publications.

In our study, Majority of the study subjects (60%) in ERAS group and (59%) in control group were satisfied with the protocols and 100% of the patients in both the groups are satisfied with the outcome of the surgery. According to Bahadur et al.[15] 65% of patients in the group ERAS reported satisfaction ratings of higher than 9/10, while the median score for both groups was 8/10. Philp et al. employed the in-patient satisfaction with care measure using the questionaries' INPATSAT-32, which was mailed out one month after surgery, to assess patient satisfaction in a fast-track setting in 2014. Overall, 96% of patients rated good to outstanding in coordination of care from diagnosis to discharge and 92% said the nursing care was efficient.[18]

In the present study in the ERAS group, all the surgeons were comfortable with anesthesia given to patients in the study group and similarly, 96.7% of the surgeons were comfortable with anesthesia given to patients in the control group, while 3.3% were uncomfortable. Overall in both the groups surgeons were satisfied with the abdominal wall distension and relaxation during the surgery.

Conclusion

The efficacy of ERAS depends on its capacity to end the stress cascade and, to the greatest extent feasible, preserve normal physiology both before and after surgery. Early ambulation, early initiation of feeds, early removal of the Foley catheter, use of antiemetics, and multimodal analgesia used during the course of therapy help patients leave the hospital sooner.

The current study adds to the body of research showing that the ERAS program, when used effectively, promotes earlier release and quicker recovery, which ultimately results in better patient satisfaction and quality of life. Although there are many studies evaluating its impact in gynecologic surgery, further research is needed, particularly less invasive gynecological surgeries.

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