

Original Research Article

EFFECTIVENESS OF ENHANCED RECOVERY AFTER SURGERY (ERAS) PROTOCOL WITH CONVENTIONAL PROTOCOL IN TOTAL LAPAROSCOPIC HYSTERECTOMY: A HOSPITAL BASED COMPARATIVE STUDY.

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Abstract

Objectives: The present study was to compare the effectiveness of Enhanced recovery after surgery (ERAS) protocol with conventional protocol in total laparoscopic hysterectomy patients.

Methods: All the patients were explained about the two types of protocols: Group I. ERAS protocol for laparoscopic hysterectomy and Group II. Conventional protocol for laparoscopic hysterectomy. The patients were randomly allocated into two groups using sealed opaque envelope technique. Prior to surgery, preoperative interviews and physical and gynecological tests were conducted with women who had their eligibility examined. Women in the study group (I) got care in accordance with ERAS procedure, whereas those in the control group (II) received care in accordance with standard practice. Assessment of postoperative complications was done within 1 week of surgery in both the groups. A satisfaction questionnaire of patients and surgeon was taken after the surgery from both the group in a prescribed Performa.

Results: All the 100 subjects were randomly selected into two groups. Each group had 50 subjects. Group I: ERAS group (Study group) = 50 and Group II: Control group = 50 patients. Most of the patients 19(38%) were in age group 40 – 50 years in ERAS group. Similarly in control group, most of the women 20(40%) were in age group of 50 – 60 years. The mean BMI of Study group was 26.57 ± 3.453 , and Control group was 27.21 ± 3.659 and it was not significant difference ($p=0.370$). In the ERAS group (study group), the mean preoperative hospital stay was 8.12 ± 3.0 hours. In the control group, mean duration of stay was 29.65 ± 5.39 hours. P-value was found to be less than 0.0001. which was extremely significant. In the ERAS group, most patients had not additional visited to a doctor (98%), and 2 % had additional visits. Similarly, in control group 98% of the patients had not additional visited to doctor, while 2% had additional visits. And 100% of the patients in both the groups (ERAS group and Control group) were satisfied with the outcome of the surgery. In the ERAS group, the surgeon was comfortable with anaesthesia given to patients. Similarly, in control group 94% of the time surgeon was comfortable with anaesthesia given to patients, while 6% were uncomfortable.

Conclusions: ERAS protocol is the best choice for the laparoscopic hysterectomy patients in terms of functional recovery, improve postoperative outcomes including postoperative pain, more rapid return of bowel function, early discharge from the hospital, and, reduction in overall health care costs without increasing complications and/or hospital readmission rates. Hence,

ERAS protocol is the most effective treatment protocol as compared to Conventional protocol for patients of laparoscopic hysterectomy.

Key words: ERAS protocol, Conventional protocol, Laparoscopic Hysterectomy

INTRODUCTION

The conventional approach to postoperative management has been in use for many years may be just as a practice of habit without any scientific basis. 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 [1].

Enhanced recovery after surgery (ERAS) care is an evidence-based multidisciplinary and collaborative protocol to perioperative care based on scientific principles designed to achieve early recovery after surgical procedures by maintaining preoperative organ function and reducing the profound stress response following surgery (Noh et al., 2021) [2]. The main objectives of ERAS protocol are to accelerate functional recovery, improve postoperative outcomes including postoperative pain, more rapid return of bowel function, early discharge from the hospital, and, reduction in overall health care costs without increasing complications and/or hospital readmission rates (Garg et al., 2021) [3].

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 [4].

ERAS protocol is designed to adjust psychological and physiological responses to major operations and has shown that complications and length of hospital stays are reduced, cardiopulmonary function improved, bowel functions returned early, and normal activities resumed earlier (Abdel-Aleem & El-Nemer, 2019) [5]. One of the most frequent problems and significant complaints experienced by women undergoing hysterectomy is pain in the postoperative period. The implementation of the ERAS protocol requires collaboration from all members of the surgical team consisting of surgeons, anesthesiologists, nutritionists, nurses, and other staff from services who are involved in patient care (Nelson et al., 2019)[6]. Objectives of our study was to compare the effectiveness of Enhanced recovery after surgery (ERAS) protocol with conventional protocol in total laparoscopic hysterectomy patients.

MATERIAL & METHODS

The present study was conducted in the Department of General Surgery with the collaboration of Department of Obstetrics & Gynaecology at Government Doon Medical College, Dehradun, Uttarakhand, India during a period from September 2022 to March 2023.

All the subjects who were scheduled for laparoscopic hysterectomy with salpingectomy or salpingoophorectomy for benign condition were enrolled. A total of 100 study subjects were selected for the purpose of the study with 50 subjects in each group.

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 were told about the research. The patients were explained about the study which included two types of protocols: Group I. ERAS protocol for laparoscopic hysterectomy and Group II. Conventional protocol for laparoscopic hysterectomy. The patients were randomly allocated into two groups using sealed opaque envelope technique. Group I : ERAS group (Study group) = 50 and Group II: Control group = 50 patients.

Prior to surgery, preoperative interviews and physical and gynecological tests were conducted with women who had their eligibility examined. Women in the study group (I) got care in accordance with ERAS procedure, whereas those in the control group (II) received care in accordance with standard practice. Assessment of postoperative complications was done within 1 week of surgery in both the groups. Patient and surgeon satisfaction questionnaire was taken after the surgery in both the groups.

STATISTICAL ANALYSIS

Data was analysed with the help of SPSS software. Mean and standard deviations were observed. P-value was taken less than or equal to 0.05 ($p \leq 0.05$) for significant difference.

RESULTS

The age ranged of ERAS group patients were 30 to 65 years. Most of the patients 19(38%) were in age group 40 – 50 years. Least number 8(4%) of patients were in age group of 60 -70 years. Similarly in control group, most of the women 20(40%) were in age group of 50 – 60 years. Least number of patients 6(3%) were in age group of 60-70 years.

The mean BMI of Study group was 26.57 ± 3.453 , and in Control group was 27.21 ± 3.659 and p-value was found to be 0.370, which is not significant difference in between two groups. In the ERAS group (study group), the mean preoperative hospital stay was 8.12 ± 3.0 hours. In the control group, the patients' the mean duration of stay was 29.65 ± 5.39 hours. p-value was found to be less than 0.0001. which is extremely significant.

Table 1: Intergroup comparison of clinical parameters in pre- and intraoperative period

Variables	ERAS group	Control group	t-value	p-value
BMI	26.57 ± 3.453	27.21 ± 3.659	0.900	0.370
Preoperative hospital stay (hours)	8.12 ± 3.0	29.65 ± 5.39	24.680	<0.0001
Fluid administered intraoperative (mL)	482.17 ± 103.65	960.29 ± 134.54	19.906	<0.0001
Intraoperative CO ₂ pressure (mm Hg)	13.65 ± 0.879	17.00 ± 0.014	26.945	<0.0001

In the control group, the mean fluid administration of the study subjects was found to be 960.29 ± 134.54 mL. The mean fluid requirement (in mL) during the pre and intraoperative period among the ERAS group was found to be 482.17 ± 103.65 mL and p-value was found to be less

than 0.0001. Which is extremely significant. Mean and standard deviation of intraoperative CO₂ pressure of ERAS group and control group was 13.65±0.879 and 17.00±0.014 respectively. And it is extremely significant ($p<0.0001$).

Table 2: Intergroup comparison of clinical parameters in postoperative period

Variables	ERAS group	Control group	t-value	p-value
Postoperative rescue analgesia	1±0.72	3±0.46	16.552	<0.0001
Fluid requirement postoperatively in mL	474.232±148.431	1324.88±321.654	16.980	<0.0001
Post-op pain (VAS)	3.54±1.236	5.765 ± 1.981	6.738	<0.0001
Postoperative removal of catheter in hours	5.871 ±1.959	9.871± 1.328	11.954	<0.0001
Postoperative time for ambulation in hours	6.219±1.876	10.23±1.287	12.467	<0.0001
Requirement of postoperative analgesia (days)	3.784±1.238	7.001±0.023	18.371	<0.0001
Postoperative hospital stay in days	1.879±0.576	4.125±0.954	14.251	<0.0001
Total duration of hospital stay	2.734±0.561	5.752±0.834	21.232	<0.0001

In the present study, (table.2) when we compared the various parameter of post operative period of ERAS group with control group patients. P-value was found to be less than 0.0001. which is extremely significant.

Table 3: Comparison of complications in both the groups patient.

Variables	ERAS group		Control group	
	No. of subjects (N=50)	Percentage	No. of subjects (N=50)	Percentage
Shoulder pain				
Yes	5	10%	9	18%
No	45	90%	41	82%
Vault infection				
Yes	1	2%	2	4%
No	49	98%	48	96%
Abdominal wall wound infection				
Yes	0	00	0	00
No	50	100%	50	100%
Readmission to EMD				
Yes	0	00	1	2%
No	50	100%	49	98%

In the ERAS group, most participants had no shoulder pain (90%), and 10% had shoulder pain. Similarly, 82% of the participants had no shoulder pain in the control group, while 18% had shoulder pain. In the ERAS group, most patients had no vault infection (98%), and 2% had vault infection. Similarly, 96% of the patients had no vault infection in the control group, while 4% had vault infection. In the ERAS group, participants had no abdominal wall wound infection (100%). Similarly, in the control group, none of the participants had abdominal wall wound infection (100%). 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 (98%), and 2% had been readmitted to the EMD.

Table 4: Showing the patient's satisfactory score.

Variables	ERAS group		Control group	
	No. of subjects (N=50)	Percentage	No. of subjects (N=50)	Percentage
Do you like the quality of the information?				
Yes	49	98%	49	98%
No	1	2%	1	2%
Did you have additional visits to a doctor?				
Yes	49	98%	48	96%
No	1	2%	2	4%
Are you satisfied with the outcome of your surgery?				
Yes	50	100%	50	100%
No	0	00	0	00
Were you comfortable with the anesthesia?				
Yes	50	100%	47	94%
No	0	00	3	6%

In the ERAS group, 98% of patients thought the material was of high quality, while only 2 % was not thought. Similarly, 98% of the patients liked the quality of the information provided in the control group, while 2% was not liked it.

In the ERAS group, most patients had not additional visited to a doctor (98%), and 2 % had additional visits. Similarly, in control group 98% of the patients had not additional visited to doctor, while 2% had additional visits. And 100% of the patients in both the groups (ERAS group and Control group) were satisfied with the outcome of the surgery. In the ERAS group, the surgeon was comfortable with anaesthesia given to patients. Similarly, in control group 94% of the time surgeon was comfortable with anaesthesia given to patients, while 6% were uncomfortable.

Table 5. Showing the study subjects based on the doctor satisfactions

Variables	ERAS group		Control group	
	No. of subjects (N=50)	Percentage	No. of subjects (N=50)	Percentage
Was the abdominal distension sufficient during surgery?				
Yes	49	98%	50	100%
No	1	2%	0	00
Was there sufficient relaxation during the surgery				
Yes	50		50	100%
No	0		0	00

In the ERAS group, surgeon felt abdominal distension was sufficient (98%), and 2% was not felt sufficient abdominal distension. Surgeon felt abdominal distension was sufficient during

surgery in the control group (100%). The surgeon in both the groups (ERAS group and control group) was satisfied (100%) with the relaxation during the surgery.

DISCUSSIONS

Hysterectomy is the most frequent gynecological surgery [7,8]. Surgical morbidity noticeably influences patients' outcomes and quality of life (QoL). Significant improvements in outcomes such as ameliorating functional rehabilitation, getting back to routine activity, lower blood loss during operation, a shorter hospitalization, and a lower rate of infection could be achieved by an evidence-based medicine strategies pre and postoperatively [9].

ERAS refers to an interdisciplinary evidence-based strategy of perioperative care (pre-operative, intra-operative, and post-operative care) to help patients recover faster (Caughey et al., 2018) [10].

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 [11].

In the present study, in the ERAS group, most of the patients 19(38%) were seen in age group 40 – 50 years. Least number 8(4%) of patients were seen in age group of 60 -70 years. Similarly in control group, most of the women 20(40%) were in age group of 50 – 60 years.

Jimenez et al. [12] reported that the mean age of the subjects was found to be 42.97 ± 7.88 years in ERAS group and in control group it was 43.07 ± 9.51 . Age-groups were insignificant between both the groups.

In the present study, The study found that the mean hospital stay preoperatively (hours) in the ERAS group was 8.12 ± 3.0 and in control group was 29.65 ± 5.39 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 was not affected postoperative complications and readmission rates. The mean BMI of ERAS group and control was not significantly difference (p-value < 0.370), which is in accordance with the study of Jimenez et al. [12].

In the present study, mean doses of postoperative rescue analgesia of ERAS group and control group was 1 ± 0.72 hours and 3 ± 0.46 respectively, which was extremely significant ($p<0.0001$). 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 of patients ERAS group and control group was 3.54 ± 1.23 and 5.765 ± 1.981 respectively. And it was extremely significant differences ($p<0.0001$). 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 [13].

The mean duration of post-op catheter removal (in hours) of patients in ERAS group and control group was 5.871 ± 1.959 and 9.871 ± 1.328 hours respectively. Which was extremely significant differences ($p<0.0001$), 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. [14] 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) of ERAS group and Control group was 6.219 ± 1.876 and 10.23 ± 1.287 hours respectively and the p-value was found to be less than 0.0001. which was extremely significant. Early catheter removal decreased postoperative fluid administration, low pain scores aid in early ambulation of patient in the ERAS group, In 2008, during the early stages of ERAS, Chase et al. [15] 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 and control group had an average hospital stay was 1.879 ± 0.3 days and 4.125 ± 0.5 days respectively, and the p-value was found to be less than 0.0001. which was extremely significant. 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 [16]. 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 [17].

In the present study, most participants of ERAS group and Control group had no shoulder pain 90% and 82% respectively. 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%, $p = 0.1$) [12]. 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 (98%), and 2% 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 [18]. 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 [19]. 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 the present study, most of the study subjects (98%) in ERAS group and control group were liked quality of information of 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' INPATTSAT-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 [20].

The findings of our study is also similar to Sibbern et al. (2017) [21] who studied "Patients' experiences of enhanced recovery after surgery" founded that more than half of the studied women stayed from 1 to 3 days in hospital compared to the control group with 4–5 days mean duration of hospitalization, the study group was significantly shorter than those in control group.

In the present study in the ERAS group, all the surgeons were comfortable with anesthesia given to patients and similarly, in control group, 94% of the surgeons were comfortable with anesthesia given to patients, while 6% were uncomfortable. Overall, in both the groups surgeons were satisfied with the abdominal wall distension and relaxation during the surgery. Thus, ERAS protocol is a beneficial approach to perioperative care in patients undergoing gynecological surgery for benign indications irrespective of the route of surgery. Though the protocol entailed some drastic changes over the conventional approach, the implementation into the routine functioning in the present scenario was not challenging and the benefits observed definitely made the continuation of usage a reality.

CONCLUSIONS

The present study concluded that the ERAS protocol is the best choice for the laparoscopic hysterectomy patients in terms of functional recovery, improve postoperative outcomes including postoperative pain, more rapid return of bowel function, early discharge from the hospital, and, reduction in overall health care costs without increasing complications and/or hospital readmission rates. Hence, ERAS protocol is the most effective treatment protocol as compared to Conventional protocol for patients of laparoscopic hysterectomy.

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